

V8 UltraCE Operator Manual

High Performance Clinical Capillary Electrophoresis

helena
Biosciences Europe

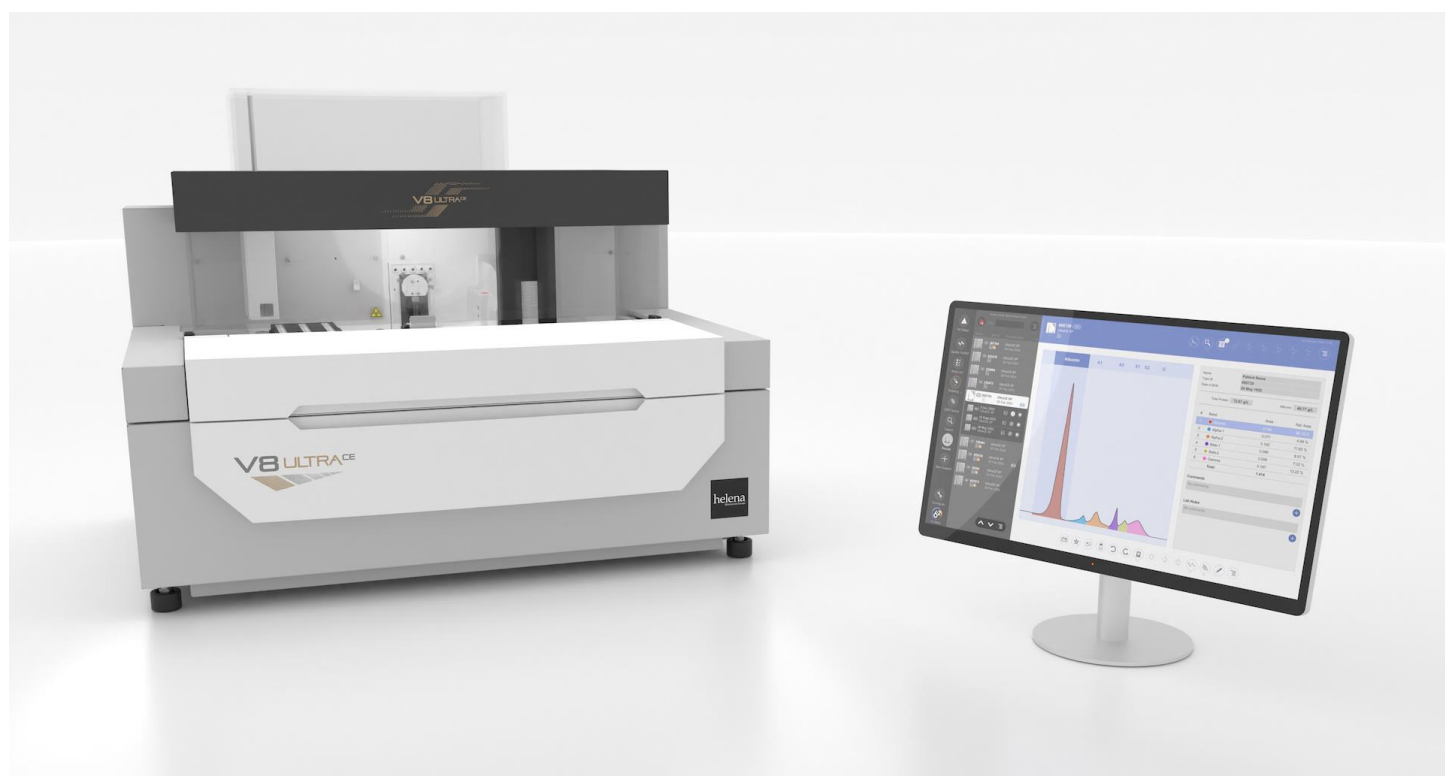


Table of Contents

Revisions to this operator manual	7	
Copyright notice	8	
Company liability	9	
Health and safety	10	
Informational Symbols	11	
Terminology used in this manual	14	
Acronyms	15	
1	Intended Purpose	16
1.1	Intended purpose	16
1.3	V8 UltraCE technologies and functionality: quick reference guide	16
2	Installation and special requirements	18
2.1	Overview	18
2.2	Storage and Transport	18
2.3	Packaging and installation	18
2.4	Included in your V8 UltraCE system	18
2.5	Basic installation requirements	20
2.5.1	Surroundings and space requirements	20
2.5.2	Electrical information	20
2.5.3	Pollution Degree	20
2.6	Platinum to V8 UltraCE configuration	20
2.6.1	Platinum initial setup	20
2.6.2	LIMS/LIS configuration	21
2.7	Operator levels	21
2.7.1	Level 1	21
2.7.2	Level 2	21
2.7.3	Level 3	21
2.8	Adding a new user	21
2.9	Configuration of menus	22
2.10	Configuration of demographics	22
2.11	Configuration of Chemistry Values	23
3	Getting to know your V8 UltraCE	24
3.1	Capillary Electrophoresis	24
4	Performance characteristics and specifications	25
4.1	V8 UltraCE technical specifications	25
4.2	V8 UltraCE schematic	26
4.2.1	V8 UltraCE system description	26
4.2.2	V8 UltraCE instrument technical overview	27
5	Operating the V8 UltraCE	34
5.1	Quick user guide to daily operation	34
5.2	Daily operating instructions	35
5.2.1	Switching the V8 UltraCE on and off	35
5.3	Preparing the V8 UltraCE for operation	35
5.4	Running in Multi-Assay mode	35
5.5	Shutting down the V8 UltraCE after use	35
5.5.1	Shutting down the V8 UltraCE without the necessary buffers onboard	36
5.6	General instrument instructions	36
5.6.1	Installation of buffer bottles	36
5.6.2	To install a new buffer	36
5.6.3	Checking buffer levels	37
5.6.4	Loading reagents	38
5.6.5	Loading sample cups	39
5.6.6	Clinical waste drawer	40
5.6.7	Sample racks and sample tubes	40
5.6.7.1	Placing samples on-board V8 UltraCE	41
5.6.7.2	Cap Piercing and Agitation	41

5.6.8	Sample tube barcodes	42
5.6.8.1	Adding a tube ID to processed samples	42
5.6.8.2	To remove a "Sample Missing Barcode" flag from Platinum	43
5.6.8.3	How to remove a rack from the worklist	43
5.6.8.4	Skip position barcode	43
5.6.9	V8 UltraCE gel tray handling	43
5.6.9.1	To affix V8 UltraCE gel tray identifying label	43
5.6.9.2	To load a SAS gel tray:	43
5.6.10	V8 UltraCE System warnings and status	44
5.6.11	List of attention messages and actions required	46
5.6.12	Managing capillaries	47
5.7	Accessing the Expert System	47
5.8	Platinum	54
5.8.1	Glossary of software icons	54
5.8.2	Log in to Platinum	63
5.8.2.1	Initial Log-in Screen	63
5.8.2.2	Operator Log	63
5.8.2.2.1	Additional Operator Log Options	64
5.8.2.3	Product Activation	64
5.8.3	V8 Status Window	64
5.8.3.1	V8 UltraCE System Warnings and Status	66
5.8.3.2	Defining Reagents and Buffers	67
5.8.3.3	Checking Buffer Levels	67
5.8.3.4	Loading Reagents	68
5.8.3.4.1	Installing Reagents using the Reagent window	68
5.8.3.4.2	Clearing a reagent from the Reagent window	69
5.8.3.5	V8 Error Log	70
5.8.3.6	V8 Communications	70
5.8.3.7	LIMS Communications	70
5.8.3.8	Diagnostics	70
5.8.3.9	Managing Capillaries	71
5.8.3.10	Messages	71
5.8.3.11	LAS	71
5.8.4	Quality Control Window	72
5.8.4.1	Key Features	72
5.8.4.2	Quality Control Page Overview	72
	How to populate the Levey Jennings Graph	73
	Setup at Installation	87
	Define QC Analysis Method	87
	Input lot information	87
	QC Settings	88
	V8 UltraCE Automatic QC Test Ordering	90
	Display Options	91
	Capillary Mode	91
	Tracking an M-Spike using Levey Jennings	92
5.8.5	Work List Window	94
5.8.6	Ordering Window	95
5.8.6.1	Selecting the Default Method	95
5.8.6.2	Test Ordering	95
5.8.6.2.1	How to Cancel an Ordered Test	96
5.8.6.3	Racks	96
5.8.6.3.1	Sample Tube Barcodes	96
5.8.7	LIMS Queue	97
5.8.7.1	Controlling Data to the LIMS/LIS	97
5.8.7.2	Sending Data to the LIMS Queue	97
5.8.7.3	Viewing and Releasing Data in the LIMS Queue	98
5.8.7.4	Sending Sample Data Directly to LIMS	98
5.8.8	Search Window	98
5.8.8.1	Searching for Data	99
5.8.8.2	Search Results	99
5.8.9	Results Window	100
5.8.9.1	Active Session Window	100
5.8.9.2	Editing	100

5.8.9.2.1	Editing Baseline	102
5.8.9.2.2	Editing Peaks	102
5.8.9.2.3	Add Trough Marker	102
5.8.9.2.4	Delete Trough Marker	103
5.8.9.2.5	Smoothing	103
5.8.9.2.6	Filtering	103
5.8.9.2.7	Overlay Functionality	103
5.8.9.2.8	Normal Overlay	103
5.8.9.2.9	Overlaying of Samples on the Screen	103
5.8.9.2.10	Match Shapes	104
5.8.9.2.11	Stretching Samples to Overlay Bands	104
5.8.9.3	Mean Traces	104
5.8.9.4	Quantitating a Monoclonal Protein	105
5.8.9.4.1	Skimmed M-spike	105
5.8.9.4.2	Adding a Skimmed M-spike	105
5.8.9.4.3	Sliced M-spike	105
5.8.9.4.4	Adding a Sliced M-spike	105
5.8.9.4.5	Removing an M-spike	105
5.8.9.5	Removing Artefacts from Traces	106
5.8.9.5.1	Slice Data	106
5.8.9.5.2	Skim Data	106
5.8.9.6	First Derivative	106
5.8.9.7	Adding Comments to a Sample Result	106
5.8.9.7.1	Adding a Comment to a Single Sample Result	106
5.8.9.7.2	Adding Comments to Multiple Sample Results	106
5.8.9.7.3	Comments Tree	106
5.8.9.7.4	Lab Notes	107
5.8.9.8	Statistics	107
5.8.9.9	Searching for and Attaching an Immunotyping Result	107
5.8.9.9.1	Attaching a sample from Patient History	107
5.8.9.9.2	Loading Source Data for Patient History	107
5.8.9.10	Grid Mode	108
5.8.9.11	Focus Mode	110
5.8.9.12	Adding a Tube ID to Processed Samples	111
5.8.9.13	How to Perform a Reflex Test	111
5.8.9.13.1	Manual Ordering for Reflex Testing	111
5.8.9.13.2	Using the Auto Dilution function to reflex test	112
5.8.9.13.3	Highlighting manually editing demographics	112
5.8.9.13.4	Flagging samples	113
5.8.10	Configure Window	114
5.8.10.1	V8 UltraCE Systems	114
5.8.10.2	Select V8 System	115
5.8.10.3	Setting the V8 UltraCE Test Mode	115
5.8.10.4	Reflex Test Priority	115
5.8.11	Comments	116
5.8.11.1	To Compose the Standard Comments	116
5.8.12	Database	117
5.8.12.1	Database Maintenance	117
5.8.12.2	Merge Demographics	117
5.8.12.3	Backup Selected Data	117
5.8.12.4	Database Backup and Recovery	117
5.8.13	Report	117
5.8.13.1	Create New Report	118
5.8.13.2	How to Create a Template Layout	118
5.8.13.3	Edit Report	118
5.8.13.4	Preview Report	118
5.8.13.5	Setting a Report as the Default	118
5.8.13.6	Configuring ID Reports	118
5.8.14	Configure V8 UltraCE Methods	119
5.8.15	Methods	120
5.8.15.1	Trace Regions	120
5.8.16	Navigation Worklist	121
5.8.17	Operator Access	121
5.8.18	Gel sessions	121
5.8.18.1	Gel Mode	121

	5.8.18.2	Select Gel	121
	5.8.18.3	Scanning Configurations	122
	5.8.18.3.1	Select a Scanner	122
	5.8.18.3.2	Prompting Platinum to Scan	122
	5.8.18.3.3	Aligning a Gel Template	122
	5.8.18.3.4	Marking a Gel	124
	5.8.18.3.5	Configure Gels	124
	5.8.19	Notice to Users	124
6		Calibration procedures	125
	6.1	Instrument calibration	125
	6.2	Quality Control calibration checks	125
7		Health and Safety information	126
	7.1	Overview	126
	7.1.1	Personal Protective Equipment	126
	7.2	On-board Health and Safety standards and protocols	126
	7.2.1	Compliance standards	126
	7.2.2	Training	126
	7.2.3	Protective hood	126
	7.2.4	Mechanical movement shut down	126
	7.2.5	Safe loading of samples	126
	7.2.6	Zero cross contamination	126
	7.2.7	Safe and convenient clinical waste collection	127
	7.2.8	Analysis security	127
	7.2.9	Quality assurance	127
	7.2.10	Audit trail accountability	127
	7.2.11	Expert System	127
	7.2.12	Instrument status communication	127
	7.3	Regulatory Information	127
	7.3.1	Proprietary notice	127
	7.3.2	Warranty	127
	7.3.3	WEEE	128
	7.3.4	Applicable standards and directives	128
	7.3.5	Precautions and limitations	129
8		Hazards: Residual	130
	8.1	Residual risks and user protection	130
	8.1.1	Cleaning of sample analysis and preparation area	130
	8.1.2	Decontamination	130
	8.1.3	Disposal of clinical waste	130
	8.1.4	High voltage system	130
	8.1.5	Handling of Patient Samples	131
	8.1.6	Handling of high risk samples	131
	8.1.7	Installation, lifting and re-location	131
	8.1.8	Removal of the protective hood	131
	8.1.9	Sample handling arm	131
	8.1.10	V8 UltraCE LED lighting system	131
	8.1.11	Barcode Reader	131
	8.1.12	Waste bin	132
	8.2	Summary: required safety checklist	132
9		Maintenance of the V8 UltraCE	133
	9.1	Overview	133
	9.2	Daily maintenance	133
	9.3	Pre-conditioning	133
	9.4	Post-conditioning	133
	9.5	Emptying waste from the instrument	133
	9.6	Emptying the waste fluid bottle	133
	9.7	Emptying the sample cup waste drawer	134
	9.8	Daily maintenance routine	134
	9.9	Intermittent Use	135
	9.10	Frequent maintenance checks	135
	9.11	Monthly maintenance	135
	9.12	Annual maintenance	135
	9.13	Decontamination	136
	9.14	Waste container decontamination	136

9.14.1	Clinical waste drawer	136
9.14.2	Waste fluids bottle	136
9.15	Re-location and re-installation of the V8 UltraCE	136
9.16	Long-term storage of the V8 UltraCE	137
9.17	High-risk samples	137
9.18	Notice to Users	137
Appendix 1	V8 UltraCE troubleshooting	138
1.1	Common problems	138
1.2	V8 UltraCE light display	139
1.3	V8 UltraCE audible feedback	139
1.4	Platinum error messages	140

Revisions to this operator manual

This section lists all amendments which have been made to the content or design of this operator manual.

Initial publication:

HL-2-P-3570 Rev. 1 May 2025

Second publication:

HL-2-P-3570 Rev. 2 July 2025	Items included in kit section updated with new image.
------------------------------	---

Third publication:

HL-2-P-3570 Rev. 3 July 2025	Updates to sections 2.10, 2.11, 2.12 & 5.8.4, 5.8.9.2.
------------------------------	--

Copyright notice

© Copyright 2025 Helena Biosciences Europe.

All rights reserved.

This operator manual may not be copied, in whole or in part, without the written consent of Helena Biosciences Europe.

Microsoft and Windows, are trademarks or registered trademarks of Microsoft Corporation. Other company and product names mentioned within this manual are trademarks of their respective companies.

Company liability

The information in this manual has been carefully compiled and verified for technical accuracy, and should be read thoroughly to ensure correct and safe usage. Helena Biosciences Europe trusts that the information contained herein is valid and accurate; and thereby accepts no liability or responsibility for system malfunctions, damage or personal injury caused by misuse or mishandling. For more information, please contact your local Helena Biosciences Europe representative.

Comments or correspondence regarding this manual should be addressed to the manufacturer:

www.helena-biosciences.com

info@helena-biosciences.com



Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Tel: +44 (0)191 482 8440



Advena Ltd.

Tower Business Centre,
2nd Flr., Tower Street,
Swatar, BKR 4013 Malta



V801

Health and safety

While the primary risks of using this product have been resolved through instrument design there are still residual risks to the operator and to third parties involved in the daily running, maintenance and installation of the V8 UltraCE.

This document details all the protective features and user instructions for ensuring health and safety. It is strongly recommended that this document is read thoroughly prior to the use of the system. Failure to comply with the stated precautions or specific warnings elsewhere in this guide violates the safety standards built relevant to the design, manufacture and intended use of this instrument.

Helena Biosciences assumes no liability for the operator's failure to comply with these requirements.



WARNING

Protection impairment if the operator uses the system in a manner not as specified by Helena Biosciences.

Informational Symbols

The following information applies to operating personnel. It is the responsibility of the user to ensure that all safety information and operating instructions are read and understood before use. General warnings and cautions will be found throughout the manual where they apply.



WARNING

WARNING: Risk of danger.



CAUTION

CAUTION statements identify conditions or practices that could result in personal injury. Proceed with caution.



CORROSIVE

A substance which may destroy living tissues on contact with them. Severe burns on the skin and flesh might result from splashes of such substances on the body.



TOXIC

A substance which, if it is inhaled or ingested, or if it penetrates the skin, may involve extremely serious, acute (immediate) health risks and even death.



WARNING

WARNING, BIOLOGICAL HAZARD



HAZARD

CAUTION: High voltage hazard



CAUTION

CAUTION separate collection of electric and electronic waste at the end of life, as required by European legislation.



HAZARD

WARNING: Pinch point hazard



LASER RADIATION

Laser Radiation: Laser beam hazard



WARNING

WARNING: Hot surface

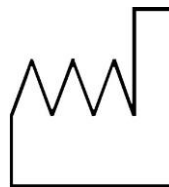


DANGER

Danger: Serious health hazard. May damage fertility or the unborn child



E.U. authorised representative



Date of manufacture



Eurasian conformity mark



European conformity mark



Federal Communication Commission conformity mark



A medical device intended for in vitro use



Manufacturer



eIFU

Consult electronic instructions for use



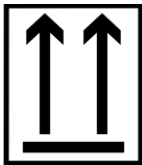
Catalogue number



Fragile



Keep Dry



This Way Up



UK Conformity Assessed Mark

Terminology used in this manual

In order to make this document as clear as possible, these conventions will be followed:

Text alerts and messages

Text, in the form of messages and alerts from Platinum or Windows™ software, will be shown as follows:

"It is now safe to remove the device."

whereas audio feedback from the V8 UltraCE is in the form of chimes of various tones.

Hardware items

When referring to parts of the V8 UltraCE instrument, accessories or other items used in conjunction with the V8 UltraCE, the following style is used: To begin analysis, close the *Sample preparation and analysis lid*. The V8 UltraCE should automatically begin processing your samples.

Platinum items

Things such as buttons, windows and menu items will be displayed as shown:

To open a new session, choose **New session > Create new V8 session**. When prompted to save or discard your current session, click **Discard**.

In dialogue boxes or when editing text fields in the Platinum session window, text which is expected to be supplied by the user is shown like this:

Enter "my_template.rep" in the Save As dialogue box.

Acronyms

CCE	Clinical Capillary Electrophoresis
CDT	Carbohydrate Deficient Transferrin
CE	Capillary Electrophoresis
CSF	Cerebrospinal Fluid
CZE	Capillary Zone Electrophoresis
CV	Coefficient of Variation
DCI	Dynamic Compression Injection
EOF	Electroosmotic Flow
ESH	Electrophoresis Sample Handler
FOB	Free on Board
Hb	Haemoglobin
IFE	Immunofixation
IFU	Instructions for Use
ID	Immunodisplacement
LAS	Laboratory Automated System
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
MIU	Method in use
PCB	Printed Circuit Board
pI	Isoelectric point
PPE	Personal Protection Equipment
Pt	Platinum
RTF	Rich Text File
SD	Standard Deviation
SP	Serum Protein
UP	Urine Protein
ID	Immunodisplacement (or Identity when used with Patient ID, tube ID and lot ID)

1 Intended Purpose

1.1 Intended purpose

The V8 UltraCE is a fully automated *in-vitro* diagnostic Capillary Electrophoresis instrument which uses electrolytic buffers and high voltage to separate the constituent fractions of human serum, urine and whole blood samples. The component fractions are then visualised by use of the absorption of light within a range of 200-600nm. The V8 UltraCE is to be used in conjunction with associated quantitative and qualitative V8 UltraCE assays. Intended for use by a trained laboratory professional in a clinical laboratory.

1.2 Test principle

V8 UltraCE is an instrument and does not have an assay principle.

1.3 V8 UltraCE technologies and functionality: quick reference guide

V8 UltraCE has been specially designed with advanced system features to provide you with a wide variety of user functionality. To get the best out of your V8 UltraCE, please read the following technology driven solutions and tips, and optimise your system to its full potential. Please refer to the relevant sections.

Complete Chemistry

All reagents and buffers held on board for next-generation automation

- Correct installation of buffer bottles, see 5.6.1
- Loading reagents on-board, see 5.6.4
- Checking fluid levels, see 5.6.3

Multi Assay

Simultaneous separation capability for high throughput multi-assay testing

- Set-up the V8 UltraCE for single assay testing, see 5.8.6.1
- Set-up the V8 UltraCE for multi-assay testing, see 5.4
- How to manage capillaries, see 5.6.12

Cap Piercing and Agitation

Cap piercing and agitation of whole blood in capped primary tubes.

- Cap piercing needle, see 5.6.7.2
- Large wash station to allow full needle washing, see 5.6.7.2
- Increased volume waste bottle, see 5.6.7.2
- 5 port buffer bay with dedicated wash station fluid position, see 5.6.7.2
- High intensity LED light source

Intuitive Status

Visual effect system for visual status updates

- Responding to visual status updates, see Appendix 1.2
- The importance of pre and post-conditioning cycles, see 9.3 and 9.4
- What to do when it goes blue, see Appendix 1

True Identity

Total audit trail accountability and analysis security

- Setting up user names and passwords in Platinum, see 2.7
- Searching and retrieving data, see 5.8.8
- Setting up the Levey-Jennings analysis, and using controls, see 5.8.4

Auto Pilot

Define your assay, load your samples and close the lid – it's as simple as that

- How to automate your testing needs, see 5.1, 5.2, 5.7 and 5.8.9.13
- Understand automated maintenance cycles, see 9.2

Expert System

Intelligent identification and retesting of abnormal samples

- Using the Expert System, see 5.7
- Switching your Expert System on and off, see 5.7

Continuous Loading

Total random access for continuous high throughput analyses

- Loading samples into the sample rack 5.6.7.1
- Adjusting the sample rack for different tube sizes, see 5.6.7
- Set-up system for high-throughput batch loading without workflow interruption, see 5.6.7.1

Fast Track

Queue jump your urgent samples for speedy results

- Fast track an urgent or STAT sample, see 5.8.10.4 and 5.8.9.13
- Set the priority of STAT samples, see 5.8.6.2 and 5.8.9.14

Sample Recall

Recall tested samples for further diagnostic analysis

- System memory of on-board/off-board samples, see 5.8.9.13
- How to recall a sample for specific testing requirements, see 5.8.9.13
- Prepare a sample for gel electrophoresis, see 5.6.9

Reflex Testing

Automated marking of abnormal samples for confirmatory reflex tests

- Understand how to set up a reflex test, see 5.8.9.13
- Automate reflex testing on the V8 UltraCE, see 5.7
- Set the priority of automated reflex tests, see 5.8.10.4
- Auto dilution calculation, see 5.8.9.14
- FlexWave retesting, see 5.8.6.2

Audible Feedback

Audible system status updates for total peace of mind, see Appendix 1.3

Smart System

Intelligent platform maximises up-time and productivity

- Perform Immunodisplacements hands free, see 5.8.9.13
- Set-up automated assay switching, see 5.4

Gel Integration

Integrated sample handling for gel electrophoresis preparation

- How to load a SAS gel tray, see 5.6.9.2
- How to prepare a sample for gel electrophoresis, see 5.6.9
- How to reflex to gel, see 5.8.9.13
- Auto dilution calculation, see 5.8.9.14

Future Proof

In-built flexibility and high-tech modular platform for product evolution

- Understand the automated maintenance procedures on the V8 UltraCE, see 9.1 and 9.2
- Future proof your V8 UltraCE, see 9.8, 9.9, 9.10 and 9.11
- Contact your local Helena Biosciences representative for the latest product information and developments; or consult www.helena-biosciences.com

Eco System

- When will my V8 UltraCE go to sleep mode to save power? see 5.2.1

2 Installation and special requirements

2.1 Overview

The V8 UltraCE (V801) is a fully automated *in-vitro* diagnostic capillary electrophoresis instrument with 8 capillaries, 14 sample racks, and a 112 sample capacity. Five bottle connectors are also supplied for the connection of buffers to the instrument and one dedicated connector for waste. The V8 UltraCE is an accessory used in conjunction with associated capillary electrophoresis kits.

V8 UltraCE uses electrolytic buffers and high voltage to separate the constituent fractions of human serum, urine and whole blood samples. The component fractions are then visualised by use of the absorption of light within a range of 200-600nm. Although the V8 UltraCE does not have an analytical function in isolation, it can be used in combination with analytical kits. These analytical kits are intended to be used with serum, urine, and whole blood samples. The instrument is intended for use by a trained laboratory professional in a clinical laboratory.

2.2 Storage and Transport

No special storage or transport conditions are required. V8 UltraCE can safely be stored and transported between -5°C to 60°C and at humidity levels between 5% and 95%.

2.3 Packaging and installation

V8 UltraCE has been carefully packaged to safely secure all items and mechanical components from damage during transportation and storage. Your V8 UltraCE will be unpacked and installed by a Helena Biosciences trained and certified service engineer, who will ensure that the entire system is fit for purpose.

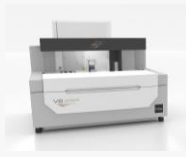


N.B. The V8 UltraCE must always be shipped in its original packaging. As a precautionary measure, please safely store all original packaging for future use.








Please do not attempt to unpack the V8 UltraCE or the PC and attempt installation without the presence or assistance of a qualified engineer. Failure to adhere to this could invalidate your warranty.

No special transport conditions are required. V8 UltraCE can safely be transported between -5°C to 60°C and at humidity levels between 5% and 95%.


2.4 Included in your V8 UltraCE system

Helena Biosciences Europe V8 UltraCE Capillary Electrophoresis System

Item	Description	Quantity Supplied
	V8 UltraCE Instrument	1
	Large Waste Bottle [0033.110]	1
	Bottle Connectors (1x Biohazard labelled) [0033.855]	6

Item	Description	Quantity Supplied
	Sample racks + inserts [0033.116]	14
	Shielded Ethernet cable (1 x cross cable, 1x patch cable) [0033.112]	2
	Power Cable [0033.077]	1
	Fuses T6.3A	2
	Barcode Scanner	1
	Barcode Scanner Holder	1
	Reagent Overlay [0033.108]	1
	Waste Drawer	1
	Fluid Port Plugs [0033.111]	5
	Skip Position Barcode Sticker Sheet [0033.107]	1
	SAS Sample Tray Sticker Sheet [0033.106]	1
	SPIFE Sample Tray Sticker Sheet [0033.109]	1
	IFU Statement [0100.340]	1
	EN61010 Compliance [0100.512]	1

PC

Item	Description	Quantity Supplied
	Touch Screen [0033.120]	1
	PC Tower [0033.119]	1
	Keyboard	1
	Mouse	1
	Power cords (black)	2

2.5 Basic installation requirements

2.5.1 Surroundings and space requirements

The setting-up location must be free of smoke, dust, or highly corrosive gases and vapours and should not be exposed to direct sunlight.

- Ambient temperature: +15°C to 30°C.
- Relative air humidity: 35% - 80%, without condensation.
- Installation height: 0m - 2000m above sea level
- Provide good access to the instrument system.
- Ensure good access to the rear power switch and power socket in the event that immediate removal of power is required. 894mm × 680mm × 700mm (W × D × H) (1500mm width with PC/Monitor).
- Bench-top sufficient to carry the full weight of the instrument and all accessories.
- Provide at least 100mm between the rear of the instrument and a back surface and a height clearance of 850mm to allow the top cover to open fully.
- Work height measured from the rack load area between 100mm and 120mm.
- Additional space will be required for optional external equipment, e.g. printer.
- V8 UltraCE will require access to at least 3 earthed power outlets.
- Your Helena Biosciences trained service engineer will advise on the best position for the system.
- Helena Biosciences recommends the use of a suitable Uninterruptible Power Supply (UPS).
- V8 UltraCE is for indoor use.

2.5.2 Electrical information

V8 UltraCE has to be connected to an approved standard socket with protective conductor. The approved wall outlet must be provided near the place of installation. The electrical supply must also be compliant with the local safety regulations and must have been approved by an authorised electrician prior to connecting the V8 UltraCE system. The V8 UltraCE power cable should be considered the disconnection device. The V8 UltraCE must be positioned to ensure access to this disconnection device.

Mains voltage	230V ± 10%
	115V ± 10%
	110V ± 10%
Input frequency	50/60Hz
Line protection (fuse)	Cat: V801 (T6.3A)
Maximum power consumption	500 VA
Caution	the supplied power cable is the only recommended power cable for use.
Electrical Safety	Class 1 device. This instrument must be earthed.
Overvoltage Category	Category II

2.5.3 Pollution Degree

The V8 UltraCE is Pollution Degree 2.

2.6 Platinum to V8 UltraCE configuration

The V8 UltraCE must be configured to the PC and Platinum which are supplied as part of the system. The Helena Biosciences installation engineer will configure the V8 UltraCE to the PC.

2.6.1 Platinum initial setup

The Platinum initial setup will be carried out during the installation process by a fully trained and certified engineer.

2.6.2 LIMS/LIS configuration

This will be carried out by a trained LIMS/LIS engineer during the installation process. Information required to set up the LIMS connection can be obtained by contacting technical support at Helena Biosciences: support@helena-biosciences.com.

2.7 Operator levels

Platinum has 3 different operator levels offering user definable access from basic through to advanced access and function. The purpose of this is to control the release of data to the LIMS/LIS system by configurable access settings for audit trail purposes as well as creating user definable functionality.

2.7.1 Level 1

This is the lowest level of access, offering basic functions to acquire and analyse data, which is completely defined and controlled by the operator with Level 3 user status (see below). This level is useful for trainee personnel, or where restriction to configurable menus is required.

2.7.2 Level 2

Definable by the operator with Level 3 user status, this is the standard level of access offering functions to acquire and analyse data, and alter configurable menus.

2.7.3 Level 3

For the purpose of ensuring the validity and quality of data stored on the system, and transference to the hospital LIMS, Level 3 status is the highest level of access, granted to the laboratory supervisor or manager. Users that are designated level 3 access will have full control of all functionality and settings in Platinum.

Level 3 access controls user settings and assigns user level permissions. As each user is given a password, the Level 3 user will have access to the operator access panel and will be able to expire (not view) passwords forcing a password change of users for additional security and control. The level of access for each operator is set by the Level 3 user.

When logging into Platinum for the first time, the Level 3 operator will be assigned a password set by Helena Biosciences. Please see your local distributor/sales representative for further information.

2.8 Adding a new user

Only users with level 3 (supervisor) can add a new user.

- Choose **Configure > Manage Operator Accounts**.
- In the dialogue boxes enter the required information according to the field. The criteria of the password, such as minimum length, expiry and format, can be assigned here by the Level 3 for added security.
- After filling in all the fields, choose **Add User**.

Operator List

Administrator5 • 27 January 2025 13:28

Operator Entry

Login name:

Full name:

Date of birth (dd/MM/yyyy):

User ID:

Password:

User level:

Add User

Password requirements

Expires in (days): 60 ☒

Minimum length: 6 ☒

☐ Must contain letters and numbers

Login name	Full name	..Us	..Dat	User ID	..Password	expir
Supervisor		3				30/04/2999
Administrator4		4				30/04/2999
Administrator5		5				30/04/2999

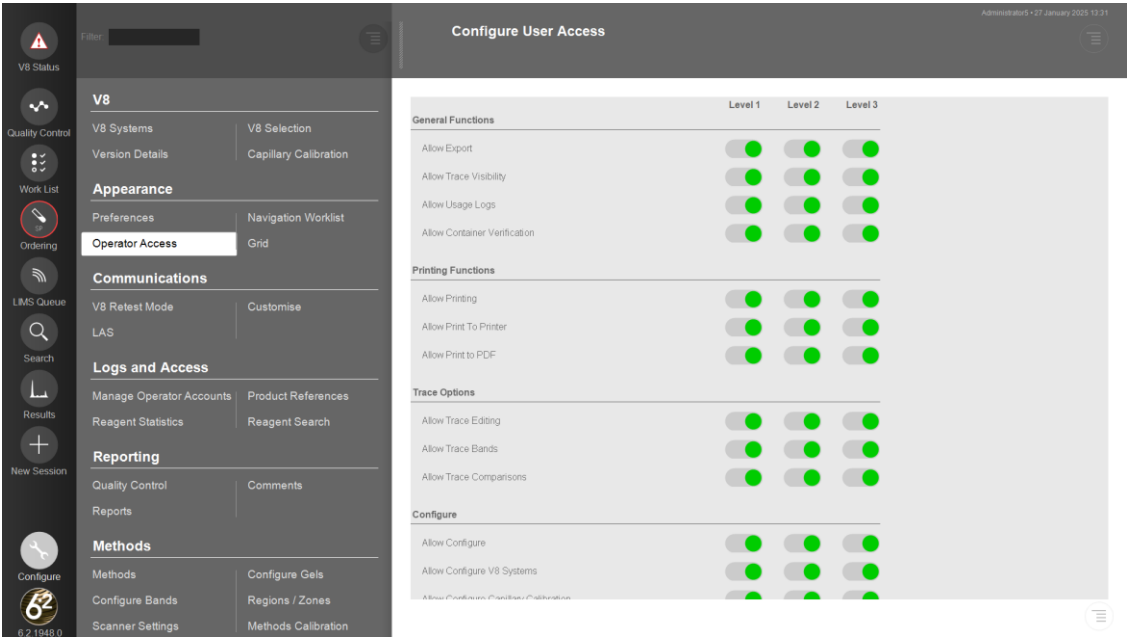
Delete user Expire password Change password

Number of minutes of inactivity after which users must renew log-in: 0 ☒ Minutes

Help Cancel

2.9 Configuration of menus

The Level 3 user can configure user access in **Configure > Operator Access**. All menu items and functions are grouped with sliders to show access at each operator level. The Level 3 user is able to customise each user level access by moving the sliders to on (green) or off (red).

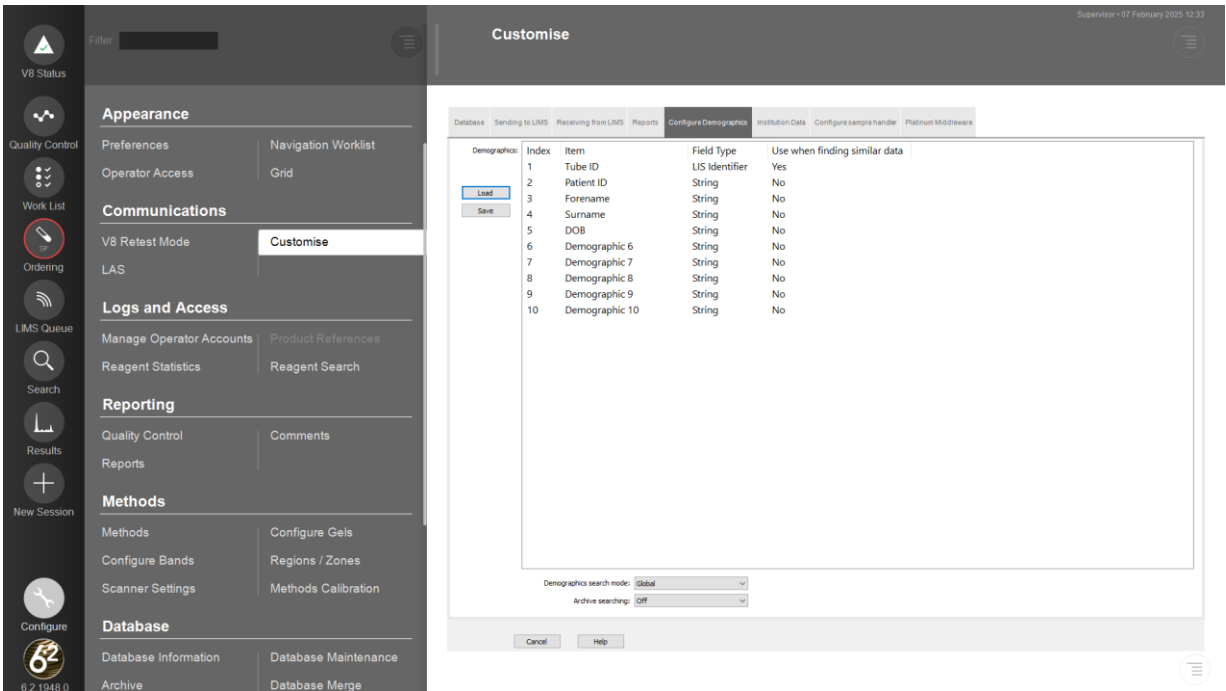


2.10 Configuration of demographics

In **Configure > Customise > Configure Demographics** input up to 10 demographic fields as required. (If the system is to be linked to a LIS/LIMS system either immediately or possibly in the future, then ensure wherever possible the demographic fields match identically to those used by the LIMS as this will significantly ease the LIMS linkup in the future).

The field type for each demographic can be selected from the drop-down list as appropriate for each demographic. The field marked as LIS identifier will be the location for the tube barcode id as read by the V8 UltraCE.

Select one demographic field to be used for searching similar data by selecting the check box. This is usually a unique patient identification number or a demographic field used as the LIS identifier. It is of paramount importance that the demographic field used as a LIS identifier, matches identically the field name being used by the LIS.



- a. Click the **Save** button, save the file under the name **demos . dem** in the Platinum folder.
- b. Click **Load**, and find the file you have saved in the previous step. Choose the required file to open. This will activate the correct demographic fields.

N.B. Users shall report patient results under unique identification to ensure they are not misreporting.

2.11 Configuration of Chemistry Values

Platinum allows up to 12 different chemistry values (e.g. Total Protein) to be input manually or imported from a LIMS per method type. To set the chemistry values for each method type, select **Configure > Methods**, select the method type and then select the **Chemistry Value** tab.

Chemistry item	Name	Unit	LIMS Name
Chemistry 1	IgG	g/L	IGG
Chemistry 2	IgA	g/L	IGA
Chemistry 3	IgM	g/L	IGM

Enter the Chemistry Name, Unit and the LIMS Name for each chemistry value. These will be saved automatically.

Total Chemistry Value Name will be used to calculate concentrations of bands except when an External Compound Name is entered. All other chemistry values should be input in the Chemistry Items below.

2.12 Normal Patient Ranges

Platinum allows entry of a normal range for patient samples for quantitative methods. To enter these values select **Configure > Methods**, select the method type and then select the **Bands** tab.

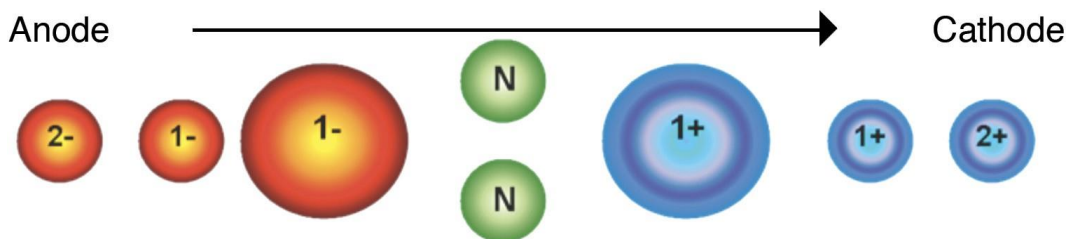
The normal range can be entered in either % or a concentration unit (as defined by the unit for total protein in the chemistry value setup).

N.B. Values entered as % must be suffixed with a % symbol.

Band	Component	Low area	Upper area limit	Ind.	Combine with pre.	Opt.	Lowe.	Uppe.	Limit	Mini.	Lar.	Col.	T.
1	Albumin	51.40%	67.43%	*	Do not combine		15.0	35.0					
2	Alpha-1	2.25%	5.65%	*	Do not combine		32.0	57.0					
3	Alpha-2	5.68%	12.75%	*	Do not combine		55.0	65.0					
4	Beta-1	6.05%	9.43%	*	Do not combine		62.0	68.0					
5	Beta-2	3.62%	8.04%	*	Do not combine		65.0	75.0	0.00%				
6	Gamma	7.88%	19.77%	*	Do not combine		72.0	90.0	0.00%				

3.1 Capillary Electrophoresis

Capillary electrophoresis is a powerful analytical technique which separates sample components based on differences in mass to charge ratio. This is achieved using a microbore, fused silica capillary filled with an appropriate electrolyte medium under high voltage. Positively charged ions are drawn through the capillary toward the cathode, the smallest ions eluting first. Electroosmosis of small ions within the buffer electrolyte draws neutral molecules through the capillary and overcomes the electrostatic attraction of negatively charged ions to the anode. This electroosmotic flow means negative ions are still drawn through the capillary.



The efficient heat dissipation of small diameter capillaries make the use of very strong electric fields possible allowing high efficiency separations and rapid migration times. This powerful analytical technique can be employed to resolve closely related compounds including large proteins with only a single amino acid difference.

4.1 V8 UltraCE technical specifications

Identification

- Positive patient identification. Sample rack barcoded identification.
- Barcoded buffer and reagent containers.

Barcode

- Embedded barcode reader. 70° angle.
- Symbolologies: Code 39, Codabar, Code 128, Interleave 2 of 5, Code 93 and UPC/EAN.

Loading

- Up to 14 sample racks of 8 primary tubes; total 112 standard operations.

Gel sample trays

- Compatible with SAS-1 Sample Tray (24 samples). SAS-3 Sample Tray (60, 80, 100 samples).
- SPIFE 60 sample tray.
- IFE-3, IFE-6, IFE-9 and IFE-15 SPIFE trays.

Sampling

- Generic sample cups.
- Capped primary tubes: BD Vacutainer (L x D) – 100mm x 16mm, 100mm x 13mm, 75mm x 13mm and Grenier Vacuette (L x D) - 100mm x 16mm, 100mm x 13mm, 75mm x 13mm
- Diameter: max. 16mm. Height: max. 100mm.
- Dead volume: 100µL (Sample tube dependent).

Pre-analytical

- Dilutions, cell lysis, reagent addition and reagent incubation.

Migration

- Eight fused-silica capillaries.
- Peltier controlled temperature for individual capillaries.

Buffers

- Five on-board buffer system containers; up to three open user-defined assay buffer positions.
- Dynamic buffer level monitoring.

Reagents

- Ten open positions for diluents and antisera; Anti-IgG, -IgA, -IgM, Kappa and Lambda.
- Peltier controlled reagent positions.

Maintenance

- On-board maintenance solutions.
- Automated maintenance procedures.
- Automated purging between assay changes.
- Automated startup and shutdown procedure.

Detection

- Light source: deuterium lamp and an LED light source with a fixed wavelength of 415nm.
- Wavelength detection: monochromator with 200 - 600nm wavelength range.
- Detection: eight photodiodes.

Walk-away automation

- 112 primary sample tubes.

Assays

- Serum Protein
- Urine Protein
- Immunodisplacement (IgG, IgA, IgM, Kappa, Lambda).

Data processing

- Trace capture.
- Trace editing.
- Statistical calculation and display.
- Quantitated calculation and display.
- Database flagging of patient status.
- Bi-directional communication; import and export of patient data and results.
- Immunodisplacement image capture & linkage to scan traces.
- Multiple search parameters with overlay capacity.
- Expert System.
- Automatic LIMS query.

Report printing

- Full in-built desktop publishing package.

Q.C. and validation

- Levey-Jennings and statistics reports.

User interface

- Platinum – advanced diagnostic software.

Dimensions

- 894mm (width) × 680mm (depth) × 700 mm (height)

Weight

- V8 UltraCE Instrument weighs 74kg.

Connections

- Ethernet connection from V8 UltraCE to PC.
- Ethernet connection to LIS / lab network.
- USB connection to peripheral utilities.
- Serial RS232 or ethernet to LIS.

Power

- Typical consumption of 489 VA (normal operation).
- Internal power supplies deliver up to 800 W.

4.2

V8 UltraCE schematic

The following schematic highlights and describes all the component parts important to the safe operation of your V8 UltraCE. Please refer to Part Five of this manual for correct operating instructions.

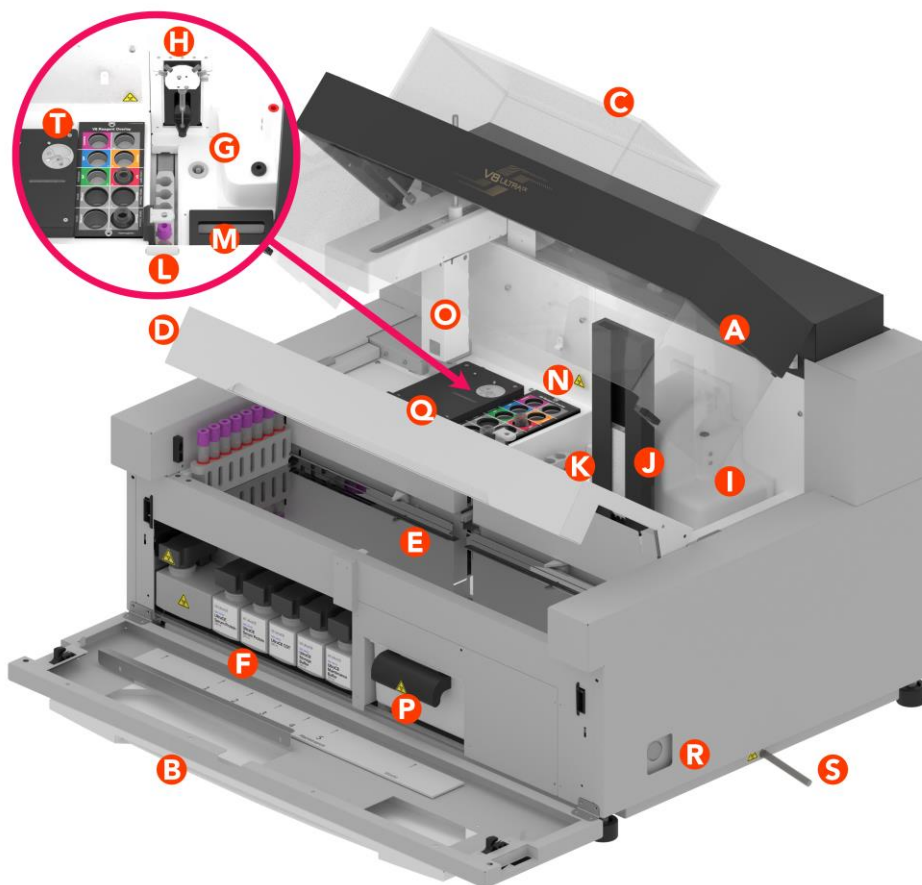
4.2.1

V8 UltraCE system description

The V8 UltraCE system combines a bench-top analyser and a free-standing PC pre-loaded with Platinum software for instrument management and results analysis. The system is self-sufficient enabling an efficient out-of-box installation requiring only electrical mains supply for system power; network ports for bi-directional host interfacing; and web access for remote service support.



The V8 UltraCE clinical capillary electrophoresis system



Instrument technical drawing

a. Top cover

The sample preparation and analysis lid contains the components which make up the sample preparation and analysis area. This part of the instrument is concealed to prevent sample and fluid contamination; and is protected from user interaction during analysis and preparation, due to the hazardous movement of the sample handling arm, and its needle.

b. Front cover

The front panel contains the buffer compartment area and the clinical waste drawer. The front panel can be opened to change buffers or empty the waste bottle or waste drawer with no interruption to the workflow. Users are notified when to empty the liquid waste bottle or clinical waste drawer.

c. Protective hood

The protective hood is made of transparent plastic and is present to prevent contamination to the sample and preparation area, and to protect the user from the mechanical movements of the sample handling arm. It should not be removed from the instrument.

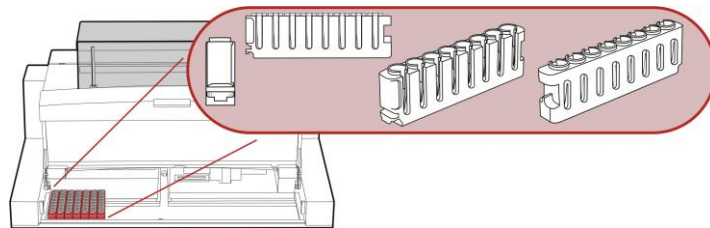
d. Rack cover (open)

The sample rack transport cover provides protection and access to all sample racks loaded on to the sample transport area of the V8 UltraCE. For continuous loading and urgent STAT samples, the user can access this area continually, although sample processing and preparation will pause, due to the potentially hazardous movement of the sample handling arm and its needle.



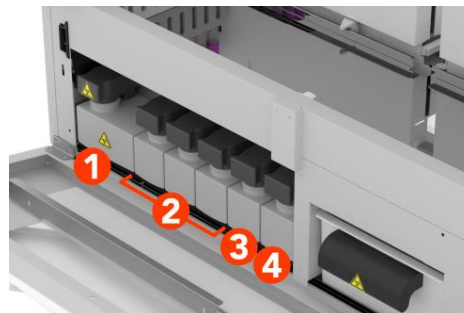
e. Sample rack transport area

The sample rack transport area handles sample racks for continuous loading, random access and urgent samples. The sample rack loading bay automates the transport and barcode reading of all sample racks and tubes placed on-board the V8 UltraCE with immediate communication of data to Platinum. It is a flexible system, allowing the user to place sample racks onto the transport area for random access and rack queue jumping for urgent testing requirements.



f. Fluid bottle compartment

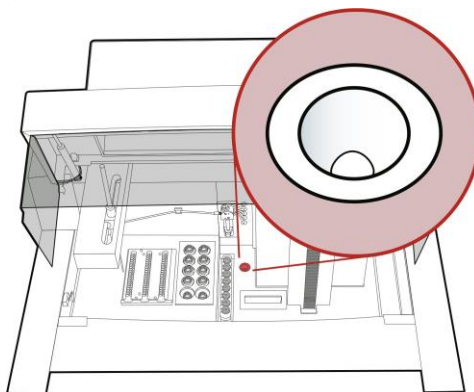
The fluid bottle compartment is accessed through the front panel. Buffer (re)installation requires careful steps and must be managed through Platinum. The buffer module has locations for six specially designed bottles. These are defined as:



- 1) Liquid waste bottle
- 2) Area for analysis buffers
- 3) UltraCE Storage Buffer position
- 4) UltraCE Maintenance Buffer position

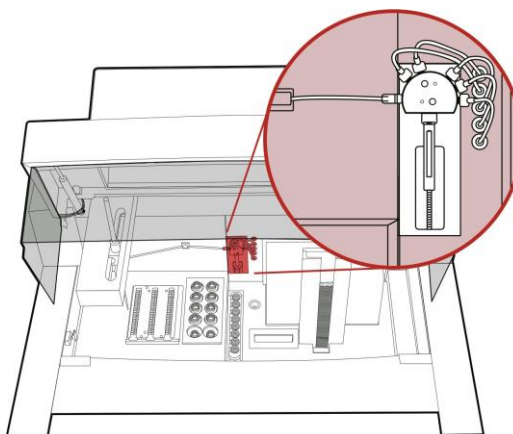
g. Wash station

The wash station is designed for full and effective needle cleaning and purging of the buffer lines. The needle moves directly to the wash station following the preparation of each sample for zero cross contamination. Cleaning and buffer fluids are purged through the needle into the wash station, automating the maintenance of system components.



h. Dispenser

The dispenser is a device that accurately aspirates and dispenses precise amounts of sample, buffer and cleaning fluid for reproducible results for each application served on the V8 UltraCE.

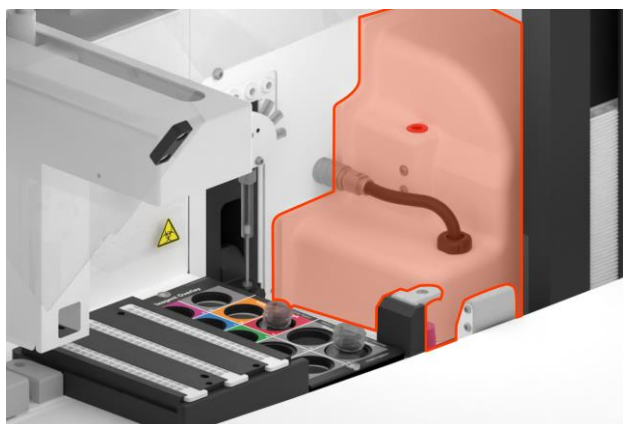


i. Separation unit



HAZARD

The V8 UltraCE separation unit is a specially designed casing that contains 8 Peltier regulated capillaries ensuring optimum performance across all separation channels. The separation unit protects the end- user from a high-voltage area containing fragile components. This area is not accessible to the end- user for health and safety reasons; and should only be directly handled by a Helena Biosciences trained and certified engineer.



j. Sample cup load tower

The sample cup dispenser is a holding magazine that contains and dispenses disposable sample cups into the sample cup fill area.



k. Sample preparation and analysis area

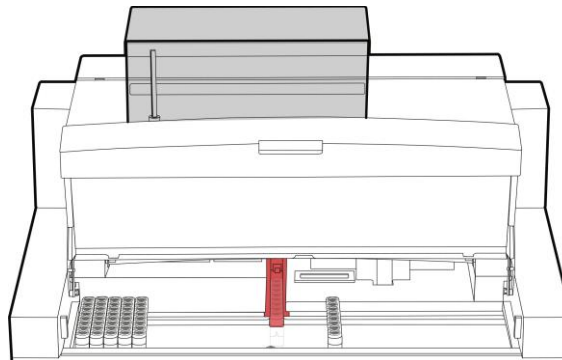
The sample preparation and analysis area contains all the primary components facilitating the automatic preparation and analysis of samples held on-board the V8 UltraCE. The user will be required to interface with this area only when:

- Changing reagent bottles.
- Cleaning and disinfecting area.
- Change removable sample tray.
- Replenish sample cups.



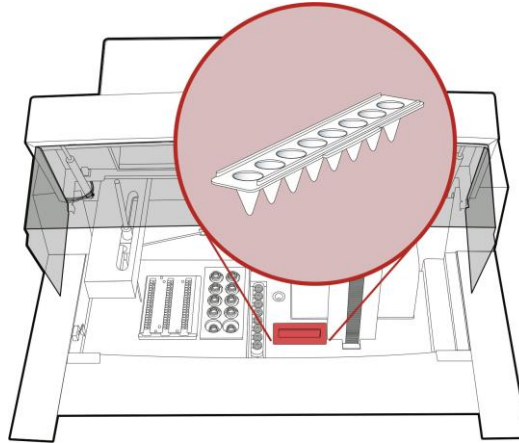
l. Sample rack loading bay

The sample rack loading bay accepts V8 UltraCE sample racks for the preparation and analysis of samples by the handling arm. The loading bay will hold the sample rack until the preparation of samples for analysis has been completed. Once finished, the sample rack loading bay will eject the processed rack to the right and accept the next rack from the left for the very same process.



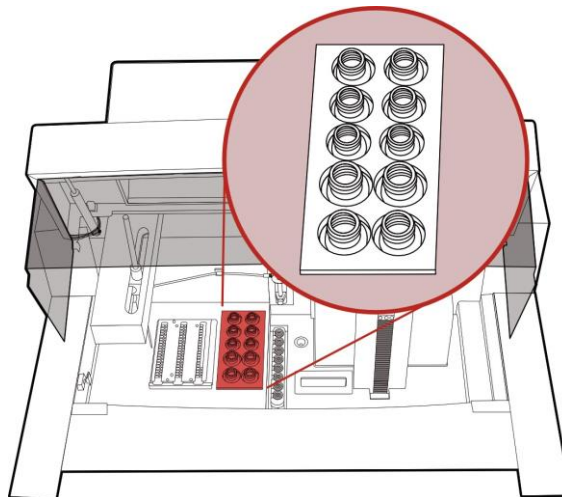
m. Sample cup fill area

The sample cup fill area accepts sample cups supplied by the dispenser for preparation of buffers and samples. Once the sample cup has been prepared for analysis, it will be transported for capillary loading under the separation unit.



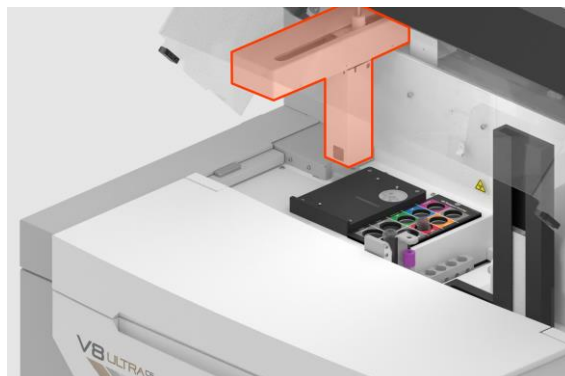
n. Reagent bottle area

The on-board reagent area has locations for ten reagent bottles e.g. antisera and sample diluent. The sample handling arm can access any of these locations which are defined by the method. An active Peltier device cools the bottle area to 15°C so that reagents can be left on-board throughout the day and overnight if required.



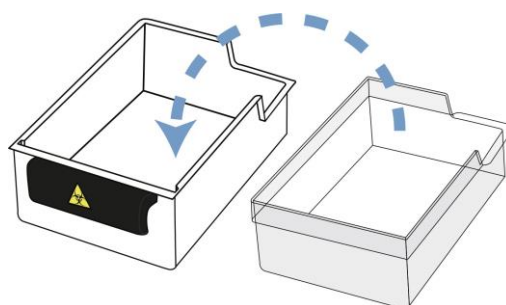
o. Sample handling arm

The sample handling arm handles all sample transfer functions including initial sampling, dilutions, reagent transfer and transfer to gel trays.



p. Clinical waste drawer

The clinical waste drawer collects and safely contains waste sample cups, residual sample, buffer, reagent and other fluids. Lined with a disposable insert, the waste drawer is designed with health and safety in mind. The clinical waste drawer is designed to hold approximately 100 sample cups and should be emptied when prompted by the V8 UltraCE.



q. Sample tray docking station

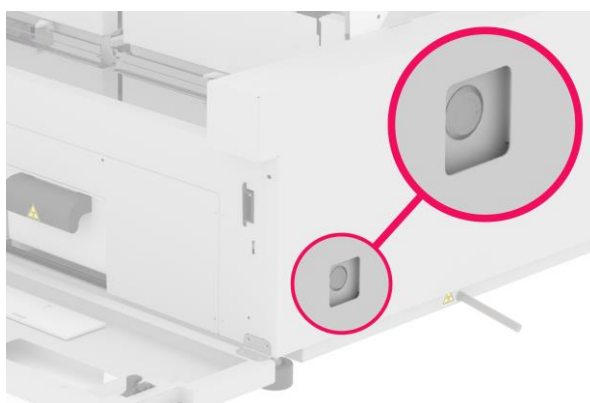
The sample tray docking area is designed to accept a range of removable sample trays for the auto-preparation of samples designated for further testing by gel electrophoresis or as additional dilution positions for further CE analysis. The docking station can accept the full range of SAS and SPIFE sample trays. The optical reader embedded in the surface automatically detects the type of tray on the system and ensures that it matches the method selected. (Sample tray must have V8 UltraCE identification sticker applied to base).



r. Side button

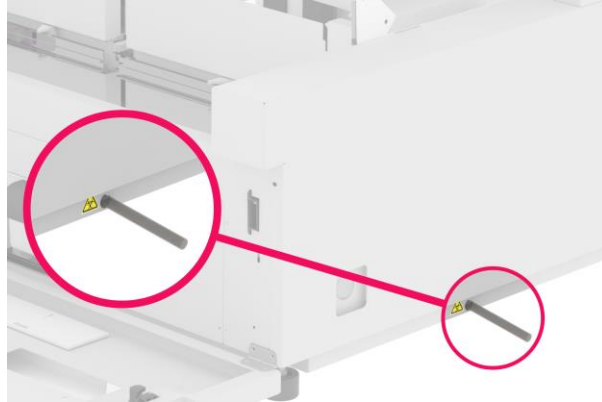
The side button is designed to initiate hands free, essential maintenance cycles without user intervention. By pushing the side button after powering up, the V8 UltraCE will begin system pre-conditioning in preparation for sample analysis. At the end of the sample analysis, the side button can be pressed to initiate Shut-down Mode, during which the V8 UltraCE will post condition. The main power switch situated on the rear of the instrument must be set to "I" in order for the side switch to work.

IT IS IMPORTANT THE V8 UltraCE IS POSTCONDITIONED AT THE END OF THE DAY AND WHEN THE INSTRUMENT IS NOT IN USE.



s. Waste pipe

The waste pipe will be utilised in the event of overflow within the system, it allows any overflow in the system to exit via a single route. This should be connected to a suitable clinical waste outlet or alternatively to the waste overflow bottle (cat: 0031-176).



t. Full needle wash station

The full needle wash station is designed for complete and effective full needle cleaning. The needle moves directly to the wash station following the preparation of each sample following cap piercing for zero cross contamination. Cleaning and buffer fluids are purged through the needle into the wash station, automating the maintenance of system components.

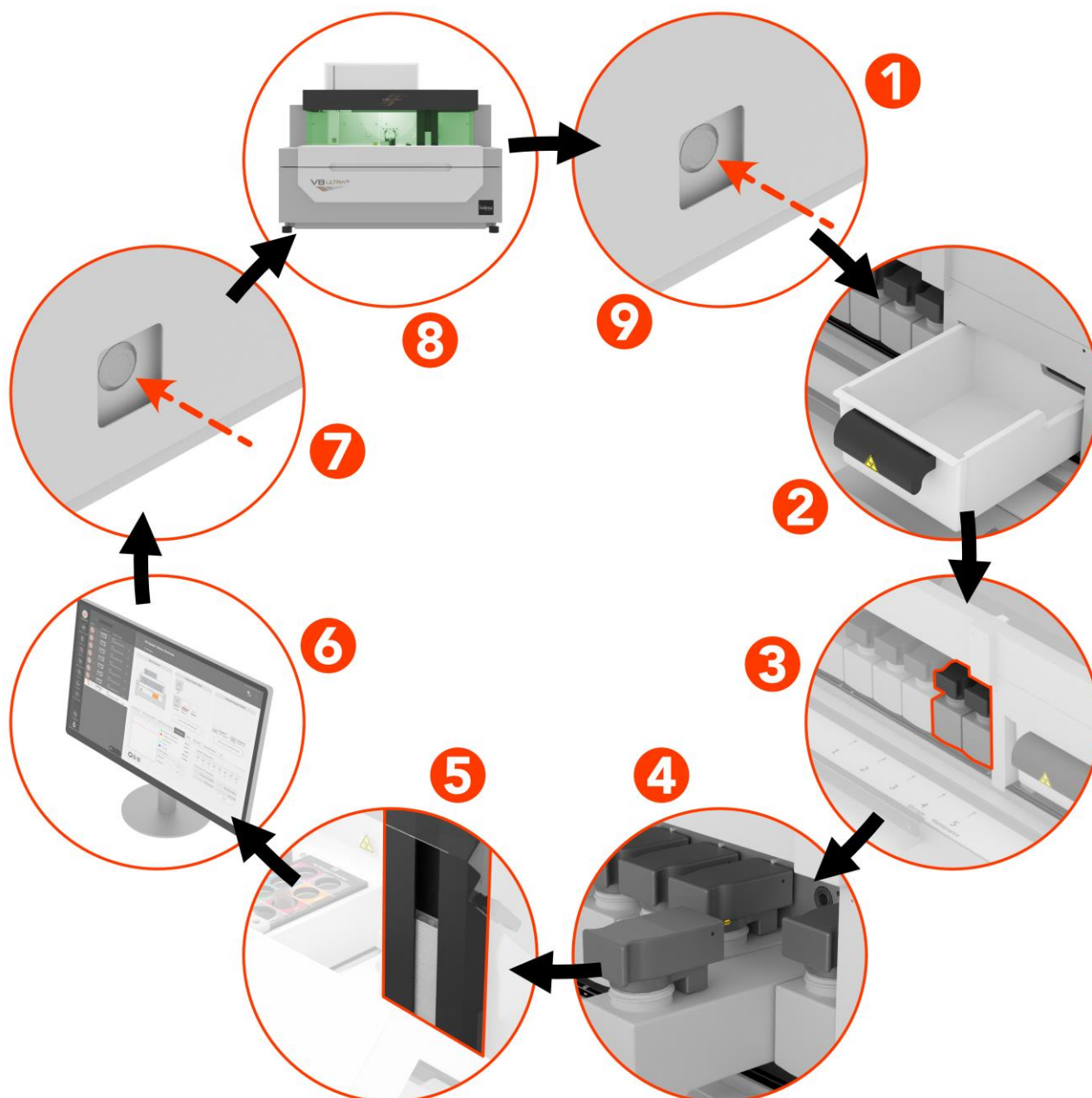


5 Operating the V8 UltraCE

The V8 UltraCE system is designed to be simple to use. As such, the daily routine of operation can be broken down into the following steps. It is strongly advised that these are conducted every day so as to maintain the optimum performance of the instrument.

For more information on how best to maintain the condition of the instrument, please refer to Part 9: Maintenance of the V8 UltraCE. For information on individual assays, please refer to the IFU located on the web, directions and password can be found in each kit box.

5.1 Quick user guide to daily operation



1. Start of day. V8 UltraCE is powered on at the back switch.
2. Ensure the waste drawer is on-board and lined with an insert and that the waste bottle is connected.
3. Check fluid levels of maintenance and storage buffers.
4. If required, replenish storage and maintenance buffers.
5. Replenish sample cups.
6. Load Platinum and begin a new CE session, select default assay, install relevant buffers, reagents, order additional tests as required gel trays.
7. Push the side switch. The V8 UltraCE will automate preconditioning maintenance cycles.
8. Place samples on-board. V8 UltraCE will begin operation. Results will be transferred to Pt for analysis. Remove samples once all assays are complete.
9. End of day. V8 UltraCE is powered off by pushing the side switch. The V8 UltraCE will automate post conditioning cycles.

5.2 Daily operating instructions

The following section describes how to prepare the V8 UltraCE for operating and shutting the system down after use.

5.2.1 Switching the V8 UltraCE on and off

Power to the V8 UltraCE is controlled by a main *ON/OFF* switch located at the rear of the instrument. This switch is used to power the instrument.

Daily operation of the V8 UltraCE should be controlled solely by the *side button* on the right hand side of the instrument. It is recommended that the rear power switch only be used when the V8 UltraCE is being unused for a period of three days or more.

In order to turn the V8 UltraCE on for operation and to initiate the preconditioning cycle, push the *side button*.

To put the V8 UltraCE back into SLEEP mode after operation, push the *side button*. This will initiate the post-conditioning cycle.

N.B. The V8 UltraCE MUST have completed the post-conditioning cycle before it is switched off using the rear switch (failure to do so WILL cause irreparable damage to the capillaries).

5.3 Preparing the V8 UltraCE for operation

The power switch located at the rear of the V8 UltraCE will be ON. The V8 UltraCE must be ready for the pre-conditioning cycle. Therefore, before pushing the *side button* the user must check the following protocols:

- The relevant test mode is selected (5.8.10.3)
- The required default assay is selected from Platinum (5.8.6.1) and the relevant buffers are on-board.
- The reflex test priority is selected. (5.8.10.4)
- The clinical waste drawer is on-board and lined with an insert (refer to section 5.6.6 and 9.14.1).
- The waste bottle is connected to the leftmost port of the fluid bottle compartment.
- UltraCE Storage Buffer and UltraCE Maintenance Buffer are on-board in ports 4 and 5 respectively (refer to section 5.6.1).
- Sample cup load tower is filled.
- To initiate pre-conditioning and capillary preparation for use, push the *side button* once all checks are complete.

5.4 Running in Multi-Assay mode

The V8 UltraCE is capable of automating assay switching with minimum instrument downtime. To run the V8 UltraCE in multi assay mode, the following steps should be followed:

- All relevant buffers and reagents should be on-board and installed as per instructions (see section 5.6).
- Select the required default assay (see section 'Selecting Default Assay', 5.8.6.1) and run samples as required.
- Serum Proteins, Urines and Immunodisplacement tests can be run simultaneously in one rack.
- To do this, ensure that the additional sample types are ordered appropriately.
 - Default assay set to run Serum Protein. All serum samples will run as default.
 - Order Urine and Immunodisplacement tests through Test Ordering (section 5.8.6.2).
 - Place samples on-board the V8 UltraCE for simultaneous analysis.
- For multiple assay switching e.g. Serum Protein and other assays, the V8 UltraCE will automatically perform pre-conditioning of the capillaries to run the new buffer.
- To do this, select one method as the default assay. All racks on-board will be analysed using this assay.
- For those samples that require analysis using the different assay, either change the default method after all other samples have been analysed, or, order the required tests through Test Ordering (section 5.8.6.2).
- For multi-assay switching between SP and other assays, samples should be batch loaded, using separate racks per test.

N.B. Assay switching between Serum Protein and other assays require capillary preconditioning. This will take approximately 20 minutes. Helena Biosciences recommends that you batch load samples according to assay.

5.5 Shutting down the V8 UltraCE after use

It is important that the V8 UltraCE is shut down correctly after use to maintain optimum performance. The system MUST post-condition fully to ensure capillary integrity.

To shut the V8 UltraCE down:

Remove all sample racks from the sample rack loading bay. Remove and cap all reagents in the reagent block. If required these should be refrigerated. Push the *side button*.

The V8 UltraCE will begin post conditioning and pulse yellow. This takes around 15 minutes.

When post-conditioning has finished, the V8 UltraCE lights will turn off. This indicates that the instrument is now in SLEEP mode.

N.B The V8 UltraCE will automatically shut down after a period of inactivity. This period is user definable through the service page, the default setting is 4 hours.

If the V8 UltraCE's *side button* is pressed whilst it still has racks onboard to be tested, the V8 UltraCE will complete all necessary testing before automatically beginning the shutdown procedure. If the operator intends to use this method for shutting down the V8 UltraCE they must first ensure that all necessary buffers, reagents, sample cups and provision for waste is made to allow the instrument to complete its testing and shutdown correctly, otherwise the instrument may be prevented from shutting down.

5.5.1 Shutting down the V8 UltraCE without the necessary buffers onboard

If the V8 UltraCE is shut down without all the buffers onboard necessary for post conditioning to occur the V8 UltraCE will stay in the yellow light maintenance mode indefinitely. It will chime and display onscreen the details of the buffer that needs to be replaced in order for post conditioning to occur. If this happens the missing liquid(s) need to be replaced. Post conditioning will then be carried out automatically.

It is important that Platinum remains open during the post-condition process.

5.6 General instrument instructions

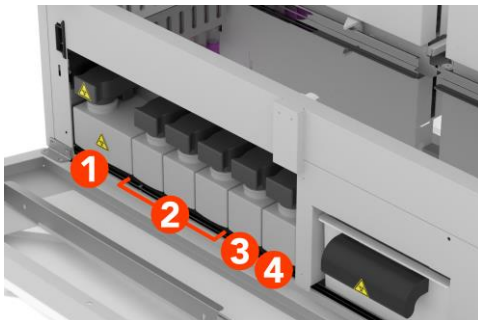
The following section describes the general instrument instructions and procedures for effective running of the system.

5.6.1 Installation of buffer bottles

The V8 UltraCE will only accept Helena Biosciences V8 UltraCE buffers and reagents. Each bottle has a unique barcode and this information **MUST** be entered when the user is prompted before the buffer will be accepted on-board. Once a bottle has been exhausted, it cannot be refilled and placed back on-board. This is to ensure QC and system integrity.

If installing a bottle before operation please ensure the system is in standby mode. Once installed, start a new V8 UltraCE session and wait until prompted to enter all barcode information. If installing a bottle during operation, there is no need to start a new session.

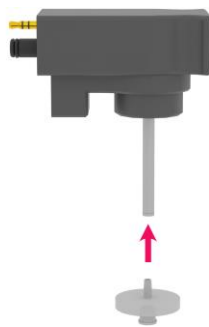
The V8 UltraCE fluid bottle compartment contains space for five buffer bottles. Three of these positions are user-definable and will be loaded with the appropriate analysis buffer (marked as position 2 below). The position marked as 3 should contain UltraCE Storage Buffer, and the position marked as 4 should contain UltraCE Maintenance Buffer.



The V8 UltraCE has will notify the user when a buffer bottle requires changing or when the waste bottle is full. The waste cap designated with the biohazard sticker should **ONLY** be used with the waste bottle (leftmost) port. The waste bottle should not be removed from the system whilst it is actively wasting fluid. The strip light on the waste bottle connector will flash whilst it is active, wait until the flashing stops to remove and empty the waste bottle.

5.6.2 To install a new buffer

- a. Attach a new filter unit to the inlet pipe of the bottle connector cap. The narrow end of the filter unit should be carefully inserted inside the pipe and securely fitted.



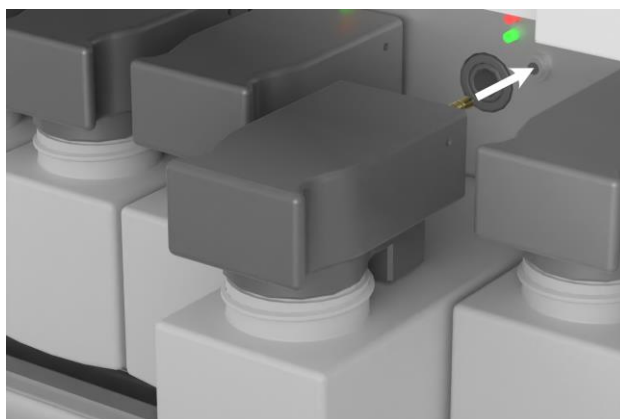
- b. Access the fluid bottle compartment by opening the *Front Cover*.
- c. Remove any exhausted buffer bottles by holding the bottle connector and pulling backwards gently, but firmly.



CAUTION

N.B. Care must be taken when installing and removing bottles. Do not pull on the bottle to remove as this can lead to damage of the cap. Do not invert the fluid cap after removal.

- d. Dispose of the old buffer bottle, filter unit and any excess liquid.
- e. Carefully place the bottle connector into the buffer port ensuring the cap is firmly located within the buffer unit. The LED light will change to green.



- f. The V8 UltraCE will chime and the **Define Buffer** window will open, with one of the buffer ports will be highlighted.
- g. Scan or enter the barcode information into the highlighted barcode box using the hand-held barcode scanner. Select **OK** to close the window.

N.B. If installing multiple bottles do not attempt to scan all barcodes at once. Wait until prompted to do so. Do not manually open the [Define Buffer] windows, always wait until prompted.

- h. The highlight will move to the next port that has been changed and the V8 UltraCE will chime. Scan or enter the barcode for this buffer. Click **OK** to close the window. This process will continue until all new buffers have been identified to the Platinum software.
 - i. Close the front panel. The V8 UltraCE will then purge all new liquids, accompanied by a chime. Depending upon how many liquids have been changed, this process should take approximately 2-6 minutes.
- N.B. In sites with multiple V8 UltraCE instruments, partially used bottles cannot be taken off one V8 UltraCE and installed on another. When switching assays, it is recognised by Helena Biosciences that partially used bottles will be removed and re-installed on the V8 UltraCE at a later time. Re-installation is the same as if you were installing a new bottle, as Platinum will recognise the barcode and extract stored information on previous use. However, this information is stored only on the system which was first loaded with the buffer. Another instrument cannot retrieve this information, and thus, the bottle is likely to run dry and air introduced into the system.

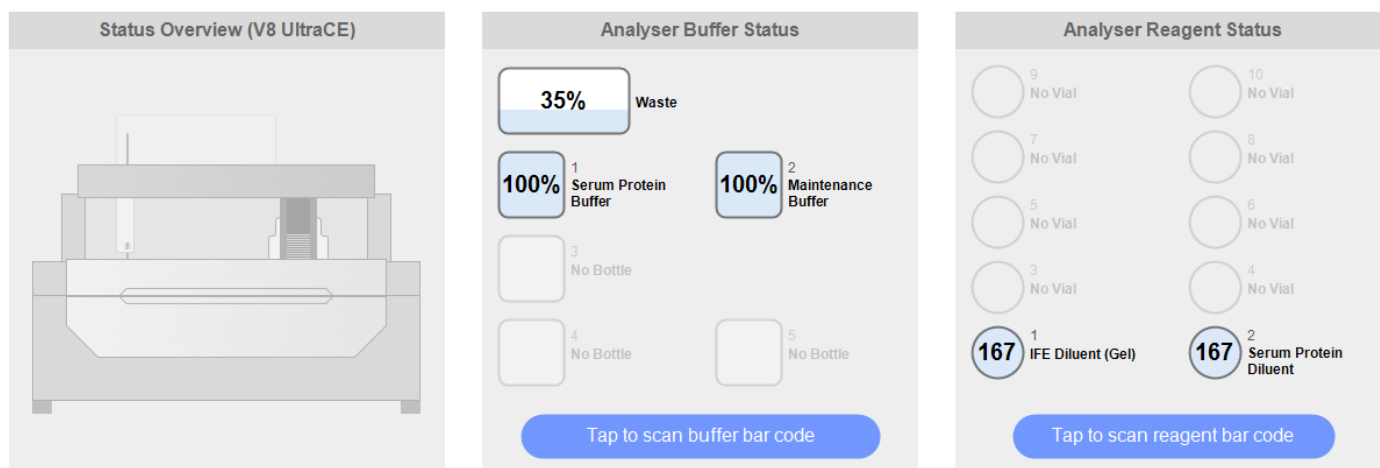
5.6.3 Checking buffer levels

It is possible to check the levels of remaining buffer on-board to ensure sufficient buffer is installed for complete analysis.

To check the buffer fluid levels:

- a. Go to the **V8 Status** window.
- b. In the **V8 Status** window there is an **Analyser Buffer Status** and an **Analyser Reagent Status** which displays the live fluid levels.
- c. To refresh the values, tap on the **V8 Status** window icon.

No Messages



EXPIRED REAGENTS CANNOT BE USED AND WILL NOT BE ACCEPTED BY THE INSTRUMENT

5.6.4

Loading reagents

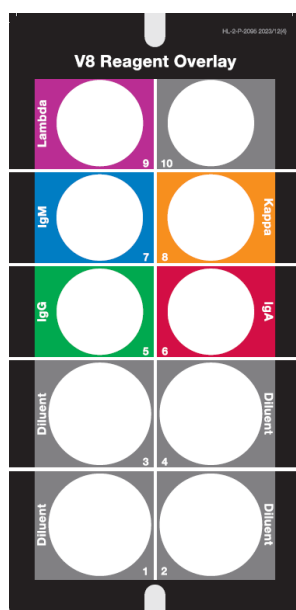
V8 UltraCE antisera and supplementary reagents/diluents can be placed on-board the V8 UltraCE for automated immunodisplacement and sample preparation. The V8 UltraCE has the capacity to hold on-board ten different reagents with open access positions. Positions are user defined and dependent upon the assay being performed. However, to ensure correct loading, the V8 UltraCE comes with an overlay for the reagent bottle area. This is supplied with the V8 UltraCE.

The reagent block is Peltier temperature controlled ensuring that the reagents can remain on-board throughout the day and without a compromise to reagent stability. It is suggested that reagents are placed on-board at the start of the day before any sample analysis commences.

N.B. Installation of reagents is not an automated process. The user MUST enter the barcode information into Platinum for the V8 UltraCE to recognise the reagents on-board.

To install reagents:

- Access the reagent panel by raising the top cover to the sample preparation and analysis area.
- Antisera can be placed in locations 5-10 of the reagent panel.
- Assay diluents can be placed into position 1, 2, 3 or 4 of the reagent panel.



- Choose **V8 Status > Tap to scan reagent bar code** to open the Define Reagents window.
- Scan or enter barcode information on the side of the reagent bottle, ensuring that the positions in Platinum correspond with those on-board the V8 UltraCE.

- f. Multiple reagents can be entered in one go.
- g. Once entered, click **OK** and close the lid to the sample preparation area. The V8 UltraCE will commence analysis.

V8 Reagents

	Reagent 1	Reagent 2	Reagent 3	Reagent 4	Reagent 5
Barcode :	37521A172511796490	E52L3V179F	0000000000	0000000000	L66T064RL7
Product reference :	Serum Protein Diluent	UltraScreen Diluent	none	none	IgG (Green)
Expiry :	1026	1026	0101	0101	0126
Lot :	11984115	16	0	0	28
Batch index :	233	398	0	0	103
Tests Left :	103	136	0	0	50
Max tests :	167	200	0	0	50
Cap Opened on :	03/03/2025	17/02/2025	n/a	n/a	06/03/2025
Open Stability (days left) :	26	165	n/a	n/a	28

	Reagent 6	Reagent 7	Reagent 8	Reagent 9	Reagent 10
Barcode :	EESL325TEF	B7BBCOUG8A	I66T260BL7	KSEKFFOFSE	0000000000
Product reference :	IgA (Red)	IgM (Blue)	IgK (Orange)	IgL (Purple)	none
Expiry :	0126	0126	0126	0126	0101
Lot :	13	2	12	26	0
Batch index :	394	422	229	11	0
Tests Left :	50	50	50	50	0
Max tests :	50	50	50	50	0
Cap Opened on :	06/03/2025	06/03/2025	06/03/2025	06/03/2025	n/a
Open Stability (days left) :	28	28	28	28	n/a

OK
Cancel
Help

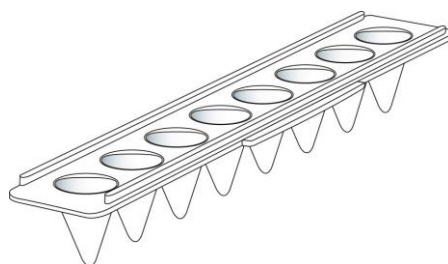
EXPIRED REAGENTS CANNOT BE USED AND WILL NOT BE ACCEPTED BY THE INSTRUMENT

5.6.5

Loading sample cups

The sample cups have eight wells and an asymmetric orientation. They contain a flat edge and a lipped edge. They are packed in clusters of eighteen all in the same orientation. It is important when loading the sample cup load tower to keep all cups in this orientation.

Sample cups are provided in every kit except UltraCE Storage Buffer and UltraCE Maintenance Buffer kits. Every time buffer and reagents are loaded onto the V8 UltraCE, please ensure the Sample Cup Load Tower is equipped with the sample cups provided within your kits.

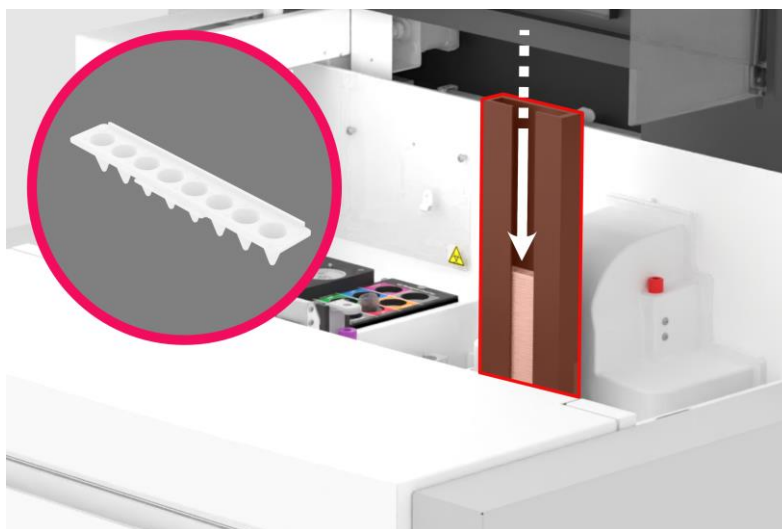


To load sample cups:

- a. Access the sample cup load tower by raising the top cover to the sample preparation and analysis area.

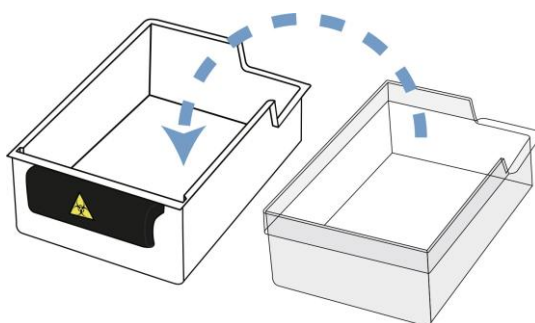
N.B. If the V8 UltraCE is in operation, raising this top cover will cause the V8 UltraCE to 'PAUSE' all sample handling activity. Once closed, normal operation will continue.

- b. Remove stacked sample cups from packaging; ensuring cups remain in the same orientation.
- c. Hold the stacked cups between thumb and forefinger, with the lipped edge facing forward.
- d. Carefully slide the stack from the top of the sample cup load tower, down to the bottom, ensuring that the cups remain stacked and level, and that the lipped edge of the sample cup appears through the sample cup load tower window. It is recommended that they are not dropped from the top, but guided down to the bottom.
- e. Continue to fill the cups in this manner until the load tower is full and close the top cover.



5.6.6 Clinical waste drawer

It is important to change the clinical waste drawer when prompted by the V8 UltraCE. The waste drawer inserts are designed to hold circa 100 sample cups and can be disposed of as clinical waste in accordance with local waste guidelines. The clinical waste drawer inserts are orientation specific. Please ensure the insert fits neatly inside the waste drawer to avoid interference with internal mechanical movements.



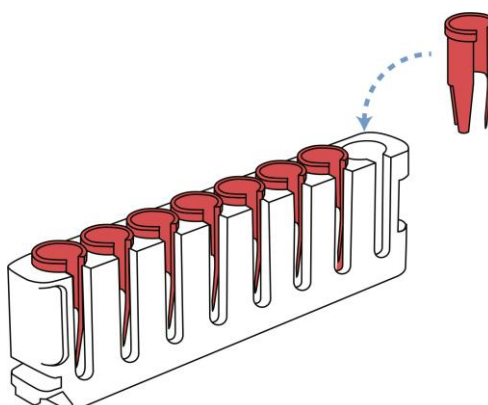
5.6.7 Sample racks and sample tubes

The V8 UltraCE is supplied with 14 custom-moulded sample racks capable of holding 8 sample tubes. The maximum number of sample racks that the V8 UltraCE can hold is 14 totaling 112 samples at full on-board capacity. Each sample rack is individually barcoded (R01 – R14) for identification by the V8 UltraCE. These barcodes must not be removed or changed.

Sampling is direct from uncapped or capped primary tubes.

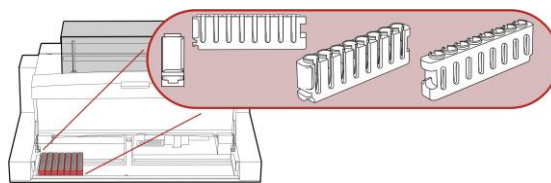
Barcodes must be within the height of 2cm and 8cm from the bottom of the sample tube in order for the internal V8 UltraCE barcode reader to be able to read the barcode.

Diameter:	max-16mm
Height:	max-100mm



Placing samples on-board V8 UltraCE

Sample racks are loaded on to the left hand side of the sample rack transport area ensuring that the rack barcode is facing the top left hand corner of the sample rack transport area.



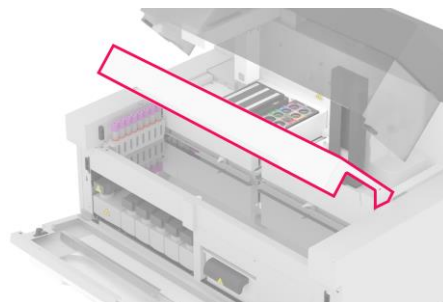
Racks can only be loaded in one orientation. At the barcoded end of the rack is a lip that slots into the side of the sample rack transport area base plate. This is to ensure that the V8 UltraCE can move the racks safely and efficiently. The V8 UltraCE will move sample racks into the rack loading bay for sampling. Once samples have been prepared, the rack will be placed to the right hand side of the sample rack transport area.

Due to the continuous loading and multi-assay functions of the V8 UltraCE, samples can be loaded in any order, and as such there is no specific batch loading option. Up to 14 racks can be loaded at one time. Once the samples in a rack have been processed by the default assay, the user or the Expert System will determine if there are any further tests to be conducted. If there are no further ordered tests or reflex assays assigned to that rack, the rack can be removed.

However, if there are outstanding tests for the analysed rack, then the V8 UltraCE will recall the rack for further analysis on the samples. The time at which this happens is determined by the Set Test Priority as defined by the user (see 5.8.10.4).

To load a sample rack:

Open the rack cover to the sample transport area. The V8 UltraCE will pause sample handling.



Place the sample racks onto the left hand side of the sample rack transport area, ensuring that the rack barcode is facing the top left hand corner and the tube barcodes are facing left. Close the rack cover to the sample rack transport area. The V8 UltraCE will begin scanning the rack and sample tube bar codes.

N.B. The racks can only be loaded onto the system in one orientation, with the rack barcode facing the left and to the top of the sample rack transport area.

Cap Piercing and Agitation

Mode of action

- a. Capped tubes are brought into the sampling area and scanned via the inbuilt barcode reader.
- b. The rack is positioned so that the first tube location is positioned under the tube stripper.
- c. The tube stripper clamps the capped tube in place and the needle pierces the cap septum.
- d. The sample is agitated by the needle using plasma picked up at the surface of the sample and expelled deep within the red blood cell layer.
- e. Further mixing is carried out within the cell layer.
- f. A sample aliquot is taken to the V8 UltraCE sample cup.
- g. The needle is washed both inside and out.
- h. The stripper rises and the next tube location is positioned beneath it.

Considerations

- Buffer position 4 is dedicated to the full needle wash station. UltraCE Storage Buffer must be placed on this position at all times.
- If samples have been stood for longer than 24 hours it is recommended that the sample is manually agitated or vortexed and analysed within the next 24 hours.
- Packed cells cannot be used.
- Tubes must contain at least 1 ml functional sample volume
- Agitation should not be attempted on uncapped tubes.
- Cap piercing and agitation methods cannot be used when a sample tray is onboard, as this will block access to the big wash station for full needle washing.
- The use of cap piercing and agitation at the external sample position when using a track connection can be accommodated upon request.

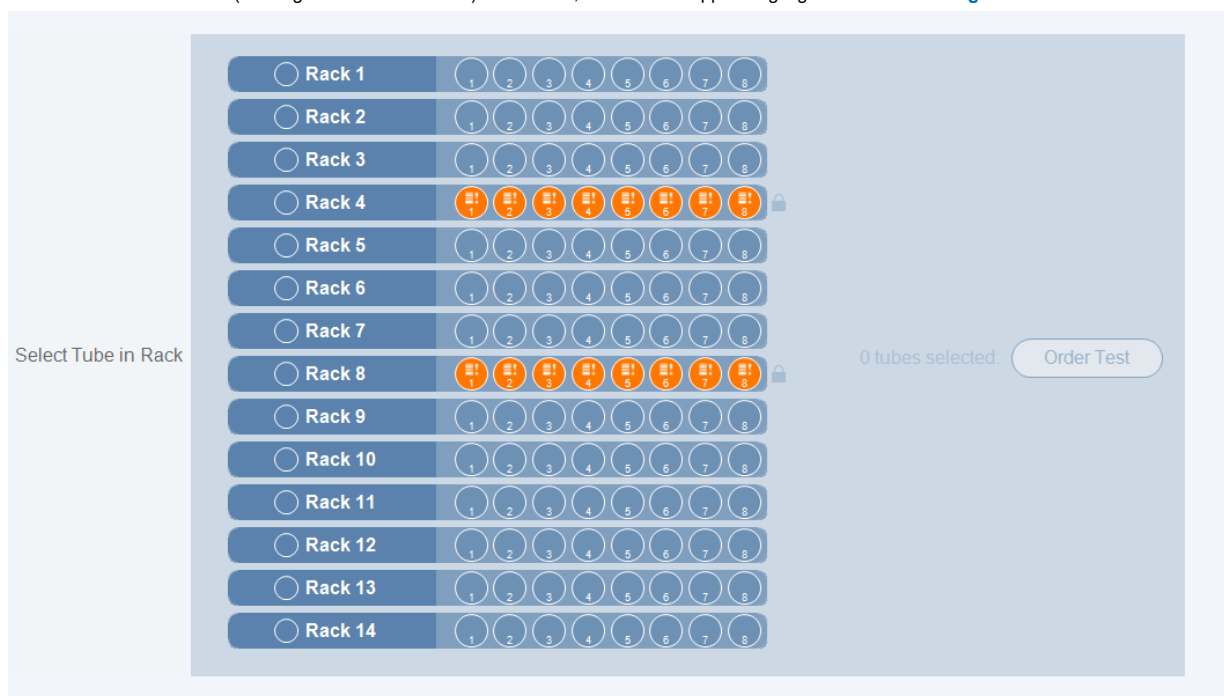
Sample tube barcodes

Tubes can be loaded on to the V8 UltraCE with or without individual bar codes. However, this does affect the manner in which Platinum processes samples and reflex tests.

- Barcodes present: the V8 UltraCE will process each sample individually and will be driven preferentially by barcode; not rack number and position.
- Barcodes not present: the V8 UltraCE will process each sample individually and recognise each one only by rack number and position. As such, racks MUST NOT be removed from the system or Platinum if reflex testing is needed.

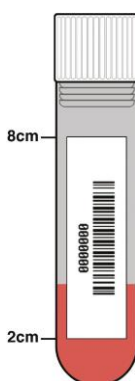
The V8 UltraCE holds the tube identification encoded in the barcode in the navigation list under the column marked as LIS identifier. If the V8 UltraCE has not been able to read the barcode on the sample tube, or there is not a sample tube in every position of a sample rack this will be left blank.

To avoid disruption to the workflow, the V8 UltraCE will process all the samples, performing the default assay for any unlabelled or mis-read tubes. When an unknown tube (missing or misread barcode) is detected, the tube will appear highlighted in the **Ordering** window.



The V8 UltraCE will check all positions in the rack for samples, and so tubes with unread barcodes will be sampled.

N.B. The barcode must be placed onto the tube between 2cm and 8cm from the bottom of the sample tube.



V8 UltraCE Tube Specification

No tube greater in height than 100 mm (or 106mm with a cap) should be used on the V8 UltraCE system. The sample racks can accommodate tubes with an outer diameter of 13 mm when using red inserts or < 16 mm with the inserts removed.

75 mm tubes with no cap will not be detected by the tube stripper.

Adding a tube ID to processed samples

Sample tubes with no barcode or ones that have been mis-read are identifiable in the navigation list as the tube ID is blank. The user can enter this information only **AFTER** the V8 UltraCE has processed the sample **and all the data has been obtained**.

- To do this, click on the Tube ID on the right-hand side of the screen.
- This will enable the user to scan the tube with the barcode scanner, or to manually enter a tube ID.

- It is also possible to enter sample barcode information in the **Worklist** window.

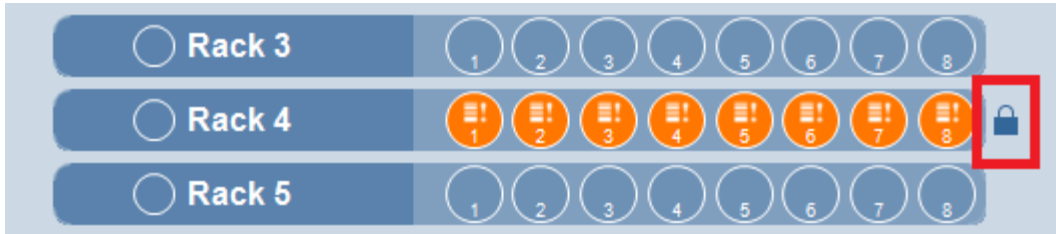
5.6.8.2 To remove a “Sample Missing Barcode” flag from Platinum

Sample tubes with missing barcodes or mis-read barcodes will be highlighted in the **Ordering** window. Before this rack can be used again on the V8 UltraCE, this list must be manually emptied by the user. The purpose of this is to ensure the correct assay has been performed and to notify the system that the user has changed the samples in the rack.

N.B. Removing a rack from the system also removes the sample tube contained within it. As such automated reflex testing cannot be performed.

5.6.8.3 How to remove a rack from the worklist

To remove the rack click the **padlock icon** to the left of the rack and then select OK on the pop up window that appears.



N.B. Do not click the remove rack button until the data is visible on screen.

5.6.8.4 Skip position barcode

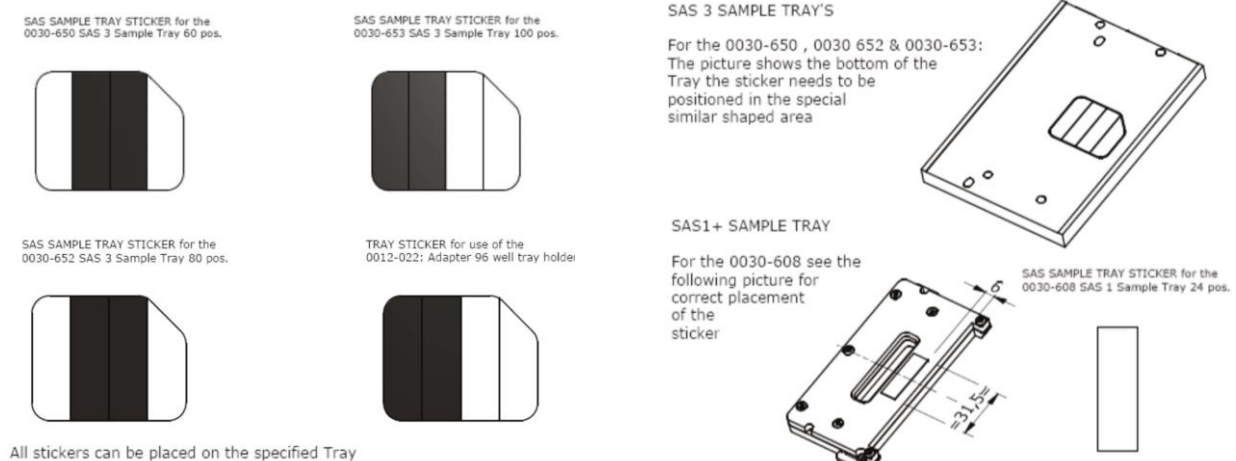
If you wish to run a rack containing empty sample positions, skip position barcodes should be used. These barcodes are made up of a series of 6 or 7 zeros (depending if a check digit is used). When the V8 UltraCE pulls a rack into the sample handling area and this barcode is detected, the V8 UltraCE will not sample from this position and this position will not appear in the Platinum worklist.

This is particularly useful when running Immunodisplacement as a default method with unfilled racks to save on unnecessary ID reagent wastage, when using the gel integration feature of the system with a 9 position IFE gel to save time, or when using the control methods to save on wastage of control material.

5.6.9 V8 UltraCE gel tray handling

The V8 UltraCE automates sample handling and preparation of recalled samples for analysis by agarose gel electrophoresis. The sample handler is able to aliquot samples into a removable gel sample tray which can then be transferred onto one of Helena Biosciences SAS/SPIFE instruments for further analysis. The gel tray must contain a V8 UltraCE gel tray identifying label (supplied as part of the V8 UltraCE), a paired tray barcode, and Disposable Sample Cups (210100).

5.6.9.1 To affix V8 UltraCE gel tray identifying label



5.6.9.2 To load a SAS gel tray:




- Access the sample tray docking station by raising the top cover to allow access to the sample preparation and analysis area.
- Prepare the required SAS sample tray as per SAS operation manual.
- Place the SAS tray onto the sample tray docking station ensuring the locator pins are engaged into the SAS tray.






- d. The V8 UltraCE optical sensors will detect the type of SAS tray placed on-board and will adjust all sample handling and preparation accordingly.
- e. Scan or enter the SAS tray ID number in the window prompt in Platinum.

N.B. paired barcode stickers can be ordered from Helena Biosciences (catalogue number 312300) for gel tray identification. IFU will be included.

- f. Order the required assay from Platinum – either by reflexing the sample in question or by going to the test ordering window. Alternatively for methods consisting of a larger number of samples the default method may be changed.
 - g. The position in which the sample is prepared into the gel tray is traceable via both the Results window and Work List window:
- In the **Results** window, the position can be seen in the circle that appears over the gel tray icon, once the gel tray has been removed:

Status	Name	Analysis name
	1	Serum Protein SAS-3 Serum... 05 Mar 2025 15:41
	2	Serum Protein SAS-3 Serum... 05 Mar 2025 15:41
	3	Serum Protein SAS-3 Serum... 05 Mar 2025 15:41

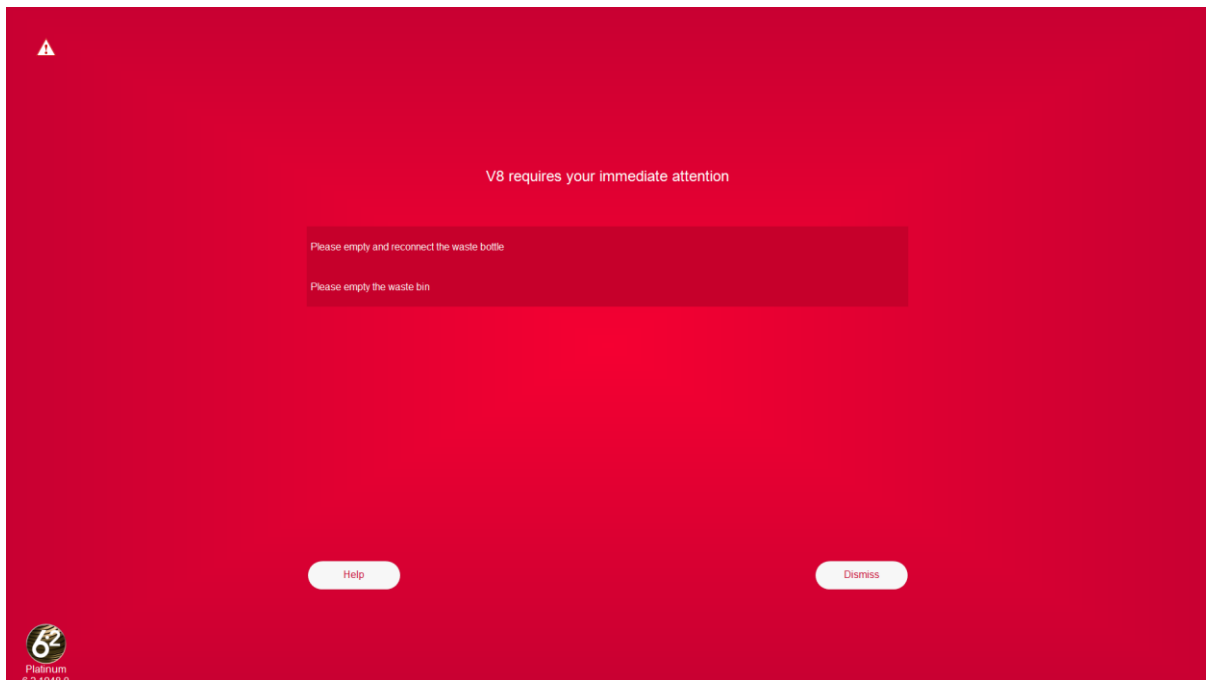
In the **Work List** window, a 'Tray Position' column is displayed which lists the gel tray ID and the position:

Status	Line	Tray Position	Sample/Control	Method
	1	123: 1	Sample	Serum Protein SAS-3 Serum Protein
	2	123: 2	Sample	Serum Protein SAS-3 Serum Protein
	3	123: 3	Sample	Serum Protein SAS-3 Serum Protein

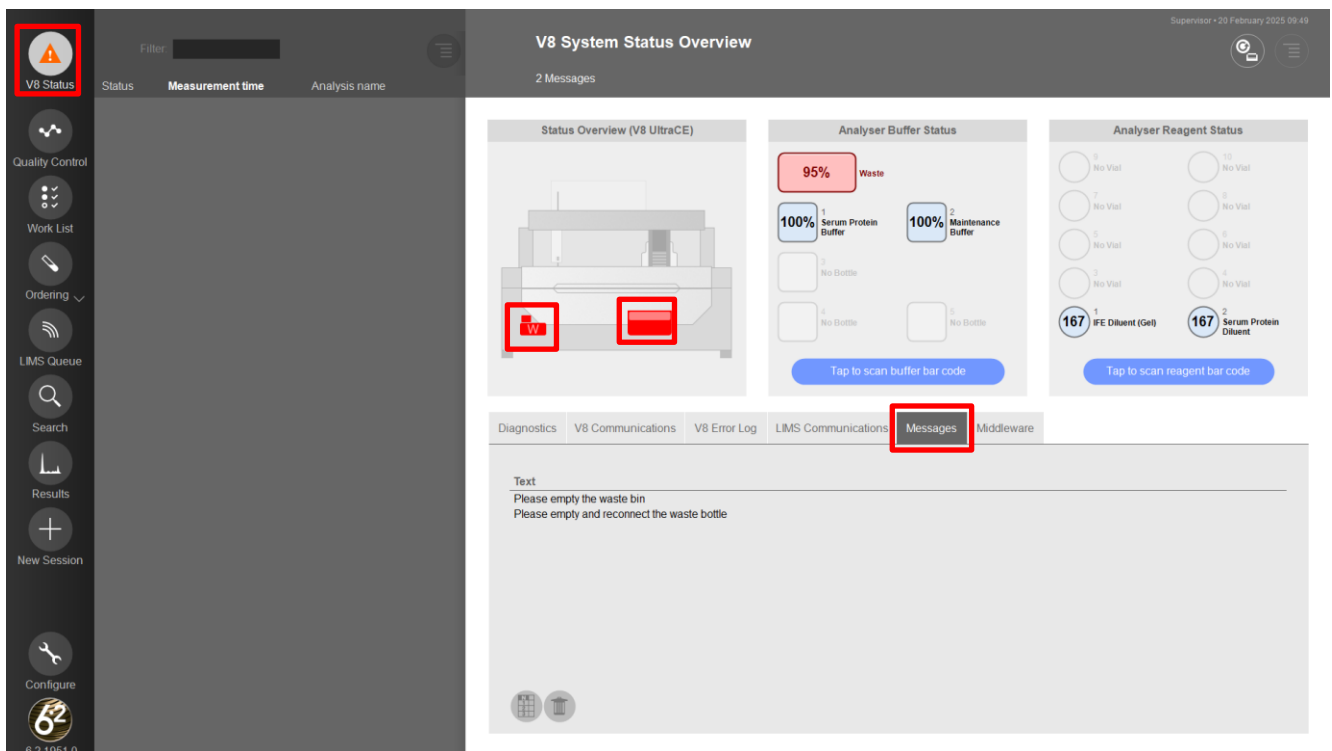
5.6.10 V8 UltraCE System warnings and status

Platinum software continually informs the user of the instrument status, or action, and of any warning or error messages. All information regarding the status of the instrument can be found in the **V8 Status** window.

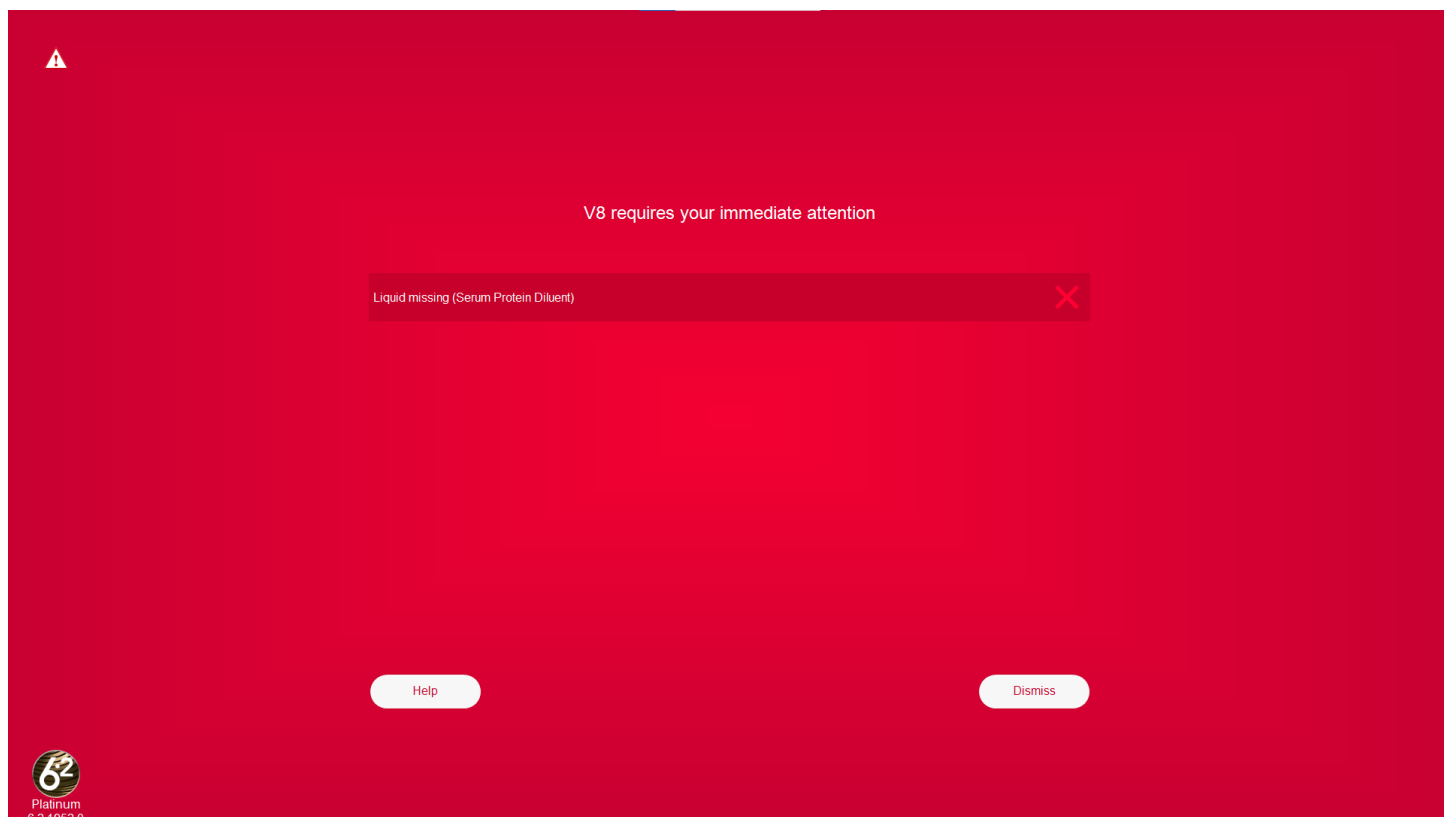
Critical messages will appear in a full screen warning window. To temporarily dismiss the message, select 'Dismiss'. The window will continue to reappear until the error has been addressed.



If 'Dismiss' is selected, the V8 Status icon will continue to show an orange warning triangle, the area which requires attention will be highlighted in red in the V8 System Status Overview, and the specific error message will also show in the 'Messages' Tab:



Once the operator has resolved the identified issue, all warning indications will disappear from the screen. In certain circumstances however; e.g. if the instrument runs out of Serum Protein Diluent; the instrument is unable to detect that the necessary resolution action has been carried out. In this situation the user must click the cross that appears in the full screen warning.

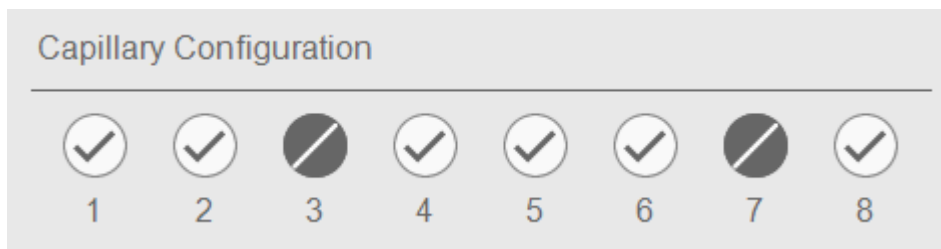


5.6.11 List of attention messages and actions required

Attention message	Machine pauses	Action required
Liquid missing (specified)	Yes	Replace missing liquid, if necessary click clear button
10% liquid remaining in bottle	No – Though will imminently	Change depleted buffer bottle or load a second bottle into an available port.
Unknown liquid, please scan bottle barcode	Yes	Scan bottle barcode of new bottle added to system
Sample cup load tower nearly empty	No – Though will imminently	Sample cups will need to be replenished soon.
Cup load tower empty, please load sample cups	Yes	Sample cups need replenished in sample cup load towers
Front cover open	No	Close front cover of instrument
Top cover open	Yes –Sample handling	Close top cover to resume sample handling
Rack cover open	Yes – Sample handling	Close rack cover
Please replace the waste bin	No	Replace waste drawer to continue testing
Please empty the waste bin	No	The waste drawer needs to be emptied and replaced
Please replace the waste bottle	Yes	Replace the waste bottle
Please empty and reconnect the waste bottle	Yes	The waste bottle is full and needs to be emptied and replaced
Empty sample tray required	Yes	Sample tray held on board full, to prepare further gel samples remove the full tray and place a new sample tray on board for gel tray preparation to continue
Sample tray missing	Yes	Need to place sample tray onboard for gel tray preparation to continue
Method is not OK, Big wash and Sample tray can't be used at the same time	Yes	Remove the sample tray from the system to allow access to the big wash station
Duplicate barcodes in rack	No	All barcodes will be removed and may need to be entered manually
Rack barcode has not been scanned	Yes	Rack will not be run and will need to be moved back to the left of the sample preparation area, or samples will need to be moved to a new rack

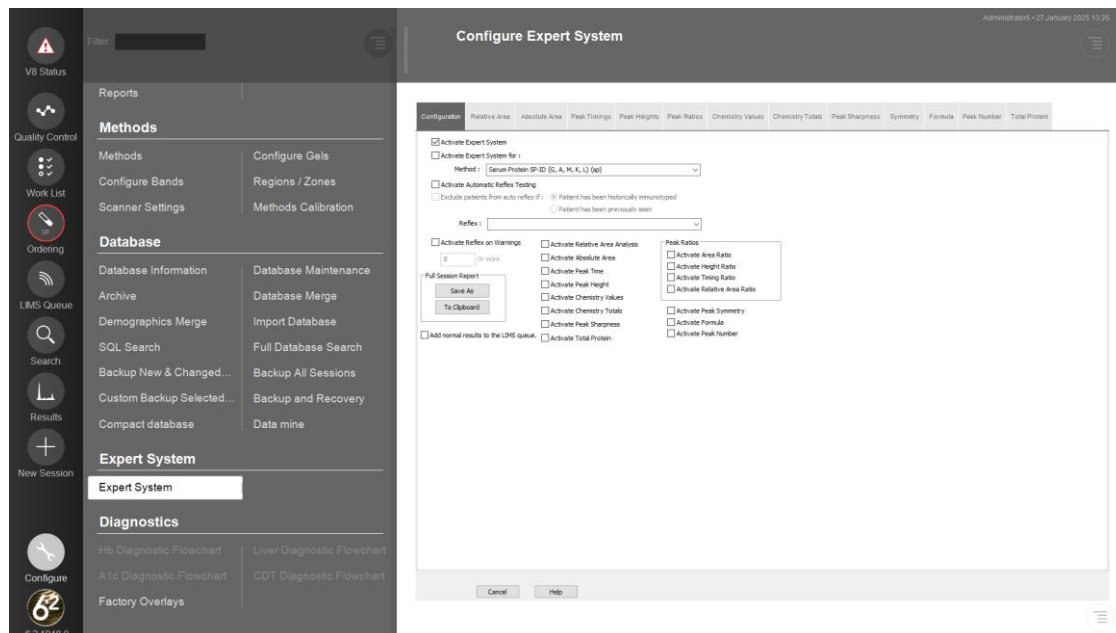
In the event that a capillary is damaged or deemed unusable, the sample handling for that capillary can be disabled and the capillary isolated from use. The order of work will adjust so that samples will be automatically processed between several V8 UltraCE runs with no further instruction required from the user. The results will be displayed showing only the available capillaries.

- Go to **V8 Status > Diagnostics > Capillary Configuration**.
- Capillaries are displayed, and numbered from 1-8, corresponding with positions left to right on the instrument. To isolate a capillary and switch it off, un-tick the checkbox above the capillary of interest. To switch the capillary on, ensure the checkbox is ticked.



5.7 Accessing the Expert System

The Expert System can be turned on, turned off, configured or results viewed only when viewing an active session or any previous sessions, via **Configure > Expert System**:



Configuring the Expert System

When the Expert System option is activated, the settings and parameters will become fully configurable for the Expert System:

Once the Expert System is activated, many more tabs are available and the Configuration tab can be set up:

1. The tabs that run along the configuration window are for each set of parameters that can be configured to assign samples to being normal, warning, abnormal or wrong number of bands.
2. The 'Activate Expert System for:' section allows the user to turn the Expert System on only for relevant methods. Therefore multiple methods can be selected for use with the Expert System, each with differing parameters. The Method dropdown menu is only populated with methods set as Main and Reflex in the Configure V8 Methods section of Platinum.
3. Automatic reflex testing can be turned on for use on samples which are assigned as definite abnormal samples. Leave Automatic Reflex testing unselected if you don't wish to reflex test abnormally marked samples.
4. Should automatic reflex testing be selected, the Expert System has the ability to not reflex test under certain circumstances. If you don't want to automatically reflex patient samples, ensure "Exclude Patients Form Auto Reflex Test" is selected.
5. If it is selected to exclude results from automatic reflex testing, the user can base this on two variables (1) the patient has an immunodisplacement or immunofixation result in the database or (2) the patient has any previous result in the database. This aspect will only work if a unique identifier which is used for similar data is configured in the demographics configuration part of Platinum.
6. If automatic reflex testing has been selected, the user can select which test to use for the reflex test. The dropdown menu is only populated with 'Main and Reflex' and 'Reflex Only' methods from the Configure V8 Methods section of Platinum.
7. The Expert System works on three main principal results: normal sample, abnormal sample, warning sample. Warning samples have unusual traits compared to normal results, but not indicative of a definite abnormal sample. The user can select to assign a result as abnormal should the result have at least a preset number of warnings. The user turns this aspect on and sets the warning number here.
8. Each set of parameters used for assigning sample results must be turned on to be used in the analysis. Each of the parameters can be activated either in the parameter tab or on the configuration page.
9. The results of a session can be saved or copied for pasting into a particular program. This will list all sample results from the Platinum file and the Expert System status linked to each.
10. If required, all the results assigned as normal can be added to the LIMS queue ready for approval. Should Platinum be set up, these results can then also be sent directly to the LIMS without validation.

Configuring Parameters – Area, Position, Heights, Sharpness, Symmetry and Total Protein

The configuration tabs for Relative Area, Absolute Area, Peak Timings Peak Heights, Peak Sharpness, Symmetry and Total Protein are all the same and allow configuration for all of the six bands:

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein																																																
<div> <input type="checkbox"/> Activate Relative Area Analysis </div> <table border="1"> <thead> <tr> <th>Active</th> <th>Abnormal <</th> <th>Warning <</th> <th>Band</th> <th>> Warning</th> <th>> Abnormal</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>40.00</td> <td>Albumin</td> <td>100.00</td> <td>100.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Alpha-1</td> <td>10.00</td> <td>20.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Alpha-2</td> <td>15.50</td> <td>28.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Beta-1</td> <td>10.00</td> <td>15.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Beta-2</td> <td>12.50</td> <td>17.50</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>10.00</td> <td>Gamma</td> <td>20.00</td> <td>30.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td></td> <td>0.00</td> <td>0.00</td> </tr> </tbody> </table>													Active	Abnormal <	Warning <	Band	> Warning	> Abnormal	<input type="checkbox"/>	0.00	40.00	Albumin	100.00	100.00	<input type="checkbox"/>	0.00	0.00	Alpha-1	10.00	20.00	<input type="checkbox"/>	0.00	0.00	Alpha-2	15.50	28.00	<input type="checkbox"/>	0.00	0.00	Beta-1	10.00	15.00	<input type="checkbox"/>	0.00	0.00	Beta-2	12.50	17.50	<input type="checkbox"/>	0.00	10.00	Gamma	20.00	30.00	<input type="checkbox"/>	0.00	0.00		0.00	0.00
Active	Abnormal <	Warning <	Band	> Warning	> Abnormal																																																							
<input type="checkbox"/>	0.00	40.00	Albumin	100.00	100.00																																																							
<input type="checkbox"/>	0.00	0.00	Alpha-1	10.00	20.00																																																							
<input type="checkbox"/>	0.00	0.00	Alpha-2	15.50	28.00																																																							
<input type="checkbox"/>	0.00	0.00	Beta-1	10.00	15.00																																																							
<input type="checkbox"/>	0.00	0.00	Beta-2	12.50	17.50																																																							
<input type="checkbox"/>	0.00	10.00	Gamma	20.00	30.00																																																							
<input type="checkbox"/>	0.00	0.00		0.00	0.00																																																							

1. The activate button at the top of the tab is linked to the activate button on the configuration page and turns on the use of the parameters selected.
2. The active column allows for only certain bands to have parameters activated for analysing results.
3. The low abnormal column allows the user to input the lowest value before which the result is definitely abnormal.
4. The low warning column allows users to input the lowest value that is deemed normal. Any values that fall between this and the low abnormal are deemed as a warning. Any values that fall between this and the high warning are deemed as normal. This value cannot be lower than the low abnormal value or higher than the high warning value.
5. The band column lists the band that the parameters are being set for.
6. The high warning column allows users to input the highest value that is deemed normal. Any values that fall between this and the low warning are deemed normal. Any values that fall between this and the high abnormal are deemed as a warning. This value cannot be higher than the high abnormal value or lower than the low warning value.
7. The high abnormal column allows users to input the highest value after which the result is definitely abnormal.

When activated, each value can be changed to ensure optimal settings are in place for determining the state of each result. Default values are in place, but it is recommended that each laboratory fine tunes the settings:

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein																																																
<div> <input checked="" type="checkbox"/> Activate Relative Area Analysis </div> <table border="1"> <thead> <tr> <th>Active</th> <th>Abnormal <</th> <th>Warning <</th> <th>Band</th> <th>> Warning</th> <th>> Abnormal</th> </tr> </thead> <tbody> <tr> <td><input checked="" type="checkbox"/></td> <td>0.00</td> <td>40.00</td> <td>Albumin</td> <td>100.00</td> <td>100.00</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Alpha-1</td> <td>10.00</td> <td>20.00</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Alpha-2</td> <td>15.50</td> <td>28.00</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Beta-1</td> <td>10.00</td> <td>15.00</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Beta-2</td> <td>12.50</td> <td>17.50</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>0.00</td> <td>10.00</td> <td>Gamma</td> <td>20.00</td> <td>30.00</td> </tr> <tr> <td><input checked="" type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td></td> <td>0.00</td> <td>0.00</td> </tr> </tbody> </table>													Active	Abnormal <	Warning <	Band	> Warning	> Abnormal	<input checked="" type="checkbox"/>	0.00	40.00	Albumin	100.00	100.00	<input checked="" type="checkbox"/>	0.00	0.00	Alpha-1	10.00	20.00	<input checked="" type="checkbox"/>	0.00	0.00	Alpha-2	15.50	28.00	<input checked="" type="checkbox"/>	0.00	0.00	Beta-1	10.00	15.00	<input checked="" type="checkbox"/>	0.00	0.00	Beta-2	12.50	17.50	<input checked="" type="checkbox"/>	0.00	10.00	Gamma	20.00	30.00	<input checked="" type="checkbox"/>	0.00	0.00		0.00	0.00
Active	Abnormal <	Warning <	Band	> Warning	> Abnormal																																																							
<input checked="" type="checkbox"/>	0.00	40.00	Albumin	100.00	100.00																																																							
<input checked="" type="checkbox"/>	0.00	0.00	Alpha-1	10.00	20.00																																																							
<input checked="" type="checkbox"/>	0.00	0.00	Alpha-2	15.50	28.00																																																							
<input checked="" type="checkbox"/>	0.00	0.00	Beta-1	10.00	15.00																																																							
<input checked="" type="checkbox"/>	0.00	0.00	Beta-2	12.50	17.50																																																							
<input checked="" type="checkbox"/>	0.00	10.00	Gamma	20.00	30.00																																																							
<input checked="" type="checkbox"/>	0.00	0.00		0.00	0.00																																																							

Configuring Parameters – Ratios

The peak ratios tab allows the user to select certain ratios based on relative area, absolute area, peak timings (position) and peak heights:

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein																																				
<div> <div>Peak Height Ratios</div> <div>Relative Area Ratios</div> <div>Absolute Area Ratios</div> <div>Peak Timing Ratios</div> </div>																																																
<div> <div>1 <input type="checkbox"/> Activate Ratio</div> <div>2</div> <div>3</div> <div>4</div> <div>5</div> <div>6</div> <div>7</div> </div> <table border="1"> <thead> <tr> <th>Active</th> <th>Band 1</th> <th>Band 2</th> <th>> / <</th> <th>Warning</th> <th>Abnormal</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td>Albumin</td> <td></td> <td>></td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Albumin</td> <td></td> <td>></td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Albumin</td> <td></td> <td>></td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Albumin</td> <td></td> <td>></td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>Albumin</td> <td></td> <td>></td> <td>0.00</td> <td>0.00</td> </tr> </tbody> </table>													Active	Band 1	Band 2	> / <	Warning	Abnormal	<input type="checkbox"/>	Albumin		>	0.00	0.00	<input type="checkbox"/>	Albumin		>	0.00	0.00	<input type="checkbox"/>	Albumin		>	0.00	0.00	<input type="checkbox"/>	Albumin		>	0.00	0.00	<input type="checkbox"/>	Albumin		>	0.00	0.00
Active	Band 1	Band 2	> / <	Warning	Abnormal																																											
<input type="checkbox"/>	Albumin		>	0.00	0.00																																											
<input type="checkbox"/>	Albumin		>	0.00	0.00																																											
<input type="checkbox"/>	Albumin		>	0.00	0.00																																											
<input type="checkbox"/>	Albumin		>	0.00	0.00																																											
<input type="checkbox"/>	Albumin		>	0.00	0.00																																											

1. The activation option allows the user to activate some or all of the peak ratio parameters.
2. The drop down menu allows the user to select which ratio parameter is selected for editing.
3. The active column allows the user to select the number of ratios for the particular parameter that will be used.
4. Band 1 is the column that will be used first in the ratio calculation (e.g. Albumin as peak 1 and Gamma as peak 2 would see the Albumin peak divided by the Gamma peak).
5. Band 2 is the column that will be used as the divisible in the ratio calculation (e.g. Albumin as peak 1 and Gamma as peak 2 would see the Albumin peak divided by the Gamma peak).
6. The higher than (>) and lower than (<) column allows the user to configure whether the parameters set for the ratio result should be higher than or lower than.
7. The warning value is the lowest or highest value that a normal sample can be (depending on whether it is set to < or >). Any value between the normal and abnormal value will be flagged up as a warning result.
8. The abnormal value is the lowest or highest value a sample can be before it is deemed definitely abnormal. Any value above or below (depending on </>) will be marked as abnormal.

Example:

Albumin peak height = 0.1 Gamma peak

height = 0.005

Active	Band 1	Band 2	> / <	Warning	Abnormal
<input checked="" type="checkbox"/>	Albumin	Gamma	>	15.0	25.0

Ratio result = 0.1 : 0.005
= 20

Therefore, the result will be marked as a warning.

Configuring Parameters – Chemistry Values

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Peak Ratios	Total Protein																																				
<div> <div>1 <input checked="" type="checkbox"/> Activate Chemistry Values Analysis</div> <div>2 <input type="checkbox"/> Ignore Zeros</div> </div> <table border="1"> <thead> <tr> <th>3 Active</th> <th>4 Abnormal <</th> <th>5 Warning <</th> <th>6 Band</th> <th>7 > Warning</th> <th>8 > Abnormal</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>IgG</td> <td>15.00</td> <td>25.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>IgA</td> <td>3.50</td> <td>6.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>IgM</td> <td>3.00</td> <td>5.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Kappa</td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.00</td> <td>0.00</td> <td>Lambda</td> <td>0.00</td> <td>0.00</td> </tr> </tbody> </table>													3 Active	4 Abnormal <	5 Warning <	6 Band	7 > Warning	8 > Abnormal	<input type="checkbox"/>	0.00	0.00	IgG	15.00	25.00	<input type="checkbox"/>	0.00	0.00	IgA	3.50	6.00	<input type="checkbox"/>	0.00	0.00	IgM	3.00	5.00	<input type="checkbox"/>	0.00	0.00	Kappa	0.00	0.00	<input type="checkbox"/>	0.00	0.00	Lambda	0.00	0.00
3 Active	4 Abnormal <	5 Warning <	6 Band	7 > Warning	8 > Abnormal																																											
<input type="checkbox"/>	0.00	0.00	IgG	15.00	25.00																																											
<input type="checkbox"/>	0.00	0.00	IgA	3.50	6.00																																											
<input type="checkbox"/>	0.00	0.00	IgM	3.00	5.00																																											
<input type="checkbox"/>	0.00	0.00	Kappa	0.00	0.00																																											
<input type="checkbox"/>	0.00	0.00	Lambda	0.00	0.00																																											

The chemistry values tab works in a similar way to the area, position, height, sharpness and symmetry tabs. When chemistry data is set up in the Configure V8 methods window, these chemistry names are automatically populated in the Expert System.

1. The Activate Chemistry Values Analysis button allows the user to select to use chemistry data imported from the LIMS or manually inputted to be included as part of the interpretation.
2. When selected, the Ignore Zeros button does not flag up a sample because the result does not have any chemistry data attached to it (i.e. not downloaded from LIMS or manually inputted).
3. The active column allows for only certain chemistry values to be used for analysing results.
4. The low abnormal column allows the user to input the lowest value before which the result is definitely abnormal.
5. The low warning column allows users to input the lowest value that is deemed normal. Any values that fall between this and the low abnormal are deemed as a warning. Any values that fall between this and the high warning are deemed as normal. This value cannot be lower than the low abnormal value or higher than the high warning value.
6. The band column lists the chemistry data that the parameters are being set for.
7. The high warning column allows users to input the highest value that is deemed normal. Any values that fall between this and the low warning are deemed normal. Any values that fall between this and the high abnormal are deemed as a warning. This value cannot be higher than the high abnormal value or lower than the low warning value.
8. The high abnormal column allows users to input the highest value after which the result is definitely abnormal.

It is recommended that users assign suitable values for each chemistry data based on the reference ranges for each chemistry value. Default settings in the Expert System for chemistry values cannot be reliably used as different users set up their LIMS settings differently.

Configuring Parameters – Chemistry Totals

The chemistry totals tab works in a similar way to the area, position, height, sharpness and symmetry tabs in terms of set up. When chemistry data is set up in the Configure V8 methods window, the chemistry values can be used as a sum as opposed to using single chemistry values. This is useful, for example, where total immunoglobulin concentration is important, but only the breakdown is available.

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein																																																
<div>1 <input type="checkbox"/> Activate Chemistry Totals Analysis</div> <table border="1"> <thead> <tr> <th>2 Active</th> <th>3 Abnormal <</th> <th>4 Warning <</th> <th>5 Chem1 +</th> <th>6 Chem2 +</th> <th>7 Chem3</th> <th>8 > Warning</th> <th>9 > Abnormal</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td>0.0</td> <td>0.0</td> <td></td> <td></td> <td></td> <td>0.0</td> <td>0.0</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.0</td> <td>0.0</td> <td></td> <td></td> <td></td> <td>0.0</td> <td>0.0</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.0</td> <td>0.0</td> <td></td> <td></td> <td></td> <td>0.0</td> <td>0.0</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.0</td> <td>0.0</td> <td></td> <td></td> <td></td> <td>0.0</td> <td>0.0</td> </tr> <tr> <td><input type="checkbox"/></td> <td>0.0</td> <td>0.0</td> <td></td> <td></td> <td></td> <td>0.0</td> <td>0.0</td> </tr> </tbody> </table>													2 Active	3 Abnormal <	4 Warning <	5 Chem1 +	6 Chem2 +	7 Chem3	8 > Warning	9 > Abnormal	<input type="checkbox"/>	0.0	0.0				0.0	0.0	<input type="checkbox"/>	0.0	0.0				0.0	0.0	<input type="checkbox"/>	0.0	0.0				0.0	0.0	<input type="checkbox"/>	0.0	0.0				0.0	0.0	<input type="checkbox"/>	0.0	0.0				0.0	0.0
2 Active	3 Abnormal <	4 Warning <	5 Chem1 +	6 Chem2 +	7 Chem3	8 > Warning	9 > Abnormal																																																					
<input type="checkbox"/>	0.0	0.0				0.0	0.0																																																					
<input type="checkbox"/>	0.0	0.0				0.0	0.0																																																					
<input type="checkbox"/>	0.0	0.0				0.0	0.0																																																					
<input type="checkbox"/>	0.0	0.0				0.0	0.0																																																					
<input type="checkbox"/>	0.0	0.0				0.0	0.0																																																					

1. The Activate Chemistry Totals Analysis button allows the user to select to use a sum of chemistry data imported from the LIMS or manually inputted to be included as part of the interpretation.
2. The active column allows for only certain chemistry totals to be set up and used for analysing results.
3. The low abnormal column allows the user to input the lowest value before which the result is definitely abnormal.
4. The low warning column allows users to input the lowest value that is deemed normal. Any values that fall between this and the low abnormal are deemed as a warning. Any values that fall between this and the high warning are deemed as normal. This value cannot be lower than the low abnormal value or higher than the high warning value.
5. The Chem 1 column allows the user to select the first chemistry value to be used in the sum.
6. The Chem 2 column allows the user to select the second chemistry value to be used in the sum.
7. The Chem 3 column allows the user to select the third chemistry value to be used in the sum (this does not have to be used).
8. The high warning column allows users to input the highest value that is deemed normal. Any values that fall between this and the low warning are deemed normal. Any values that fall between this and the high abnormal are deemed as a warning. This value cannot be higher than the high abnormal value or lower than the low warning value.
9. The high abnormal column allows users to input the highest value after which the result is definitely abnormal.

It is recommended that users assign suitable values for each chemistry total based on the reference ranges for the chemistry values.

Configuring Parameters – Formula

The formula tab works in a similar way to the ratios in that there is only one warning and abnormal option and the user selects whether the value is less than or greater than (< or >). The formula allows the user to make distinct characteristic assessment based on relative or absolute area, position, height, sharpness and symmetry. The user can select any of the six bands and any of the six parameters to create a 5 ruled formula. For a sample to be assigned as a warning, all parameters must be met, if any are normal, the result will be assigned as normal. However if there are a mix of warning and abnormal results, the sample will be assigned as warning. This is because all characteristics must also be abnormal to be assigned as abnormal. Up to five formulas can be created.

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein																																				
<div> <div>1</div> <input type="checkbox"/> Activate Formula Analysis <div>Configure</div> </div>																																																
<div>2</div> <div>Formula 1</div> <div>Formula 2</div> <div>Formula 3</div> <div>Formula 4</div> <div>Formula 5</div>																																																
<div>3</div> <input type="checkbox"/> Activate formula																																																
<div>4</div> <div>5</div> <div>6</div> <div>7</div> <div>8</div> <div>9</div> <table border="1"> <thead> <tr> <th>Active</th> <th>Criteria</th> <th>Band</th> <th>> / <</th> <th>Warning</th> <th>Abnormal</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/></td> <td></td> <td></td> <td><</td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td></td> <td></td> <td><</td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td></td> <td></td> <td><</td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td></td> <td></td> <td><</td> <td>0.00</td> <td>0.00</td> </tr> <tr> <td><input type="checkbox"/></td> <td></td> <td></td> <td><</td> <td>0.00</td> <td>0.00</td> </tr> </tbody> </table>													Active	Criteria	Band	> / <	Warning	Abnormal	<input type="checkbox"/>			<	0.00	0.00	<input type="checkbox"/>			<	0.00	0.00	<input type="checkbox"/>			<	0.00	0.00	<input type="checkbox"/>			<	0.00	0.00	<input type="checkbox"/>			<	0.00	0.00
Active	Criteria	Band	> / <	Warning	Abnormal																																											
<input type="checkbox"/>			<	0.00	0.00																																											
<input type="checkbox"/>			<	0.00	0.00																																											
<input type="checkbox"/>			<	0.00	0.00																																											
<input type="checkbox"/>			<	0.00	0.00																																											
<input type="checkbox"/>			<	0.00	0.00																																											

1. The Activate Formula Analysis button allows the user to select to use a combination of band statistics as a way to interpret an electropherogram.
2. The formula tabs allows the user to select and configure up to 5 different formulas.
3. The activate formula option allows for the particular formula configuration to be activated.
4. The activate column allows for up to five different parameters to be configured for each formula.
5. The criteria column allows for one of the six parameters to be selected (Relative Area, Absolute Area, Peak Timings, Peak Height, Peak Sharpness, Symmetry).
6. The Band column allows for the band in which the parameter is set to be selected.
7. The >/< column allows for the user to select whether the parameter value is to be greater than or less than.
8. The warning value is the lowest or highest value that a normal sample can be (depending on whether it is set to < or >). Any value between the normal and abnormal value will be flagged up as a warning result.
9. The abnormal value is the lowest or highest value a sample can be before it is deemed definitely abnormal. Any value above or below (depending on </>) will be marked as abnormal.

Configuring Parameters – Peak Number

The peak number analysis allows the user to assign the number of bands present that may still give an acceptable trace and the number by which the trace is most likely unacceptable.

Configuration	Relative Area	Absolute Area	Peak Timings	Peak Heights	Peak Ratios	Chemistry Values	Chemistry Totals	Peak Sharpness	Symmetry	Formula	Peak Number	Total Protein
<div>1</div> <input checked="" type="checkbox"/> Activate Peak Number Analysis												
<div>2</div> Peak number expected : <input type="text" value="7"/>												
<div>3</div> <input checked="" type="checkbox"/> Lower Range: <div>5</div> <input type="text" value="0"/> and <div>6</div> <input type="text" value="5"/>												
<div>4</div> <input checked="" type="checkbox"/> Higher Range: <div>7</div> <input type="text" value="7"/> and <div>8</div> <input type="text" value="25"/>												

1. The Activate Peak Numbers Analysis button allows the user to select to use the number of bands in the trace as part of the interpretation.
2. The number of peaks expected is linked to the 'Bands' section of the Configure [V8](#) Methods window. The number of bands that are expected for the method will be populated here. This is not editable.
3. Activating the lower range allows the user to mark results with a band number within the lower range. The low range is set to mark samples where the result is expected to be unusable.
4. Activating the higher range allows the user to mark results with a band number within the higher range. The high range is set to mark samples where the result is expected to be unusable.
5. The bottom value of the lower range can be set in this box. It is recommended that this value be set to 0.
6. The top value of the lower range can be set in this box. Based on the expected number of bands, it is recommended that this value be one to two values below this.
7. The bottom value of the higher range can be set in this box. It is recommended that this value be set one or two values above the expected range.
8. The top value of the higher range can be set in this box. It is recommended that this value be a high number well above the expected band number.

In the above example, any result with a band number of between 0 - 4 or 8 - 25 will be flagged up as an expected unusable result. Any result with five or seven bands will be flagged up as having lower or higher bands than expected respectively, but most likely acceptable.

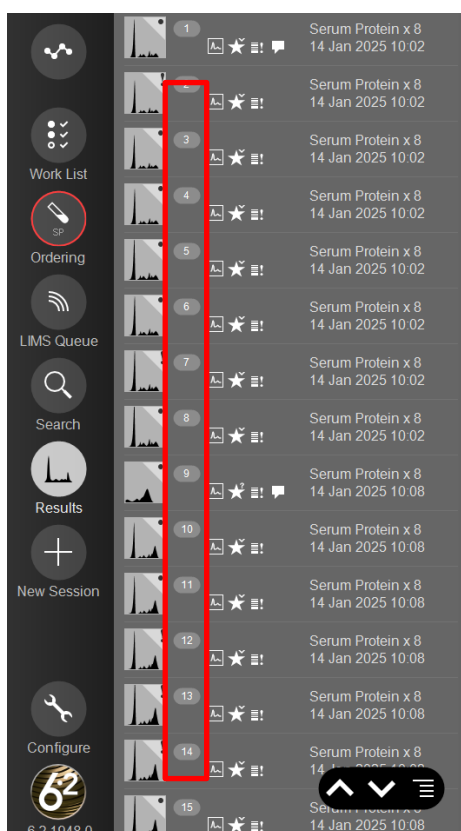
Viewing the Expert System Results

The Expert System alerts the user to the state of the sample result via several icons listed in the navigation worklist.

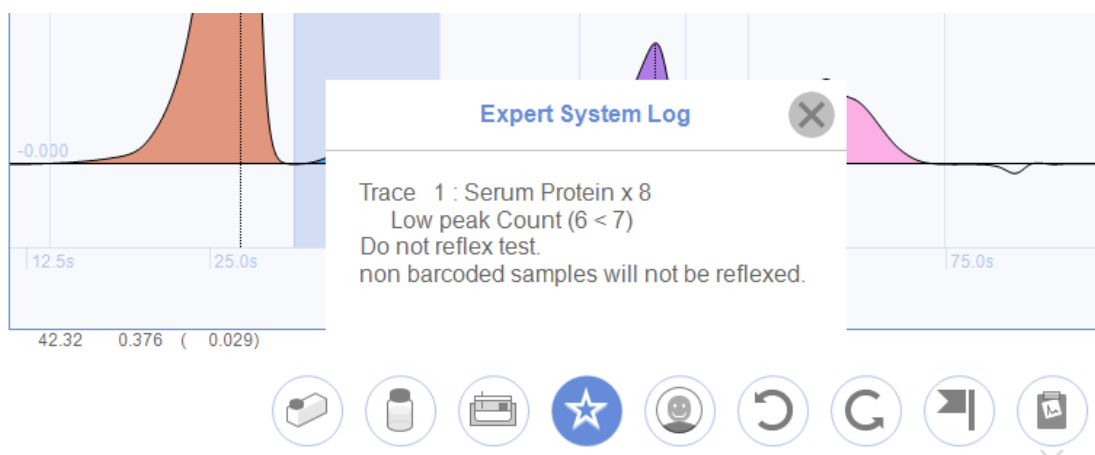


1. The Expert System is turned on but there is no data acquired for the sample or the Expert System is not activated for that method.
2. The Expert System assigns the sample result as normal.
3. The Expert System assigns the sample result as a warning and needs to be reviewed.
4. The Expert System assigns the sample as abnormal. If automatic reflex testing is turned on, the sample will be reflex tested as per the Platinum settings (batch reflex, immediate reflex, rack priority).
5. The Expert System assigns the sample as having extra bands, but the result is probably acceptable.
6. The Expert System assigns the sample as having fewer bands, but the result is probably acceptable.
7. The Expert System assigns the sample as have significantly fewer or extra bands and the result is probably unusable.

The results are displayed within the navigation worklist to easily identify the patient result and can be sorted by Expert System status by sorting by 'Status':



To view the parameters that have caused a sample to be marked as anything other than normal, the Expert System Log can be viewed in the Results windows:



It is recommended that all Expert System parameters are adjusted and validated prior to relying on the Expert System solely for interpretation.


Platinum is one of the world's most advanced software package for automated clinical capillary electrophoresis. Designed specifically to make the management, analysis and interpretation of clinical test results as simple, accurate and as efficient as possible, Platinum provides a comprehensive set of analytical tools and user-defined options that can meet the data analysis needs of the clinician. Please refer to the following instructions for correct operation of Platinum software.

5.8.1

Glossary of software icons

The following software icons have been designed to make operator use simple and efficient.


Main Window Icons




Home Page




Warning




Connected to V8 UltraCE




Not Connected to V8 UltraCE



Quality Control Window




Quality Control Failed



Quality Control Timed Out




Quality Control Accepted




Quality Control Undefined



Work List



Search Window



Ordering Window



LIMS Queue Window



Results Window



New session



Create new Session



Create new Gel Session



Open Session from File



Create new Middleware Session



Create new Gateway Session



Configuration Window

General Icons (Icons that appear in more than one window)



Delete



Undo



Redo



Save



Print



Open



Select



View as Traces



View as Grid



Sort



Date



Load Source Data



Reset Zoom



Zoom Out



Zoom In



Zoom



Focus Mode



Show IgG Attached



Show IgA Attached



Show IgM Attached



Show IgK Attached



Show IgL Attached



Show IFE Attached



Trace



IFE Image



Grid Mode



Gel Image



Bands



Copy



Show

Home Page Icons



Language



Help Page



PDF

Platinum User Manual/Operator Manual



Exit



Product Activation

V8 Status Icons



Reset Connection



V8 Service Log



Start/Stop Logging



Translate Status



Show Timestamp



Show System Data



Show Trace Preview



Show Image



Show Performance Data



Show Index



Show End of Line Characters



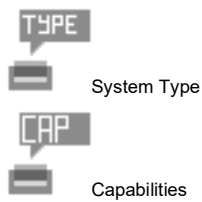
Update



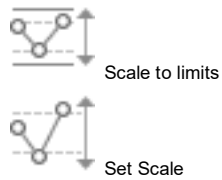
Capillary Disabled



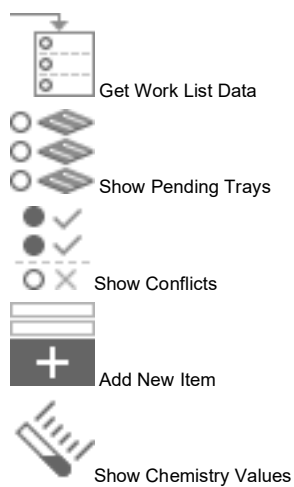
Capillary Enabled



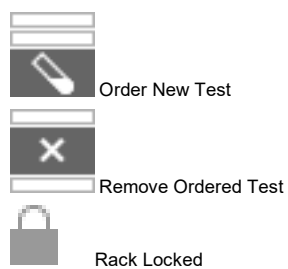
Quality Control Icons



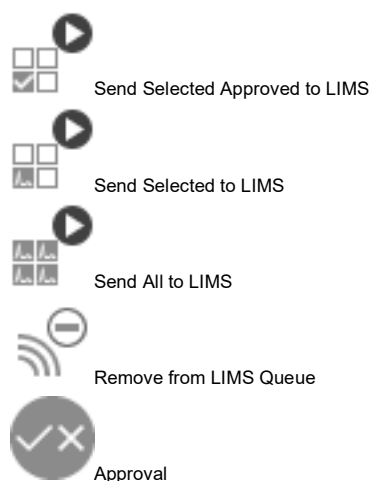
Work List Icons

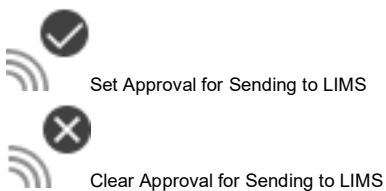


Ordering Icons



LIMS Queue Icons

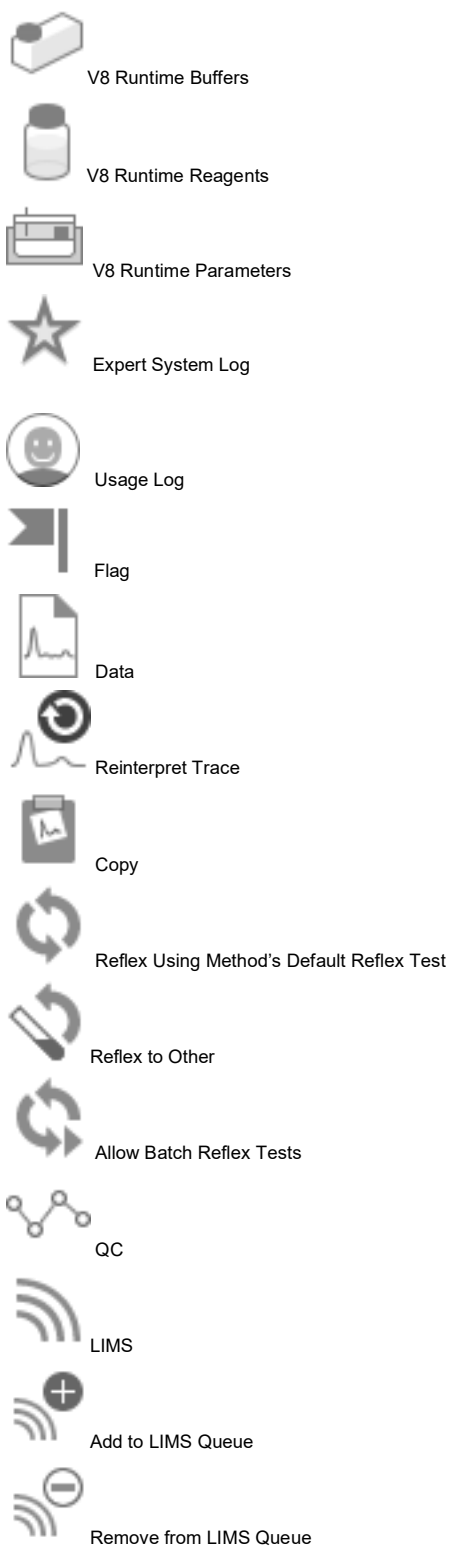


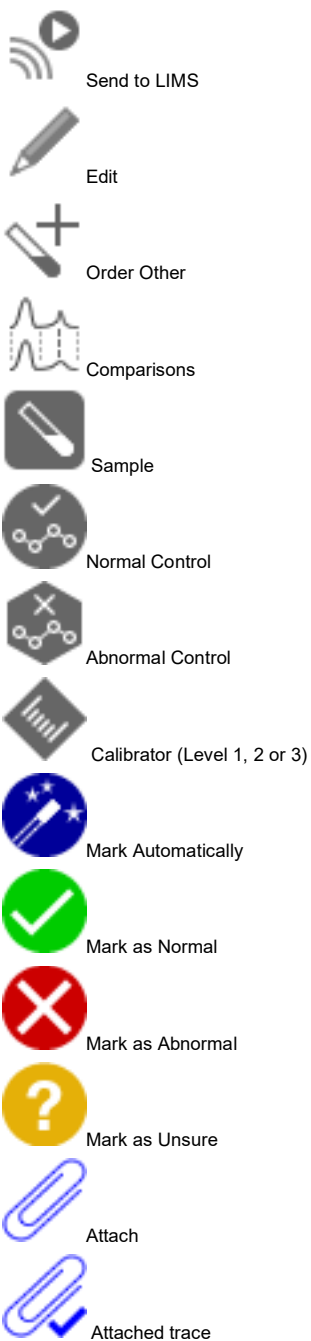


Search Icons

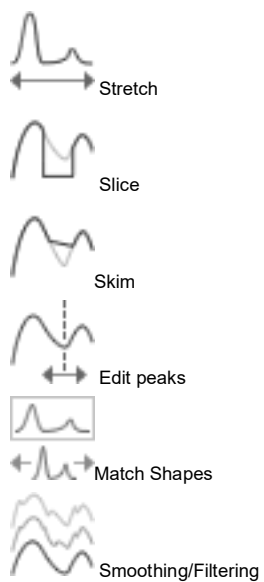


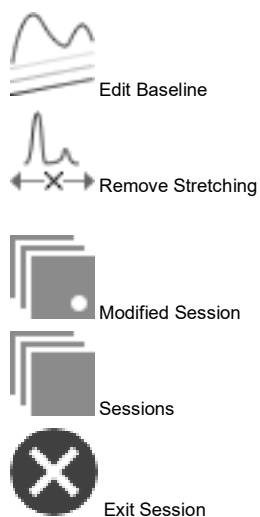
Results/Search Results Icons



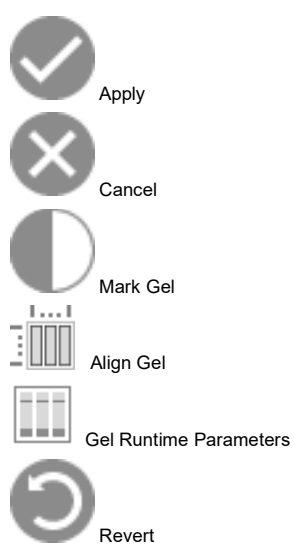


Other Results Icons

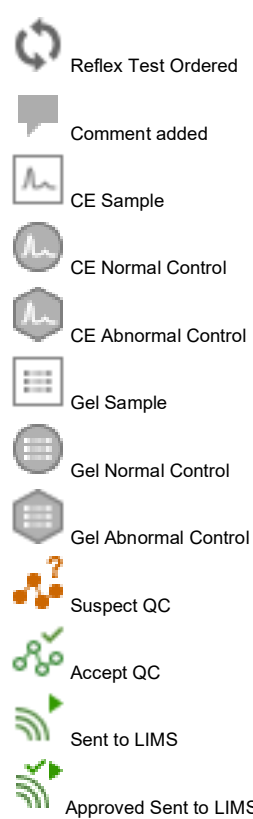





















Gel Icons






Navigation Worklist Icons




























-  Pending Send to LIMS
-  LIMS Approved
-  Expert System Warning
-  Expert System Normal
-  Expert System No Result
-  Expert System Too Few Bands
-  Expert System Too Many Bands
-  Expert System Bad Results
-  Expert System Reflex Test
-  Previous Monoclonal Result in Database
-  Previous Normal Result in Database
-  Previous Abnormal Result in Database
-  Rack Present
-  Traces Attached
-  Patient history present
-  No Barcode
-  Comments Tree

Progress Pies

-  Sample Preparation
-  Start of Electrophoresis
-  Analysis

Report Icons

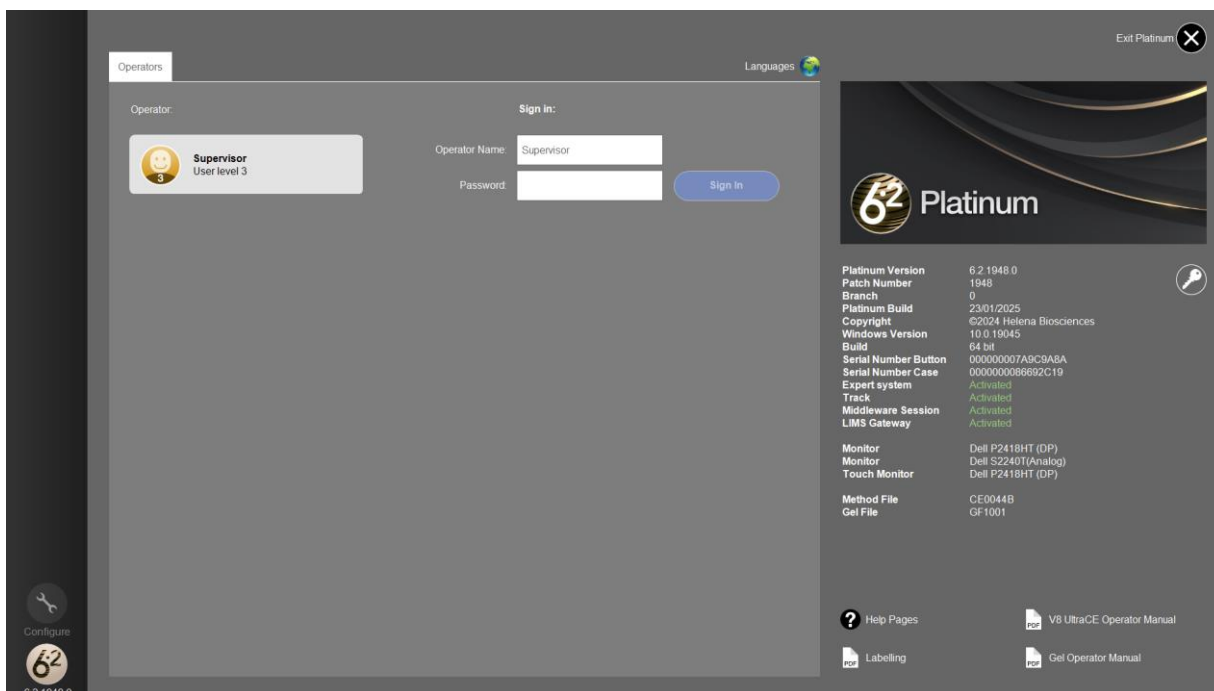
-  Centre text
-  Left align text
-  Right align text
-  Bold text
-  Underlined text
-  Italic text
-  New bands list
-  New demographics item
-  New gel image plot

-  New IFE image
-  New Levey-Jennings plot
-  New Levey-Jennings table
-  New line
-  New logo
-  New multiple bands list
-  New reagents list
-  New rectangle
-  New scan trace
-  New statistics list
-  Text box
-  New whole gel image
-  New Worklist
-  New Immunodisplacement
-  New Liver Result
-  New HB Summary

5.8.2 Log in to Platinum

5.8.2.1 Initial Log-in Screen

When Platinum is opened, the initial log-in screen will appear. A user name and associated password must be entered in order to proceed using the software.



5.8.2.2 Operator Log

The operator log stores a full history of operator data and decision-making. This function allows all viewing/editing functions carried out by a specific user for a defined time period to be identified.

5.8.2.2.1 Additional Operator Log Options

Print – the table can be printed by selecting the Print button.


Export – The data can be saved as a tabbed .txt file by selecting the Export button and entering a file name and location in the appropriate boxes of the Save As window.

5.8.2.3 Product Activation

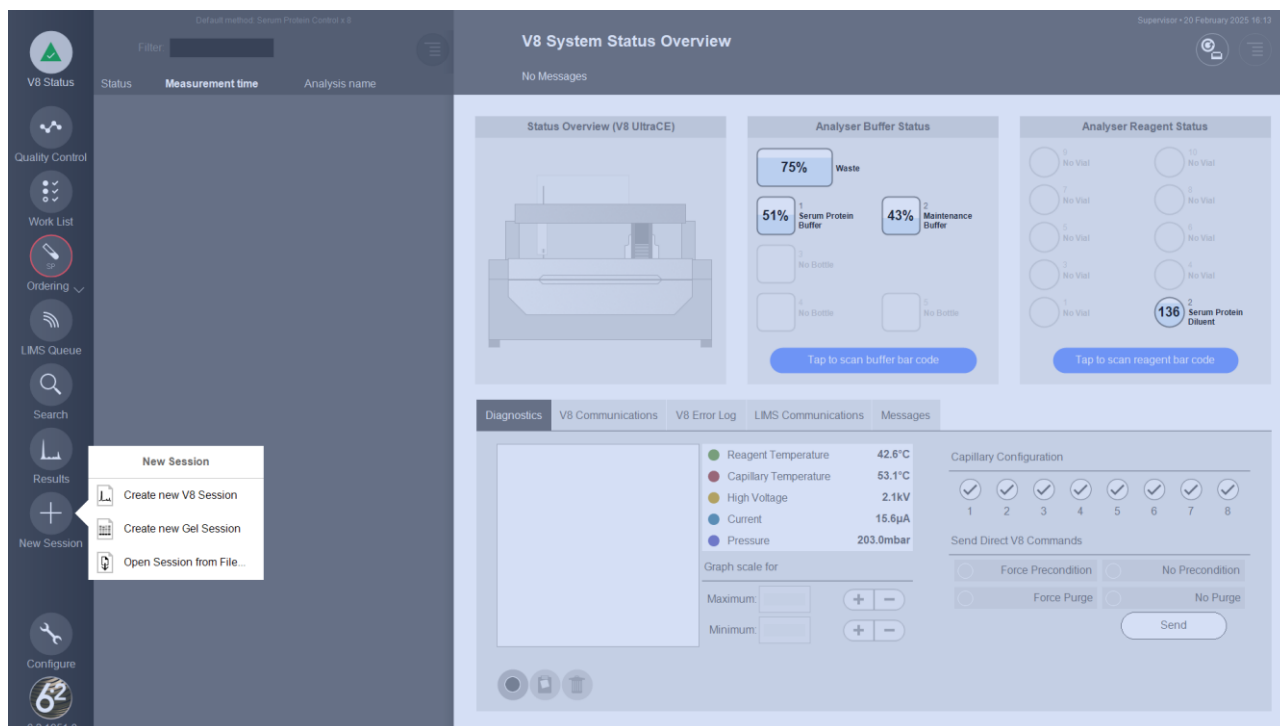
Purchasing Platinum Plus will allow the activation of extra features, including Networking, Track, Expert System, Middleware and Gateway. Select the Product Activation icon and enter the Activation Code to enable the purchased features.

Further information on these additional features and Activation Codes can be provided by Technical Support (support@helena-biosciences.com).

5.8.3 V8 Status Window

Once logged in, Platinum will switch to the V8 Status window (only if a V8 UltraCE system has been configured, see 5.8.10.1), and icons will appear on the left hand side of the screen. From here, select the  icon from which you are given options that will determine the main action of the session:

- Create new V8 Session
- Create new Gel Session
- Open Session from File...
- Create new Middleware Session (if Middleware is activated and connected to a Middleware PC)
- Open new Gateway Session (if Gateway has been activated)



The V8 Status icon will change according to its current connection status with the V8 UltraCE:



Not connected



V8 UltraCE requires attention



Successfully connected



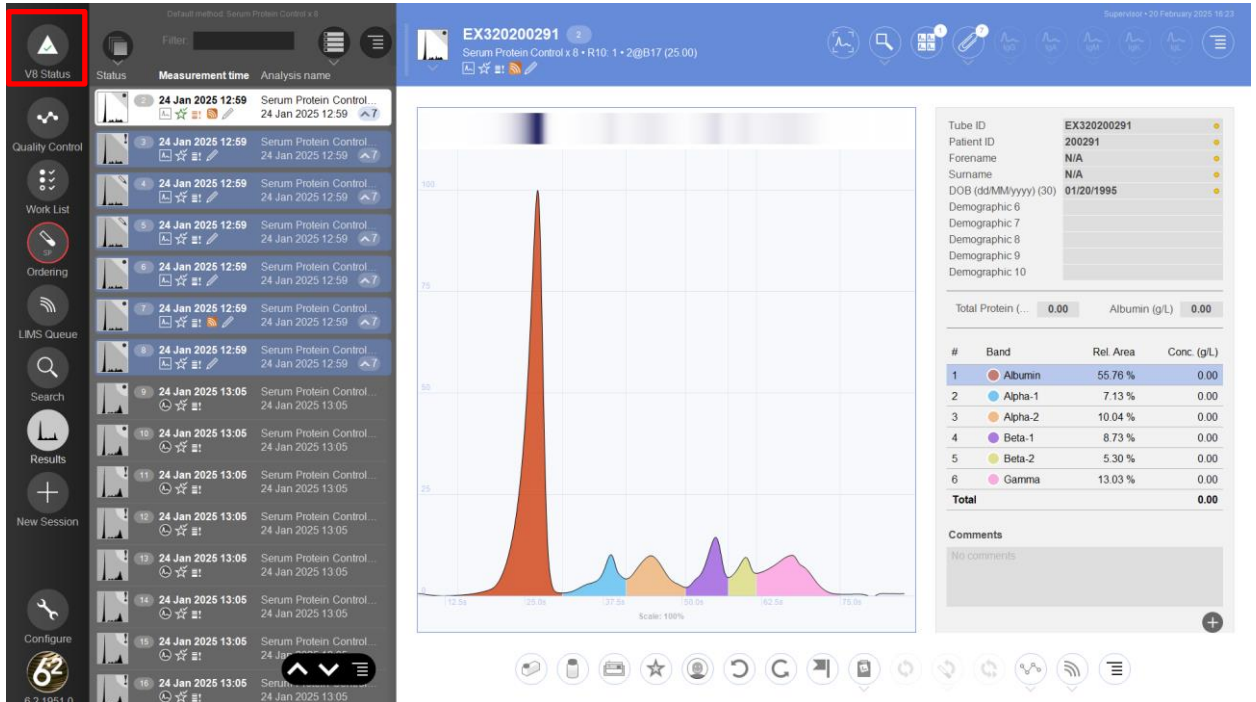
Preconditioning



Postconditioning

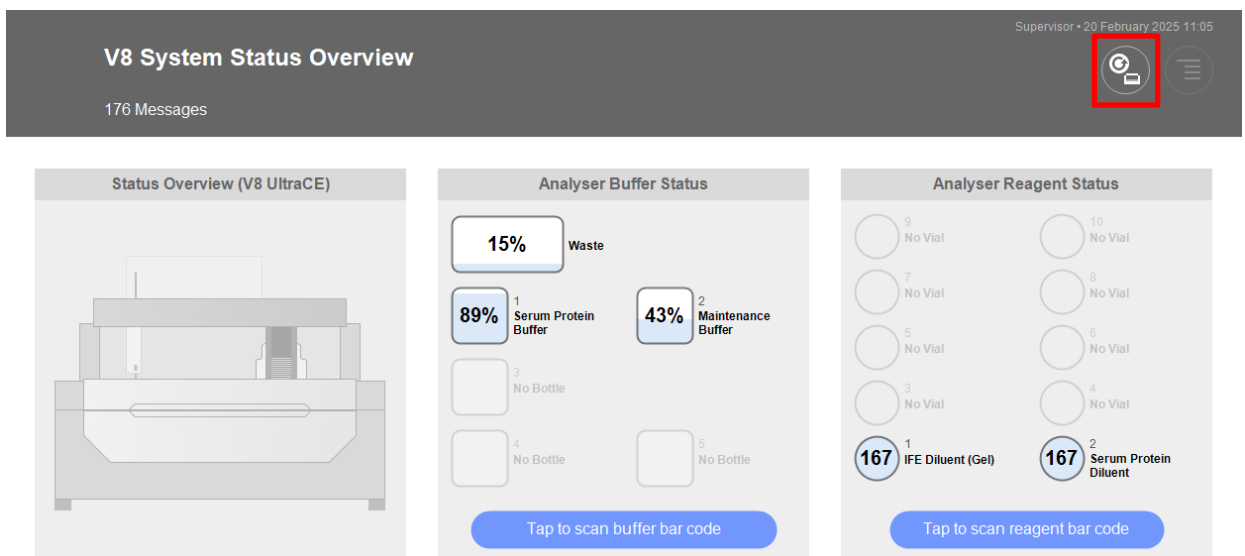
When the V8 Status window initially appears, there will be no communication with the V8 UltraCE until a new session has been started. This is indicated by the red V8 Status icon and no buffer or reagent information.

Once a connection is successful, the icon will turn green and buffer and reagent information will become available.



Following a breakdown in communication between Platinum and the V8 UltraCE instrument, reset the communication by going to the V8 Status

window and selecting the  icon in the top right hand corner:

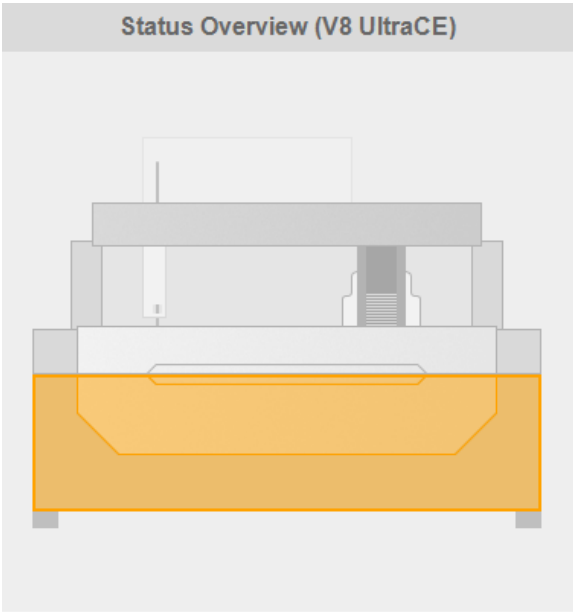


V8 UltraCE System Warnings and Status

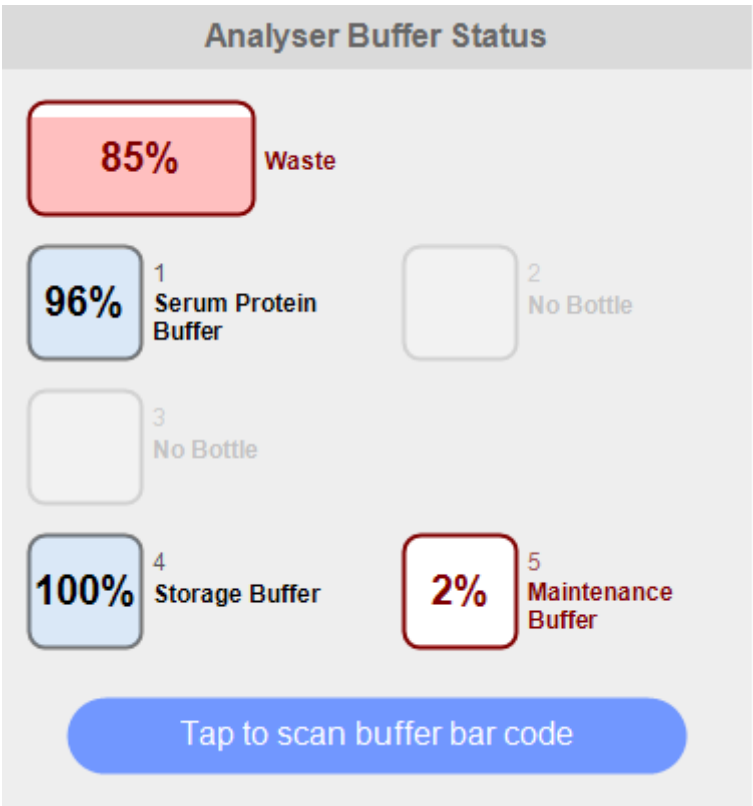
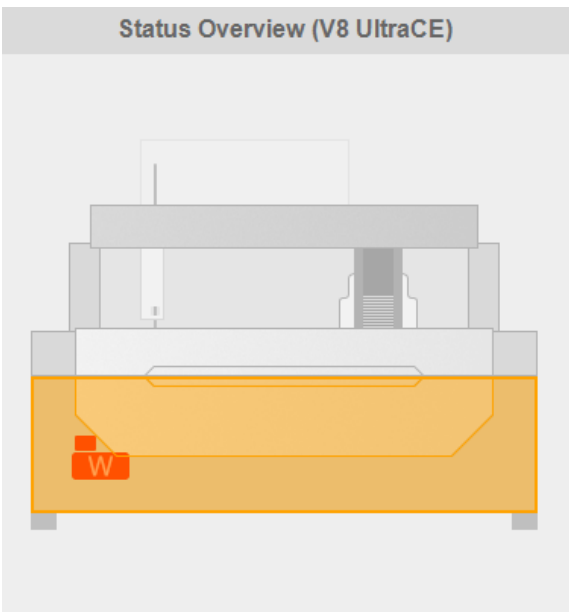
The V8 Status window continually informs the user of the instrument status, or action, and of any warning or error messages. All information regarding the status of the instrument can be found here.

Any V8 UltraCE System status that requires the user's attention will appear in the Status Overview in orange. Any status that requires immediate attention will appear in red. When a buffer drops below 10% liquid remaining, or when a reagent has no more tests remaining, they will appear red in their respective Status windows.

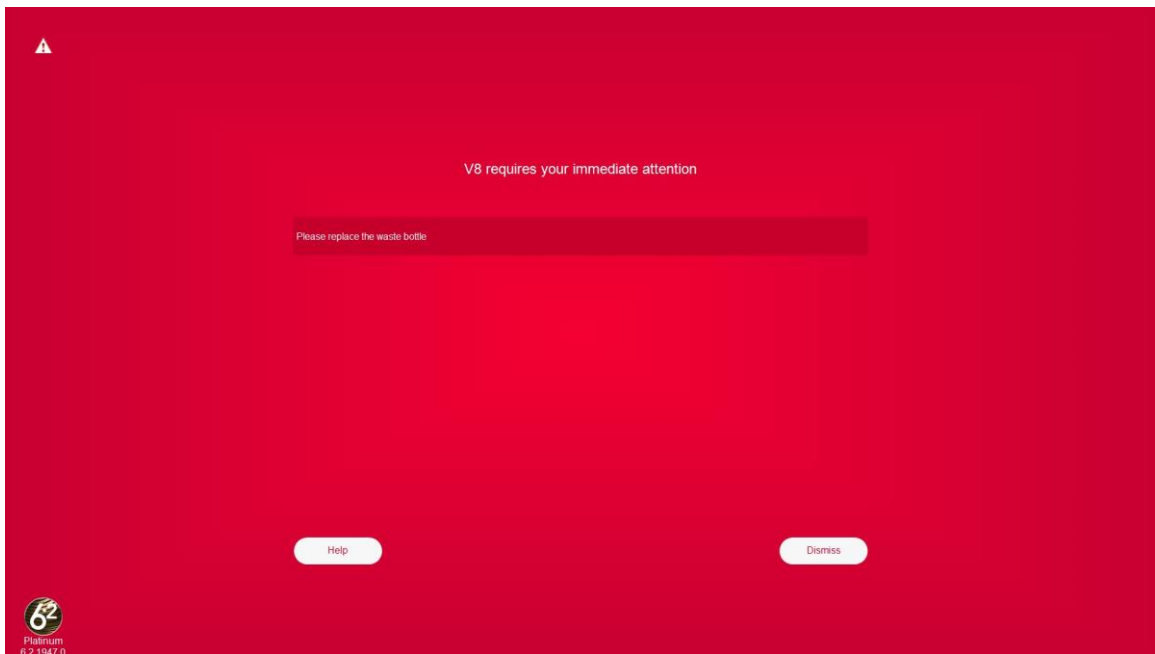
Front cover open:



Front cover open and waste bottle needs replacing:



If an item requires immediate attention from the user before the V8 UltraCE can continue, a larger warning message will appear on the screen. This will clearly state the issue encountered and what needs to be done to resolve the issue.

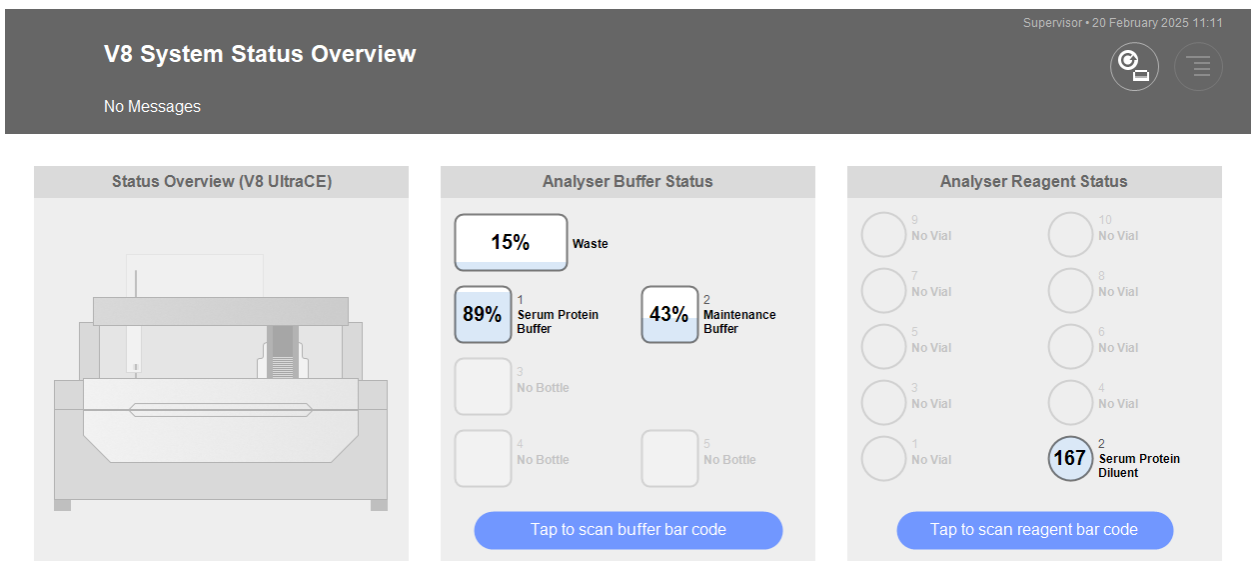


Once the operator has resolved the identified issue, the warning indication will disappear from the screen.

If the user is busy and wants to temporarily hide the window, the 'Dismiss' option can be selected and the window will disappear, however, there will still be an area of the V8 UltraCE highlighted in the Status Overview until the issue has been resolved.

5.8.3.2

Defining Reagents and Buffers



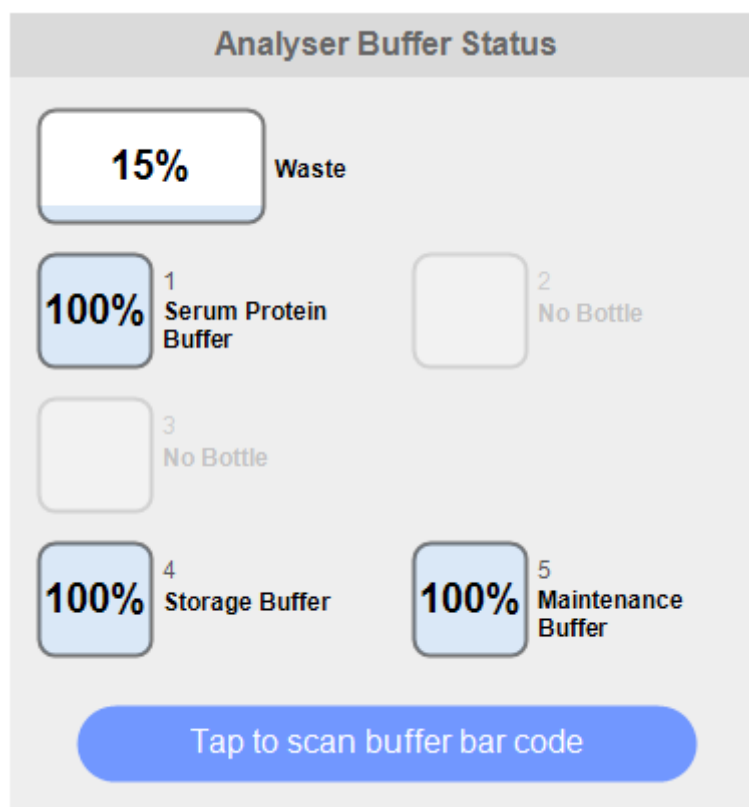
All reagents and buffers used on the V8 UltraCE are individually barcoded. Using the Analyser Buffer Status and Analyser Reagent Status function allows the user to view what is in use, and the position of the buffers and reagents. It also permits the user to change buffer bottles or reagents via a prompt from the V8 UltraCE or upon change of assay.

5.8.3.3

Checking Buffer Levels

It is possible to check the levels of remaining buffer onboard to ensure sufficient buffer is installed for complete analysis.

To check the buffer fluid levels go to the V8 Status window. Select the V8 Status icon again to update the values.

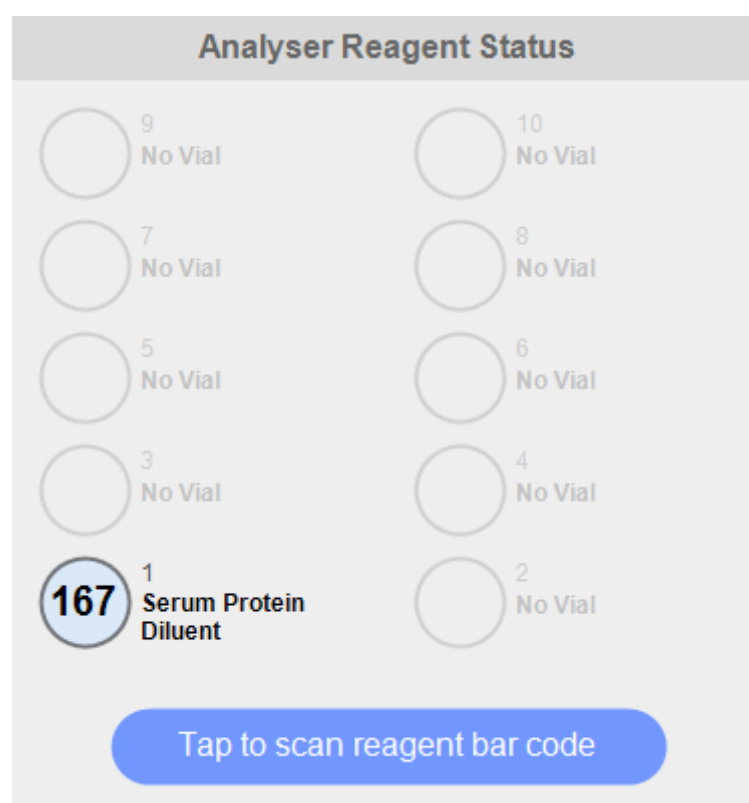


5.8.3.4 Loading Reagents

5.8.3.4.1 Installing Reagents using the Reagent window

To install reagents:

- Go to **V8 Status > Analyser Reagent Status > Tap to scan reagent bar code**.
- Scan or enter barcode information found on the side of the reagent bottle, ensuring that the positions in Platinum correspond with those on-board the V8 UltraCE.
- Multiple reagents can be entered at once.
- Once entered, select OK in the V8 Reagent window and add the reagent to the reagent bay.



	Reagent 1	Reagent 2	Reagent 3	Reagent 4	Reagent 5
Barcode :	212221272120027200	272221272520027200	0000000000	0000000000	0000000000
Product reference :	Serum Protein Diluent	Serum Protein Diluent	none	none	none
Expiry :	0127	0127	0000	0000	0000
Lot :	02222222	02222222	0	0	0
Batch index :	0	0	0	0	0
Tests Left :		136	0	0	0
Max tests :	50	167	0	0	0
Cap Opened on :	n/a	11/02/2025	n/a	n/a	n/a
Open Stability (days left) :	28	5	n/a	n/a	n/a

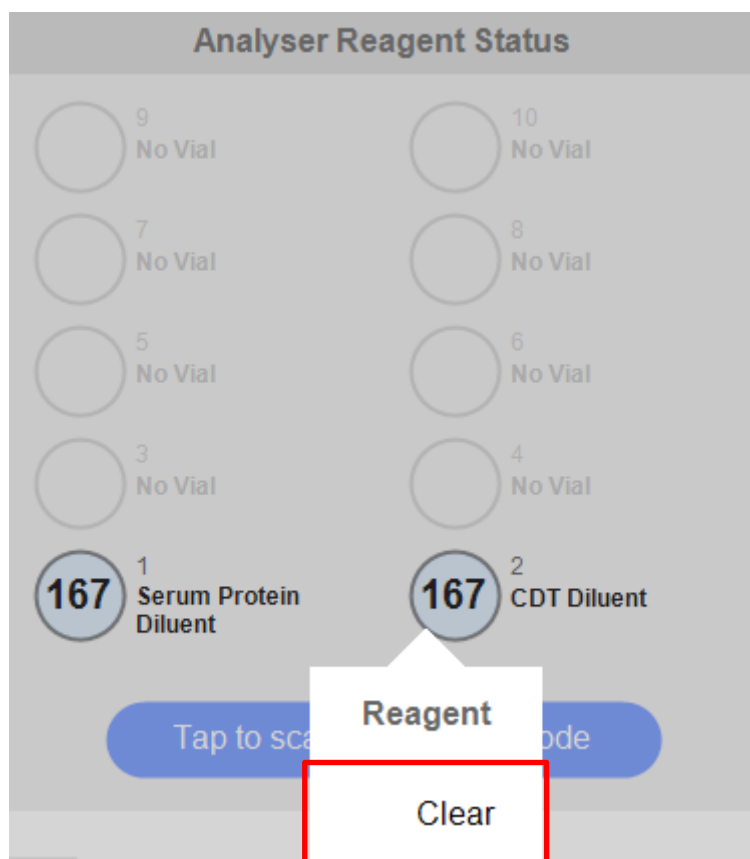
☐ Verify

	Reagent 6	Reagent 7	Reagent 8	Reagent 9	Reagent 10
Barcode :	0000000000	0000000000	0000000000	0000000000	0000000000
Product reference :	none	none	none	none	none
Expiry :	0000	0000	0000	0000	0000
Lot :	0	0	0	0	0
Batch index :	0	0	0	0	0
Tests Left :	0	0	0	0	0
Max tests :	0	0	0	0	0
Cap Opened on :	n/a	n/a	n/a	n/a	n/a
Open Stability (days left) :	n/a	n/a	n/a	n/a	n/a


OK Cancel Help

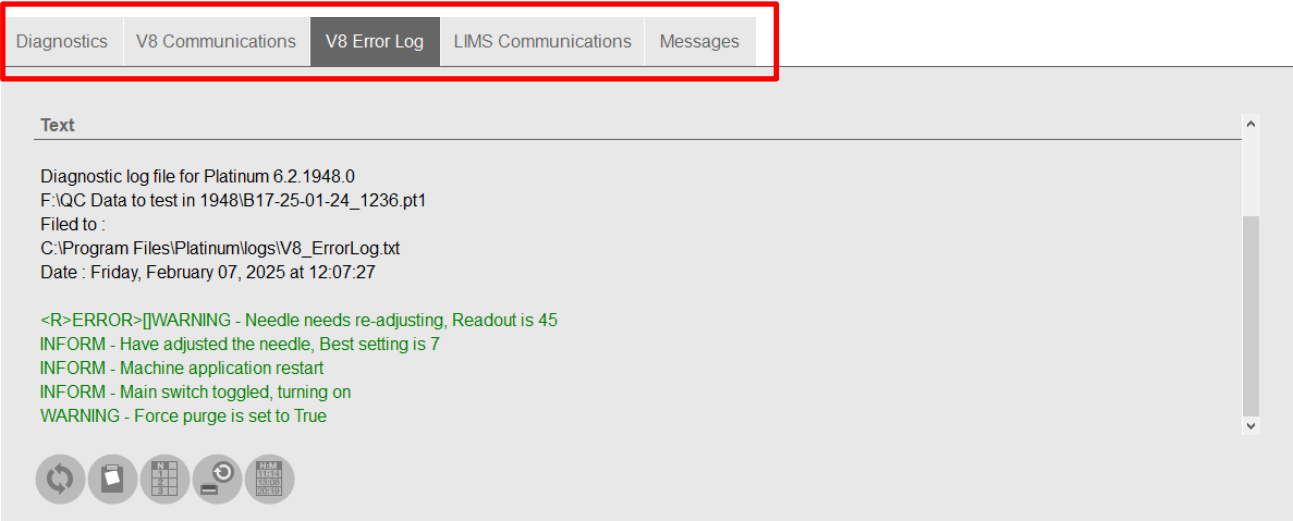
5.8.3.4.2 Clearing a reagent from the Reagent window

To clear a reagent from the Reagent window, tap on the square (displaying the number of tests remaining) next to the reagent to be removed. When the menu appears, select 'Clear'.



5.8.3.5 **V8 Error Log**

The error log will display all errors detected by the V8 UltraCE. Select the “Update” icon  to view the log, or to update it after it has already been viewed. The user can copy and save the error log outside of the Platinum software for easier viewing or to send to technical support.

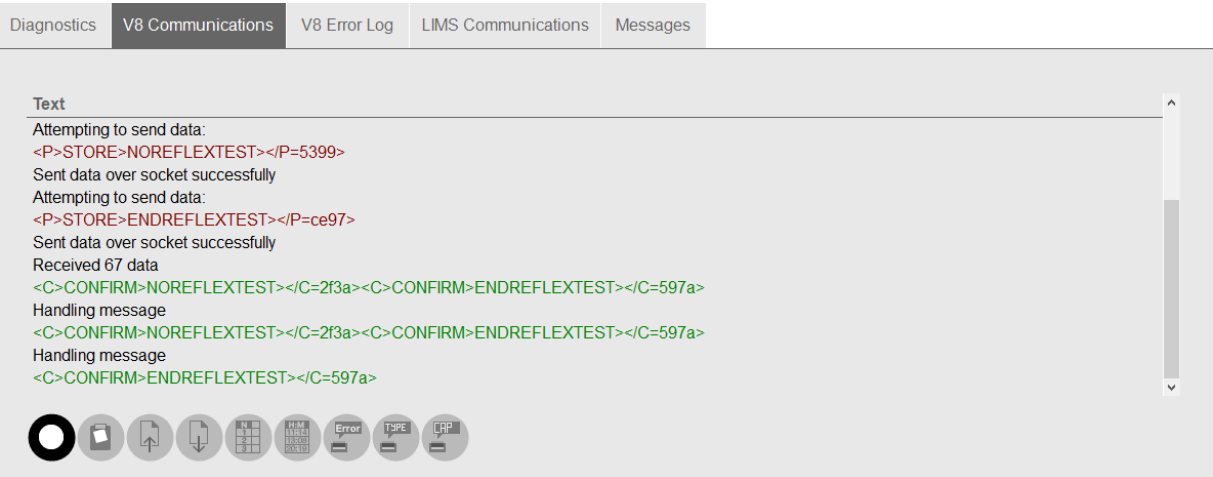


The Service Page can be directly accessed from this window using the ‘V8 Service Log’ icon:




5.8.3.6 **V8 Communications**

The V8 Communications log enables the user to view communications between the V8 UltraCE and Platinum. Press the “Record” button to start logging these messages. The log can then be, copied, saved, or an old log opened and viewed.



5.8.3.7 **LIMS Communications**

This tab will only show communications between the Platinum and LIMS software. Select the “Record” icon  to start logging these messages. The user can copied and saved outside of the Platinum software.

5.8.3.8 **Diagnostics**

V8 System Diagnostics show the user the capillary temperature, reagent block temperature, pressure, voltage and current. It also enables the user to control the capillary configurations and direct commands to the V8 UltraCE on startup.

Here the user can also record graphs of the run time parameters to track the systems performance.

To update these values, select the V8 Status window icon.

5.8.3.9 Managing Capillaries

In the event that a capillary is damaged or deemed unusable, the sample handling for that capillary can be disabled and the capillary isolated from use. The order of work will adjust so that samples will be automatically processed between several V8 UltraCE runs with no further instruction required from the user. The results will be displayed showing only the available capillaries.

- Go to **V8 Status > Diagnostics > Capillary Configuration**
- Capillaries are displayed and numbered from 1-8, corresponding with positions left to right on the instrument. To isolate a capillary and switch it off, un-tick the checkbox above the capillary of interest.
- To switch the capillary on, ensure the checkbox is ticked.

5.8.3.10 Messages

This tab continually informs the user of the instrument status and actions.

5.8.3.11 LAS

This tab will only show communications between Platinum and Inpeco for customers with a track system.

5.8.4 Quality Control Window

5.8.4.1 Key Features

- Comprehensive Levey Jennings suite
- Comprehensive Westgard Ruleset integration
- Automatically generate local reference ranges
- Monitor Running Mean and Running SD
- Barcode recognition and automated QC process
- Real time QC status of the analyser displayed
- Automated failure state warnings

5.8.4.2 Quality Control Page Overview

The Quality Control page can be accessed using the QC Status icon near the top left of the screen.

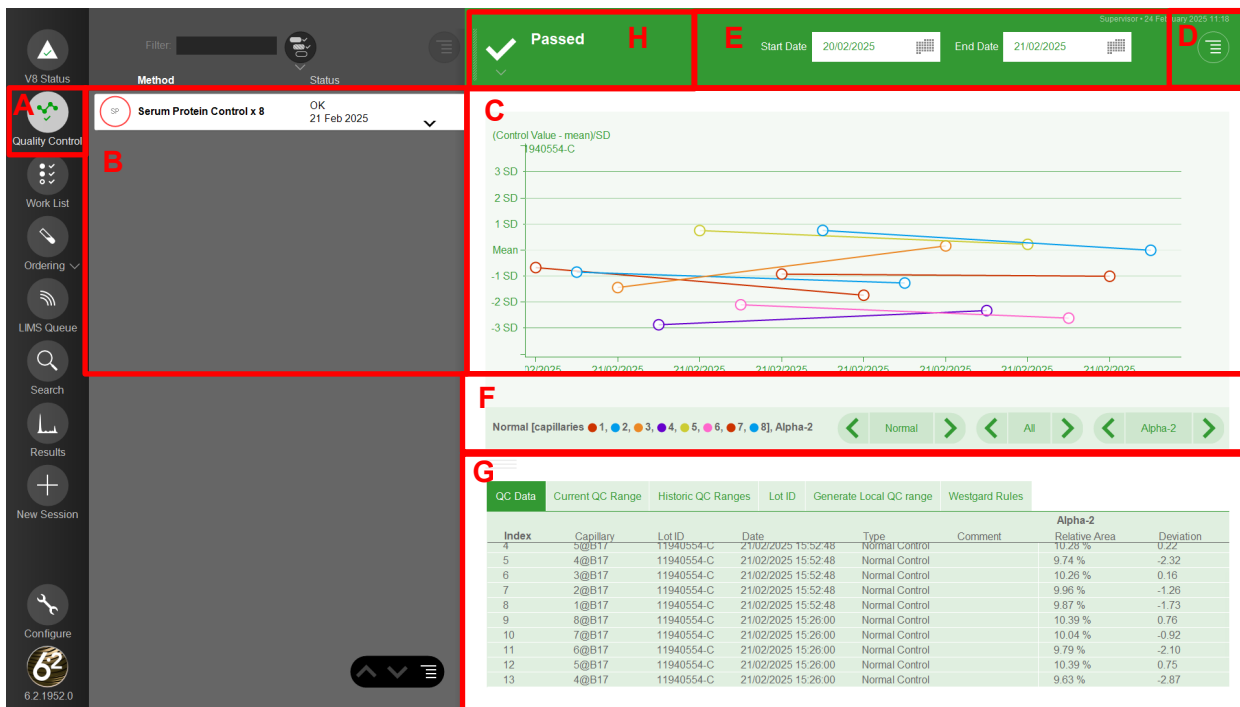


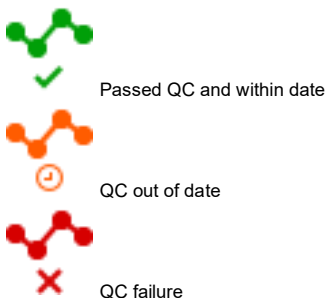
Figure 1: Quality Control page overview.

It can be broken down into several distinct sections with distinct functionality:

- QC Status icon
- QC Test list
- Levey Jennings window
- Levey Jennings window customisation options
- Date range
- QC, Band, and Capillary Selector
- QC Function window
- QC Status list

A. QC Status icons

This icon is a Live icon and will change to represent the current QC status of the analyser.



- The status of the icon is customised in the configure page: ['Configure > Reporting > Quality Control'](#)
- The live status of the icon is linked to a single QC method listed in the QC Test list.
- The pass / fail criteria of the live icon are linked to multiple user defined criteria:
 - Assay ranges
 - Westgard rules

- Timeout limits
- SD limits

B. QC Test List

The QC Test list, Section B of Figure 1, will display all test methods used to run control material.

Each method will independently track a set of normal and abnormal QC results run using this method, allowing flexibility on how control materials are reviewed.

Each tab has independent assay ranges allowing for third party materials to be used alongside Helena control materials.

Adding a new method to the QC test list:

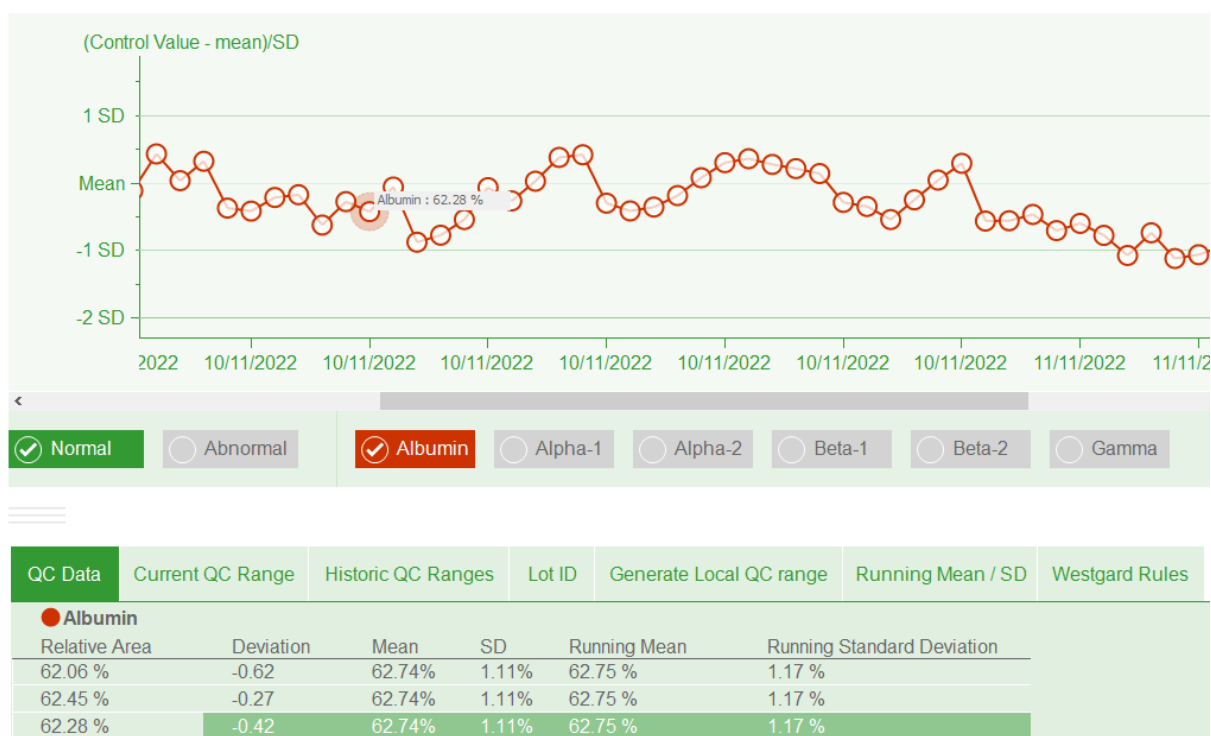
- If a new QC test is required, the normal/abnormal values should be added to the method.
- Once this has been done, the control should be run on the new method.
- The new method will then appear in the QC test list along with a normal/abnormal QC status alongside the results if the values were added previously.
- To review results, select the appropriate QC test name from the list.

Method	Status
SP Serum Protein Control x 8	OK n/a
SP Serum Protein x 8	OK n/a

C. Levey Jennings Window

The Levey Jennings window shows all current selected QC data plotted against a Levey Jennings chart.

Hovering the mouse over a point in this chart will show the value of this data point and jump to the raw data displayed in the QC Data tab.



How to populate the Levey Jennings Graph

To manually populate a Levey Jennings chart, the user must manually validate results and assign as a QC before results will appear in the Levey Jennings Chart. Automatic barcodes can be set up to automatically populate the Levey Jennings, this is detailed on page 89.

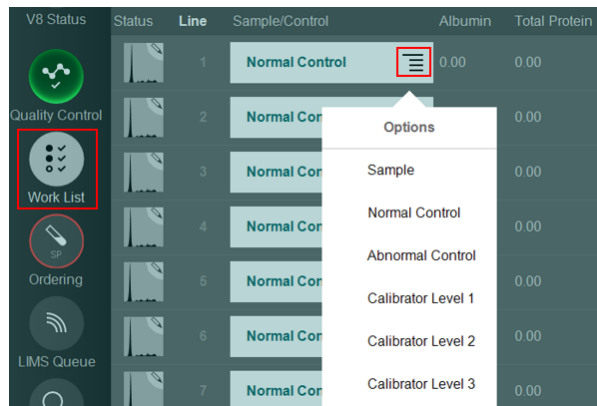
To Add results:

- Run the QC using the appropriate control method ensuring the control lot information is populated. Each method will generate a separate Levey Jennings graph, even if the base method is the same: eg 'SPE' and 'SPE Control x8'.
- Interpret trace ensuring all bands are gated correctly.

- Highlight the control and mark as either a normal or abnormal control using either of the three options:

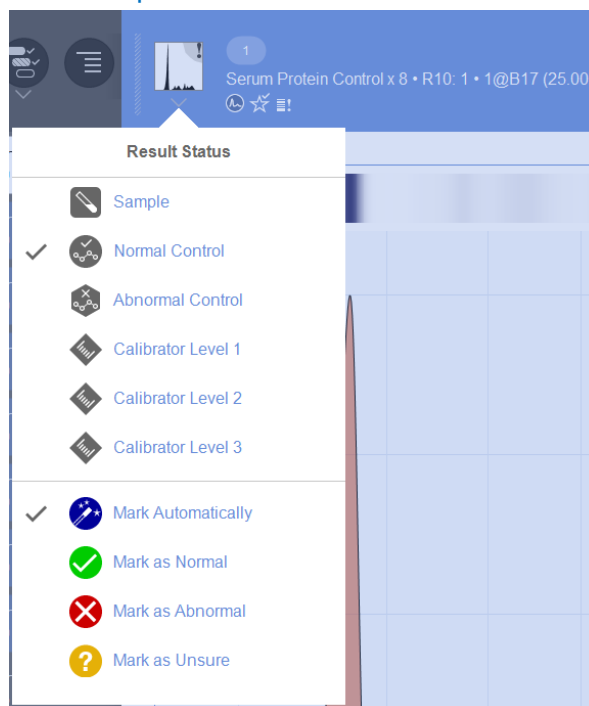
- Navigation List:

Work List > options icon.



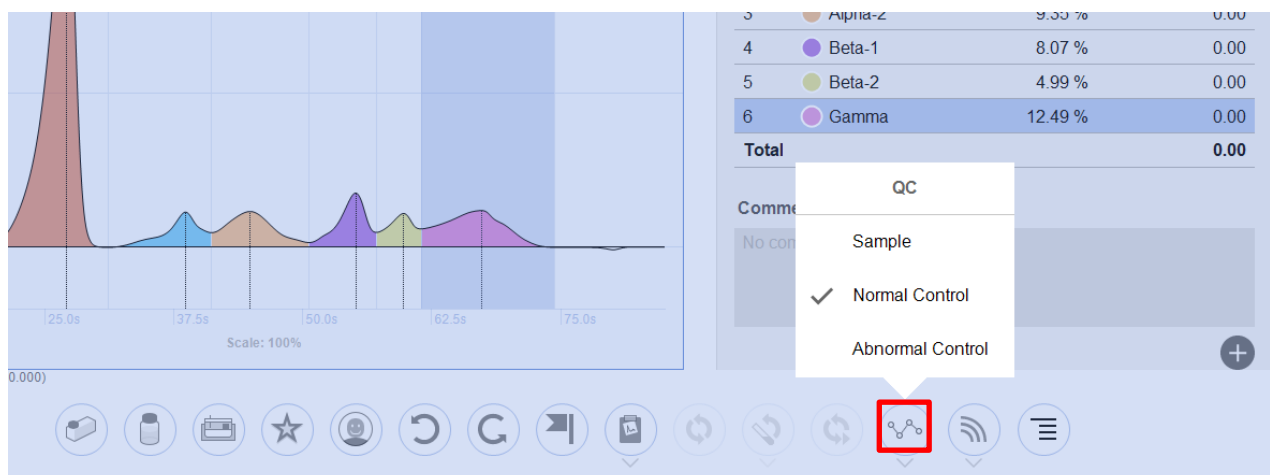
- Results Page:

Trace icon > select an option from the drop down menu. .



- QC icon in Results Window.

Results window > QC icon > select an option from the list.

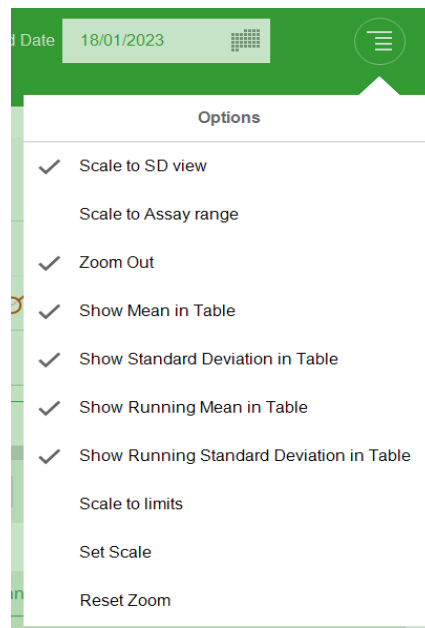


- The control will then populate the Levey Jennings graph in the Levey Jennings window.

D. Levey Jennings Window customisation options

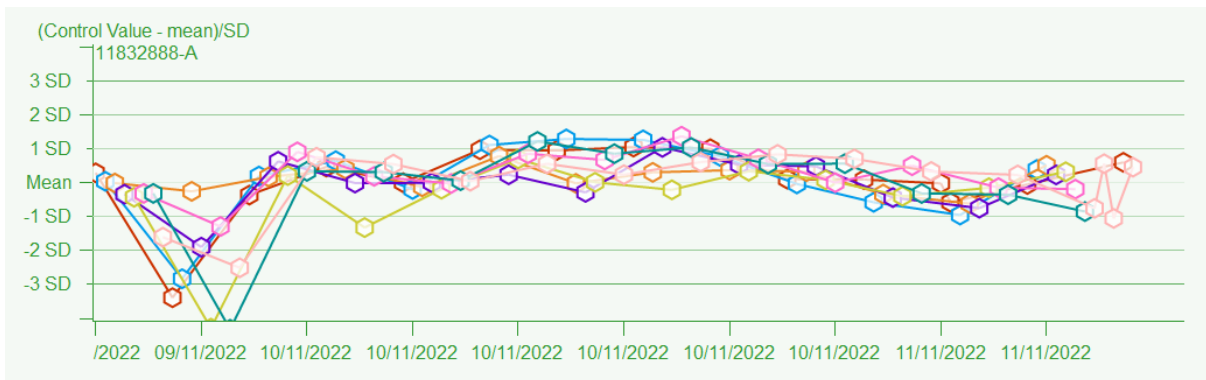
The visual specification of the Levey Jennings window can be configured using the Levey Jennings customisation options.

[Levey Jennings window > Options tab](#)



Scale to SD View

The Y axis of the Levey Jennings chart is scaled to 4SD either side of the mean. This view will scale to the SD values setup in the Lot IDs tab, or to the Local Range SDs if a Local Range has been created.



Scale to Assay range

The Y axis of the Levey Jennings chart is scaled to the upper and lower limits defined in the 'Lot ID' tab of the 'QC Function window' (G). The in use Mean and SD of the QC are plotted relative to these limits.

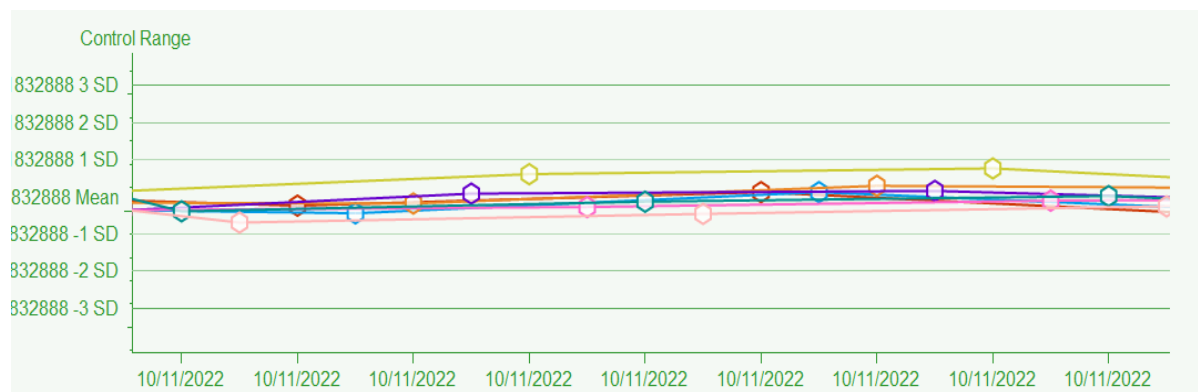


Table settings

The 'Show Mean Table', 'Show Standard Deviation in Table', 'Show running Mean in Table', and 'Show Running Standard Deviation in Table' settings will add or remove the appropriate column from the 'QC Data tab' of the 'QC Function window' (G).

Gamma					
Relative Area	Deviation	Mean	SD	Running Mean	Running Standard Deviation
16.38 %	-0.14	16.41%	0.25%	16.41 %	0.25 %
16.38 %	-0.14	16.41%	0.25%	16.41 %	0.25 %
16.33 %	-0.35	16.41%	0.25%	16.41 %	0.25 %
16.47 %	0.24	16.41%	0.25%	16.41 %	0.25 %
16.40 %	-0.04	16.41%	0.25%	16.41 %	0.25 %
16.51 %	0.40	16.41%	0.25%	16.41 %	0.25 %
16.54 %	0.52	16.41%	0.25%	16.41 %	0.25 %
16.47 %	0.24	16.41%	0.25%	16.41 %	0.25 %
16.50 %	0.33	16.41%	0.25%	16.41 %	0.25 %
16.37 %	-0.18	16.41%	0.25%	16.41 %	0.25 %
16.20 %	-0.84	16.41%	0.25%	16.41 %	0.25 %
16.23 %	-0.75	16.41%	0.25%	16.41 %	0.25 %

Scale to Limits

The scale to limits option scales the Y axis of the Levey Jennings window to the highest and lowest data point visible. This will revert back to standard settings when reset zoom is selected.

Set Scale

Set scale option allows the user to manually define the scale of the window.

Reset Zoom

The reset zoom option will reset the zoom of the 'Levey Jennings Window', to the defaults settings which are defined in the Display Options tab ([Configure > Quality Control > Display Options](#)) after manual adjustment using a mouse and keyboard or touch interface.

E. Date Range

The 'Start date' and 'End date' settings will define the date range displayed in the 'Levey Jennings window', once manually adjusted the date range will remain until Platinum is closed.

To adjust the date ranges, select the calendar icon, which will display a drop down to allow a certain date to be selected.

Start Date

10/11/2022

End Date

18/01/2023

January 2023

Mon	Tue	Wed	Thu	Fri	Sat	Sun
26	27	28	29	30	31	1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31	1	2	3	4	5

Today: 18/01/2023

By default, the start date will be the 1st day of the previous month and the end date will be the day of use. This will ensure that between one and two months data is shown at all times, allowing for a quick review of recent data.

F. QC, Band, and Capillary Selector

There are four distinct sections to this window; QC selector, Capillary selector, Band selector, and Selector display, which allows the QC data to be viewed in multiple ways, including by individual or groups of capillaries, by normal/abnormal controls and by band.

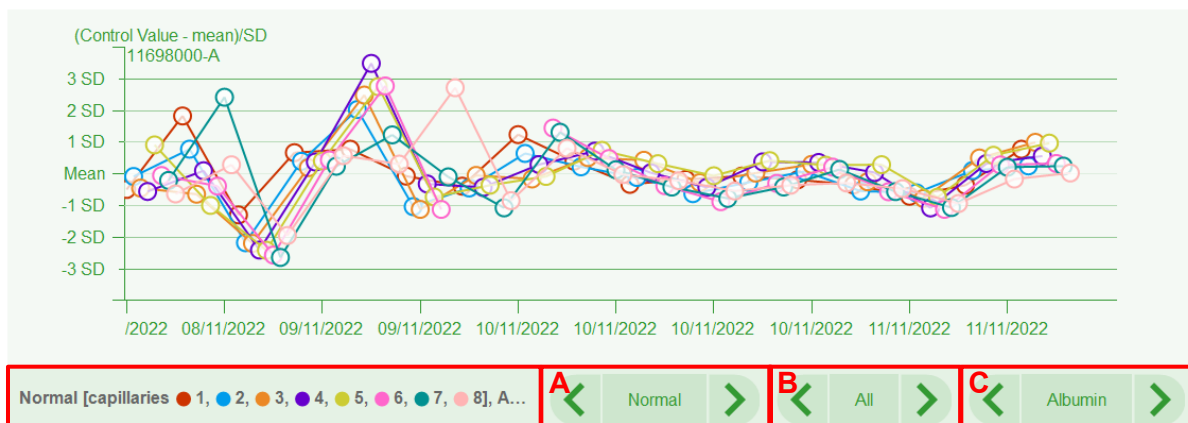
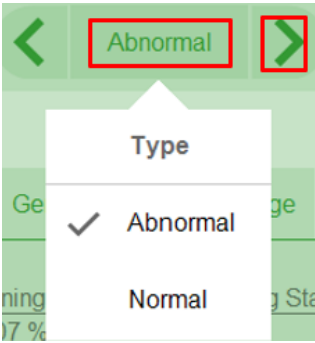


Figure 2: QC, Band and Capillary Sector

There are two ways in which the user can adjust the options in each section, either by using the green arrows or selecting the text between the arrows to display a drop-down menu.



The QC selector (Figure 2, A) allows the user to toggle between the normal and abnormal QC associated with the currently selected QC Test.

The Capillary selector (Figure 2, B) allows the user to toggle the capillaries currently displayed in the Levey Jennings window. One or more capillaries can be manually selected by the user.

All eight are shown when the 'All capillaries option' is selected.

Capillary	
<input checked="" type="checkbox"/> All Capillaries	Capillary 5
<input type="checkbox"/> Capillary 1	Capillary 6
<input type="checkbox"/> Capillary 2	Capillary 7
<input type="checkbox"/> Capillary 3	Capillary 8
<input type="checkbox"/> Capillary 4	

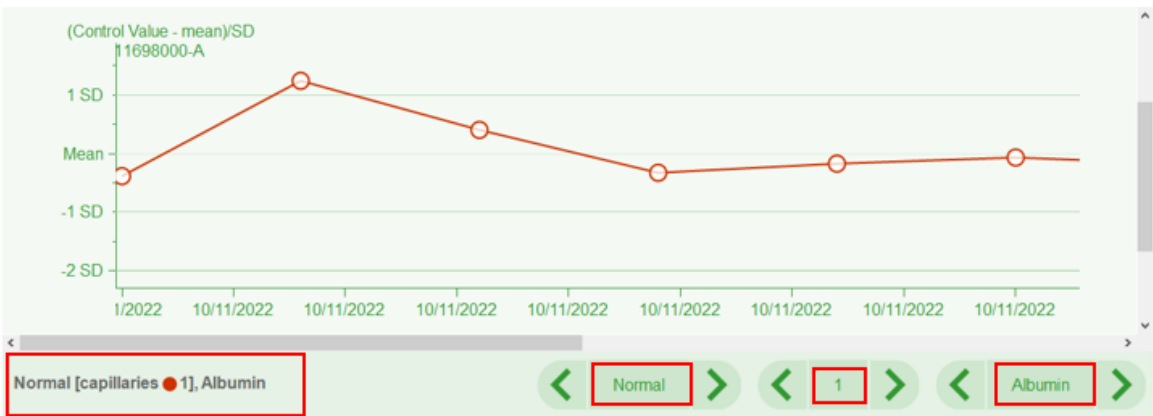
It is not possible to display all capillaries and all bands simultaneously, the 'All Bands' option will be greyed out if 'All Capillaries' are selected and vice versa.

The Band selector (Figure 2, C) allows the user to toggle the bands currently displayed in the Levey Jennings window. One or more bands can be manually selected by the user, all bands are shown when the 'All bands' option is selected.

It is not possible to display all bands and all capillaries simultaneously, the option will grey out if the other is selected.

Band	
<input checked="" type="checkbox"/> All Bands	Beta-1
<input type="checkbox"/> Albumin	Beta-2
<input type="checkbox"/> Alpha-1	Gamma
<input type="checkbox"/> Alpha-2	M-spike 1

The example below shows the QC data for the Albumin band for the Helena Normal control on capillary 1 only:



G. QC Function Window

The Levey Jennings tab list allows the user to switch which tab is visible in the 'QC function window':

QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Running Mean / SD	Westgard Rules
---------	------------------	--------------------	--------	-------------------------	-------------------	----------------

There are seven Tabs in the Tabs list:

1. QC Data Tab

The QC Data tab displays results related to the data displayed in the Levey Jennings window. Hovering over a data point in the Levey Jennings window will automatically jump to this data in the QC tab.

Data can be manually scrolled vertically using the mouse scroll wheel, holding the shift key will scroll horizontally. Physically swiping up and down on the touch screen monitor can also be used to scroll through the data.

QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Running Mean / SD	Westgard Rules
Albumin						
Relative Area	Deviation	Mean	SD	Running Mean	Running Standard Deviation	
61.56 %	-1.07	62.74%	1.11%	62.74 %	1.11 %	
61.93 %	-0.73	62.74%	1.11%	62.74 %	1.11 %	
61.51 %	-1.11	62.74%	1.11%	62.74 %	1.11 %	
61.58 %	-1.06	62.74%	1.11%	62.74 %	1.11 %	
61.72 %	-0.93	62.74%	1.11%	62.74 %	1.11 %	
62.36 %	-0.35	62.74%	1.11%	62.74 %	1.11 %	
62.87 %	0.11	62.74%	1.11%	62.74 %	1.11 %	
63.31 %	0.51	62.74%	1.11%	62.74 %	1.11 %	
63.11 %	0.33	62.74%	1.11%	62.74 %	1.11 %	
63.40 %	0.59	62.74%	1.11%	62.74 %	1.11 %	
63.06 %	0.29	62.74%	1.11%	62.74 %	1.11 %	
62.98 %	0.22	62.74%	1.11%	62.74 %	1.11 %	
62.57 %	-0.16	62.74%	1.11%	62.74 %	1.11 %	
63.61 %	0.78	62.74%	1.11%	62.74 %	1.11 %	
63.03 %	0.26	62.74%	1.11%	62.74 %	1.11 %	

To load the source data for a specific data point, select it in the table and then select 'Load Source Data' from the menu to the left of the table.

The screenshot shows the QC Function Window interface. At the top, there's a status bar with 'Passed' and dates. Below that, a Levey Jennings chart for 'Serum Protein Control x 8' is displayed. The chart shows data points for various capillaries over time. Below the chart, there's a table with columns: Index, Capillary, Lot ID, Date, Type, Comment, Alpha-2, Relative Area, and Deviation. A context menu is open over the table, showing options: 'Options', 'Print', 'Copy', and 'Load Source Data' (highlighted with a red box).

Index	Capillary	Lot ID	Date	Type	Comment	Alpha-2	Relative Area	Deviation
4	5@B17	11940554-C	21/02/2025 15:52:48	Normal Control			10.26 %	0.22
5	4@B17	11940554-C	21/02/2025 15:52:48	Normal Control			9.74 %	-2.32
6	3@B17	11940554-C	21/02/2025 15:52:48	Normal Control			10.26 %	0.16
7	2@B17	11940554-C	21/02/2025 15:52:48	Normal Control			9.96 %	-1.26
8	1@B17	11940554-C	21/02/2025 15:52:48	Normal Control			9.87 %	-1.73
9	8@B17	11940554-C	21/02/2025 15:26:00	Normal Control			10.39 %	0.76
10	7@B17	11940554-C	21/02/2025 15:26:00	Normal Control			10.04 %	-0.92
11	6@B17	11940554-C	21/02/2025 15:26:00	Normal Control			9.79 %	-2.10
12	5@B17	11940554-C	21/02/2025 15:26:00	Normal Control			10.39 %	0.75
13	4@B17	11940554-C	21/02/2025 15:26:00	Normal Control			9.63 %	-2.87

2. Current QC Range Tab

The current QC Range tab will show the QC data currently being used to generate Levey Jennings chart. This will automatically update when a new range is entered, or local ranges are implemented.

QC Data	Current QC Range		Historic QC Ranges		Lot ID	Generate Local QC range	Running Mean / SD		Westgard Rules	
Current QC Range		Lot: 11698000-A	First Used: 25 November 2022		Expiry Date: July, 2023					
Band	Low normal (%)	Upper normal (%)	Low abnormal (%)		Upper abnormal (%)		Mean normal (%)	SD normal	Mean abnormal (%)	SD abnormal
Albumin	53.02	71.74					62.74	1.11		
Alpha-1	4.24	5.74					5.11	0.23		
Alpha-2	7.98	10.80					8.85	0.45		
Beta-1	6.17	8.35					7.58	0.33		
Beta-2	3.24	4.39					3.75	0.11		
Gamma	10.33	13.98					11.95	0.44		

3. Historic QC

The Historic QC tab stores assay data for all previously used QC ranges. A drop-down menu allows the user to toggle the assay ranges visible. The lot number will correlate to that displayed in the Levey Jennings window at the change of lot.

QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Running Mean / SD	Westgard Rules			
Historic Data									
Lot:	11832888	<div><div></div></div>	First Used:	n/a	Expiry Date:	May, 2024			
Band	Low normal (%)	Upper normal (%)	Options	Low abnormal (%)	Upper abnormal (%)	Mean normal (%)	SD normal	Mean abnormal (%)	SD abnormal
Albumin			11832888	1	69.95			60.83	0.59
Alpha-1			11832888	4	5.19			4.52	0.10
Alpha-2			11832888-A	5	9.27			8.06	0.38
Beta-1			11832824	2	7.74			6.73	0.21
Beta-2			11832824	2	3.82			3.32	0.08
Gamma			11832824-A	6	19.03			16.55	0.25
M-spike 1			11698042						
			11698042-A						

4. Lot ID Tab

The Lot ID tab allows the user to manually enter assay data for a new control material. The lot number, upper / lower limits, expiry, and total protein concentration of that material will remain constant throughout use.

Data can be manually entered by clicking on the field.

Select the Edit Lot % button to allow data entry in percentage for the bands and deselect this to lock in the entered ranges. If concentration is to be applied rather than percentage, input the corresponding values in the Normal Control Total Protein and Abnormal Control Total Protein after configuring the **Chemistry Value** tab for the control method to include Total Protein.

The unit that is displayed can be changed by activating **Use Concentration unit for QC** in **Configure > Quality Control > Display Options**. Ticking this box will change the display units to those configured in **Configure > Methods > Chemistry Value > Concentration unit**. By default, the units are set to g/L. This is a visual change only, no calculations are done based on this change of display unit, and will also be reflected in the Results window.

QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Running Mean / SD	Westgard Rules		
Normal Lot ID:	11698000	Expiry Date:	07/2023	Normal Control Total Protein:	0.00	g/L		
Abnormal Lot ID:	11832888	Expiry Date:	05/2024	Abnormal Control Total Protein:	0.00	g/L		
Tap to scan barcode				Edit lot %				
Band	Low normal (%)	Upper normal (%)	Low abnormal (%)	Upper abnormal (%)	Mean normal (%)	SD normal	Mean abnormal (%)	SD abnormal
Albumin	53.02	71.74	51.71	69.95	62.38	0.48	60.83	0.59
A1AG								
Alpha-1	4.24	5.74	3.84	5.19	4.99	0.14	4.52	0.10
Alpha-2	7.98	10.80	6.85	9.27	9.39	0.19	8.06	0.38
HPX								
Beta-1	6.17	8.35	5.72	7.74	7.26	0.17	6.73	0.21
Beta-2	3.24	4.39	2.82	3.82	3.82	0.11	3.32	0.08
Gamma	10.33	13.98	14.06	19.03	12.15	0.20	16.55	0.25
M-spike 1								

Note: The Lot ID tab can only be used to update lot information. To set up a new control material this should be entered into the methods file, via [Configure > Methods > Lot IDs](#).

If the Lot ID information is updated within the Levey Jennings Lot ID tab, the lot information will automatically update the information stored under [Configure > Methods > Lot ID](#) and vice versa.

Using the Levey Jennings functionality, monoclonals can now be independently tracked.

When entering Lot ID information the user can define a Mean, SD, and upper / lower range for a monoclonal present in the QC material. These ranges are not provided on the assay sheet due to the highly variable nature of gating monoclonals.

Ranges can be automatically generated using the Generate Local Range tab.

5. Generate Local QC Range

A local mean can be created by going to **Generate Local QC Range**. Only the current Helena Lot number will be used, but a user specified number of days can be used to create the range.

Enter the number of days the Local Range should use and then select 'Generate Local Range'. A mean, SD and +/-1 to 4SD will be generated for each band.

To overwrite the Helena Ranges (or an old Local Range), select 'Overwrite Local Range'. The new Local Range will apply to all future controls.

QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Running Mean / SD	Westgard Rules				
Lot ID: 11698000 • Local Range set on: 25 November 2022 • Using QC data between: 15/12/2022 - 14/01/2023										
Generate Local Range: Using previous data: <input type="text" value="30"/> days Generate Local Range Overwrite Local Range <small>Local Mean and SD values will be calculated using QC data from the previous period defined here.</small>										
Band	Mean	Standard deviation	-4 SD	-3 SD	-2 SD	-1 SD	1 SD	2 SD	3 SD	4 SD
Albumin	62.74	1.11	58.32	59.43	60.53	61.64	63.85	64.96	66.06	67.17
Alpha-1	5.11	0.23	4.19	4.42	4.65	4.88	5.34	5.57	5.80	6.03
Alpha-2	8.85	0.45	7.07	7.51	7.96	8.40	9.30	9.74	10.19	10.64
Beta-1	7.58	0.33	6.27	6.60	6.93	7.26	7.91	8.24	8.57	8.90
Beta-2	3.75	0.11	3.29	3.41	3.52	3.64	3.87	3.98	4.10	4.21
Gamma	11.95	0.44	10.21	10.64	11.08	11.52	12.39	12.83	13.26	13.70

Note: Monoclonals can now be independently tracked using the Levey Jennings functionality.

When generating a local QC range for an abnormal control, if an M-spike is marked this will generate a new band in the QC data with its own Levey Jennings chart (instructions are referred to on page 91).

6. Running Mean / SD

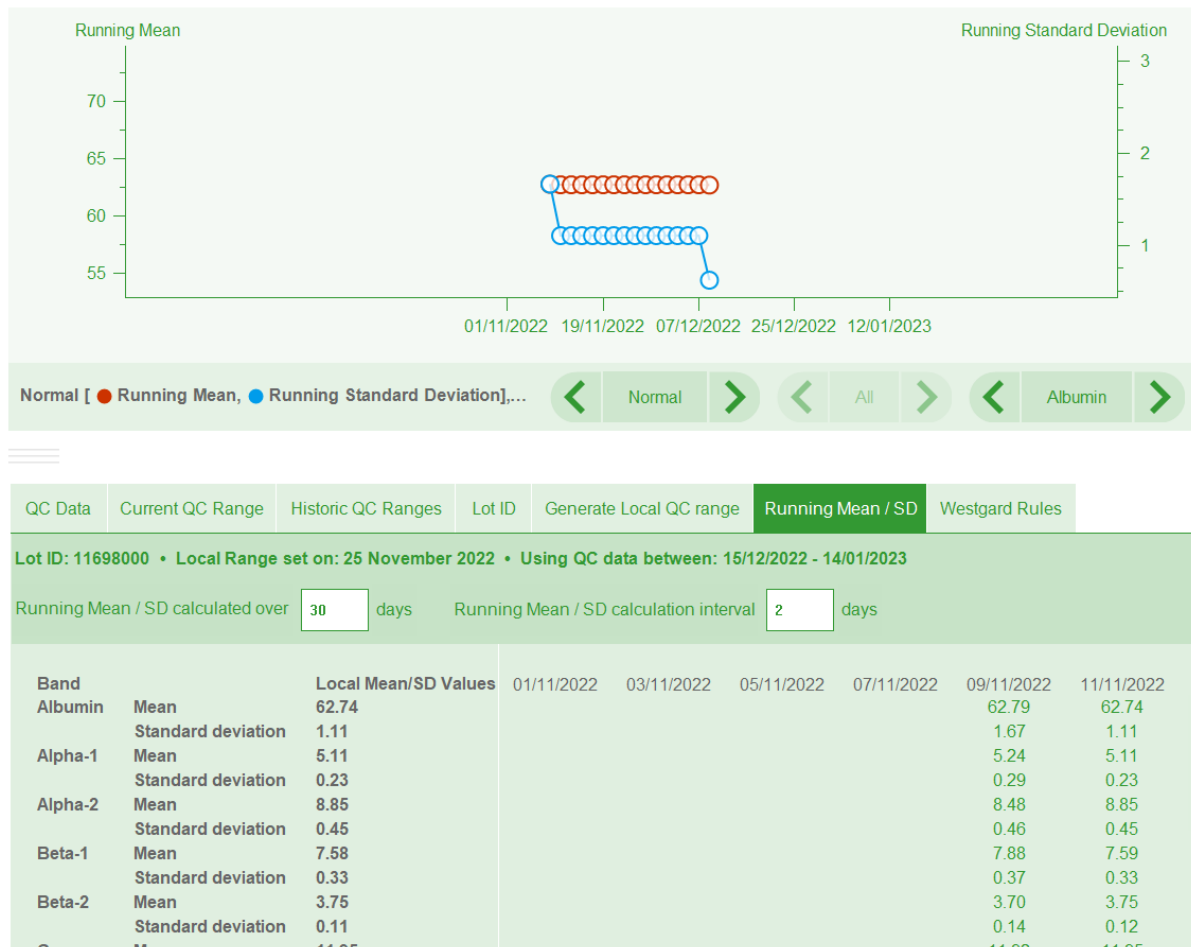
When the Running Mean tab is selected, a graph showing the running mean will replace the Levey Jennings graph.

Note: The Running Mean/SD tab will only appear if the local mean/SD has been generated.

This tracks Running Mean and running SD of the band selected, the output is the cross-capillary mean of that band over time.

The number of days over which the mean is calculated is defined, and customised, in the 'Running Mean / SD calculated over' box.

The intervals at which the Running Mean and SD are plotted is calculated, defined, and customised, in the 'Running Mean / SD calculated interval' box.



7. Westgard Rules Tab

The Westgard Rules tab allows the user to apply additional failure states to the QC Status of the system.

These additional rules will also trigger the QC Status icon and trigger all QC failure features. To view all Westgard Rules, 'Use Enhanced Westgard Rules' must be ticked in [Configure > Quality Control > Main Preferences](#).

Each user should fully evaluate any Westgard ruleset in their own laboratory before implementing into routine use.

QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Running Mean / SD	Westgard Rules																																		
<div style="display: flex; justify-content: space-between;"> <div style="width: 30%;"> <p>A <input type="radio"/> N of "3 of 6" <input type="radio"/> N of "2 and 4" <input checked="" type="checkbox"/> Manual Setting</p> </div> <div style="width: 30%;"> <p>C User defined SD Failure Limit when no rules applied: <input type="text" value="3"/> SD</p> </div> </div>																																								
<div style="display: flex;"> <div style="width: 30%;"> <p>B</p> <table border="1"> <tr><td>✓</td><td>✓</td></tr> <tr><td></td><td>✓</td></tr> <tr><td>✓</td><td></td></tr> <tr><td>✓</td><td>✓</td></tr> <tr><td>✓</td><td>✓</td></tr> <tr><td></td><td>✓</td></tr> <tr><td>✓</td><td></td></tr> </table> </div> <div style="width: 70%;"> <table border="1"> <tr><td>1_{3s}</td><td>Reject QC if a single results is outside of 3SD from the mean</td></tr> <tr><td>2_{2s}</td><td>Reject QC if 2 consecutive results are outside the same 2SD limit from the mean</td></tr> <tr><td>2_{of 3 2s}</td><td>Reject QC if 2 out of 3 consecutive results are outside the same 2SD limit from the mean</td></tr> <tr><td>R_{4s}</td><td>Reject QC if 2 results within the same run exceed 2SD both sides of the mean</td></tr> <tr><td>4_{1s}</td><td>Reject QC if 4 consecutive results exceed 1SD limit on one side of the mean</td></tr> <tr><td>3_{1s}</td><td>Reject QC if 3 consecutive results exceed 1SD limit on one side of the mean</td></tr> <tr><td>10_x</td><td>Reject QC if 10 consecutive results fall on one side of the mean</td></tr> <tr><td>12_x</td><td>Reject QC if 12 consecutive results fall on one side of the mean</td></tr> <tr><td>8_x</td><td>Reject QC if 8 consecutive results fall on one side of the mean</td></tr> <tr><td>7_T</td><td>Reject QC if 7 consecutive results trend in the same direction</td></tr> </table> </div> </div>							✓	✓		✓	✓		✓	✓	✓	✓		✓	✓		1 _{3s}	Reject QC if a single results is outside of 3SD from the mean	2 _{2s}	Reject QC if 2 consecutive results are outside the same 2SD limit from the mean	2 _{of 3 2s}	Reject QC if 2 out of 3 consecutive results are outside the same 2SD limit from the mean	R _{4s}	Reject QC if 2 results within the same run exceed 2SD both sides of the mean	4 _{1s}	Reject QC if 4 consecutive results exceed 1SD limit on one side of the mean	3 _{1s}	Reject QC if 3 consecutive results exceed 1SD limit on one side of the mean	10 _x	Reject QC if 10 consecutive results fall on one side of the mean	12 _x	Reject QC if 12 consecutive results fall on one side of the mean	8 _x	Reject QC if 8 consecutive results fall on one side of the mean	7 _T	Reject QC if 7 consecutive results trend in the same direction
✓	✓																																							
	✓																																							
✓																																								
✓	✓																																							
✓	✓																																							
	✓																																							
✓																																								
1 _{3s}	Reject QC if a single results is outside of 3SD from the mean																																							
2 _{2s}	Reject QC if 2 consecutive results are outside the same 2SD limit from the mean																																							
2 _{of 3 2s}	Reject QC if 2 out of 3 consecutive results are outside the same 2SD limit from the mean																																							
R _{4s}	Reject QC if 2 results within the same run exceed 2SD both sides of the mean																																							
4 _{1s}	Reject QC if 4 consecutive results exceed 1SD limit on one side of the mean																																							
3 _{1s}	Reject QC if 3 consecutive results exceed 1SD limit on one side of the mean																																							
10 _x	Reject QC if 10 consecutive results fall on one side of the mean																																							
12 _x	Reject QC if 12 consecutive results fall on one side of the mean																																							
8 _x	Reject QC if 8 consecutive results fall on one side of the mean																																							
7 _T	Reject QC if 7 consecutive results trend in the same direction																																							

Figure 3: Westgard Rule Tab

There are multiple ways to apply Westgard rules which are detailed below from Figure 3 (A-D):

Choose a predefined set of Westgard rules by selecting either 'N of "3 of 6"' or 'N of "2 and 4"' (Figure 3, A).

These two rulesets are common Westgard rulesets used in diagnostics.

Selecting either ruleset using the selector option in window N, will implement the ruleset indicated below that option. A brief description of each rule is outline against each selection.

While multi-rule QC has advantages in identifying failures, it should be noted that the more complex the ruleset the higher the false positive failure rate. This will also be linked to the performance of the assay in question.

Manual Setting (Figure 3, B)

The manual settings column can be customised by the user to build a bespoke ruleset appropriate to the requirements of the lab.

Individual Westgard rules can be highlighted and combined by ticking the appropriate box in the manual settings column.

To implement a manual ruleset the column should be selected using the manual settings option.

Note: it is generally accepted that 3SD should be used as a single point failure limit in combination with Westgard rules, therefore when the 1_{3s} rule is selected the option to manually define the SD failure limit (Figure 3, C) is greyed out and not used.

Manually adjust the SD failure limit of the software (Figure 3, C).

This option can be used to manually define an appropriate SD cut-off in place of single point of failure Westgard rules, adjusting the value will move the SD failure limit calculated by the current Mean and SD defined in the 'Current QC Range' tab.

This option can only be applied when no other manual / predefined rulesets are in place.

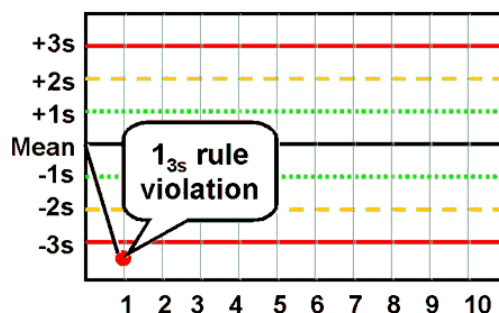
Westgard Rules (Figure 3, D)

The Westgard rulesets used in Platinum have been taken from the source at: <https://www.westgard.com>

These rulesets are outlined below with aid of images and references, which have also been taken from this source.

1_{3s} - Reject if a single result is outside of 3SD

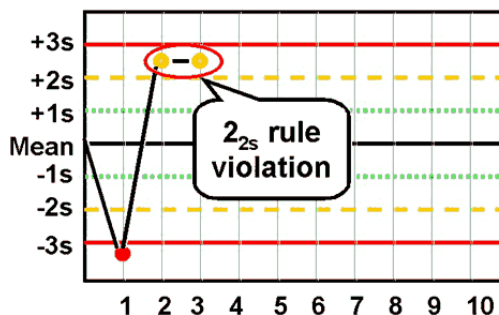
A single result either side of the Mean which exceeds 3SD will trigger a QC failure.



2_{2s} - Reject if two consecutive results exceed 2SD on one side of the Mean

Two consecutive results exceeding 2SD on one side of the Mean will trigger a QC failure.

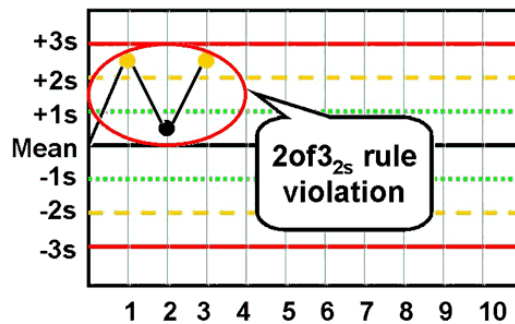
In Capillary Mode all capillaries are independently monitored, meaning the two consecutive failures should also be within capillary.



$2_{of3_{2s}}$ - Reject if two of three consecutive results exceed 2SD on one side of the Mean

Over a run of three consecutive results, a QC failure is triggered if two results exceed 2SD on one side of the mean.

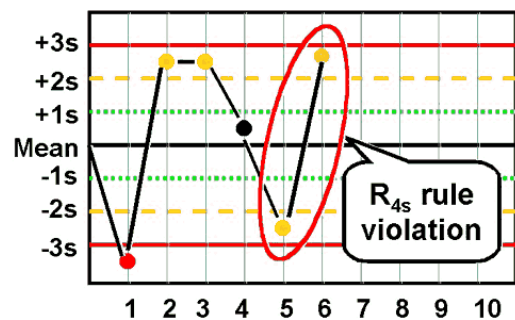
In Capillary Mode all capillaries are independently monitored, meaning the two failures should also be within capillary.



R_{4s} - Reject if results within the same run exceed 2SD on both sides of the Mean

Over a set of up to eight results generated in a single result by the V8 UltraCE, if 2SD is exceeded on both sides of the mean a QC failure state will be triggered.

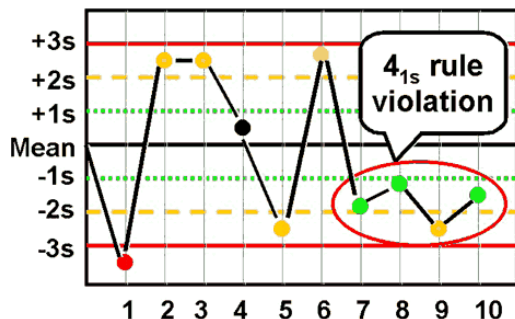
This rule does not function differently between standard and Capillary Mode, failure is limited to a single run of results across all eight capillaries.



4_{1s} - Reject if four consecutive results exceed 1SD on one sides of the Mean

Four consecutive results exceeding 1SD on one side of the Mean will trigger a QC failure.

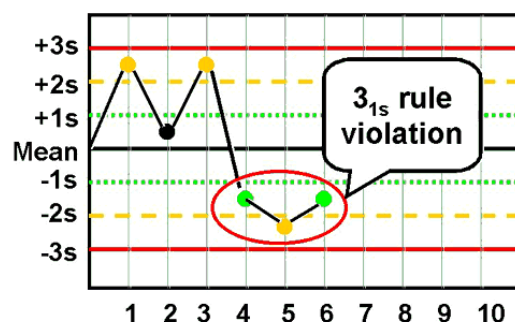
In Capillary Mode all capillaries are independently monitored, meaning the four failures should also be within capillary.



3_{1s} - Reject if four consecutive results exceed 1SD on one sides of the Mean

Three consecutive results exceeding 1SD on one side of the Mean will trigger a QC failure.

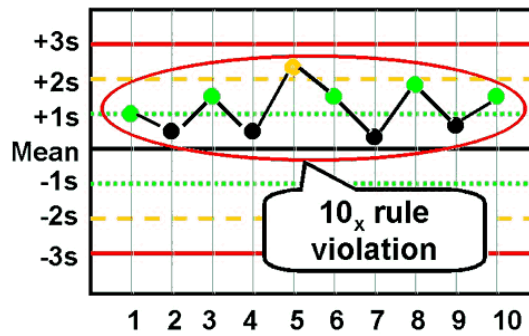
In Capillary Mode all capillaries are independently monitored, meaning the three failures should also be within capillary.



10_x - Reject if ten consecutive results are on one sides of the Mean

10 consecutive results laying on one side of the Mean will trigger a QC failure.

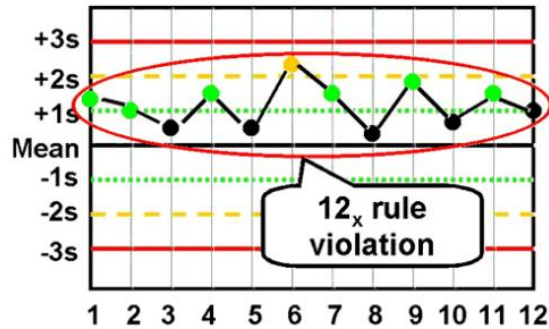
In Capillary Mode all capillaries are independently monitored, meaning the 10 results should also be within capillary.



12_x - Reject if twelve consecutive results are on one sides of the Mean

12 consecutive results laying on one side of the Mean will trigger a QC failure.

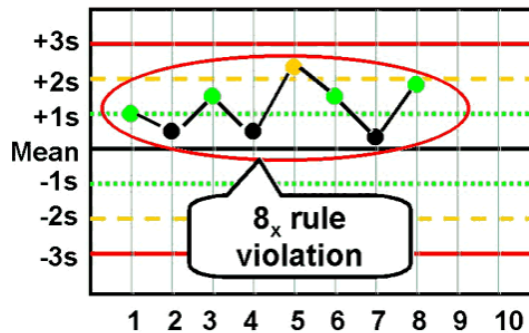
In Capillary Mode all capillaries are independently monitored, meaning the 12 results should also be within capillary.



8_x - Reject if eight consecutive results are on one sides of the Mean

8 consecutive results laying on one side of the Mean will trigger a QC failure.

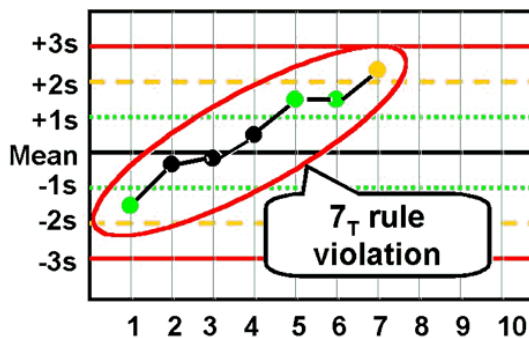
In Capillary Mode all capillaries are independently monitored, meaning the 8 results should also be within capillary.



7_T - Reject if eight consecutive results trend in one direction

7 consecutive results trend in one direction will trigger a QC failure.

In Capillary Mode all capillaries are independently monitored, meaning all 8 results should also be within capillary.



The Recommended Application of Westgard Rules

Westgard rules are a powerful tool for identifying aberrant results, bias, and imprecision.

It is important that when Westgard rules are employed, the system is using a local Mean and SD generated using results analysed on the system under investigation.

Please refer to page 79 for instructions on how to generate this.

Using Westgard rules centred on a Mean / SD generated using another system or an inter analyser mean will result in inappropriate failures of the ruleset. In this instance the system bias against the inter-analyser mean will be added to the local SD inappropriately increasing or decreasing the failure limit all Westgard rules are gauged against.

Non-Capillary Mode Westgard Rules

When non Capillary Mode is in use, all data points are assessed in the same Levey Jennings plot.

As a result, a minimalistic approach to Westgard rules is preferred.

Ruleset:

- SD failure limit
 - Manually define a failure limit of 2 or 3SD
- R_{4S} - Reject if results within the same run exceed 2SD on both sides of the Mean

These settings will provide a simple set of rules which will identify outlying results using the SD failure limit and identify unacceptable precision using the R_{4S} rule. In addition, any result falling outside the Min/Max manufacturer ranges will trigger a failure.

Choosing between 2 and 3SD as a failure limit should be decided based on the clinical performance of the assay and the local laboratory requirements.

Predefined Westgard Rulesets

The two predefined Westgard rulesets are comprehensive and represent the most stringent QC settings available. In both instances these rulesets will identify aberrant results, bias, and imprecision.

The advantage of using these rulesets is that additional Westgard rules will help to identify potential issues earlier.

The distinction between the two rule sets is the stage at which trends are identified and the stringency of the 2SD failure limit.

The N of "2 and 4" rule set builds in a set of trend analysis rules which will improve the sensitivity of identifying aberrant results but will also increase false negative failures.

N of "3 of 6" further expands on the N of "2 and 4" rules by making the failure condition more stringent. This further improves the detection of failures and trends, but also increases the incidence of false negative failures.

When considering the use of predefined rule sets, a full local evaluation of the assay and lab practices should be performed to ensure these rules are appropriate in the local setting in which they are being used.

Custom Westgard Rulesets

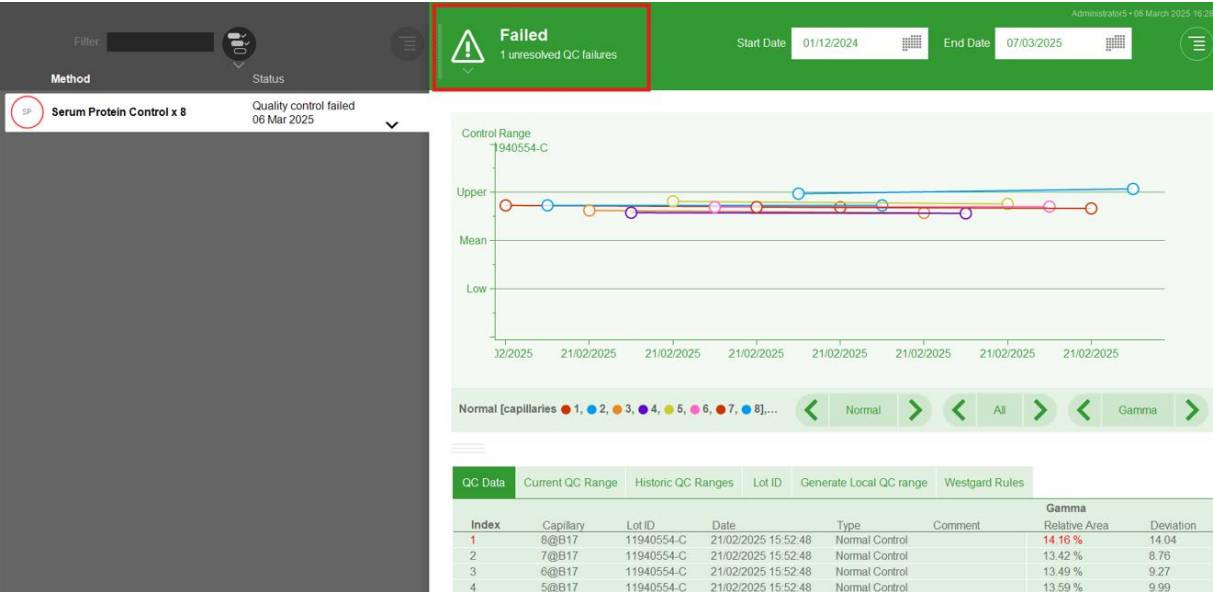
The most widely used application of Westgard rules is to select the appropriate rules suited to the local requirements of the laboratory.

While the two predefined rules set offer the best detection of failures, these failures may not be clinically relevant in context with the use of the assay.

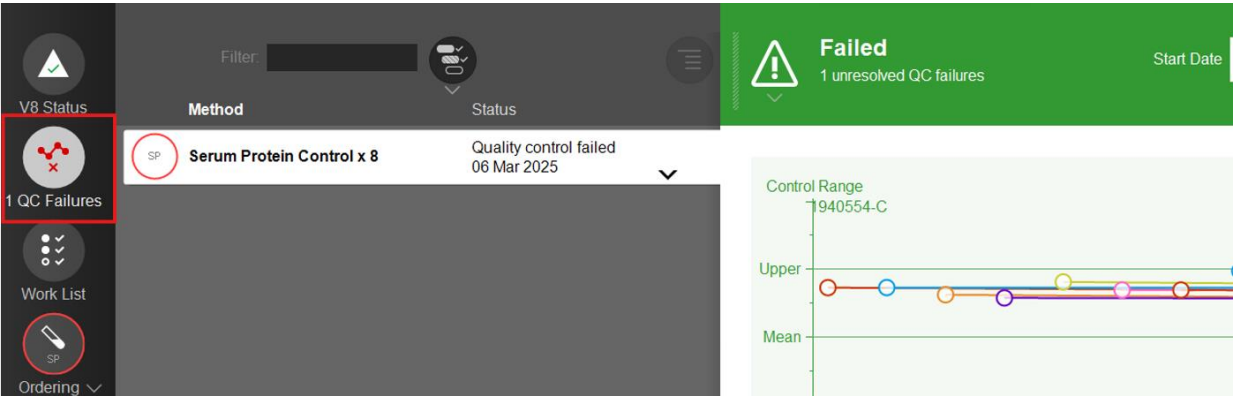
For example, a test with a small SD may have outliers which breach 1 SD consistently, and therefore removal of the 1SD trend analysis rules would be appropriate in this situation.

Should you wish to remove rules, switch to manual settings, and only transcribe the ruleset you wish to employ.

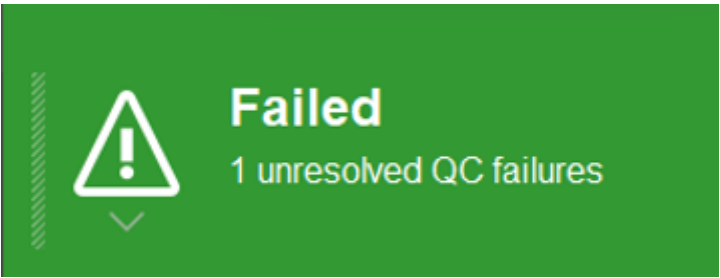
In the QC Status List found in the header of the Quality Control window, the current status of the control being displayed in the graph is shown.



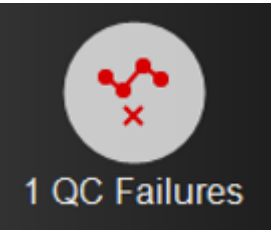
It is possible, for example, for the Normal Control to pass and the Abnormal to fail, so this header may change when switching between the two control types on the graph. The main Quality Control icon, however, will always display the overall status. If one of the control types has failed, this will show a failure state:



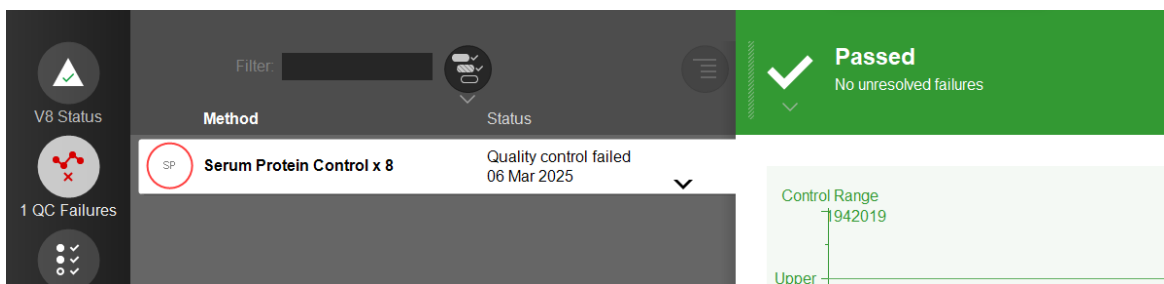
An optional feature is to display number of unresolved failures. This relates to any failures that have not had a comment applied if the 'Force QC failure comment' has been activated in the Quality Control Preferences. The number of unresolved failures will be shown per control type underneath the status in the header:



The number will also appear below the Quality Control window icon:



As with the Quality Control status of 'Passed' or 'Failed', the number of unresolved failures will be representative of the Normal or Abnormal Control under the header, and both combined under the Quality Control window icon:



Setup at Installation

At installation the core functionality of the QC suite should be customised to the customer's needs.

The default setup of the system is minimalistic and does not enforce QC options onto the user.

Default setup:

- SPE Control method
- Live icon disabled
- Automated QC setup awaiting user defined barcodes
- Levey Jennings results recorded globally across all eight capillaries
- No Westgard rules defined
- 2SD defined as default failure limit
- No automated warning messages

The procedure for the implementation of advanced QC features is outlined below.

This can include:

- Define QC analysis method
- Input lot information
- QC Settings
 - QC Status and Live icon configuration
 - Define global or per capillary Levey Jennings analysis
 - Configure failure warnings and audit trail messages
 - Automated QC recognition
 - Display Settings
- Define Westgard rule set

Define QC Analysis Method

Navigate to [Configure > Methods](#).

Determine the QC requirements and select an appropriate test method from the methods list.

For all required methods toggle the usage column to 'Main and reflex', this will allow the test to be ordered from the ordering page.

Configure Standard Methods			Method type	Chemistry Value	Geometry	Lanes
Standard Methods :						
M...	Usage	Name				
1	Main and reflex	Serum Protein				
2	Main and reflex	Serum Protein x 2				
3	Reflex only	Serum Protein x 8				
4	Hide	Serum Protein x 4				

Input lot information

For each QC test method, navigate to the Lot IDs page, located in [Configure > Methods and Quality Control > Lot IDs](#).

Enter the assay data provided with the control material:

- Select the appropriate method from the methods list
- Select the **Lot IDs** tab
- Use the assay sheet provided with the control material to fill in the appropriate ranges, including Lot ID and expiry date.
- Select the 'Edit Lot %' button to enable editing of the band statistics. Values will automatically be entered as a percentage when there is no Total Protein value available.
- If a Total Protein value is available, enter the band statistics as a percentage and select 'Edit Lot %' again once complete. The values will automatically switch to the specified units when this button is pressed.

Configure Standard Methods	Method type	Chemistry Value	Geometry	Lanes	Bands	Smoothing/Filtering	Gain Settings	Lot IDs	Barcode	Controls	Carbamylated Albumin	Regions/Zones
Barcode entry : <input type="text"/>												
Normal lot ID : <input type="text" value="123"/>		Expiry Date (MM/YYYY) : <input type="text" value="12/2022"/>		Normal Control Total Protein (g/L) : <input type="text" value="0.00"/> <input checked="" type="checkbox"/>								
Abnormal lot ID : <input type="text" value="345"/>		Expiry Date (MM/YYYY) : <input type="text" value="12/2022"/>		Abnormal Control Total Protein (g/L) : <input type="text" value="0.00"/> <input checked="" type="checkbox"/>								
Band statistics : <input type="button" value="Edit Lot %"/>												
B...	Component	Low norm...	Upper nor...	Low abno...	Upper ab...	Mean n...	SD nor...	Mean a...	SD abn...			
1	Albumin	51.55	69.75	50.55	68.39	60.65	0.48	59.47	0.41			
2	A1AG	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
3	Alpha-1	5.66	7.66	5.50	7.44	6.66	0.22	6.47	0.22			
4	Alpha-2	6.79	9.19	5.78	7.82	7.99	0.23	7.54	0.22			
5	HPX	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00			
6	Beta-1	7.32	9.90	6.41	8.67	8.61	0.24	7.54	0.22			
7	Beta-2	3.64	4.93	3.15	4.27	4.29	0.10	3.71	0.16			
8	Gamma	6.33	8.56	13.61	18.42	7.45	0.13	16.02	0.27			
9	M-spike 1											

Once the QC method is setup, this information can be updated both using [Configure > Methods > Quality Control > Lot IDs](#) and in the Lot ID tab of the QC function window of the Quality Control page:

QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Westgard Rules			
Normal Lot ID :	<input type="text" value="11758282"/>	Expiry Date :	<input type="text" value="07/2023"/>	Normal Control Total Protein :	<input type="text" value="0.00"/> g/L			
Abnormal Lot ID :	<input type="text" value="11747079"/>	Expiry Date :	<input type="text" value="05/2023"/>	Abnormal Control Total Protein :	<input type="text" value="0.00"/> g/L			
Tap to scan barcode			<input type="button" value="Edit lot %"/>					
Band	Low normal (%)	Upper normal (%)	Low abnormal (%)	Upper abnormal (%)	Mean normal (%)	SD normal	Mean abnormal (%)	SD abnormal
Albumin	52.17	70.58	50.56	68.41	61.37	0.48	59.49	0.44
A1AG	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

QC Settings

Optional QC settings are defined in the Quality Control preferences located in [Configure > Quality Control](#).

Main Preferences	V8 Auto Control Barcode Setup	Display Options
<p>A <input checked="" type="checkbox"/> Display Levey-Jennings Status</p> <p>Active control method :</p> <p>B <input type="text" value="Serum Protein Control x 8"/> <input checked="" type="checkbox"/></p> <p>C <input checked="" type="checkbox"/> Display Levey-Jennings Warning</p> <p>D <input checked="" type="checkbox"/> Force QC failure comment</p> <p>E <input checked="" type="checkbox"/> Use default comment</p> <p>QC Failure : <input type="text"/></p> <p>F <input checked="" type="checkbox"/> Capillary Mode</p> <p>G <input checked="" type="checkbox"/> Use Enhanced Westgard Rules</p>		
<p>Count down timer</p> <p>H <input checked="" type="checkbox"/> Use Countdown Timer.</p> <p><input type="text" value="12"/> <input checked="" type="checkbox"/> Hours</p> <p>Time Left</p> <p>I <input type="text" value="0"/> Hours</p>		
<p>Verification M</p> <p><input type="checkbox"/> Activate</p> <p><input checked="" type="checkbox"/> Warn when unverified reagents or buffers are used</p> <p><input checked="" type="checkbox"/> Do not validate unverified results</p>		
<p>Failure Conditions</p> <p>J <input checked="" type="checkbox"/> Lot ID Ranges</p> <p>K <input checked="" type="checkbox"/> Active SD Limit Exceeded</p> <p>SD Limit: <input type="text" value="2"/></p> <p>L <input checked="" type="checkbox"/> Westgard Rules</p>		

Figure 4: QC Settings/Preferences listed A-M.

Display Levey Jennings Status (Figure 4, A)

Ticking the 'Display Levey Jennings Status' function will activate the QC Status icon, and show the Pass, Fail, Out Of Date icon for a single control method.

This method should be selected in the 'Active control method' (B) to activate real time tracking of the QC status.

The Quality Control icon on the left-hand side of the screen will change according to the QC status of the method highlighted in the active control method box.

The countdown timer will indicate how long this result is valid.

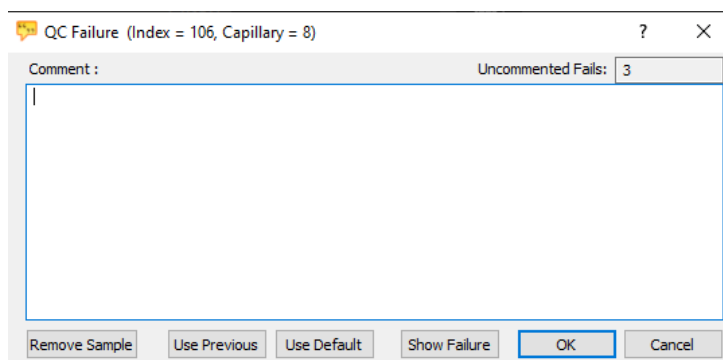
Display Levey Jennings Warning (Figure 4, C)

Activating the 'Display Levey Jennings Warning' feature will prompt a warning box if the user runs the machine when the QC is out of date or has failed.

Force QC Failure Comment (Figure 4, D)

Activation of the 'Force QC failure comment' will initiate a popup comments box when you open the Quality Control window if any of your QC results are out of range.

Selecting this option will make it a requirement that a comment is entered before you can close the QC failure comments box.



This comment is audit traceable and can be used to document corrective action and/or justification for accreditation purposes.

Use Default Comment (Figure 4, E)

A user defined default comment, generated in response to a 'Force QC failure comment', can be customised in the Quality Control Preferences window.

This comment will automatically populate the comments box unless amended by the user before accepting the failed QC.

Capillary Mode (Figure 4, F)

'Capillary Mode' will allow the tracking of capillaries individually.

Please refer to Capillary Mode, page 90 for more information.

Use Enhanced Westgard Rules (Figure 4, G)

This setting will activate the new Westgard ruleset.

Activate if you intend to use Westgard rules beyond functionality already available in Platinum 6.2.

Countdown Timer (Figure 4, H)

To assign a countdown timer and QC expiry to your QC results activate the countdown timer setting.

The time period a QC is valid for is defined in hours using box 1 (Figure 4).

The time remaining before QC expiry is indicated in this window.

Failure Conditions

The failure conditions box contains settings which will activate rules that will change the status of the QC Status icon.

Lot ID Ranges (Figure 4, J) will link the assay limits defined by the lot information in the Lot ID tab.

Activate SD Limit (Figure 4, K) will implement the 'User defined failure limit' box in the Westgard Rules tab.

Westgard Rules (Figure 4, L) will link the Westgard ruleset defined in the Westgard Rules tab to the QC Status icon.

Reagent Verification (Figure 4, M)

When activated, 'Verification' will allow onboard buffers and reagents to be verified by the user. If 'Warn when unverified reagents or buffers are used' is also selected, a warning message will be shown when one or more reagents that are onboard the instrument are not verified whenever a rack is scanned.

V8 UltraCE Automatic QC Test Ordering

The V8 UltraCE can be configured to automatically identify, test and authorise QC material, this will remove the requirement to manually order QC tests and automatically pass or fail the QC status of the instrument based on the results.

Automatic QC Test Ordering can be activated by ticking the 'Enable Automated V8 Control Barcode' option in the 'V8 Auto Control Barcode Setup' window.

Features of Automatic QC Test ordering:

- Automatically order a predefined QC test method
- Set the Normal/Abnormal control or Calibrator status of results in the worklist
- Add these results to the Levey Jennings chart and activate any associated settings

Users can configure up to 8 automated barcodes through the Quality Control menu, the barcodes used during setup must be affixed to all similar QC material going forwards.

Also included is an alert function to warn the user if Lot IDs haven't been entered for the control method being ordered.

Set up of Automatic Barcodes:

- Once 'Enable Automated V8 Control Barcode' has been ticked, a specific barcode must be created and configured within the "Barcode From V8" section. (It is important to ensure the exact text that has been configured on the barcode is typed correctly into the text box in order for the V8 UltraCE to recognise this as a control barcode).
- Select the type of control/calibrator the specific barcode will be assigned/marked as, eg Normal/Abnormal control.
- Then select the method in which the specific barcode will be ran on each time the V8 UltraCE recognises this barcode.
- The first example below shows barcode "QC1" will always be ran on the Serum Protein x 8 method and will be automatically marked as a Normal Control.
- The data from this sample will then be automatically entered into the Levey Jennings.

Quality Control Preferences

Main PreferencesV8 Auto Control Barcode SetupDisplay Options

☒ Enable Automated V8 Control Barcode

Barcode From V8:	is marked as:	runs with the method:
QC1	Normal Control	Serum Protein x 8
QC2	Abnormal Control	Serum Protein Control
QC3	Normal Control	Serum Protein Control
QC4	Calibrator Level 1	Serum Protein Control
CAL1	Calibrator Level 2	CDT
CAL2	Calibrator Level 3	CDT
CAL3	None	CDT
	None	None

☒ Show warning for missing Lot ID

Display Options

The Display Options tab in [Configure > Quality Control](#) allows the user to implement additional visual aids in the Levey Jennings window.

By default, these are turned off to prevent blanket changes to all users.

All options will implement a new threshold on the Levey Jennings chart.

Mean ranges will put an allowable inter analyser threshold from the manufacturer Mean onto the Levey Jennings chart. This is set to 15% when in use.

The Display +/- 3SD and Display +/- 1SD options will include these thresholds into the Levey Jennings chart. By default, only 2SD is visible.

[Use Concentration unit for QC](#) allows the configuration of the display units to the user's preference. By default, the units are set to g/L. Ticking this box will change the display units to those configured in [Configure > Methods > Chemistry Value > Concentration unit](#). This is a visual change only, no calculations are done based on this change of display unit, and will also be reflected in the Results window.

[Show newest first in QC Data tab](#) controls the order of the samples in the QC Data tab. When ticked, the newest sample is at the top with older samples going down the list. When unticked, the oldest sample is at the top with newer samples going down the list.

[Multi Machine QC](#) allows multiple V8 UltraCE machines on the same networked database to be viewed remotely, removing the need to have access to the original PC that captured the data. 'V8 Name for System' shows the name that will be displayed to identify the machine in the 'Sender' column of the Quality Control page. 'Load V8 Names' will add System IDs that are not in the list and generate a name for them. The name comes from [Configure V8 Systems > V8 System Name](#) of the most recently run sample for the system. Double clicking on a name allows editing.

The screenshot shows the 'Display Options' tab with the following settings:

- Mean Range Display:**
 - ☐ Mean Range On
 - Upper (%): 0.00
 - Lower (%): 0.00
- ☒ Display +/- 3 SD
- ☒ Display +/- 1 SD
- ☐ Use Concentration unit for QC
- ☒ Show newest first in QC Data tab

Multi Machine QC

- ☒ Enable
- Load V8 Names

V8 name for System:

V8 System	System ID
V8-A06	0000000018A5FA9E
B16	00000000240C517F
Emulator	00000000B5642A97
B20	000000002372CD5E
V8-A05	0000000035B0DC25
B19	000000006B677551
B21	0000000072E63464
B17	00000000D3CE63D3
V8	04000000144DEC84
	410000001B799884
	A20000004DB73124
58-24-11-7-041	D700000046A38624

Capillary Mode

When Capillary Mode is activated, each capillary is visualised and monitored in its own Levey Jennings chart. Results will no longer trend between capillaries unless explicitly indicated in a ruleset or feature.

Capillary Mode will identify bias in individual capillaries which otherwise would have been masked by aggregating together.

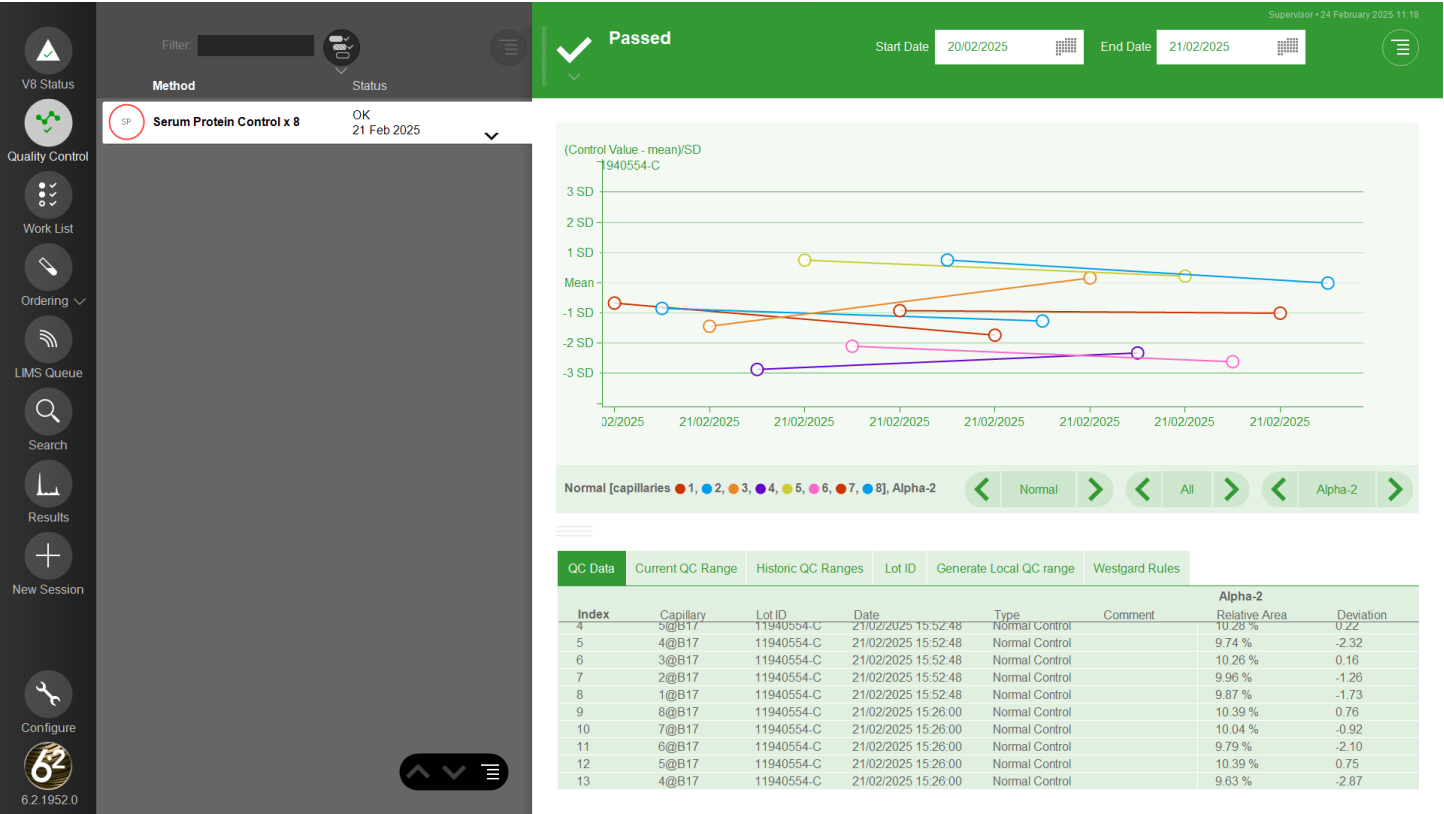
The activation of Capillary Mode is done through [Configure > Quality Control > Capillary Mode](#).

The screenshot shows the 'Capillary Mode' settings in the 'Display Options' tab. The 'Capillary Mode' checkbox is highlighted with a red box.

- ☒ Display Levey-Jennings Status:
 - Active control method : Serum Protein Control
- ☒ Display Levey-Jennings Warning
- ☒ Force QC failure comment
 - ☐ Use default comment
 - QC Failure :
- ☒ Capillary Mode
- ☒ Use Enhanced Westgard Rules

Multiple capillaries can be viewed at one time by selecting them in the box underneath the main Levey Jennings graph.

Each capillary will be shown in a different colour. The key underneath the graph shows which capillaries the colours correspond to.



Tracking an M-Spike using Levey Jennings

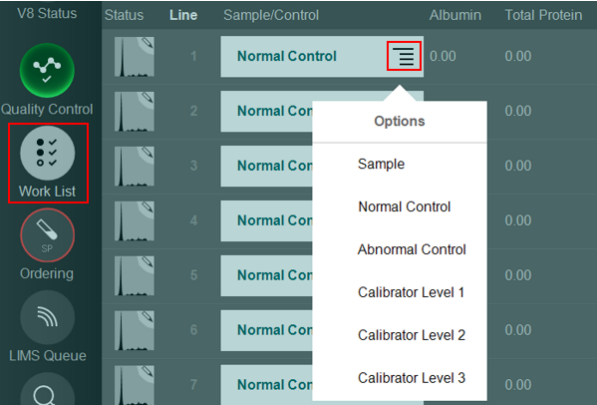
It is possible to add M-Spikes to the Levey Jennings and running mean graphs. To do this:

- Input the assay ranges into the Lot IDs tab for a Helena Abnormal Control. No range is required for the M-Spike, although a user specified range can be added if desired.
- Run the abnormal control.
- Once it has run, check the controls have been banded correctly.
- Add an M-Spike to the gamma region of the abnormal controls.
- Mark the trace as a control.

This can be performed via the navigation worklist or through the results page, both options are shown below:

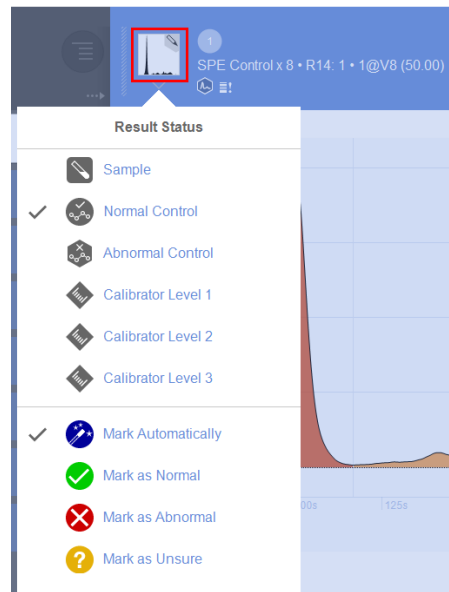
- Navigation List:

Select Work List and click on the options icon to display the drop-down menu.

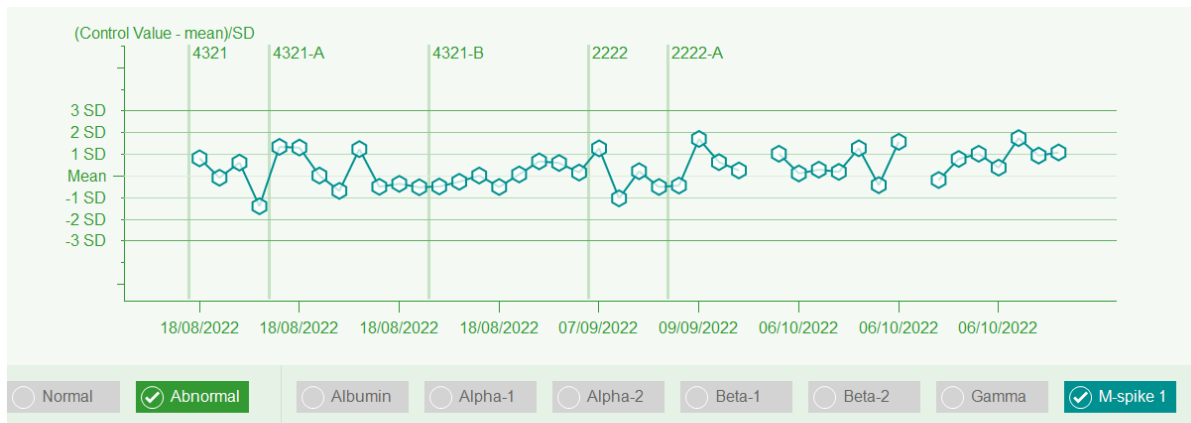


- **Results Page:**

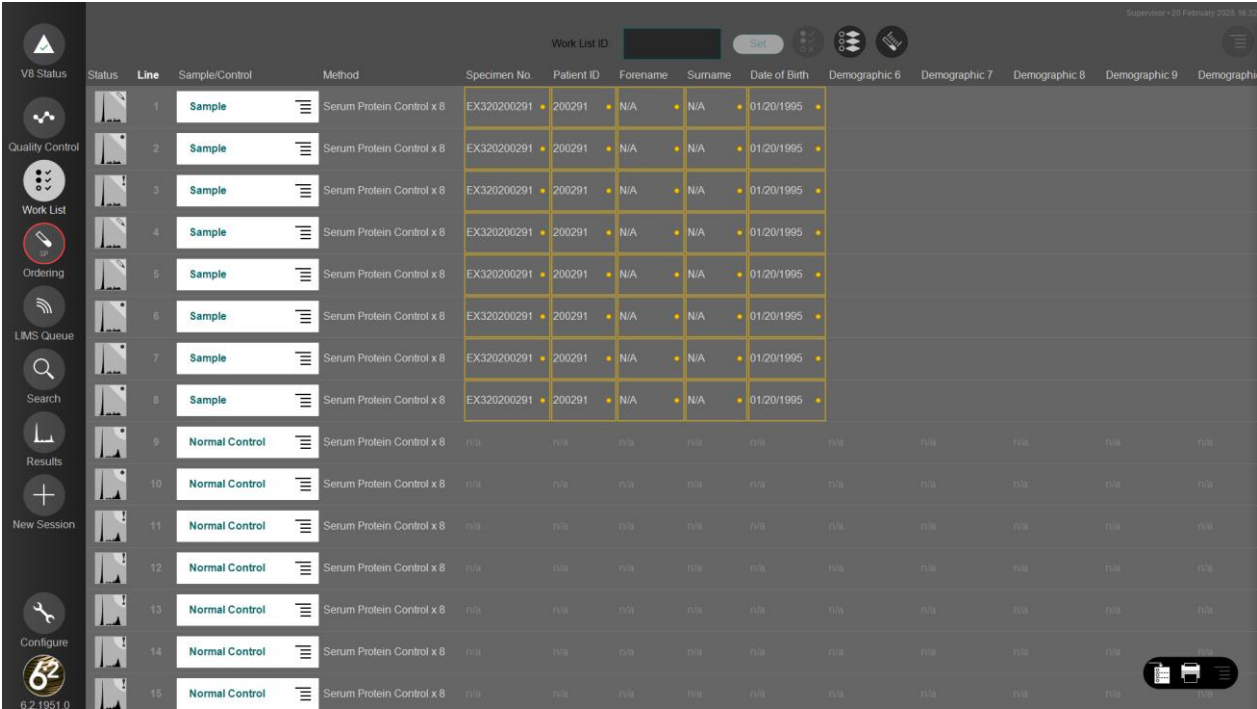
On the main results page, above the trace, select the trace icon and select an option from the drop-down menu.



- Open the Quality Control Window and select the appropriate control method which the control was ran on.
- Go to 'Generate Local QC Range'. Make sure the number of days will cover all of the control data you want included. Select 'Generate Local Range'.
- Data should be generated for all of the bands, including the M-Spike.
- Select 'Overwrite Local Range' to apply the newly generated Local Range to all future controls.

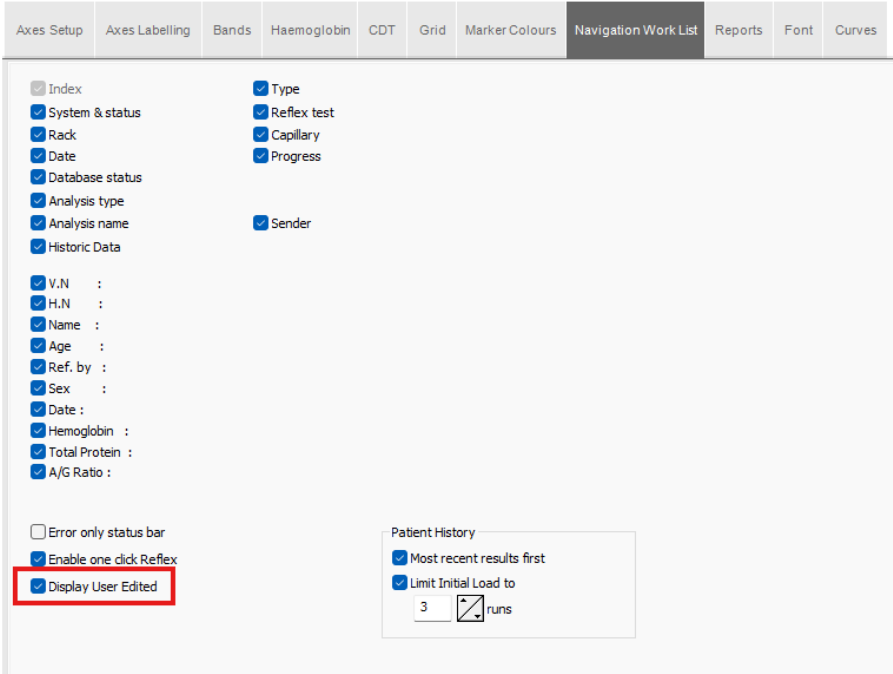



QC Data	Current QC Range	Historic QC Ranges	Lot ID	Generate Local QC range	Running Mean / SD	Westgard Rules		
● M-spike 1								
Date	Type	Comment	Relative Area	Deviation	Mean	SD	Running Mean	Running Standar
18/08/2022 15:52:36	Abnormal Control		2.42 %	-0.49	2.53%	0.21%	2.55 %	0.16 %
18/08/2022 15:52:36	Abnormal Control		2.45 %	-0.35	2.53%	0.21%	2.55 %	0.16 %
18/08/2022 15:52:36	Abnormal Control		2.42 %	-0.51	2.53%	0.21%	2.55 %	0.16 %
18/08/2022 15:54:09	Abnormal Control		2.42 %	-0.47	2.53%	0.21%	2.55 %	0.16 %
18/08/2022 15:54:09	Abnormal Control		2.47 %	-0.26	2.53%	0.21%	2.55 %	0.16 %
18/08/2022 15:54:09	Abnormal Control		2.53 %	0.03	2.53%	0.21%	2.55 %	0.16 %
18/08/2022 15:54:09	Abnormal Control		2.42 %	-0.50	2.53%	0.21%	2.55 %	0.16 %
23/08/2022 09:19:07	Abnormal Control		2.54 %	0.08	2.53%	0.21%	2.55 %	0.16 %
23/08/2022 09:19:07	Abnormal Control		2.67 %	0.69	2.53%	0.21%	2.55 %	0.16 %
23/08/2022 09:19:07	Abnormal Control		2.66 %	0.61	2.53%	0.21%	2.55 %	0.16 %
23/08/2022 09:19:07	Abnormal Control		2.56 %	0.17	2.53%	0.21%	2.55 %	0.16 %
07/09/2022 09:36:52	Abnormal Control		7.71 %	1.29	7.06%	0.51%	7.34 %	0.39 %
07/09/2022 09:36:52	Abnormal Control		6.54 %	-1.02	7.06%	0.51%	7.34 %	0.39 %
07/09/2022 09:36:52	Abnormal Control		7.17 %	0.23	7.06%	0.51%	7.34 %	0.39 %



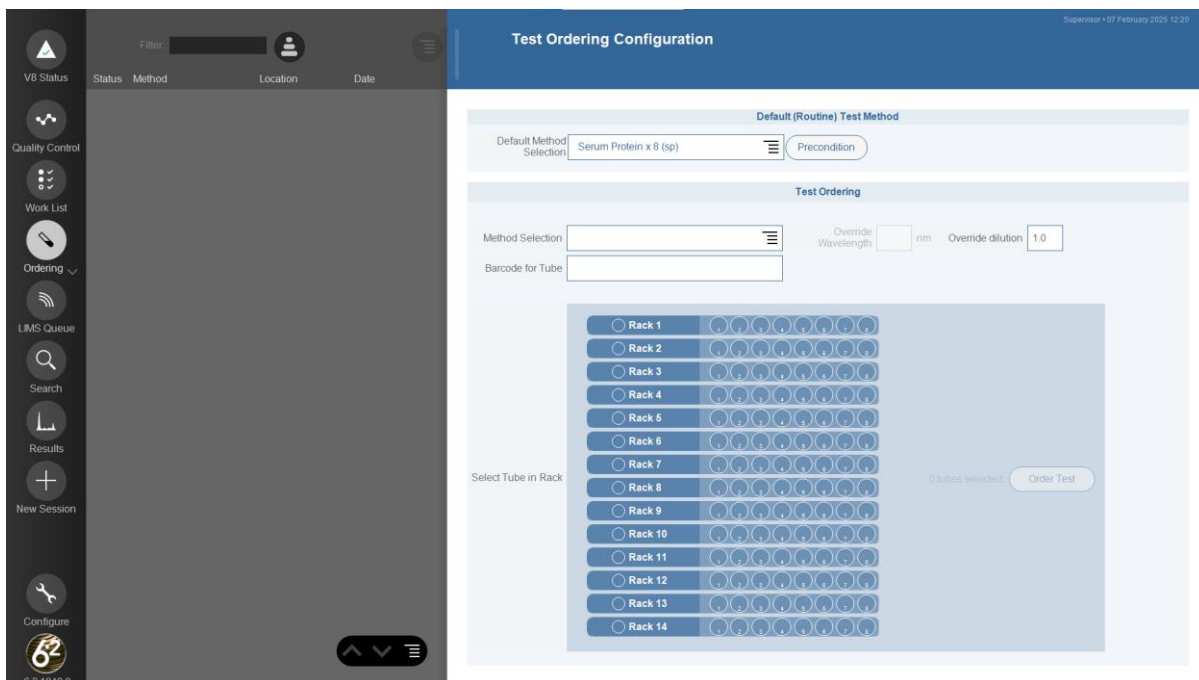
The Work List window shows all samples that have been added to the session, whether it is an active session or an older Platinum session. Here, the user can set controls, and also input any demographic or chemistry values for the sample. Gel worklists can also be created in this window. If connected to LIMS the demographics will be automatically populated whenever barcoded samples are scanned in if auto query is enabled. If auto query is not enabled, the demographics can be populated by manually querying the LIMS.

Any data that is entered here should appear in the trace demographics in the results window. Please note there is a character limit of 38 for the demographics fields. The option to highlight any manually edited demographics can be activated in [Configure > Preferences > Navigation Work List](#).



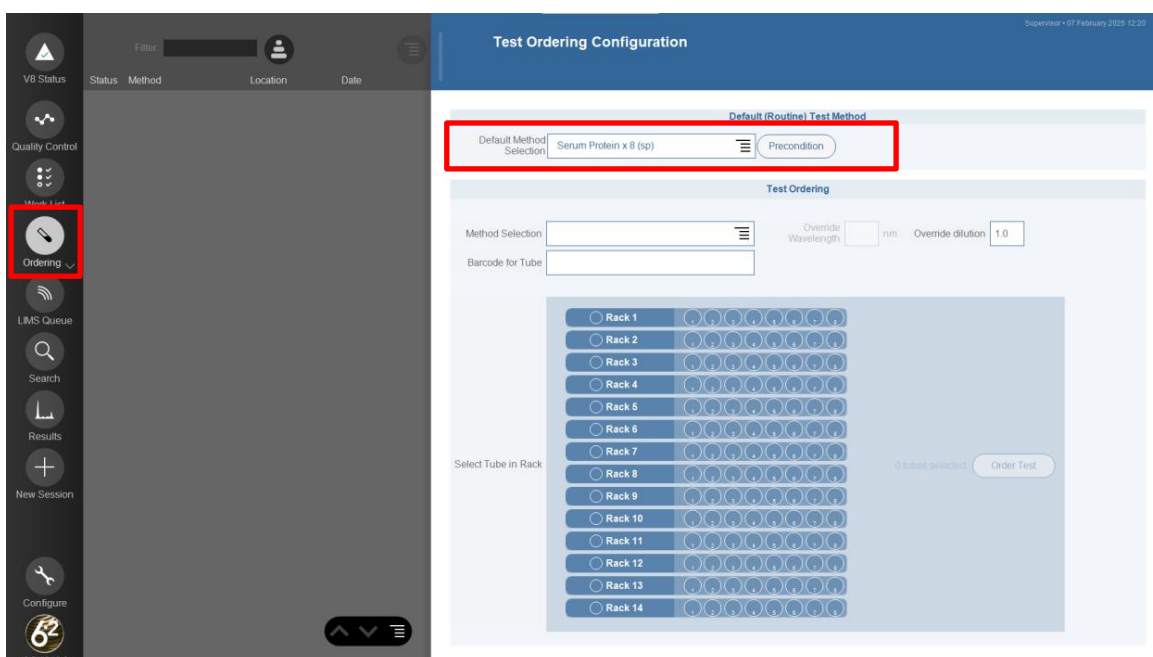
The Work List window can also be used to create a gel worklist by using the  icon to add new samples when in a gel scan session.

5.8.6 Ordering Window



5.8.6.1 Selecting the Default Method

The default method can be set in the ordering window and using the 'Default Method Selection' dropdown menu.



5.8.6.2 Test Ordering

Test ordering refers to the assignment of an assay to a sample. A test can be ordered when assays other than the default assay are required.

To order a test:

- Go to the Ordering window
- Select the method you require by clicking on the "Method Selection" dropdown box
- Enter the barcode of the sample being ordered (if applicable)
- Input any Override Wavelength (FlexWave Technology) or Override Dilution if they are not the same as the default.
- Select the tube position and/or barcode for which the tests will be run (the same method can be ordered for multiple samples/racks at the same time)
- Select 'Order Test'
- The tests will appear on the left hand side of the screen in the ordered tests list
- Load the sample(s) in the sample rack, ensuring the sample rack and ID correspond with those set in Platinum.
- Place the sample rack(s) into the sample rack transport area and close the rack cover
- The V8 UltraCE will automatically process the ordered assay
- Once complete, the sample will no longer appear in the Ordering window

How to Cancel an Ordered Test

Tests that have been ordered or are awaiting Reflex testing will remain on the system as outstanding, regardless of whether the samples have been taken off-board the V8 UltraCE. If samples are removed from the V8 UltraCE then placed back on-board, then the ordered tests will be performed unless cancelled from the system. If a tube with a missing/misread barcode has an outstanding test, then this test will be removed automatically from the system when the rack is removed from the 'No Barcode Worklist'.

- Open the Ordering window
- Select the ordered test which you wish to remove
- Select the "Remove ordered test" icon found in the 'Options' menu at the bottom of the screen



5.8.6.3 Racks

Racks

This will display all racks that contain any non-barcoded or misread tubes.

5.8.6.3.1 Sample Tube Barcodes

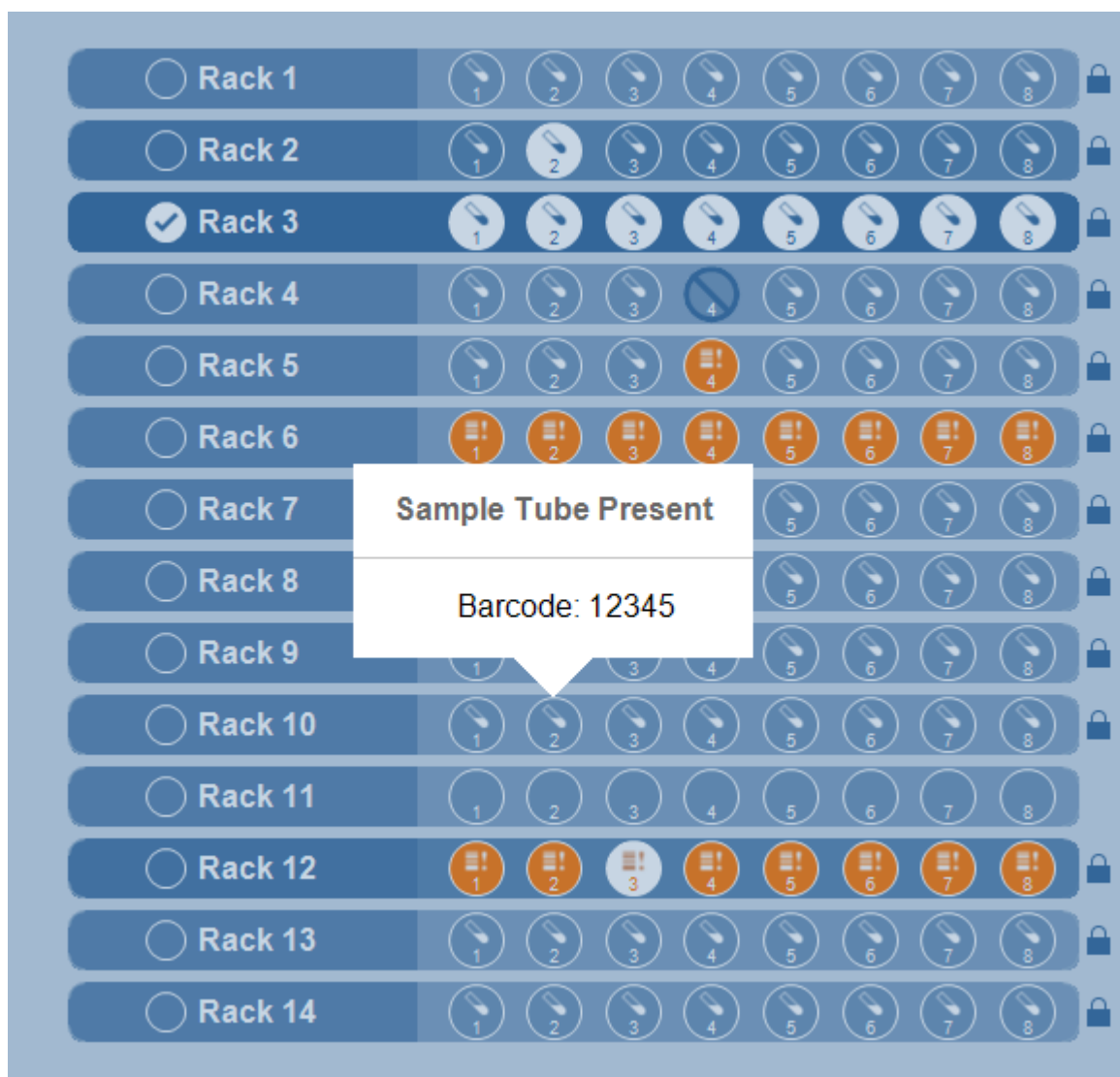
Sample Tube Barcodes

Tubes can be loaded on to the V8 UltraCE with or without individual bar codes. However, this does affect the manner in which Platinum processes samples and reflex tests.





- If barcodes are present the V8 UltraCE will process each sample individually.
- If barcodes are not present the V8 UltraCE will process each sample individually and recognise each one only by rack number and position. As such, racks MUST NOT be removed from the system or Platinum if reflex testing is needed.

The V8 UltraCE will enter the barcode into the navigation list under the first demographic usually marked as LIS identifier. If the V8 UltraCE has not been able to read the barcode on the sample tube, or there is not a sample tube in every position of a sample rack this field will be left blank.

To avoid disruption of the workflow, the V8 UltraCE will process all the samples, performing the default assay for all tubes, unless another test is ordered.



Each tube can show:

- No rack, Tube is empty: 
- Rack Present, Skip barcode: 
- Rack Present, no barcode: 
- Rack Present, valid barcode: 

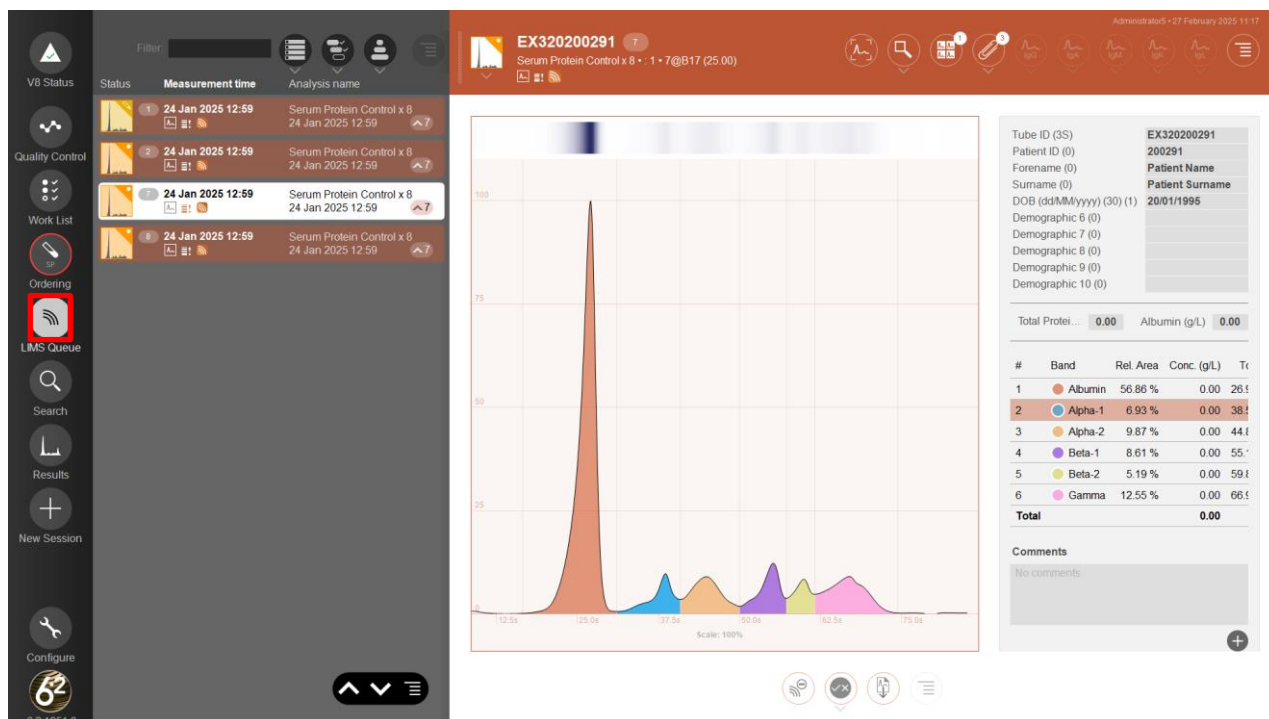
Right clicking or long pressing a tube will show a popup with information about the tube. Tapping the “Barcode” line will launch a relevant help page.

A whole rack can be selected by tapping the circle next to the rack number, or multiple individual tubes can be selected by tapping on the tube position.



A padlock is displayed to show the rack is present and must be removed to be reused. Tapping this will perform “Remove Rack” and disappear.

5.8.7 LIMS Queue





5.8.7.1 Controlling Data to the LIMS/LIS



There are two ways to send data to the LIMS/LIS. It can either be to the LIMS queue, where the data can be validated before sending to the LIMS/LIS, or it can be sent directly without validation to the LIMS/LIS.


5.8.7.2 Sending Data to the LIMS Queue

Samples are sent to the Laboratory Information Management System (LIMS/LIS) holding queue so that once a user of a suitable seniority has validated the data as acceptable it can be sent to the LIMS database.

To send an individual lane or several lanes to the LIMS queue, select the sample which you would like to send from the Results window and then


select the LIMS icon  and then Add to LIMS Queue .


To send the whole session or gel scan to LIMS, select the  icon from the NWL 'Options' menu and Select All, then Select the Add to LIMS queue option  from below the trace.


Those samples sent to the LIMS queue will be marked with a work list icon .


5.8.7.3 Viewing and Releasing Data in the LIMS Queue


To view samples in the LIMS queue, go to the LIMS Queue window.




To approve an individual sample to be released from the LIMS queue, select the Send Selected to LIMS icon  from the NWL 'Options' menu.

A blue tick will appear next to the LIMS icon .

To approve multiple selected samples to be released from the LIMS queue, highlight the samples you wish to approve by touching the small trace icon in the NWL and then select Set Approval for Sending to LIMS . Blue ticks should appear next to the LIMS icon for all selected samples.

To prevent a previous approved individual sample from being released from the LIMS queue, highlight the sample and select "Clear Approval for Sending to LIMS" . The blue tick should then be removed from the NWL. To do this for multiple samples, highlight all the samples you wish to remove the approval from by touching the small trace icon in the NWL before selecting "Clear Approval for Sending to LIMS".

To remove an individual sample from the LIMS queue, select the "Remove from LIMS queue" icon . To remove multiple samples, highlight all of the samples you wish to remove by touching the small trace icon in the MWL before selecting "Remove from the LIMS queue".

Once the appropriate samples have been authorised to be sent to the LIMS database, select either "Send All to LIMS" , "Send Selected to LIMS"  or "Send Selected Approved to LIMS"  depending on the requirement to send the results to the LIMS database.

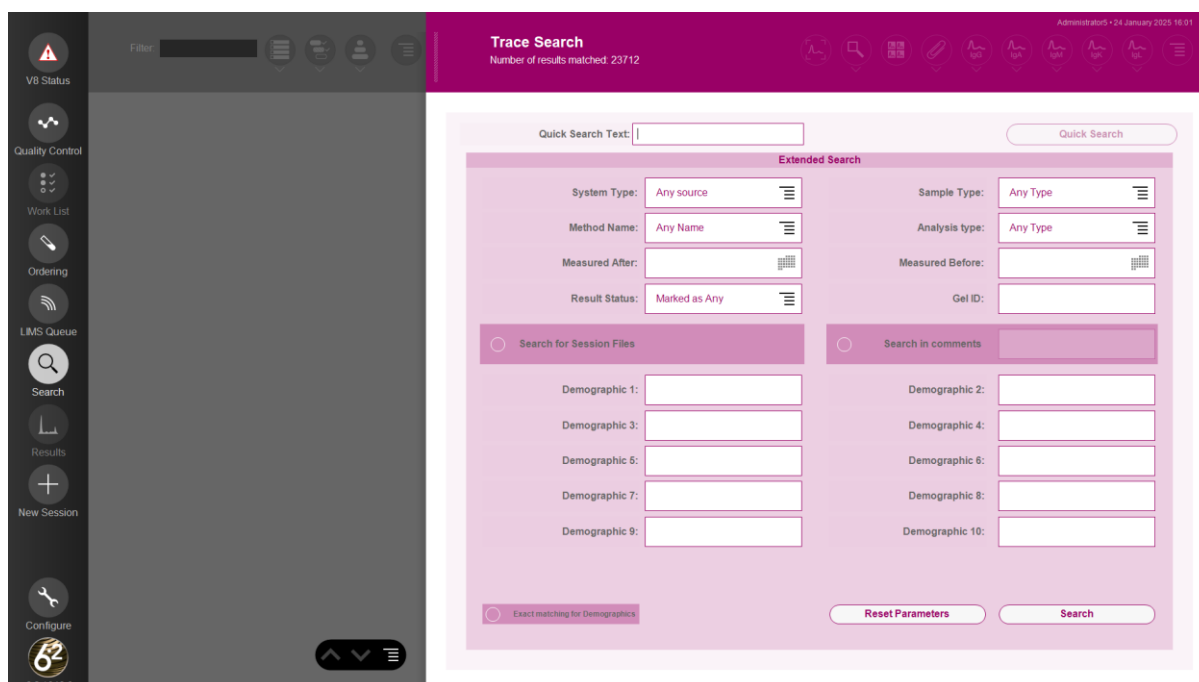
To display the progress of the LIMS transfer, go to [Configure > Customise > Sending to LIMS](#) and make sure the "Display inspector window" option is ticked.

5.8.7.4 Sending Sample Data Directly to LIMS

Sample can be sent directly to LIMS/LIS bypassing the use of the queuing system.

To send the whole session to LIMS, go to the Select icon  and "Select All". Then go to the LIMS icon  and select Send to LIMS .

5.8.8 Search Window



To locate previous sample results, whole gels or V8 UltraCE sessions in the database, the Search window can be used. The search window will automatically search for individual samples, unless one of the following is selected:

- Search for Session Files
- Search in Comments

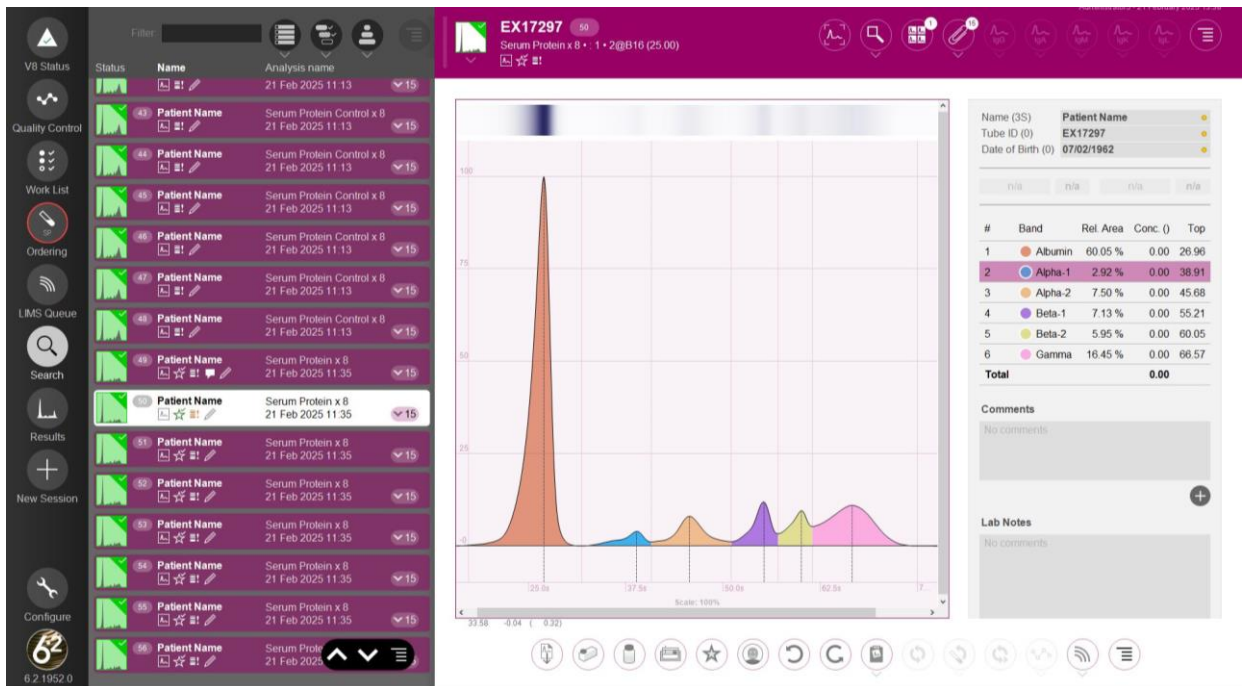
When searching for individual sample results, any of the 10 demographic fields can be used to identify the sample and filter the results.

Additionally, 7 generic filters are available:

- System Type
- Sample Type
- Method Name
- Analysis Type
- Measurement Time (Measured After/Before)
- Gel ID
- Result Status

When searching for a session, only the above 7 generic filters are available. By inputting any required demographic filters i.e. patient ID and clicking the Search button, a list of the search results will appear.


5.8.8.2 Search Results




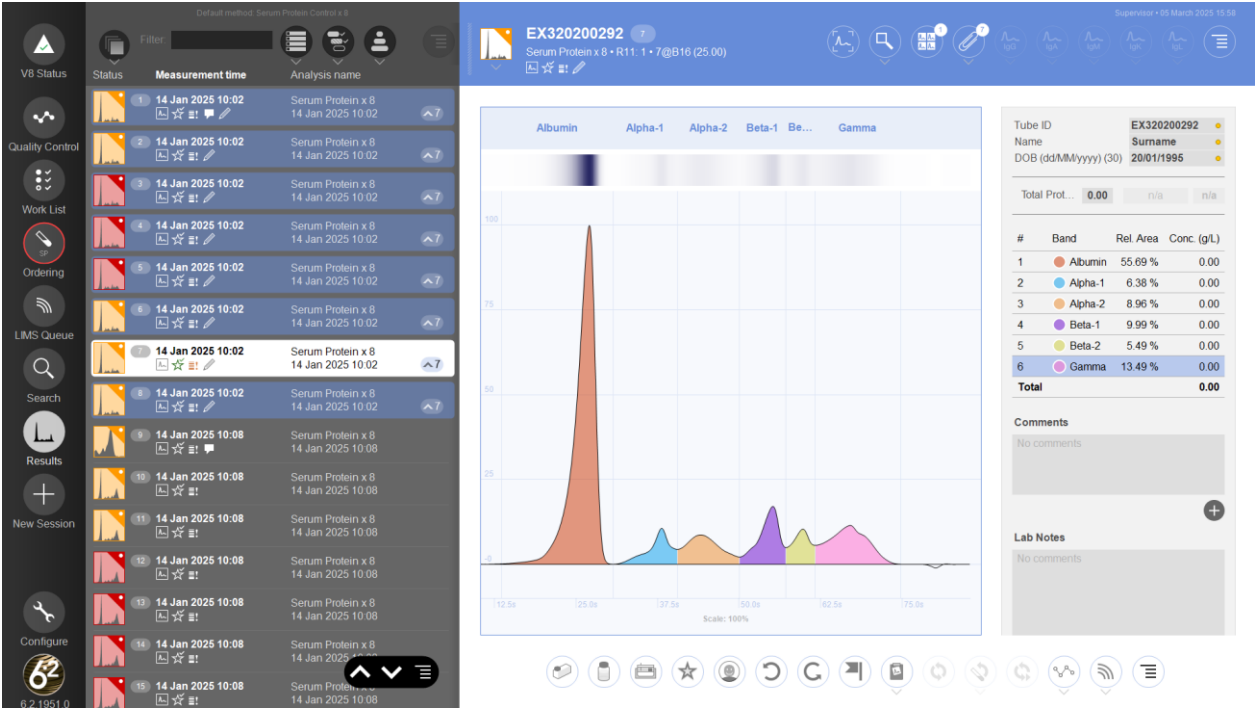
A maximum of 1000 traces can be shown at one time – if more than this is found a dialogue box will appear.

Search results can be filtered in the top left hand corner of the screen.


Once the search results are displayed, basic viewing functions can be carried out. The original V8 UltraCE session can be loaded by selecting

the  icon to enable more detailed sample editing.

Once viewing is complete, a new search can be started by selecting the  icon from the Options menu at the bottom of the Navigation List.



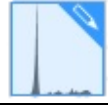



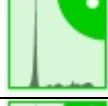



5.8.9.1 Active Session Window

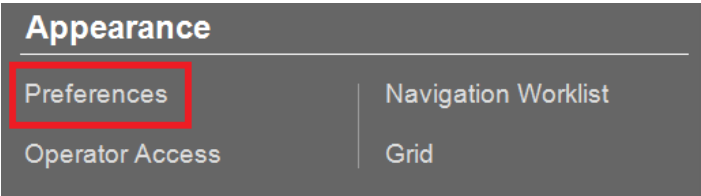
It is possible to have multiple session windows open in Platinum at one time. To avoid confusion as to which window is the current active session, the session is listed as the 'Active V8 System Session' when the user selects the  icon.

5.8.9.2 Editing

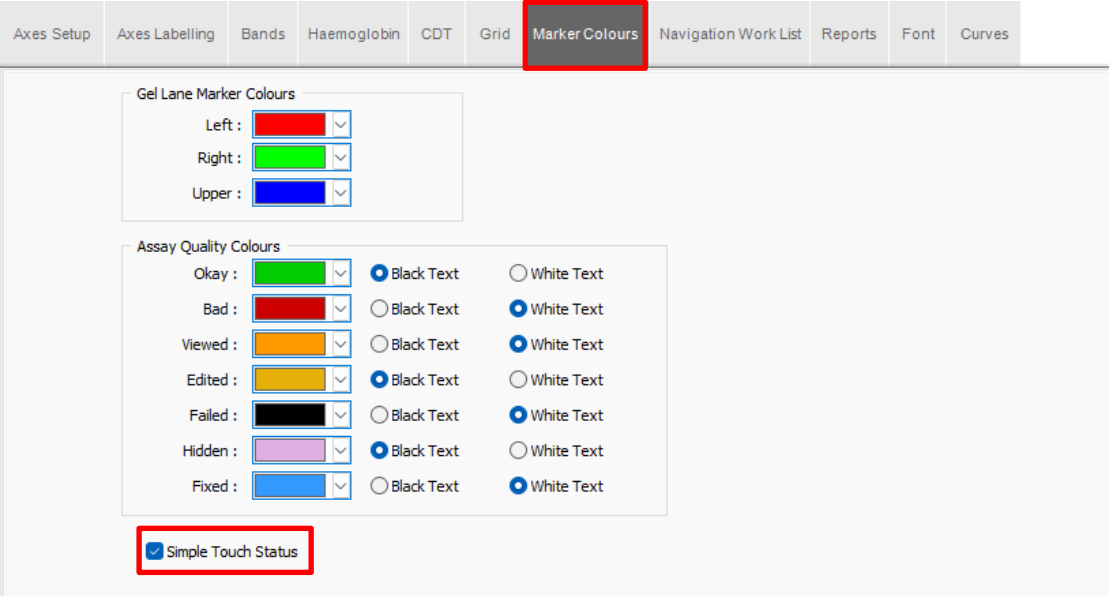
When a trace or gel image is first displayed, it may require some form of adjustment so that the correct interpretation of the result can be reported. Every sample trace can therefore be edited to user preferences. Samples are displayed in the navigation work list and are colour coordinated to visually show the editing status. **PLEASE NOTE: COLOUR-CODING IS NOT CONFIRMATION THAT ANY RESULT IS NORMAL OR ABNORMAL.** The colours correspond as follows:

Icon	Status
	The lane has the correct number of bands with all values in range, suggesting a normal sample.
	The lane has the correct number of bands with all values in range, suggesting a normal sample. The lane has also been viewed.
	The lane has the correct number of bands with all values in range, suggesting a normal sample, but the sample has had some editing.
	Lane is unedited and may have an incorrect number of peaks/bands or values are out of range indicating the sample may be abnormal.
	Lane has been viewed and remains unedited. The sample has an incorrect number peaks, or peaks/bands or values are out of range. Sample may be abnormal.
	Lane has been viewed and edited. The sample has an incorrect number or peaks/bands or values are out of range. Marked monoclonal bands will result in a yellow colour. Sample may be abnormal.
	The lane is a normal control with the correct number of bands and all values in range. The dot shows that the lane has been viewed.
	The lane is an abnormal control with the correct number of bands and all values in range. The dot shows that the lane has been viewed.

In order to turn the colour interpretation on, go to [Configure > Preferences](#).








Next, select the tab [Marker Colours > Simple Touch Status Checkbox](#)







To manually edit the trace, use the  icon to display all of the editing options.

When a trace or gel image is first displayed, it is likely that the data will require some form of adjustment so that the correct interpretation of the result(s) can be reported. Every sample trace can therefore be edited to user preferences.


Samples are displayed in the navigation work list and are assigned specific icons to visually show the user the status:

Icon	Editing Status
	The result has been viewed.
	Lane is unedited and may have an unexpected number of peaks/bands or values are out of range.
	Lane has been viewed and edited.
	Result has been hidden from the navigation worklist but 'Show Hidden' has been enabled.
	The result has been marked as a Normal Control.

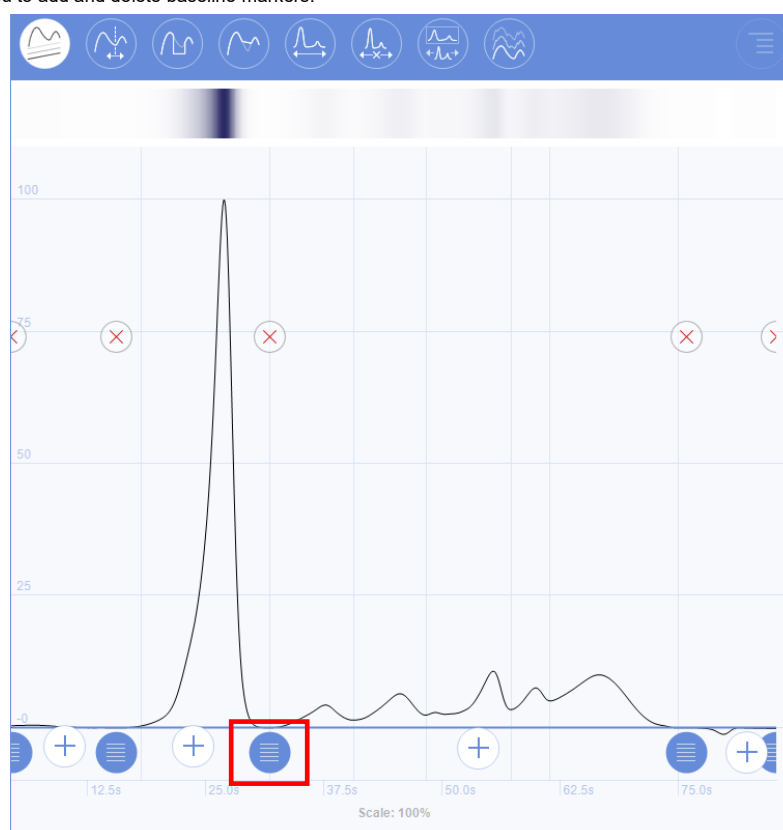
	The result has been marked as an Abnormal Control.
	The result has been marked as 'Normal' by the user.
	The result has been marked as 'Abnormal' by the user.
	The result has been marked as 'Unsure' by the user.

5.8.9.2.1

Editing Baseline


Should it be required to edit the baseline, clicking the icon  will allow manual movement of the baseline.

Selecting this icon will display large blue circles which can be moved to adjust the baseline. Long pressing on one of these circles will bring up a menu which will allow you to add and delete baseline markers.



5.8.9.2.2

Editing Peaks

Once a sample is selected, the peaks may be edited by clicking the Edit peaks icon . Long pressing on a peak marker on the sample trace provides specific options that are possible for the selected peak.

5.8.9.2.3

Add Trough Marker

To add an additional trough marker to a trace, long press on the desired location for the marker. Choose "Add Trough" from the drop down menu and the marker will be placed on the trace. Any further movement can be made by dragging the marker to the correct location within the band.

5.8.9.2.4 Delete Trough Marker

To delete a surplus trough marker, long press on the marker you wish to remove. Now choose “Remove Trough” from the drop down menu; the marker will then be removed from the trace.

5.8.9.2.5 Smoothing

To smooth a trace, select the “Filtering/Smoothing” icon and use the Smoothing slider to select your preferred setting 

5.8.9.2.6 Filtering

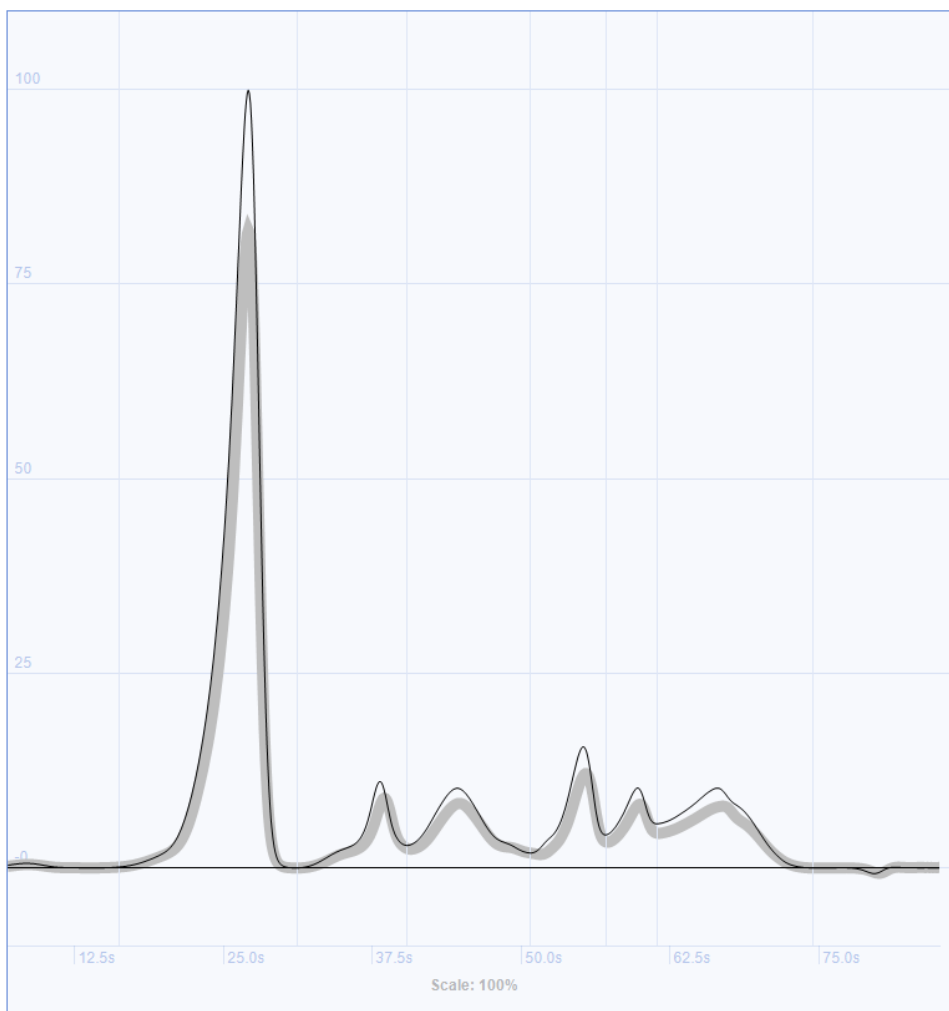
To filter a trace, select the “Filtering/Smoothing” icon (see Smoothing section above) and use the Filtering sliders to select your preferred setting.

5.8.9.2.7 Overlay Functionality

The Overlay functionality enables the comparison of a sample against a previously specified trace or against another sample.

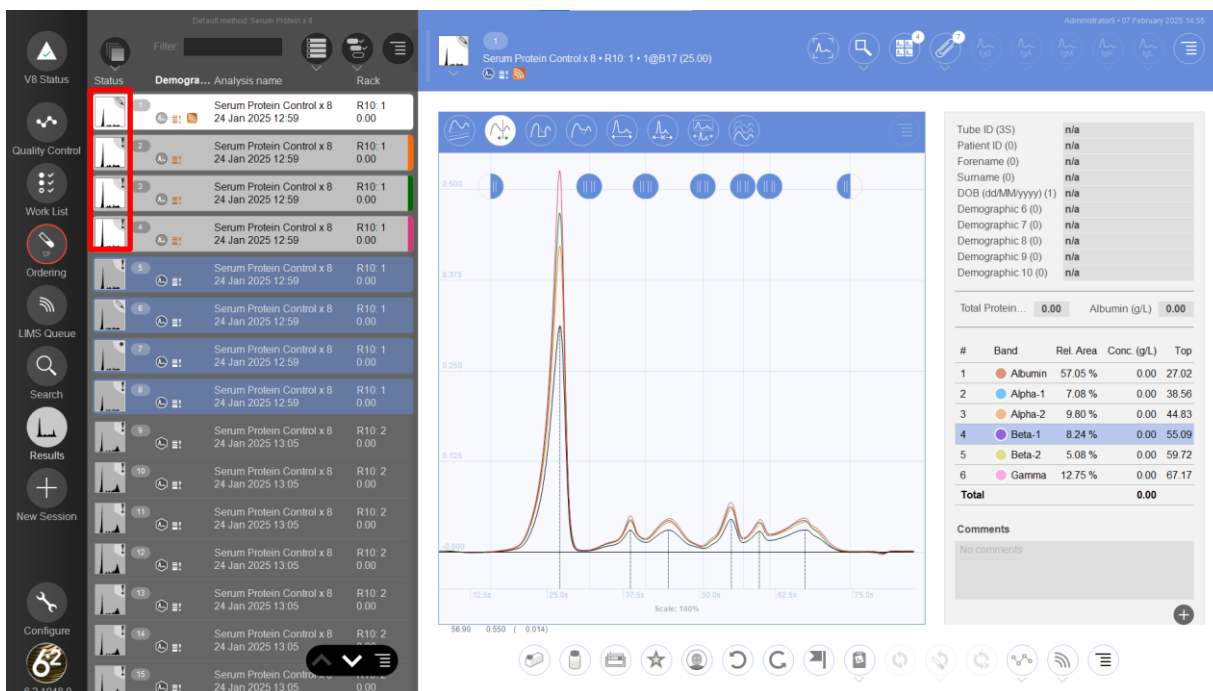
5.8.9.2.8 Normal Overlay


The normal trace is defined by the user, depending on specified laboratory boundary reference ranges. A specific trace can be set as the default normal overlay by going to the options menu in the bottom right hand corner and selecting [Comparisons > Use as Normal Overlay](#). The defined trace will then be shown in grey on the screen as shown below. To switch the normal overlay on/off, then deselect [Trace Options Menu > Show Normal Overlay](#).




5.8.9.2.9 Overlaying of Samples on the Screen

By clicking on the small trace icon in the Navigation List you can select as many samples as you like to overlay. Clicking on the icon again will deselect it. .



It is also possible to select all of the samples by going to Select  in the Options menu at the bottom of the Navigation List and choosing "Select All".

5.8.9.2.10 Match Shapes

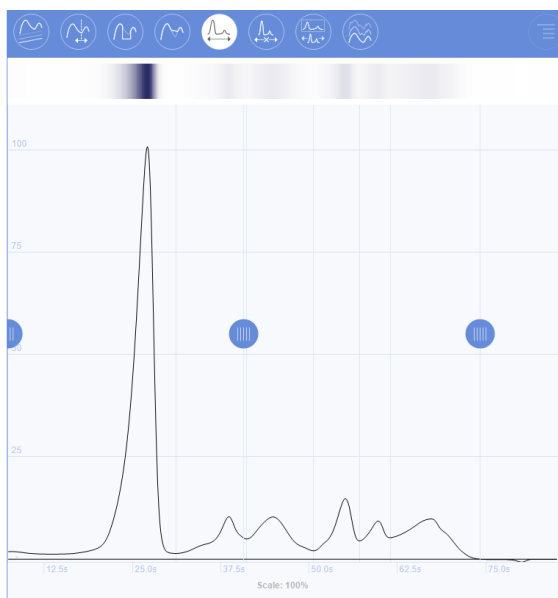
When Overlaying sample traces in Platinum it is often necessary to match the overlay from one sample to another, this is especially so with immunodisplacement samples. Platinum automates this to make it as quick and simple as possible. To do this, simply highlight two or more traces that you would like to be matched and select the  icon.

5.8.9.2.11 Stretching Samples to Overlay Bands

When overlaying samples from different time periods, it may be necessary to stretch a trace to overlay each peak over its corresponding peak in the second trace.

Overlay the required samples by clicking on their trace icons in the Navigation List, and then select the  icon.

This will auto align the traces over each other. Should the samples require further manipulation; the trace can be manually stretched by dragging the three vertical markers which appear on the screen. .



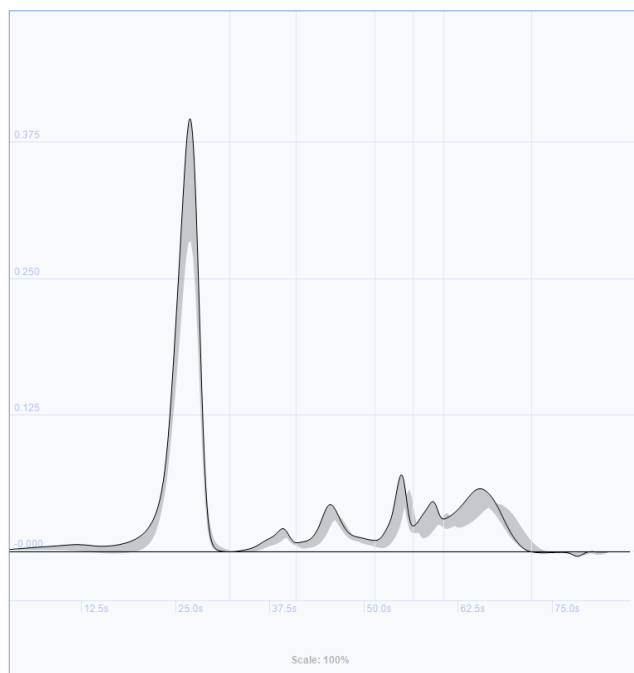
5.8.9.3 Mean Traces

Allows a visual range of normal samples to be viewed on screen relative to the currently selected trace.

from the drop down menu.

To view the traces used to compose the mean overlay, go to the same Options menu, select 'Comparisons' and then select "Load Mean Traces" from the drop down menu.

The 'Comparisons' dropdown menu also gives you the option to remove a specific sample from the mean overlay.



5.8.9.4 Quantitating a Monoclonal Protein


To quantitate a monoclonal protein, it is necessary to isolate the monoclonal band on the trace. There are two possible methods to do this which give slightly different values of the monoclonal protein; slicing and skimming. If the total protein value of the sample is known, then Platinum will automatically calculate the protein contribution of any marked M-spike.

N.B. It is recommended that users choose one method or the other, as switching between them could lead to changes in patient monoclonal quantitation over time, due to the different methods of measurement used.

5.8.9.4.1 Skimmed M-spike

This methodology takes into account the polyclonal background of a sample by allowing the user to estimate the amount of polyclonal background and remove this from the quantitation.

5.8.9.4.2 Adding a Skimmed M-spike


Select the Edit peaks icon , then long press on the monoclonal spike and select "Add Skimmed M-spike".

Platinum will then estimate the extent of the monoclonal peak and highlight this area by filling in the trace with 'hashed lines'. To edit the location of the start and end points of the area quantitated, drag the trough marker to a suitable location. The band list will now contain an extra band called M-spike with additional prefixes and suffixes depending on its location in the trace, and the number of M-spikes added e.g. 7 M Gamma M-spike 1 13.39%, where '7' is the peak number the M-Spike is found plus 1, 'M' shows it as an M-spike rather than a normal peak, 'Gamma' is the region in which the M-spike is located, 'M-spike 1' shows it is the first marked M-spike in that fraction (as more than one can be added), and 13.39% shows the relative area of the M-spike.

5.8.9.4.3 Sliced M-spike

This methodology assumes the monoclonal protein band is the only protein in the gel at this position, and therefore quantitates the band down to the baseline of the trace.

5.8.9.4.4 Adding a Sliced M-spike

Select the Edit peaks icon , then long press on the monoclonal peak and select "Add Sliced M-spike". Platinum will then estimate the size of the monoclonal peak and highlight this area by filling it with 'hashed lines'. To edit the location of the start and end points of the area quantitated, drag the trough marker to a suitable location.


5.8.9.4.5 Removing an M-spike

To remove an unnecessary M-spike, long press on the M-spike and choose "Remove M-spike". The hashed area will then be removed.


5.8.9.5 Removing Artefacts from Traces

Artefacts are not common, but are sometimes a problem; this function enables the removal of an artefact from a trace without disturbing the data.

5.8.9.5.1 Slice Data


To edit a trace to remove an unwanted artefact (to the baseline), click the  icon and drag across the area to be removed.

5.8.9.5.2 Skim Data

To edit a trace to remove an unwanted artefact whilst maintaining the general progression of the curve (peak to peak), select the skim icon  then drag over the area to be removed. This will be highlighted by a series of vertical bands.

5.8.9.6 First Derivative


Shows the first derivative of the selected trace. It is useful for identifying small monoclonal bands as it highlights the rate of change in the curve.

Select the Options menu from the top right of the screen , select "Show derivative" and the first derivative will appear as a dotted line. To remove the first derivative from the trace, deselect it through the same menu option.



5.8.9.7 Adding Comments to a Sample Result




5.8.9.7.1 Adding a Comment to a Single Sample Result

Comments for a trace can be found on the right hand side of the Results window. Comments can then be typed manually, or it is also possible to add pre-defined comments to the comments box via two different routes by selecting the  icon:


- Standard Comments
- Comments Tree

Please note there is a character limit of 2000 for comments.

5.8.9.7.2 Adding Comments to Multiple Sample Results

To add the same comment to multiple traces highlight all traces that require the same comment adding to the result and tap the small trace icon in the Navigation Worklist. Select the 'Options' menu  beneath the worklist and select **Data > 'Add Comment to Selected Traces'**. From there manually type the comment or select the  icon to add comments from 'Standard Comments' or the 'Comment Tree'. Select 'Add' to add them to the selected traces. A comment icon  will appear on all traces in which the comment has been added.

5.8.9.7.3 Comments Tree

To add a pre-set comment from the Comments Tree to a result, select the  icon under the comments box, open the Comments Tree, then select the comment(s) which you would like to add using the check boxes. Use the 'Add Selected' option to add them to the trace and then select 'Close'. The comment(s) should now appear in the 'Patient Comments' section below the trace.

New comments can be added to the tree by using the 'New Comment' or 'New to Root' options, depending on whether the comment is linked to a certain assay or not. Comments Trees that have already been configured can be loaded using the 'Load Tree' option, or the current tree can be saved to a file using the 'Save Tree' option.


N.B. IFE comments can only be added/edited in the original IFE scan.


5.8.9.7.4 **Lab Notes**

Comments that do not need to be saved to the database as they are for internal lab use only can be entered into the Lab Notes section. This means they will not be saved to the database, are not searchable, and cannot be sent to LIMS or for any other type of reporting. They will, however, be saved with the session, so reopening a historic Platinum file will continue to show any attached Lab Notes.

5.8.9.8 **Statistics**

Within Platinum, it is possible to perform basic statistical analysis on the data and to print or display this information.


To compare data from multiple samples, it is necessary to have all of the results in the same analysis window, either on a single gel image, or as the result of a database search. To select all samples for analysis, select the  icon and then "Select All".

To display the statistics window after all of the required samples have been highlighted, select the 'Options' menu  beneath the worklist and select **Data > Statistics**.

The index of each band is displayed in the Index column with the number of samples in brackets. The name of each band is indicated in the band column, whilst the remaining columns can be determined in the band tab of **Configure > Preferences > Bands**. These columns are used to display the mean, the standard deviation, and the CV for the area, relative area, or concentration.

5.8.9.9 **Searching for and Attaching an Immunotyping Result**

It is possible within a single Platinum window to link and display Immunodisplacement traces/IFE gels relating to a specific patient next to the corresponding serum protein trace for use as a reference.

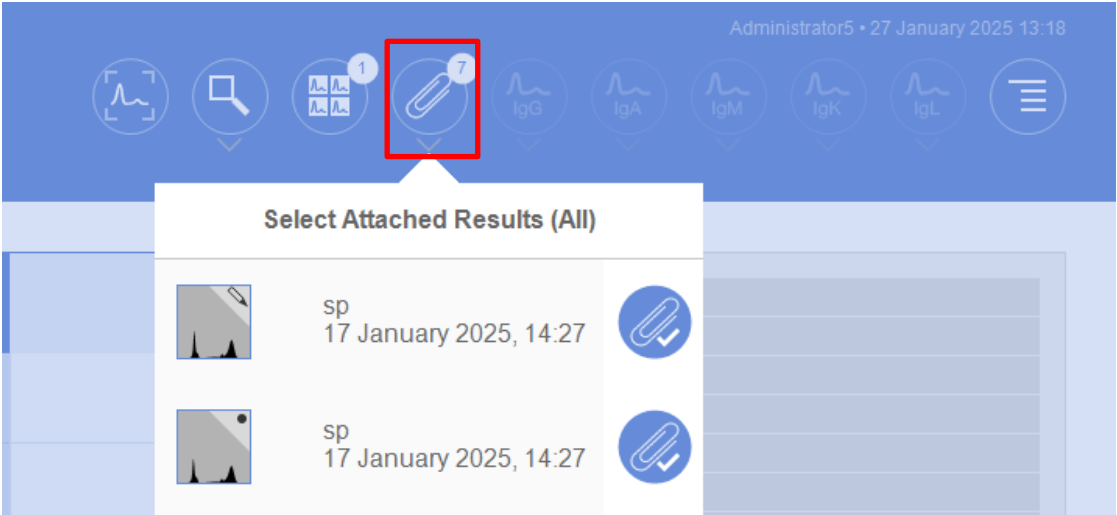
Select the serum protein sample that the Immunodisplacement/IFE is to be linked to, and select the Data icon  from the 'Options' menu, followed by 'Search and Attach Immunotyping'.

A search window will appear. Select the search button, and once the results have appeared, select any immunotypes to be attached to the serum protein. Select OK. The attaching will take place and the window will close.


5.8.9.9.1 **Attaching a sample from Patient History**

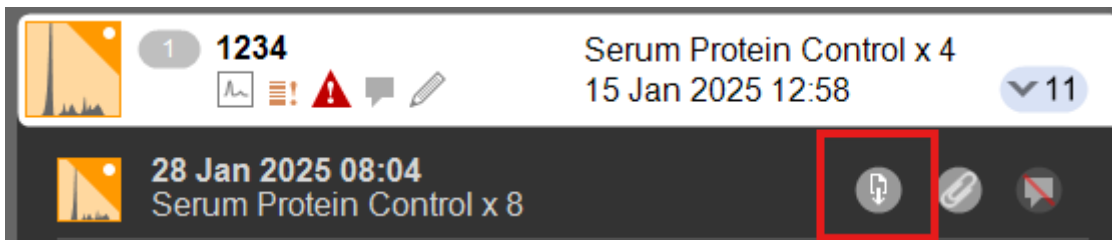
To attach a sample directly from Patient History, select the paperclip icon.

If successfully attached, the paperclip will have a small tick, and in the top right hand corner of the screen, a '1' should appear (or the number should increase by 1 if other samples are already linked/attached) over the  icon.

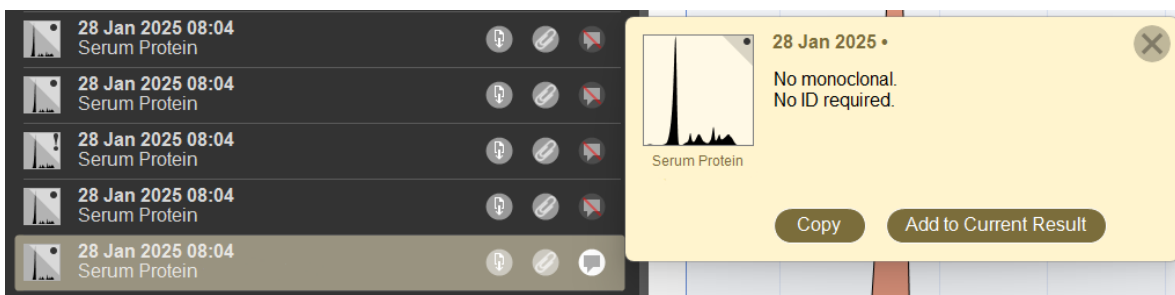


5.8.9.9.2 **Loading Source Data for Patient History**

To load the source data for any of the samples found in Patient History, tap the  icon to the right of the Patient History entry.



If the historic sample has any comments attached, the comments icon will become available. Select this icon to display the available comments:




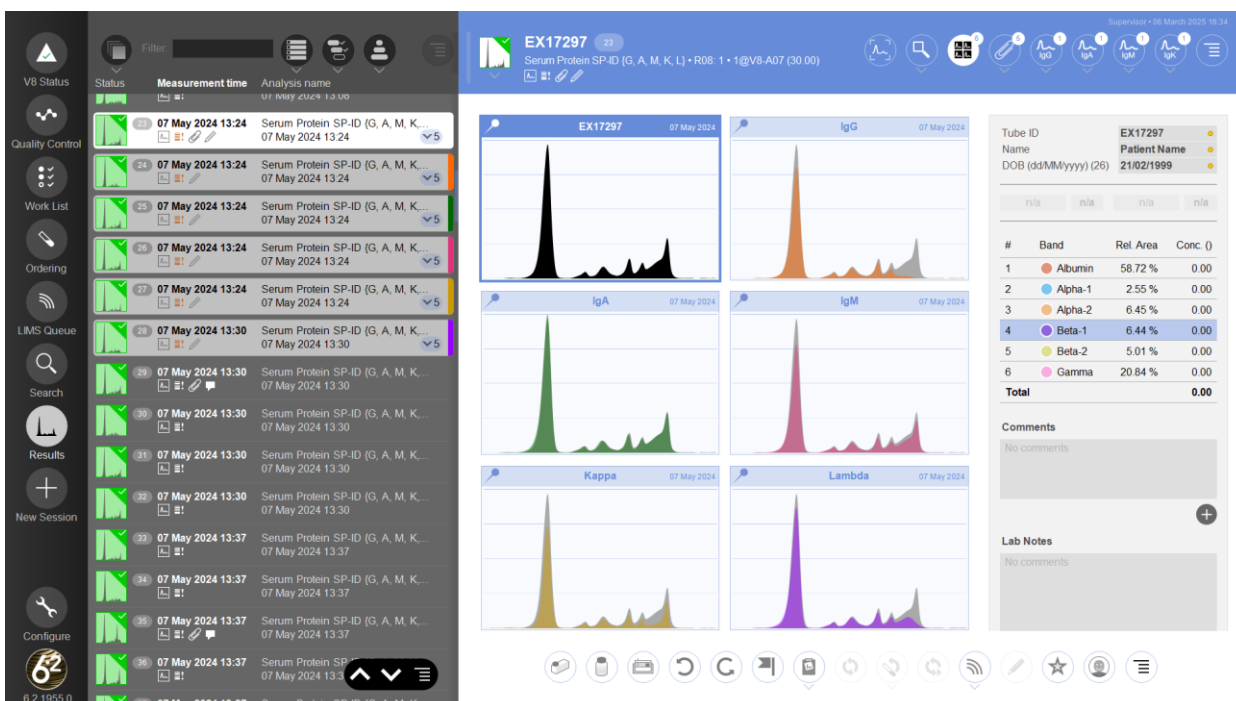
The comments can be copied, or directly added to the current result using the 'Copy' and 'Add to Current Result' options.

5.8.9.10

Grid Mode


Grid Mode now provides two features for viewing multiple samples – Immunowindow and Grid View.

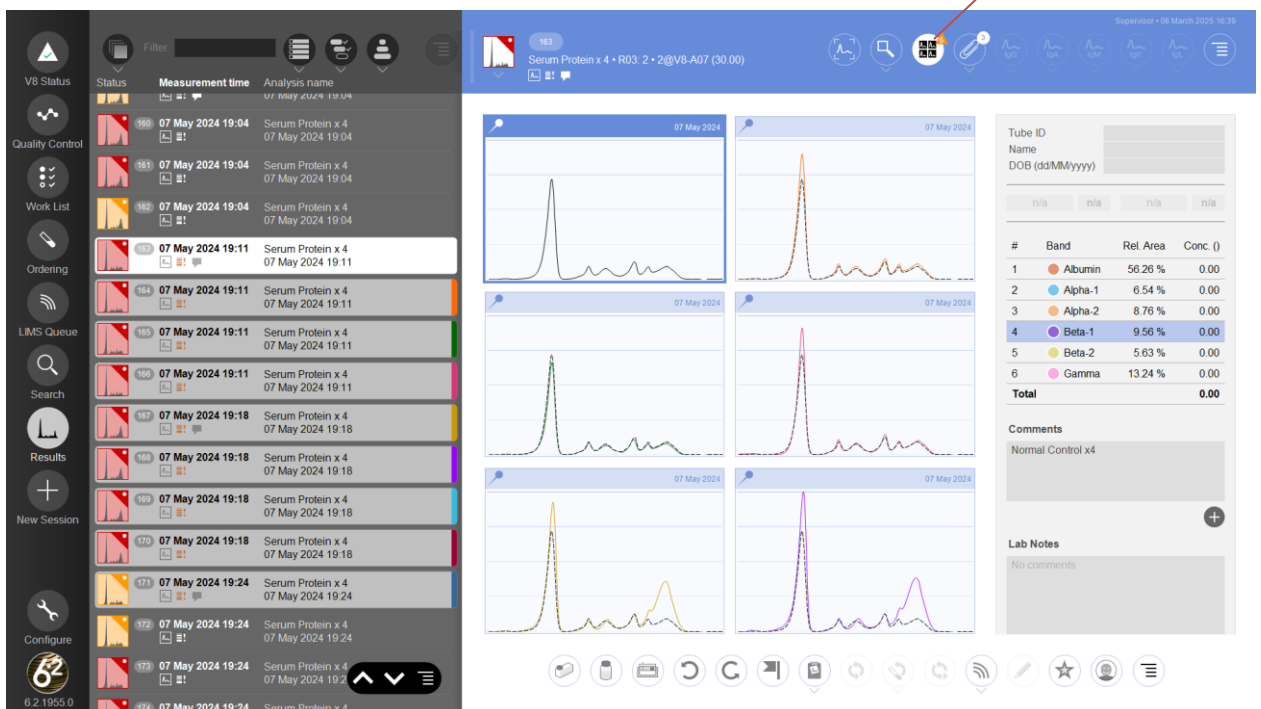
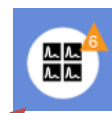
To view an Immunodisplacement using Grid Mode, select one of the Immunodisplacement samples and select the  icon.




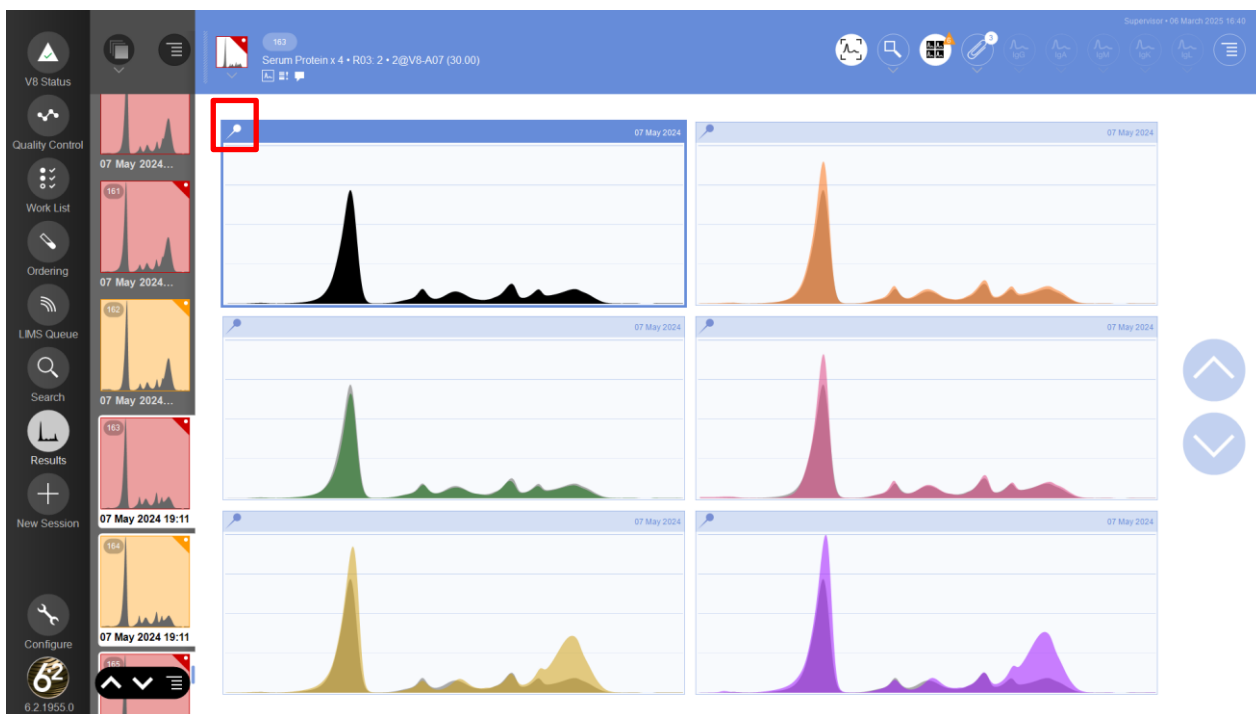
Grid Mode offers a number of viewing options to aid interpretation of immunodisplacement results. They can be found in the 'Options' menu in the top right corner, then 'Grid View Options'. This is only accessible whilst in Grid Mode. The Super Align tool is the recommended option and uses a peak matching algorithm to compare and overlay main SP and ID traces. This is especially useful when a large amount of protein has been removed during the immunodisplacement.



To view multiple traces of any type in Grid Mode, tap on the small trace icon of the sample to highlight it, and then select the  icon. A maximum of 6 samples can be shown in Grid Mode at any one time. This includes samples displayed in 'Patient History', IFE samples and gel samples. Once the maximum number of traces has been reached, a small orange triangle will be shown on the Grid Mode icon:

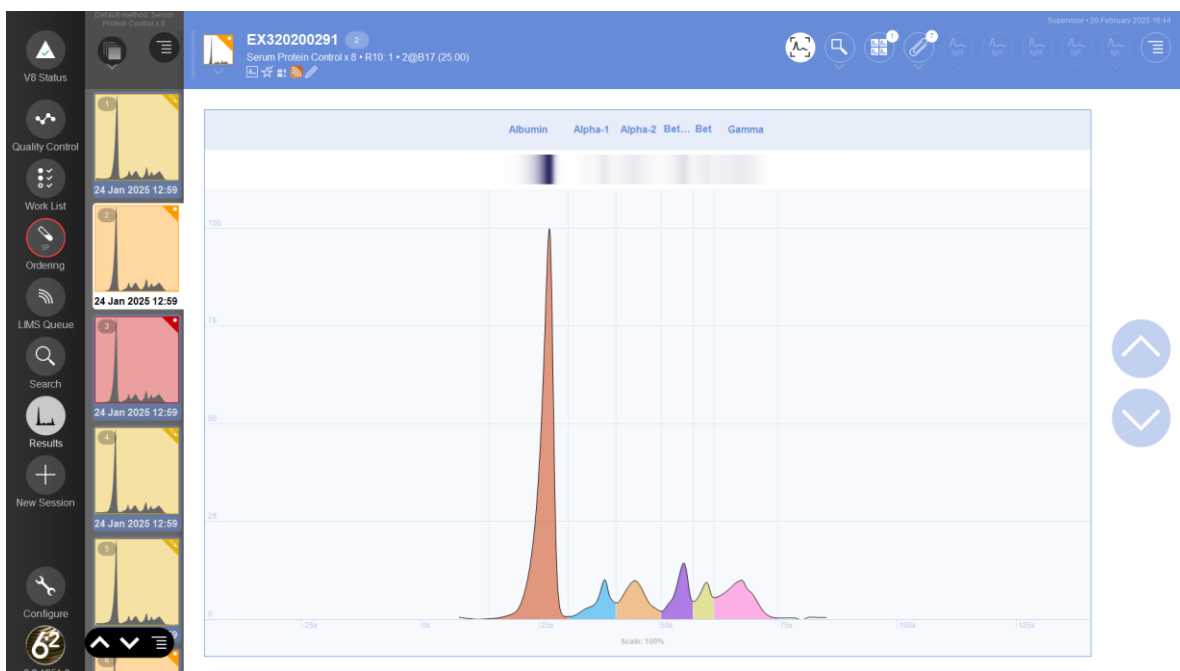


Whilst in Grid Mode, any of the samples can be 'nominated' as the main trace. This allows the sample to be overlaid on top of all other traces in Grid Mode as a serum protein trace would in the Immunowindow. To nominate a trace select the  icon in the top left corner of the trace you wish to nominate.



5.8.9.11 Focus Mode

Focus Mode provides a basic view of the results. The currently selected trace is shown on a much larger portion of the screen making it easier to see the trace. Navigation between samples can be done using the large arrows on the right of the screen, or by scrolling through the trace icons on the left side. Multiple samples can be overlaid by tapping with two fingers on the trace icon.



Grid Mode can still be used whilst in Focus Mode with samples remaining selected even when switching between views.



5.8.9.12 Adding a Tube ID to Processed Samples

Sample tubes with no barcodes or ones that have been misread are identifiable in the Navigation List as the tube ID is blank. The user can enter this information only AFTER the V8 UltraCE has processed the sample and all the data has been obtained.

- To do this, select the Tube ID column of the unlabelled sample in the Work List window.
- This will enable the user to scan the tube with the barcode scanner, or manually enter a tube ID.
- It is also possible to enter the sample barcode information in the Results window by entering it into the demographics on the right hand side.
- Select the Tube ID demographic and type the barcode in manually.


5.8.9.13 How to Perform a Reflex Test

Reflex tests can be performed manually or automatically (using the Expert System). It is essential that the required reflex test is assigned as a response to the associated assay, such as Immunodisplacement, being the reflex test for a Serum Protein assay. This differs from test ordering as reflex assays are only ordered after a sample has already been run, it has been detected as abnormal, or a confirmation run is required.

Please refer to section 5.8.10.4 for information regarding reflex test priority.

5.8.9.13.1 Manual Ordering for Reflex Testing

Manual reflex tests can be ordered whether or not the Expert System is switched on. To order a reflex test manually, data acquisition must have been completed. It is possible to analyse, manipulate and order reflex tests on a completed sample rack whilst another is being prepared or analysed by CE.


In the Results window, highlight the result of the sample that requires further analysis and select the  icon.

The following test ordering dialogue box will appear:


Select the Reflex Test option. From the drop down menu choose "Ordered test name" and then select the appropriate reflex assay.

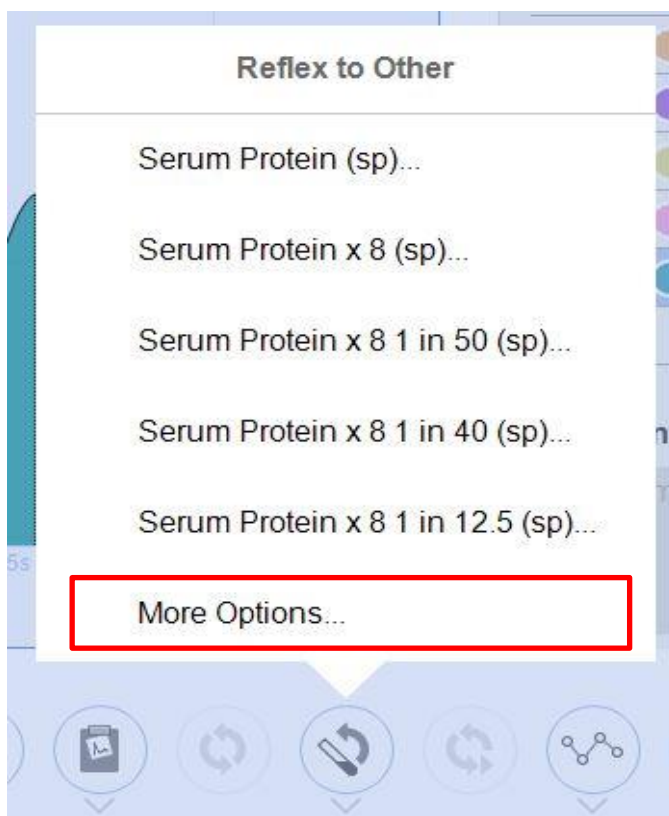
If there is no barcode present, the rack number and position are the only factors that can be used to identify the sample. As such, it is ESSENTIAL that the tubes are not changed before the reflex test has been performed.

If a barcode is present, this will be used preferentially to perform the reflex test.

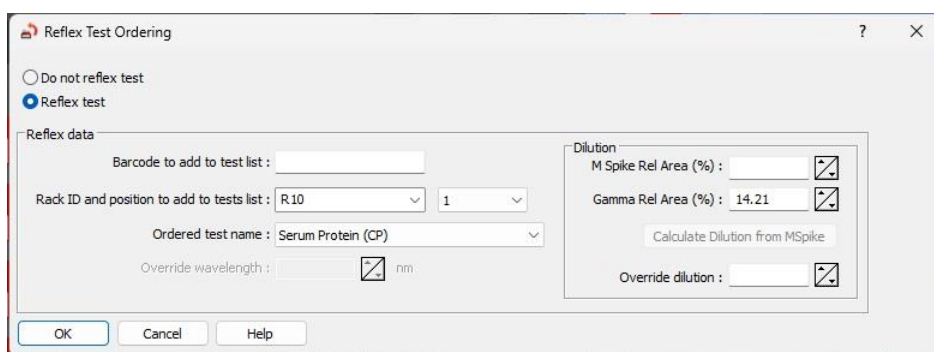
Once selected, click OK. Depending upon the preferences of the reflex test selected, the V8 UltraCE will either automatically perform the reflex analysis immediately, performing each reflex test one by one, OR, the operator is required to choose the "Allow Reflex Test Batches" icon , where the V8 UltraCE will store all reflex tests until required by the user to perform analyses.

5.8.9.13.2 Using the Auto Dilution function to reflex test

1. Select a sample with a monoclonal band and gate the monoclonal band using the skim/slice function see section 5.8.9.4.
2. Order a reflex test by selecting the "Reflex to Other icon  under the sample trace image.
3. Select the [MIU] Serum Protein x 8 (MIU = Method in use) if it is available in the pop up menu. If not select "More Options".



4. In the "Reflex Test Ordering" window select "Calculate Dilution from MSpike"



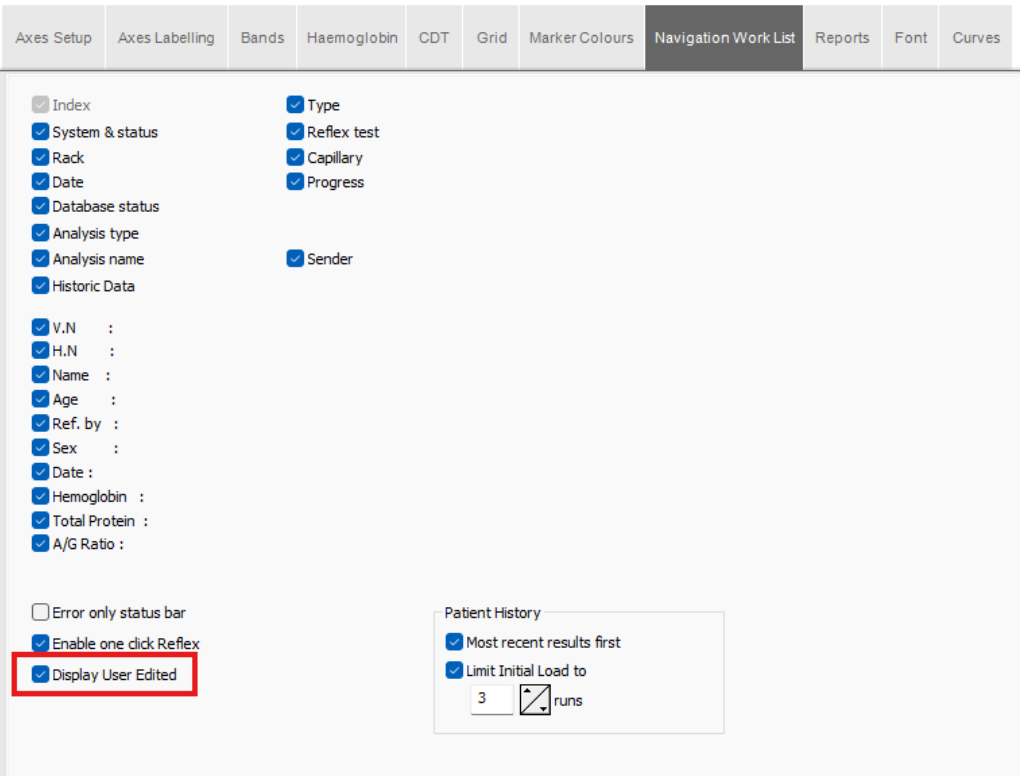
Reflex Test Ordering window with the dilution calculated.

5. Select **OK** and the V8 UltraCE will prepare the dilution (in Batch Priority Mode the user must select "**Allow Reflex Test Batches**" for the reflex test to begin).

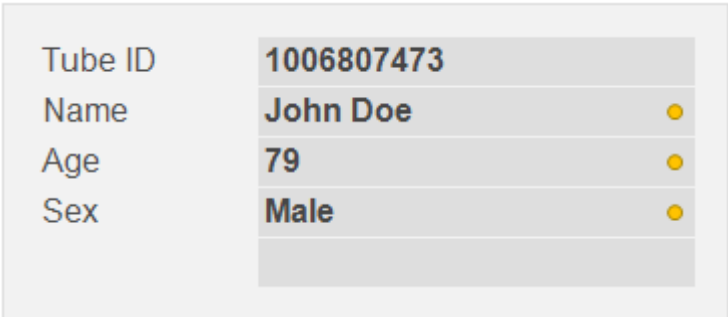
5.8.9.13.3 Highlighting manually editing demographics

For traceability, when demographics are manually entered or changed, they can be highlighted to differentiate them from demographics that have been auto-filled from LIMS.

To activate this functionality, go to [Configure > Preferences > Navigation Work List](#) and select 'Display User Edited':



Once activated, any demographics that have been manually entered or changed will be highlighted by a yellow dot in the results window:

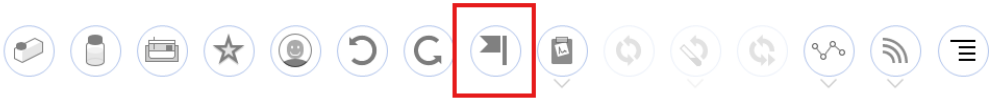


Or by a yellow box in the Work List window:

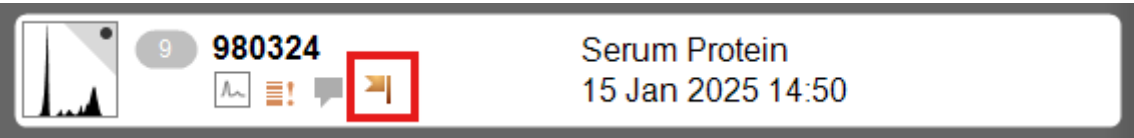
	31	Sample	0.00	Serum Protein SP-ID {G, A, M, K, L}	1006807473	John Doe	79	Male
	32	Sample	0.00	Serum Protein SP-ID {G, A, M, K, L}	1006807473	John Doe	79	Male
	33	Sample	0.00	Serum Protein SP-ID {G, A, M, K, L}	1006807473	John Doe	79	Male
	34	Sample	0.00	Serum Protein SP-ID {G, A, M, K, L}	1006807473	John Doe	79	Male
	35	Sample	0.00	Serum Protein SP-ID {G, A, M, K, L}	1006807473	John Doe	79	Male
	36	Sample	0.00	Serum Protein SP-ID {G, A, M, K, L}	1006807473	John Doe	79	Male

5.8.9.13.4 **Flagging samples**

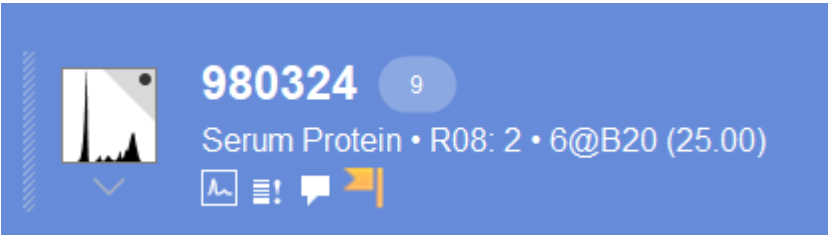
Samples can be flagged for additional follow-up testing, such as an IFE test, using the flag icon below the trace:



A yellow flag will then be displayed in the Navigation List to highlight that further attention is required:



Additionally this is visible in the trace header:



A new column will appear in the Work List window where the flag will also be displayed:

Status	Line	Sample/Control	Flagged	Method	V.N
	9	Sample		Serum Protein	980324

The flagged state is available in the Platinum session file only, it is not retrievable from the database, for example for searching or to send to LIMS.

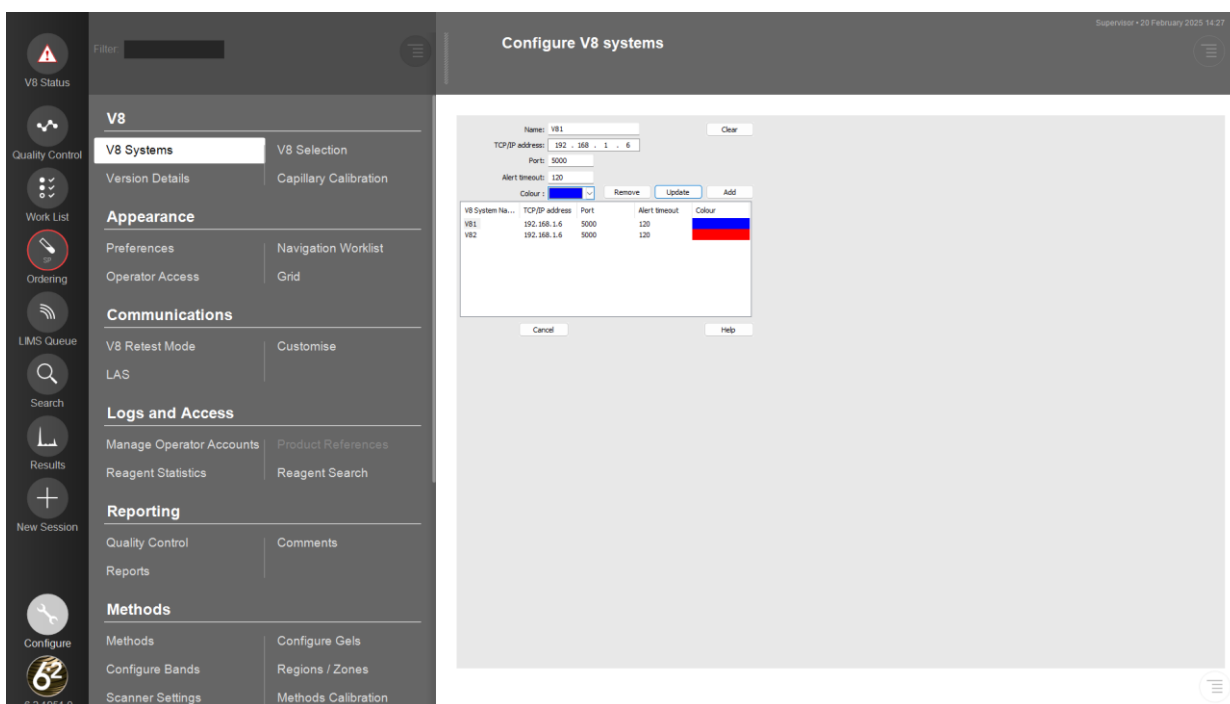
5.8.10 **Configure Window**

5.8.10.1 **V8 UltraCE Systems**

Platinum must be linked to the V8 UltraCE instrument that is to be used.

Go to **Configure > V8 > V8 Systems**. This will allow for new V8 UltraCE systems to be linked to Platinum, and list the current/past systems that have been used. To calibrate the V8 UltraCE to Platinum, enter the following:

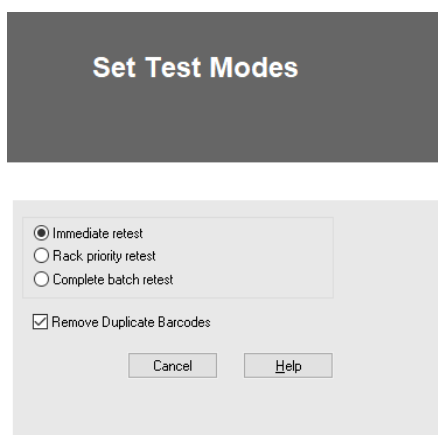
Section	Description	Example
Name	To describe the V8 UltraCE system. This is user definable.	Biomedical Lab CCE
TCP/IP address:	Unique IP address of the V8 UltraCE. Contact your local Helena Biosciences representative for further information	192.168.1.2
Port:	Unique port number for the V8 UltraCE. Contact your local Helena Biosciences representative for further information.	5000
Alert time out:	This is the time gap before window reappears (s).	120
Colour	Colour that will appear in the title bar of the active session.	Red



5.8.10.2 Select V8 System

This allows the user to view a list of all V8 UltraCE systems that have been linked to the PC, and to initiate a connection between Platinum and the V8 UltraCE System. The user can manually select from the list should the default system be changed for a different instrument. To select a V8 UltraCE system, go to [Configure > V8 > V8 Selection](#).

5.8.10.3 Setting the V8 UltraCE Test Mode



The V8 UltraCE has two main modes of operation; (1) sampling of new samples, and; (2) reflex testing of recalled samples.

Sampling of new samples

In this mode, the V8 UltraCE will process all samples on-board the instrument, scanning the rack ID and primary sample tubes, and sending the barcodes to Platinum for instruction regarding the assay to be performed.

Reflex Testing

In this mode, the V8 UltraCE will only process and analyse those samples that have been flagged for reflex testing (and appear in the test list within Platinum), or those that have been individually ordered. Other samples within the sample rack will be ignored.

N.B. Test mode cannot be changed during a session. If it is required to change test mode or reflex priority then a new session must be started.

To select test mode:

To select the test mode of reflex priority, a new V8 session window must be opened. Go to [Configure > Communications > V8 Retest Mode](#).

5.8.10.4 Reflex Test Priority

The reflex test priority determines when the V8 UltraCE performs reflex tests, whether these have been ordered manually or automatically. There are three reflex Test Priority modes; Immediate, Rack Priority and Batch.

- 'Immediate retest' mode will perform each ordered test immediately, thus moving racks back into the sample handling area and switching assay if required.
- 'Rack priority retest' mode will delay retesting until there are no further racks available for processing using the default assay. If further racks are loaded during rack priority re-test, then the V8 UltraCE will prioritise the new racks.
- 'Complete batch retest' mode will hold all ordered tests until prompted to perform analysis by the user.

5.8.11 Comments

It is possible within Platinum to store predefined comments which can be added to the individual sample records.

5.8.11.1 To Compose the Standard Comments

Go to [Configure > Comments](#).

Configure Standard Comments

Index	Comment
1	Normal
2	Small monoclonal
3	Large Monoclonal
+	

Appropriate text can be entered into the column marked comment. Once complete the comments will save automatically. There is a 'Load' option to import previously configured Standard Comments, and also a 'Save' option so that comments can be saved externally.

To add these comments to a sample, first select the trace and then display the inspector window by selecting the arrow to the right of the worklist:

Under the 'Patient Comments' section, select the small '+' icon and select 'Standard Comments...':

Tube ID
 Patient ID
 Forename
 Surname
 DOB (dd/MM/yyyy)
 Demographic 6
 Demographic 7
 Demographic 8
 Demographic 9
 Demographic 10

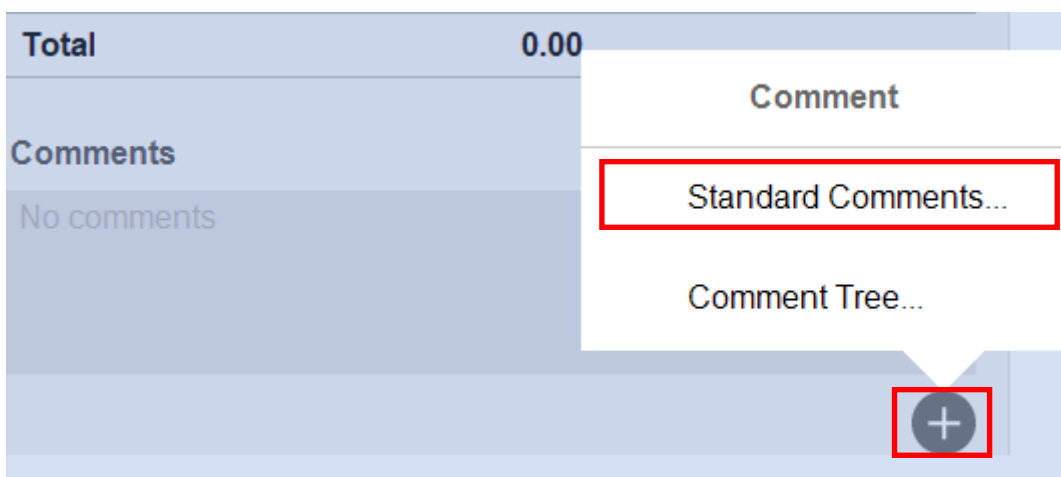
Total Protein (...)
0.00
Albumin (g/L)
0.00

#	Band	Rel. Area	Conc. (g/L)
1	● Albumin	55.76 %	0.00
2	● Alpha-1	7.13 %	0.00
3	● Alpha-2	10.04 %	0.00
4	● Beta-1	8.73 %	0.00
5	● Beta-2	5.30 %	0.00
6	● Gamma	13.03 %	0.00
Total			0.00

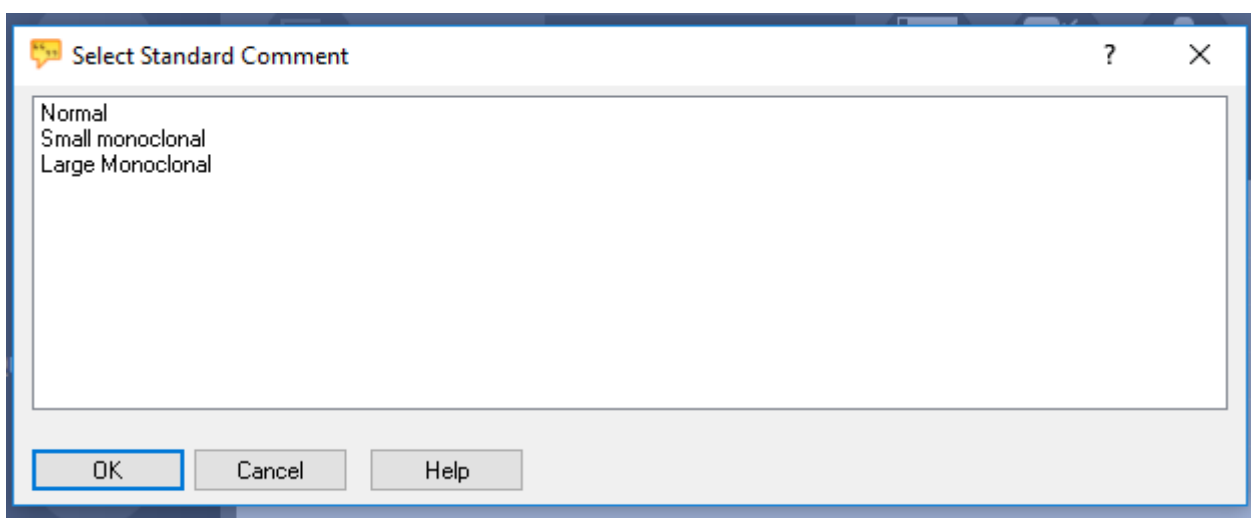
Comments

No comments

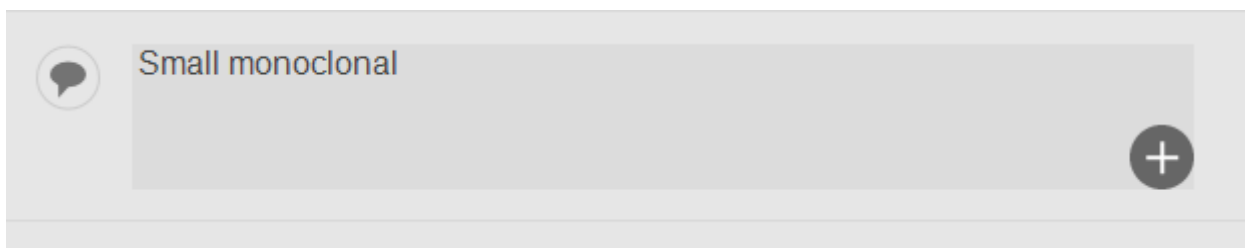
+



A window will open displaying all of the configured comments:



Select the comment that is to be added to the Comments section and then 'OK'. The comment will then appear in the 'Patient Comments' box:



5.8.12 Database

The Platinum database stores all data that is processed and imported.

5.8.12.1 Database Maintenance

To validate all sessions, fix corrupted samples or validate the database, go to [Configure > Database > Database Maintenance](#)

5.8.12.2 Merge Demographics

To merge previous demographics sets into the current Platinum demographics setup, go to [Configure > Database > Demographics Merge](#)

5.8.12.3 Backup Selected Data

To back up selected data in Platinum, go to [Configure > Database > Backup](#)


5.8.12.4 Database Backup and Recovery

To backup the current databases, recover previous databases, import sessions from another directory or create a new data directory, go to [Configure > Database > Backup and Recovery](#)

5.8.13 Report

Patient sample results can be viewed as a report and printed for use by the clinician. Templates can be altered according to preference and type of assay run.


5.8.13.1 Create New Report

In order to create a new report, go to **Configure > Reporting > Reports** and select the  icon. This will open a new report template with all of the functions that are required to create new template designs.

5.8.13.2 How to Create a Template Layout

When a template layout is created, a blank page will be displayed with tool buttons on the left hand side. Users can choose what type of results is to be shown, where it is to be situated, and what demographic data is displayed. Data such as peak values and Immunodisplacement data can also be attached.

5.8.13.3 Edit Report

To edit the current method dependent default report, choose the  icon and open the report which you wish to edit.

5.8.13.4 Preview Report

To preview a report before printing, go to the Print icon  and select "Preview Report for Selected Results...".

In Platinum it is possible to use user definable reports, but Helena Biosciences also provides an array of report templates that the user can customise to suit their own needs.

5.8.13.5 Setting a Report as the Default

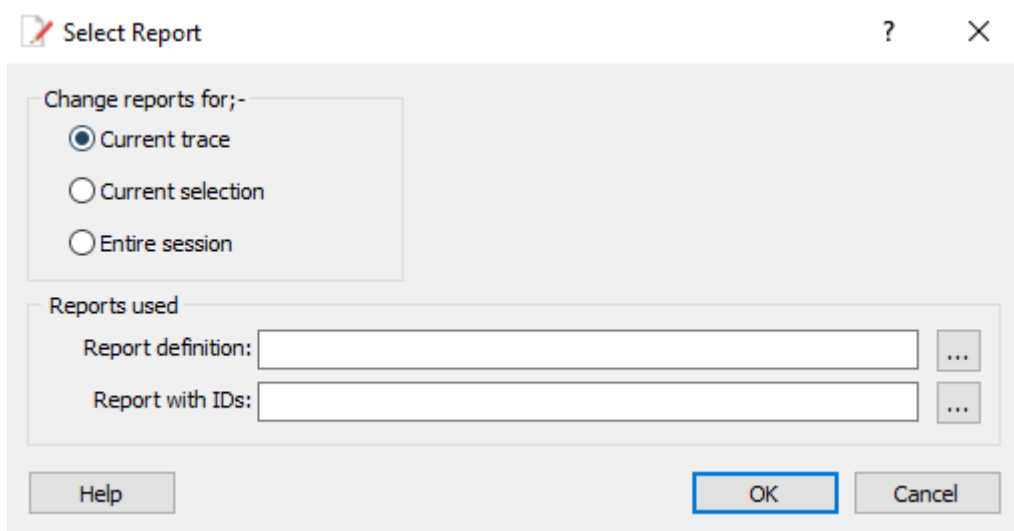
It is important to define a report type for all results; separate reports can be configured for Serum proteins and Immunodisplacement results. When an operator selects a report to be printed Platinum will automatically default to the Serum Protein report unless there are Immunodisplacement results attached to that sample, in which case Platinum will default to the Immunodisplacement report.

To select a default report for future data:

- Go to **Configure > Methods > Method Type** and in the Report Generation section make sure the "Do not report" option is unticked.
- Select the '' button next to Report Definition - this is the report to be selected for the serum protein without IDs. The default location for the report files is in the following location: C:\Program Files\Platinum.
- Repeat the selection for the Reports with IDs.
- This report definition will be applied only to the method selected. Repeat this process for each method as required.

To apply a report template to data already acquired:

- Go to **Configure > Configure Bands > Report Selection**
- Select which traces to apply the report template to
- Select the '...' button next to Report Definition - this is the report to be selected for the serum protein without IDs. The default location for the report files is in the following location: C:\Program Files\Platinum.
- Repeat the selection for the Reports with IDs.



Select OK on this window after selecting report locations. In order to change the report template without reinterpreting the data select 'Cancel' in the Configure Bands window before returning to the Results window.

5.8.13.6 Configuring ID Reports

ID reports are configured to provide an easy to interpret document.

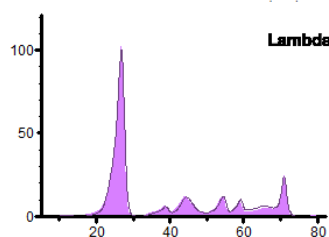
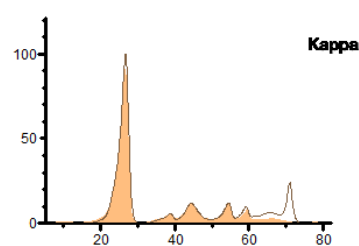
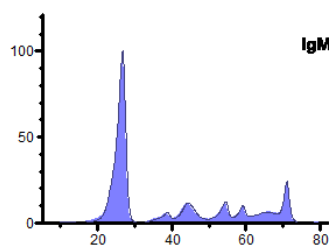
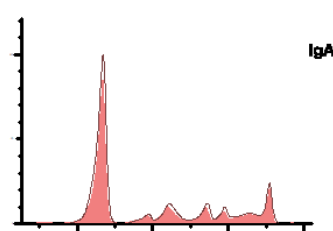
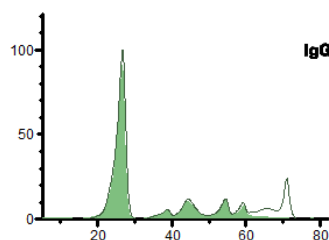
This can be further customised by the user providing a unique and tailored report, by long pressing on the individual trace and select "Configure ID Plot".

Serum Protein Immunodisplacement Report



Tube ID 1004224008
Name
Age
Sex

File Name
B13-24-07-10_1543
Method Type
Serum Protein SP-ID (G, A, M, K, L)
Measurement Time
10/07/2024 17:19:35



Comments

IgG Kappa

Helena Biosciences Europe
Clinical capillary and gel electrophoresis analysers, software and application portfolio
www.helena-biosciences.com

Each individual trace on the report can be uniquely edited to the user's preference and requirements.

ID plot configuration

☒ Plot main trace

ID plot items:

It...	ID item	I...
1	IgG	1
+		

Horizontal Alignment:

☐ As is
☒ Match Shapes
☐ Align Albumin
☐ Super Align

Vertical Alignment:

☒ As is
☐ Always Vertical Align
☐ As Immuno View

☒ Fill second trace
☐ Show method name

Close
☒ Copy settings to report definition

5.8.14 Configure V8 UltraCE Methods

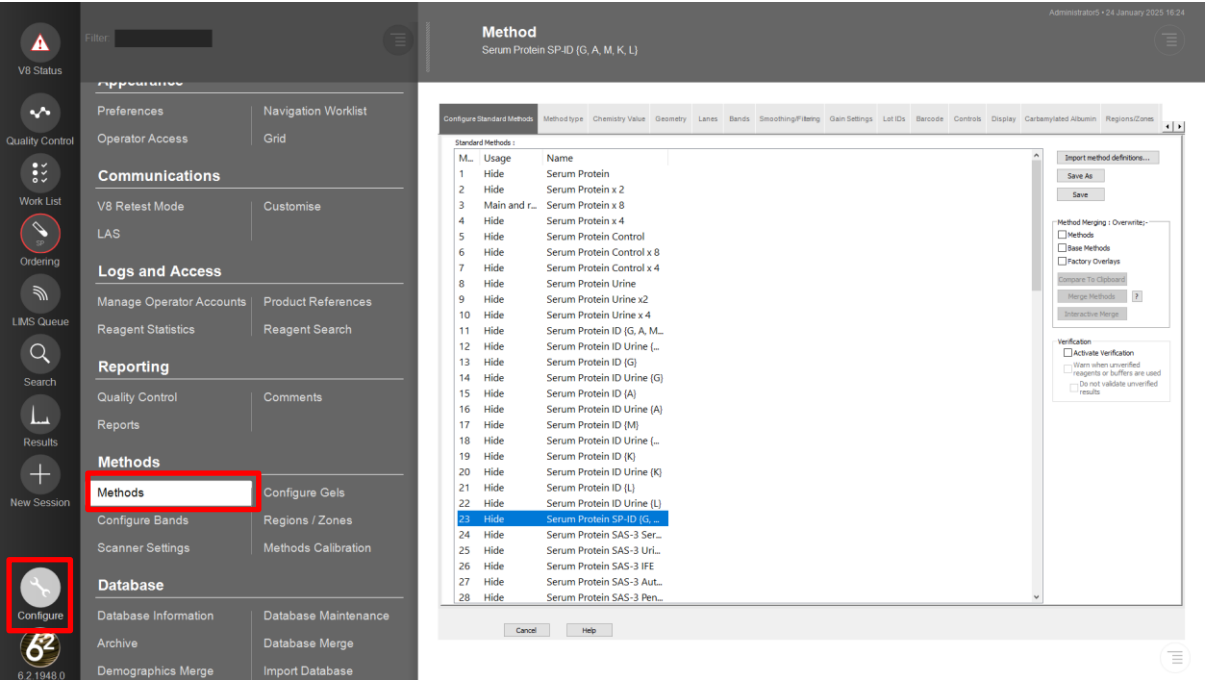
In Platinum, it is possible to configure some elements of each method used in processing samples. These elements are used to specify the limits for each band, default smoothing and filtering levels, and other factors that are interchangeable.

5.8.15 **Methods**

Go to **Configure > Methods > Configure Standard Methods**.

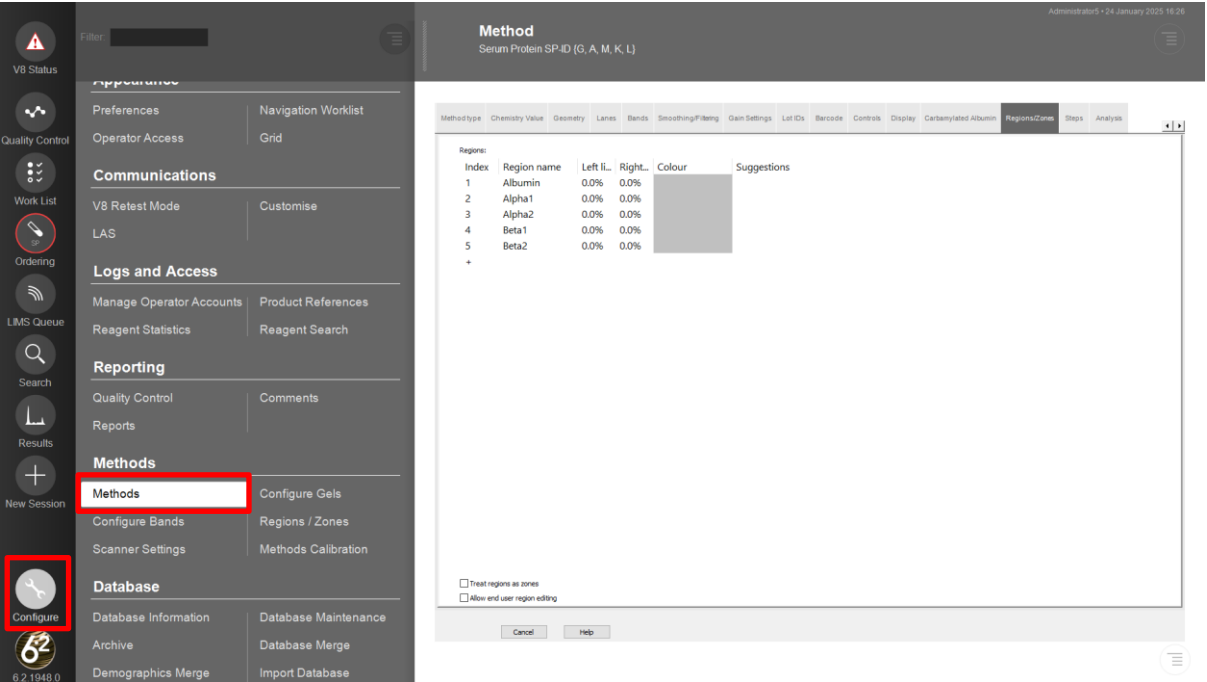
From this window, select the method you wish to configure. There is also the option here to “Show” or “Hide” methods by selecting on the “Usage” column.

Once the desired method is selected there are 14 tabular options available. It is recommended that most of these remain at their default settings.



5.8.15.1 **Trace Regions**

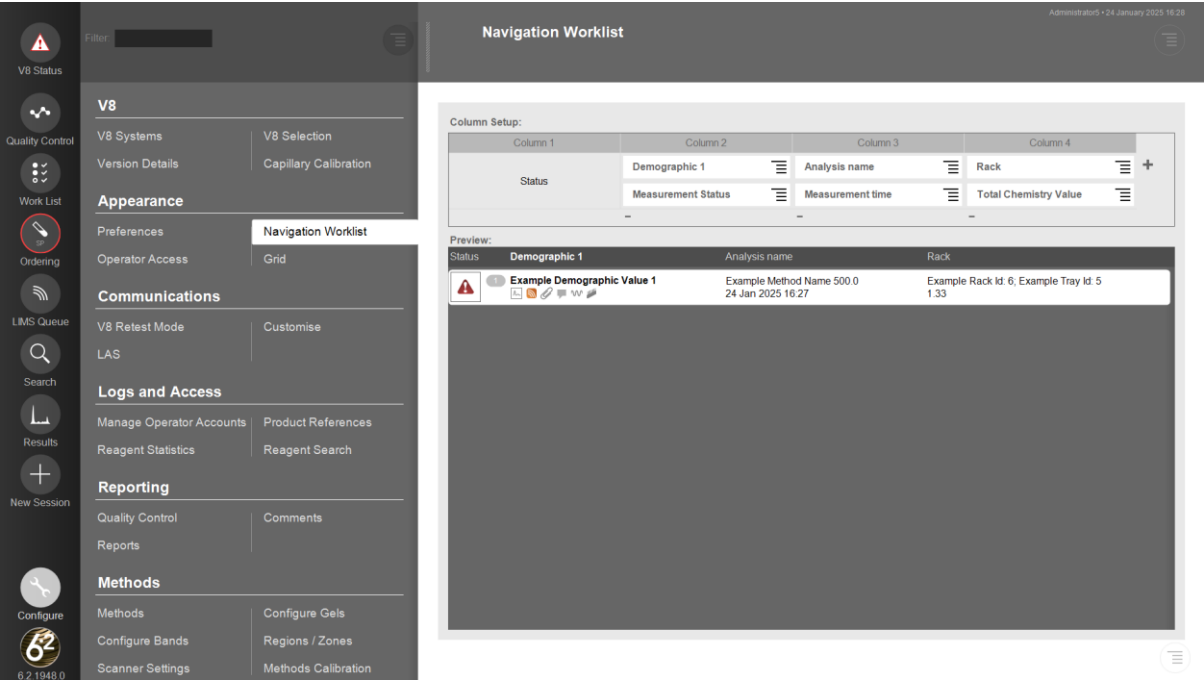
Go to **Configure > Methods > Regions/Zones** and enter the region names and limits. Suggestions of band(s) that would appear in this region can also be added in the appropriate column.



To select regions based on the trace displayed, then go to **Configure > Regions/Zones**.

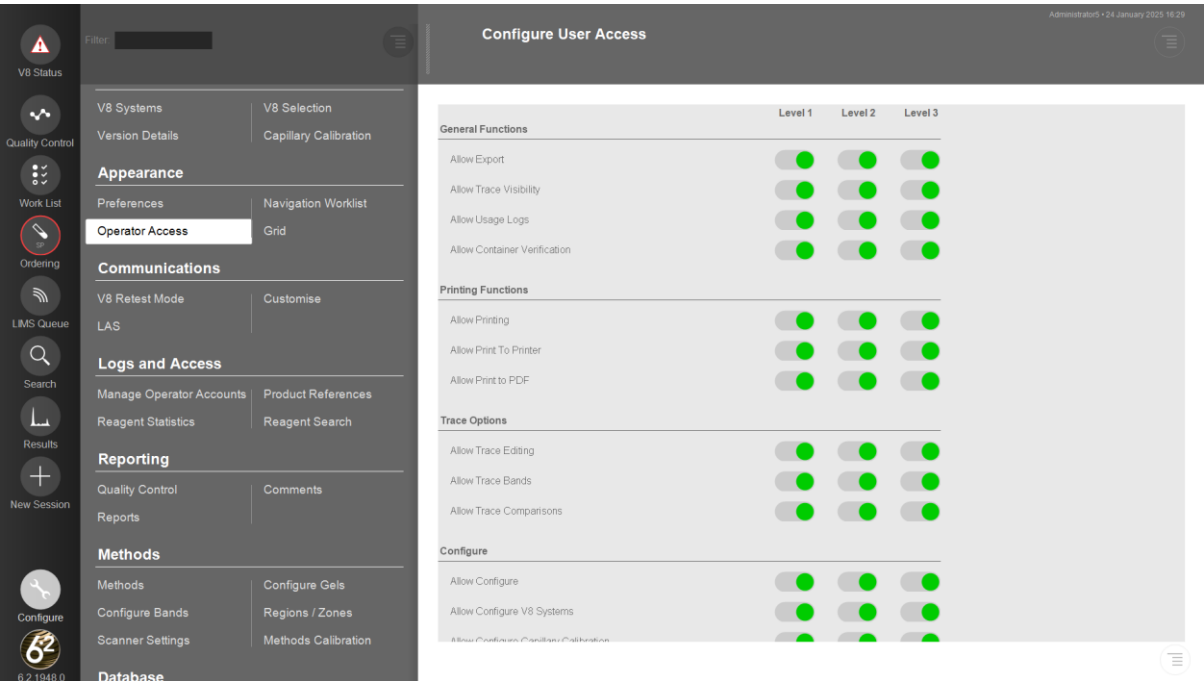
5.8.16 **Navigation Worklist**

The navigation worklist can be configured to show different runtime parameters and demographics as required. Add or remove columns using the +/- icons then select the content of each field using the options drop down menu. To configure the NWL, go to [Configure > Navigation Worklist](#).



5.8.17 **Operator Access**

The Platinum permissions for each user level can be configured through the Operator Access tab. Setting a check slider to off disables that functionality for a user of that level. To configure the user access, go to [Configure > Operator Access](#).




5.8.18 **Gel sessions**

5.8.18.1 **Gel Mode**

If a V8 UltraCE system has not been configured in Platinum, Platinum will automatically open in 'Gel Mode'. In Gel Mode the unused V8 Status and Ordering tabs will not be visible.

5.8.18.2 **Select Gel**


To select a gel method, open a new gel session by going to  and selecting 'Create new Gel session'. Use the dropdown menu to select the gel type.

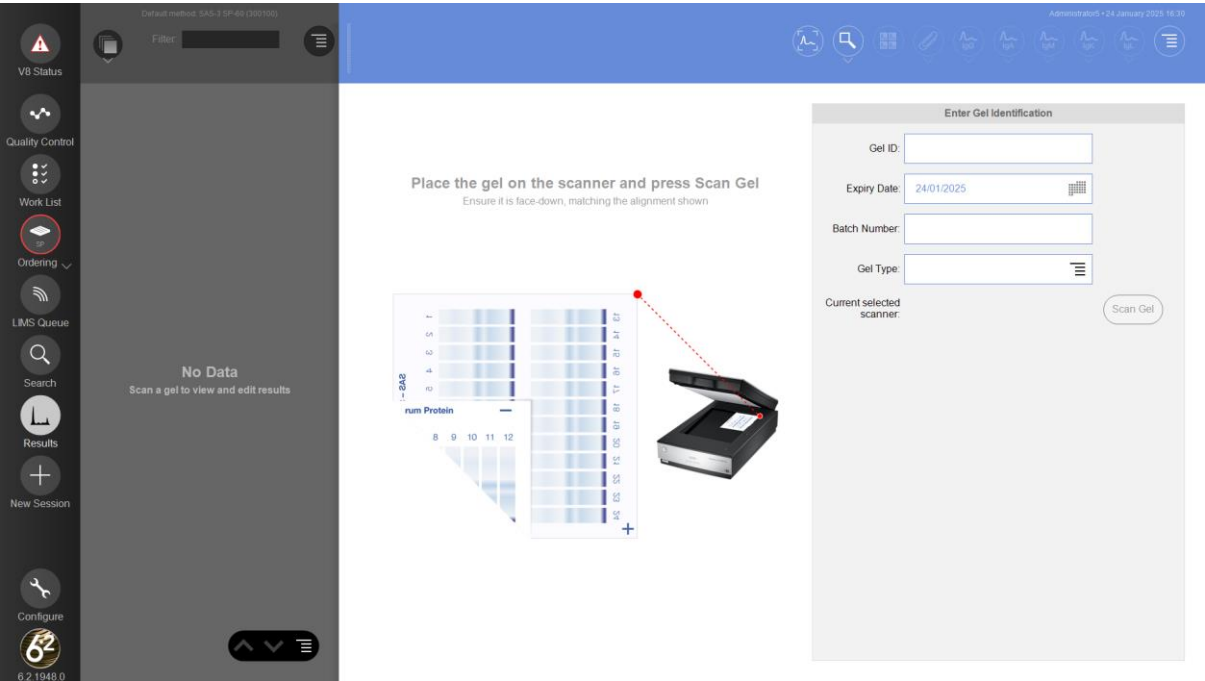
5.8.18.3 Scanning Configurations

5.8.18.3.1 Select a Scanner

The user can choose which scanner is to be used to import gel images to Platinum. All possible scan sources that are connected to the instrument will be listed in [Configure > Scanner Settings > Select Scanner](#).

5.8.18.3.2 Prompting Platinum to Scan

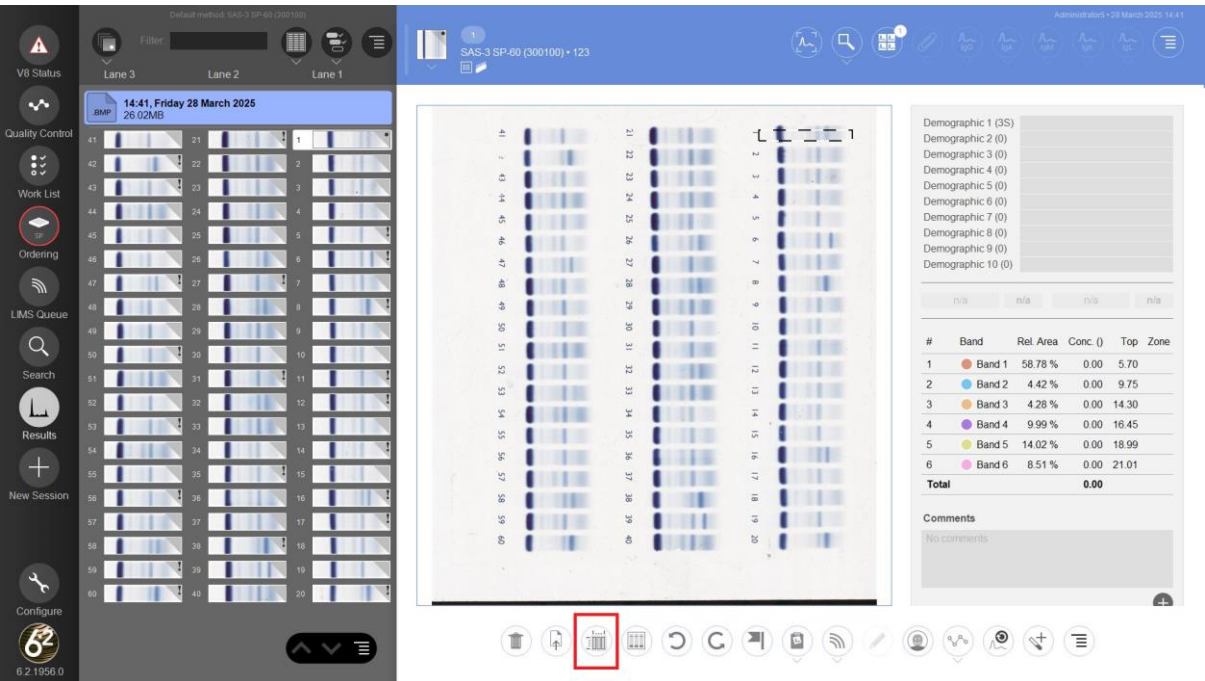
By opening a new gel session via the  icon, you will see a “Scan Gel” button which will prompt Platinum to scan the gel that is placed in the default scanner. In order to ensure data traceability, the ID of the gel must be entered (typed or scanned) in the window first before scanning commences. The correct Gel Type must also be selected to allow the appropriate template to be applied.



5.8.18.3.3 Aligning a Gel Template

Platinum automatically applies a gel template to gel images. It represents the areas of the gel from which the scan data will be analysed. There are several pre-set templates in the gel-type menu that correspond to particular configurations of gel size and sample number. These templates may, however, require slight adjustments to account for individual variation.

If the gel alignment needs adjusting, select the Align Gel icon underneath the gel image following the scan (NB. This option is only available in an active gel scan session):

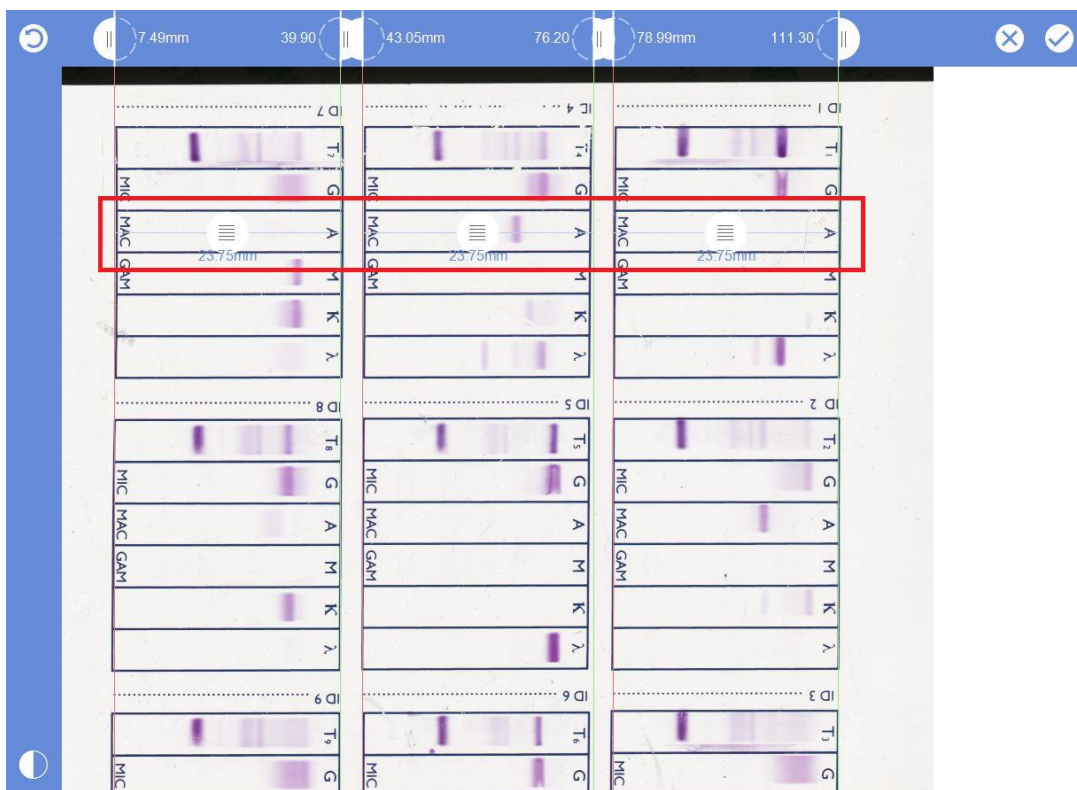


Two vertical markers represent the left (red) and right (green) limits of each row and a single horizontal marker indicates the centre position of the first samples in each row. Each marker can be positioned by manually moving them. The displayed values are in millimetres (mm), and indicate the

distance of the marker from the appropriate axis.

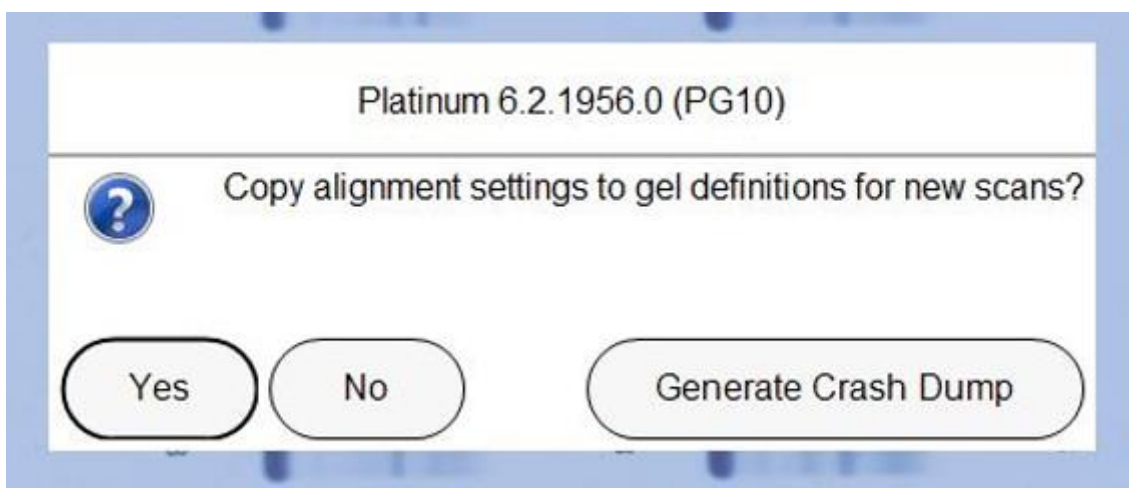


For an IFE gel, the horizontal markers should be positioned in the centre of the IgA lane:



NB. Do not move these markers beyond the edge of the gel. If this is done accidentally, the 'Undo' icon can be used to reset to the default values.

Upon accepting a change to the alignment settings by selecting the tick icon in the top right, an options box will pop up to ask if the setting should be saved for future gel scans:



Selecting 'Yes' will update the default values.

N.B. Result reporting should always be carried out directly from the original gel. The gel is scanned into Platinum only as a record of the result.

5.8.18.3.4 Marking a Gel

To see that a template fits correctly on a scanned image, use the  icon to overlay a template mask to the gel image. This allows the alignment of samples to be checked, which if out of line, can be corrected using the align gel function.

5.8.18.3.5 Configure Gels

In Platinum, it is possible to configure the methods that are used in processing the samples. These methods are used to specify the limits for each band, default smoothing and filtering levels, and other factors that are configurable.

5.8.19 Notice to Users

If any serious incident has occurred in relation to the device this should be reported to the manufacturer and the competent authority of the member state in which the user is established.

6 Calibration procedures

6.1 Instrument calibration

- a. All V8 UltraCE instrument calibration should be carried out by a Helena Biosciences trained and certified engineer; this will be carried out during scheduled site service visits and at installation.
- b. Any attempts by untrained/unqualified personnel to calibrate the V8 UltraCE instrument could invalidate the warranty.

6.2 Quality Control calibration checks

- a. It is recommended that Helena Biosciences quality control material are used to perform daily checks on the performance of the V8 UltraCE instrument. All control kits are supplied with assay sheets which provide details of the expected ranges.
- b. Further details of the quality control procedure can be found in section 5.8.4.

7 Health and Safety information

7.1 Overview

The V8 UltraCE system has been designed and manufactured to the highest standards of technical excellence, fulfilling the scope of its intended purpose, and incorporating the latest in safety design features satisfying standards for the manufacture of IVD equipment. The V8 UltraCE system has been designed to ensure the full health and safety of the end-user, and to prevent and limit all possible health and safety risks associated with operating the V8 UltraCE via in-built protective features, standards and protocols. The following section details all the protective features and user instructions for ensuring health and safety. It is strongly recommended that this section is read thoroughly before system use.

7.1.1 Personal Protective Equipment

It is recommended that suitable Personal Protective Equipment (PPE) is worn at all times. Local regulations should be adhered to for precise instructions of necessary clothing, but as a minimum Helena Biosciences recommends that the following safety equipment is used at all times: safety glasses, gloves and a laboratory coat.

7.2 On-board Health and Safety standards and protocols

7.2.1 Compliance standards

V8 UltraCE complies with a number of recognised standards and directives for the design, development and manufacture of IVD equipment. Please refer to 7.3.4 to read all of these standards.

7.2.2 Training

All users must demonstrate their competence to operate the V8 UltraCE fully in accordance with the user instructions of this manual to a certified level. Under no circumstances must anyone operate the V8 UltraCE without full user training by a qualified instructor representing or associated with Helena Biosciences Europe.

7.2.3 Protective hood



WARNING

The protective hood protects against the mechanical movements of the sample handling system, and environmental contamination from dust particles entering the sample analysis and preparation area. The protective hood should not be removed.

7.2.4 Mechanical movement shut down



WARNING

The V8 UltraCE is made up of modular components that are integrated with sensors to protect users from hazardous mechanical movements, and to ensure correct and optimal analytical conditions. All mechanical movements linked to the preparation and analysis of samples, including hazardous needle movements, will automatically shut down and remain on stand-by, upon opening of the top cover and rack cover.

7.2.5 Safe loading of samples

The sample rack can be adapted to fit all types of sample tubes, which can be fitted securely to the sample rack. All sample racks must be loaded onto the sample transport area correctly. See section 5.6.7.1. Appropriate personal protective equipment must be worn.




CAUTION

WARNING: Pinch point hazard

7.2.6 Zero cross contamination


Automatic maintenance procedures ensure that all fluidic and analysis channels are cleaned and decontaminated thoroughly for reproducible results requiring no user intervention between runs, and ensuring zero cross contamination of samples, reagents and buffers.

7.2.7 Safe and convenient clinical waste collection



WARNING

All clinical waste is channelled into two removable units held on-board the V8 UltraCE for the safe and convenient disposal of hazardous substances and material, minimising user interruption to the system and ensuring safe disposal; provided stringent safety protocols are followed as additional measures.



WARNING

ALL CLINICAL WASTE SHOULD BE HANDLED WITH CARE AND DISPOSED OF IN ACCORDANCE WITH LOCAL WASTE DISPOSAL RULES.

7.2.8 Analysis security

Platinum is password protected with designated access settings for multiple users, providing a holding pen for all results awaiting: (1) approval by the laboratory manager with Level 3 security access settings, and; (2) data transference to the Hospital's Laboratory Information Management System for official patient records. See section 2.6.

7.2.9 Quality assurance

Full Levey-Jennings capability is available providing quality control data and a graphical indication of how different methods are performing on the system. Within this, Westgard rules define the specific performance limits of the V8 UltraCE, and its assays, which act as a failsafe to detect random and systemic errors.

7.2.10 Audit trail accountability

V8 UltraCE ensures that the identity of the clinician, and of the patient sample, is logged for audit trail accountability, against the barcode data, lot number and expiry date of each buffer and reagent consumed on the system.

7.2.11 Expert System

Platinum via the Expert System facilitates the positive identification of abnormal results through automated software features for speed and convenience, but does not under any circumstances automate the diagnosis of disease states. It is the responsibility of the clinician to ensure all data is correctly diagnosed. See section 5.7.

7.2.12 Instrument status communication

V8 UltraCE communicates visually and audibly to the end-user through an on-board lighting and audio tones system. This is designed to provide the end-user with information regarding the operational status of the instrument for correct, optimum and safe usage at all times. See Appendix 1.

7.3 Regulatory Information

7.3.1 Proprietary notice

The information contained in this manual is derived from the patented and proprietary data of Helena Biosciences Europe. Publication of this information does not imply any rights to reproduce or use this manual for purposes other than installing, operating, or maintaining this instrument and software. No part of this manual may be reproduced, transcribed, transmitted, stored in a retrieval system, or translated into any language, in any form or by any means, electronic, magnetic, mechanical, optical, manual, or otherwise, without the prior permission of a representative of the executive management team of Helena Biosciences Europe.

These provisions are intended to state all of the rights and responsibilities between Helena Biosciences Europe, the distributor and the customer. They supersede all warranties, expressed or implied, and whether of merchantability, fitness or otherwise. The remedies contained in this manual are exclusive. Distributor, customer and Helena Biosciences Europe waive all other remedies, including but not limited to consequential damages.

Copyright © by Helena Biosciences Europe "ALL RIGHTS RESERVED"

7.3.2 Warranty

Helena Biosciences Europe warrants each instrument manufactured to be free of defects in materials and workmanship (excluding external power supplies) for 12 months from the date of shipment. This warranty shall be fulfilled by the repair or replacement, at the option of Helena Biosciences Europe, of any part or parts, free of charge including labour, F.O.B. it's factory or authorised service centre.

This warranty shall be voided by any repair, alteration, or modification, by persons other than employees of Helena Biosciences Europe, or those expressly authorised by Helena Biosciences Europe to perform repairs, and by any abuse, misuse, or neglect of the product, or by use not in accordance with Helena Biosciences Europe's published instructions.

Helena Biosciences Europe reserves the right to make changes in design and / or improvements to its products without any obligation to include these changes in any products previously manufactured. Correction of defects by repair or replacement shall constitute fulfilment of all warranty obligations on the part of Helena Biosciences Europe.

THIS WARRANTY IS EXPLICITLY IN LIEU OF OTHER EXPRESSED OR IMPLIED WARRANTIES, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE. THIS WARRANTY OBLIGATION IS LIMITED TO REPAIR OR REPLACEMENT OF THE UNIT RETURNED TO HELENA BIOSCIENCES EUROPE OR AN AUTHORISED SERVICE CENTRE FOR THAT PURPOSE.

7.3.3

WEEE

Helena Biosciences Europe products meet the European Union Waste Electrical and Electronic Equipment (WEEE) directive. Please refer to www.helena-biosciences.com for more information on Helena Biosciences compliance with the WEEE directive.

When supplied as B2B EEE the producer invokes regulation 12.2 and passes all WEEE obligations to the end user.

7.3.4

Applicable standards and directives

The V8 UltraCE capillary electrophoresis instrument complies with the relevant clauses and articles of the following recognised standards and directives for its development, manufacture and servicing.

Regulation (EU) 2017/746 of the European Parliament and of the Council 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
COUNCIL DIRECTIVE 2012/19/EU of 4 July 2012 concerning waste electrical and electronic equipment (WEEE)
EN 50419:2022 Marking of electrical and electronic equipment (EEE) in respect to separate collection of waste EEE (WEEE)
COUNCIL DIRECTIVE 2011/65/EU of 8 June 2011 concerning the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2)
COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances (RoHS3)
EN ISO 13485:2016+A11:2021, Medical devices — Quality management systems — Requirements for regulatory purposes
EN ISO 14971:2019+A11:2021 Medical devices — Application of risk management to medical devices
EN IEC 61010-1:2010/A1:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
EN IEC 61010-2-101:2017 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN IEC 61326-1:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EU Directive 2014/30/EU and EU Directive 2014/35/EU: Directive 2014/30/EU of the European Parliament and of the Council of 26 February 2014 on the harmonization of the laws of the Member States relating to electromagnetic compatibility
Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits
EN IEC 61326-2-6:2021 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN IEC 62366-1:2015+A1:2020 Medical devices - Application of usability engineering to medical devices
PD IEC/TR 62366-2:2016 Guidance on the application of usability engineering to medical devices
EN IEC 62304:2015 Software for medical devices - Processes for lifecycle of Programs
EN ISO 15223-1:2021 Medical Devices – Symbols to be used with medical devices, labelling and information supplied – Part 1: General requirements
EN ISO 18113:2024 (part 1 & 3) - In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling)
EN ISO 20417:2021 Medical devices. Information to be supplied by the manufacturer.
EN 13612:2003 - Performance evaluation of in vitro diagnostic medical devices
ISO 17511:2021 - In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
EN IEC 63000:2018 - Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
47 CFR Part 15 – Radio Frequency Devices

For instruments that will be sold in the United States of America, all relevant federal regulations of the Food and Drug Administration (FDA) Title 21CFR have been complied with.

Precautions and limitations

1. To fully isolate the system remove the mains power cord from the rear of the instrument. This should be easily accessible by the operator in the event of an emergency.
2. A shielded ethernet cable which is shorter than 3m in length should be used to connect the V8 UltraCE and PC.
3. It is the responsibility of the operator to fully read and understand the operator manual and be fully competent on operating the V8 UltraCE before use.
4. Ensure the fan located at the rear of instrument is not covered and has adequate air circulation (see section 2.4.1).
5. Ensure the top cover is not obstructed when fully opened.
6. Do not use abrasive cleaners on any of the instrument surfaces. Always isolate mains supply before cleaning any spills.
7. Only use cleaning fluids recommended: 70% Ethanol, Isopropanol or 1% hypochlorite solution (see WHO Laboratory biosafety manual).
8. Only use the instrument for the intended purpose stated, see section 1.1.
9. The instrument should only be operated when installed by a Helena Biosciences trained engineer.
10. If the system is operated in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.
11. Whilst the unit is in operation, the operator should keep clear the area around the reagent bay and gel tray docking station. Reagent bottles should not be stored within this area when not in the reagent bay.

8 Hazards: Residual

8.1 Residual risks and user protection

In addition to the instrument's on-board safety mechanisms, it is necessary for the user to take adequate protection measures in relation to risks that cannot be eliminated by system design, such as the disposal of clinical waste, or the handling of hazardous reagents and patient samples. Whilst the V8 UltraCE minimises user risks through expert design, the end-user remains responsible for the safe and correct handling procedures of samples and waste fluids.

Please read the details below that present all residual risks faced by the end-user when using the V8 UltraCE, in addition to the relevant equipment needed to assist with health and safety measures. The manufacturer considers residual risks to mean all potential hazards associated with using the V8 UltraCE, but unprotected by the ergonomic design and in-built safety features of the V8 UltraCE system;

- Cleaning of sample analysis and preparation area
- Disposal of clinical waste
- High voltage
- Handling of patient samples
- Handling of high risk samples
- Lifting, installation and re-location
- Removal of the protective hood
- Sampling handling arm

8.1.1 Cleaning of sample analysis and preparation area

Please refer to sections 8.1.2 and 9.8 for further information.

8.1.2 Decontamination

Any areas of instrumentation subject to potential biological sample spillage are readily accessible for decontamination procedures and disinfection. In the event of contamination to the system, the operator must post-condition the instrument via the side button which will be adequate to fully decontaminate the instrument internally and allow the user to safely deal with any sample spillages.

Decontamination of the system

All samples loaded onto the V8 UltraCE should be classed as biological contaminated agents and handled appropriately. Samples of known infectious origin, such as HIV positive samples can remain uncapped during sample processing. The V8 UltraCE can be specifically decontaminated following the analysis of such samples, or as part of the routine maintenance at the discretion of the laboratory.

To decontaminate the system ensure that UltraCE Storage Buffer (REF V8020) and UltraCE Maintenance Buffer (REF V8010) are installed. Post condition as normal by pressing the side button which will post condition the capillaries and decontaminate the V8 UltraCE system.

- Empty and disinfect the waste collection module.
- Disconnect and dispose of the waste fluids bottle.

Spillages

Mop up any excess material using an appropriate, disposable absorbent towel. Clean all affected surfaces with 70% ethanol solution or 1% hypochlorite solution (see WHO Laboratory biosafety manual) (bleach). The same protocol can be used as a periodic decontamination scheme in the rack transport area and reagent bay.

For further information and advice please contact V8 UltraCE technical support.

8.1.3 Disposal of clinical waste

Please refer to section 9.5 for further information.

8.1.4 High voltage system



HAZARD

The V8 UltraCE system is facilitated by a high voltage system. The operator must not modify or attempt to adjust the physical properties forming the design of the V8 UltraCE instrument. Failure to use the V8 UltraCE in accordance with its intended purpose set out in this user manual could cause harm or injury to the operator, and compromises the obligations of the warranty.

8.1.5 Handling of Patient Samples



WARNING

The user must wear the appropriate clothing and follow the local health and safety regulations for handling ALL patient samples. All patient samples **MUST** be treated as high risk.



WARNING

Helena Biosciences strongly recommend the routine wearing of laboratory coats, safety glasses and disposable examination gloves when operating the V8 UltraCE system.

8.1.6 Handling of high risk samples

The user must wear the appropriate clothing and follow the local health and safety regulations for handling known high risk patient samples. All patient samples **MUST** be treated as high risk.

8.1.7 Installation, lifting and re-location



CAUTION

Under no circumstances must the operator attempt to move or re-locate an installed V8 UltraCE system without notifying a Helena Biosciences certified and trained engineer. Safe installation of the V8 UltraCE system requires that a trained engineer is on-site to ensure the personal health and safety of all end-users, and third parties, involved in the re-location of the V8 UltraCE system. To prevent potential bio-hazards, a full decontamination procedure is provided whenever the system is to be removed from the user site. Repositioning or relocation of the V8 UltraCE system without the aid or assistance of a Helena Biosciences certified and trained engineer could cause serious physical harm and injury, and risk the terms and conditions of the warranty upheld by the manufacturer and/or the distributor, due to system damage.

8.1.8 Removal of the protective hood



WARNING

The protective hood exists to prevent contamination to the sample and preparation area; and to protect the user from the mechanical movements of the sample handling arm. It should not be removed from the instrument.

8.1.9 Sample handling arm

The sample handling arm is a hazardous component of the instrument and needs to be approached with extreme care. The movement of the sample handling arm pauses immediately for user safety once the top cover and rack cover have been lifted. For maintenance instructions of the sample handling arm, please refer to section 8.1.2 and 9.8.

8.1.10 V8 UltraCE LED lighting system

Looking directly at lit LEDs can dazzle. Direct eye contact with the diode should be avoided where possible. To avoid hazard the LED lighting system within the V8 UltraCE is disabled when the top cover is open.

8.1.11 Barcode Reader



LASER RADIATION

The integrated barcode reader incorporates a class 2 laser. Care must be taken to not stare directly into the beam. A warning sticker on the machine is present to indicate this hazard.



WARNING
HOT SURFACE

Care must be taken when emptying the waste bin. The lamp is located directly to the right of the waste bin compartment and there is a possibility that the surface could become hot while the system is in use. Do not place hands inside this compartment when the waste bin has been removed, and ensure the handle is used to remove and replace the waste bin.

8.2

Summary: required safety checklist

This is a brief checklist to ensure the normal operation and optimal efficiency of the V8 UltraCE adhering to the safety requirements stipulated in this user manual. Please read this checklist before use, or for a reminder of safe operation.

- a. Do not operate the V8 UltraCE unless trained and authorised for use.
- b. Ensure that all parts of the V8 UltraCE are undamaged and in good working order.
- c. Do not attempt to relocate the V8 UltraCE before use, or move the instrument during operation.
- d. Only Helena Biosciences reagents, buffers, sample racks and disposable cups should be used to guarantee system efficiency and normal operation.
- e. Check any tubes, sample cups and bottles before use to ensure they are undamaged and safe for use.
- f. Do not place more than 14 sample racks on-board the V8 UltraCE at any one time.
- g. Ensure all items for use on-board such as reagents, buffers, sample racks and disposable cups are loaded onto the V8 UltraCE correctly.
- h. Please remove lids from all reagent bottles placed in the reagent bottle area.
 - i. Do not attempt to repair any faults or hardware malfunctions. Only Helena Biosciences trained engineers can do this.
 - j. Clean up any spills off-board the V8 UltraCE immediately and follow the local safety guidelines for biological contamination.
- k. Ensure the power supply does not contact any fluid. Should fluid enter the power supply, please switch the V8 UltraCE off immediately at the mains outlet and call technical support.
- l. Do not attempt to clean up spills on-board the machine whilst it is running.
- m. Do not switch the V8 UltraCE off using the switch positioned at the rear of the instrument. This switch should only be initiated when relocating or storing the V8 UltraCE, or in cases of emergency.
- n. Do not attempt to adjust or manually move any moving parts of the machine such as the needle arm or the sample transport system.
- o. Do not remove the protective hood, or any part of the machine that is fixed to the V8 UltraCE.
- p. Failure to adhere to these safety guidelines could invalidate your warranty.

9 Maintenance of the V8 UltraCE

9.1 Overview

V8 UltraCE automates all daily service and maintenance procedures to ensure optimum performance levels, and to minimise user-intervention. Please refer to this section to understand daily, monthly and annual service and maintenance requirements.

9.2 Daily maintenance

The Helena V8 UltraCE performs all required daily maintenance automatically. There are two automated processes programmed into the instrument: pre-conditioning and post-conditioning. This is conducted when Start-up and Shut-down are initiated by the side button or when there is an idle period of 4 hours. When the V8 UltraCE is operating in either of these processes, the lights will be YELLOW.

All maintenance solutions are held on-board the instrument at all times. These are UltraCE Storage Buffer, found in port 4 of the buffer block, and UltraCE Maintenance Buffer, located in port 5. Should these become low in liquid; the V8 UltraCE will notify the user with a 'LIQUID LEVEL LOW' message in Platinum. When a chime sounds and message appear the appropriate buffer should be replaced with a fresh buffer bottle.

It is recommended that the waste bin and waste bottle are emptied on preconditioning of the V8 UltraCE.

9.3 Pre-conditioning

This is initiated when the side button is pressed at the beginning of every day. This process clears the capillaries of UltraCE Storage Buffer and prepares them with the default assay buffer that is loaded onto the instrument and set in Platinum. Pre-conditioning is dependent on the default assay and takes around 40 minutes.

N.B. Pre-conditioning is not an optional process and cannot be over-ridden by the user.

9.4 Post-conditioning

This is initiated when the side button is pressed while the system is active, or when there has been an idle period of 4 hours. This process clears the capillaries of UltraCE Maintenance Buffer to remove any residual samples or reagents and then fills the capillaries with UltraCE Storage Buffer until the V8 UltraCE is switched on again.

N.B. Post-conditioning is not an optional process. Post-conditioning ensures that buffer and residual sample do not crystallize within the capillary and prevents blockage. Filling with UltraCE Storage Buffer keeps the capillaries wet and prevents them drying out. As such it is ESSENTIAL that the V8 UltraCE be allowed to carry out this process at the end of every day/use. Failure to do so (by removing power to the instrument using the back power switch) can cause irreparable damage to the capillaries and affect the performance of the system.

9.5 Emptying waste from the instrument

Waste created by the V8 UltraCE is CLINICAL WASTE and should be treated with caution. There are two areas on the instrument that require emptying of waste: (1) the waste bottle, and; (2) the waste drawer.



Caution needs to be given on the handling of biological samples. Suitable clothing (gloves, glasses, and laboratory coat) must be worn and appropriate handling of all items must be adhered to.

9.6 Emptying the waste fluid bottle

The waste fluid bottle contains buffer, reagent, UltraCE Maintenance Buffer and sample residues used during the operation and should be treated as clinical waste and disposed of accordingly.

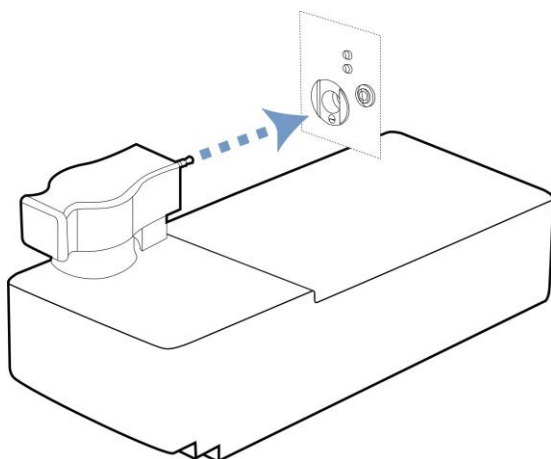
The V8 UltraCE will notify the user when emptying of the bottle is required by a chime, which will be accompanied by a message window in Platinum. The system will pause and not continue operation until the waste bottle is emptied, if the V8 UltraCE is undergoing electrophoresis this will continue without any interruption to data generation. The chime and accompanying message will not be produced until data collection is complete.

To empty the waste bottle:

- Ensure appropriate PPE (Personal Protective Equipment) is worn.
- Access the fluid bottle compartment by pulling down the Front Cover.
- Check that the light is **not flashing** to ensure no fluid is actively being pumped into the waste bottle before removal.
- Remove the waste bottle by holding the bottle connector and pulling backwards, gently but firmly.
- Pull out the bottle connector and decant the waste fluids into an appropriate container for disposal in accordance with local waste disposal rules.
- Dry the bottle connector before replacing the bottle connector ensuring that the fluid inlet port and socket is facing down the length of the bottle and is correctly engaged.

N.B. the bottle should NOT be picked up by the bottle connector.

- Replace the waste bottle into the correct position, ensuring the bottle connector is fully inserted and connected with the V8 UltraCE. A green LED light will appear over the bottle if installed correctly.



- Close the Front Cover. The V8 UltraCE will continue operation from the point at which it paused.

N.B. Please note that the waste bottle should be emptied when prompted to do so by the V8 UltraCE.

9.7 Emptying the sample cup waste drawer

The V8 UltraCE will notify the user when the waste drawer requires emptying with a chime, accompanied by the message window 'PLEASE EMPTY THE WASTE BIN.'

The waste drawer contains residual buffer, reagent, diluent and sample waste. The waste contained within this drawer is classified as clinical waste, requiring the user to wear the appropriate clothing, and adhere to the local health and safety standards and precautions. As a minimum Helena Biosciences recommends the use of safety glasses, gloves and laboratory work coat. Maximum volume of solid waste produced per hour will be 24 sample cups. The waste tray will not hold more than 100 sample cups.

To empty the waste drawer:

- Access the sample cup waste drawer by pulling down the *FRONT PANEL*.
- Remove the sample cup waste drawer.
- Dispose of the insert and the contents in accordance with local waste disposal rules.
- Place a fresh insert inside the drawer; in correct orientation.
- Replace the sample cup waste drawer.
- Close the *FRONT PANEL*.

N.B. The clinical waste drawer can be cleaned and decontaminated using sodium hypochlorite solution (see WHO Laboratory biosafety manual) at a concentration of 1% (10,000 ppm) if required.

9.8 Daily maintenance routine

- Switch the V8 UltraCE ON at the back power switch if not in STAND BY mode. The lights will turn yellow.
- Ensure that the waste bottle, UltraCE Maintenance Buffer and UltraCE Storage Buffer are on-board and that the waste drawer is lined with an insert. After checking and/or changing the default assay, ensure that the default buffer required is on-board.
- Switch the V8 UltraCE to Start-up at the side button and allow it to pre-condition.
- When the lights on the V8 UltraCE turn to green, it is ready for use. Run the V8 UltraCE as required through the day.
- When operation has ceased, remove all sample racks from the loading bay and remove all reagents from the reagent bay.
- Set the side button to shut-down and wait for the V8 UltraCE to communicate the chime and for the colour to turn to yellow.

g. When finished the lights on the V8 UltraCE will turn off. In Platinum, the V8 Status icon will turn red. The V8 UltraCE is ready to be switched off at the back power switch or to be left in stand-by mode.

9.9 Intermittent Use

It is recommended that the V8 UltraCE is preconditioned and postconditioned twice weekly when not in use.

9.10 Frequent maintenance checks

It is recommended that the operator frequently checks the needle and the sample preparation and analysis area for general cleanliness.



CAUTION

It is recommended that the needle is cleaned manually with Isopropanol or 70% Ethanol. The V8 UltraCE should be completely switched off and the needle gently wiped, taking extreme care when touching the tip.

It is recommended that the sample preparation and analysis area is wiped down with a clean/damp disposable cloth and warm water. The V8 UltraCE should be switched off completely.

Any spillage of blood and / or serum should be blotted with an absorbent cloth and then the surface cleaned with a 1% hypochlorite solution (see WHO Laboratory biosafety manual).

It is recommended that suitable Personal Protective Equipment (PPE) is worn at all times. Local regulations should be adhered to for precise instructions of necessary clothing, but as a minimum Helena Biosciences recommends that the following safety equipment is used: safety glasses, gloves, laboratory coat.

9.11 Monthly maintenance

There are no specific monthly maintenance procedures – providing that daily maintenance routines and frequent checks are carried out.

9.12 Annual maintenance

Annual maintenance of the V8 UltraCE should only be carried out by a Helena Biosciences trained and certified engineer. Capillaries will be changed and the system will be calibrated and fully serviced. No user specific intervention is required.

If using piercing and agitation methods, the needle will need to be replaced after 6,000 piercings.

9.13 Decontamination

Any areas of instrumentation subject to potential biological sample spillage are readily accessible for decontamination procedures and disinfection. In the event of contamination to the system, the operator must post-condition the instrument via the side button which will be adequate to fully decontaminate the instrument internally and allow the user to safely deal with any sample spillages.

Decontamination of the system

All samples loaded onto the V8 UltraCE should be classed as biological contaminated agents and handled appropriately. Samples of known infectious origin, such as HIV positive samples can remain uncapped during sample processing. The V8 UltraCE can be specifically decontaminated following the analysis of such samples, or as part of the routine maintenance at the discretion of the laboratory.

To decontaminate the system ensure that UltraCE Storage Buffer (REF V8020) and UltraCE Maintenance Buffer (REF V8010) are installed. Post condition as normal by switching the side button from wake to sleep this will post condition the capillaries and decontaminate the V8 UltraCE system.

- Empty and disinfect the waste drawer.
- Disconnect and dispose of the waste fluids bottle.

Spillages

Mop up any excess material using an appropriate, disposable absorbent towel. Clean all affected surfaces with 70% ethanol solution or 1% hypochlorite solution (see WHO Laboratory biosafety manual). The same protocol can be used as a periodic decontamination scheme in the rack transport area and reagent bay.

For further information and advice please contact V8 UltraCE technical support.

9.14 Waste container decontamination

9.14.1 Clinical waste drawer

The clinical waste drawer is the point of collection for disposal of the sample cups. The samples cups contain a variety of buffers, reagents and sample components and as such should be disposed of as biologically contaminated solids. The drawer **MUST** be lined with a waste drawer insert prior to use at all times. The clinical waste drawer is fitted with a sensor, and as such, the V8 UltraCE will notify the user when it is full and requires a new insert.

In the unlikely event of contamination to the drawer itself, please disinfect with 70% ethanol solution or hypochlorite solution (bleach). Please wear adequate personal protective equipment. Helena Biosciences recommends at a minimum these should include safety glasses, gloves and laboratory coat.

9.14.2 Waste fluids bottle

The waste fluid bottle is designed to be re-usable. Waste fluids should be decanted into an appropriate container for disposal in accordance with local water rules. The full waste fluid bottle must be treated as biologically contaminated waste and handled with care. The cap on the waste bottle has an active liquid level sensor and so the V8 UltraCE will notify the user when it requires emptying.



WARNING

N.B. The waste bottle should only be rinsed with water. **DO NOT** use any cleaning agents on the bottle cap or the waste bottle, as these will affect the active liquid level sensor.



WARNING

Adequate personal protective equipment must be used. Helena Biosciences recommends at minimum these should include safety glasses, gloves and laboratory coat.

9.15 Re-location and re-installation of the V8 UltraCE

The operator must not attempt to move or relocate the instrument for valid health and safety reasons; and for reasons of maintaining the optimum performance of the instrument.

The instrument must be post-conditioned, prepared correctly and packaged in its ORIGINAL packaging. As such, the V8 UltraCE should not be re-located or re-installed without informing Helena Biosciences, or the official distributor of the company. Failure to do so may invalidate your warranty.

N.B. Please ensure that a Helena Biosciences trained and certified service engineer is contacted to arrange re-location and/or re-installation of the V8 UltraCE.

9.16 **Long-term storage of the V8 UltraCE**

Helena Biosciences recommend that the instrument is preconditioned at least twice a week. If the system is to be left unused for longer periods, please consult your Helena Biosciences representative for further instructions.

9.17 **High-risk samples**



WARNING



WARNING

All samples placed on-board the V8 UltraCE **MUST** be treated as high-risk and containing infectious or innocuous material. It is the responsibility of the user to ensure correct and safe handling of all samples. In the event of sample spillage on the system, please clean immediately with the recommended disinfectant (1% hypochlorite solution (see WHO Laboratory biosafety manual)) as per local guidelines. If required, the needle can be cleaned with alcohol (70% Ethanol or Isopropanol). The needle should only be cleaned when the V8 UltraCE is switched off.

Adequate personal protective equipment must be worn at all times when operating the V8 UltraCE. Local regulations or requirements should be consulted for precise instructions of correct clothing. Helena Biosciences recommends that at a minimum the following safety equipment is used:

- Safety gloves
- Safety protective glasses
- Laboratory workcoat or gown

9.18 **Notice to Users**

If any serious incident has occurred in relation to the device this should be reported to the manufacturer and the competent authority of the member state in which the user is established.

Appendix 1 V8 UltraCE troubleshooting

1.1

Common problems

Problem	Cause	Solution
The V8 UltraCE turns BLUE	<p>The cause of the blue light can be identified in Platinum in the Status and Error Message window.</p> <p>N.B. Please make a note of any messages that occur as these will help a service engineer.</p>	<p>The first step to resolving a blue light is to restart the instrument. This resets all calibration and mechanical movement.</p> <p>To do this, switch the instrument OFF using the power switch at the back of the instrument. To restart, turn the power switch at the back to ON and then press the side button to start a pre-condition.</p> <p>If after a restart the error reoccurs, or the instrument will not restart successfully, please contact the Service Department at Helena Biosciences Europe, or at your local distributor.</p> <p>In this instance, it is important that any error messages displayed in Platinum have been noted down and are passed to the Service Department.</p>
One capillary shows no peaks	No sample	Load sample
	Tube capped	Remove cap unless using a piercing and agitation method which allows sampling from capped tubes.
	Insufficient volume	Increase sample volume if possible or transfer sample to a microtube
	Fluid detection error	Rerun sample, if problem persists contact the service department
	Sample contains precipitate	Incubate the sample for 15 minutes at 37°C to remove cryoglobulin
	Capillary blocked	Condition capillaries and rerun sample. If problem persists contact the service department
All capillaries are showing no peaks	No sample	Load sample
	Insufficient volume	Increase sample volume if possible or transfer sample to a micro tube
	Lamp failure	Contact the service department
	Fluid detection error	Contact the service department
	Insufficient injection or high voltage failure	Contact the service department
Slow sample migration on one capillary	Sample build up on capillary wall	Condition capillaries and rerun sample
	Blocked capillary	Contact service department
Slow sample migration on all capillaries	Sample build up on capillary wall	Condition capillaries and rerun samples
	Temperature control error	Contact service department
	High voltage unit failure	Contact service department
	Problems with buffer composition	Try another buffer bottle
	Insufficient volume in sample cups	Contact service department
	Capillary lift error	Contact service department
Low signal response	Insufficient volume	Increase sample volume if possible or transfer sample to a microtube
	Low lamp intensity	Contact the service department
	Blocked capillary	Condition capillaries, if the problem persists contact the service department
	Viscous sample	Warm sample to room temperature and rerun

V8 UltraCE light display

V8 UltraCE light states are not to be used as an indication of instrument state. Platinum remains the primary user interface for instrument status. The V8 UltraCE visually communicates system status such as idle, busy, maintenance and fault status through colour coded system illumination. The following light states indicate systems status:

GREEN



- V8 UltraCE is ready to accept samples following the pre-conditioning cycle.
- Normal operation/system busy — quick pulsing light.
- V8 UltraCE is Idle — slow pulsing light.

ORANGE



- Pre-condition maintenance cycle.
- Post-condition maintenance cycle.

BLUE



- System error

V8 UltraCE audible feedback

Audible status updates will inform the user of automated instrument procedures, or when user intervention is required. Low buffers levels, error messages, maintenance cycles, system status reports and clinical waste limits will be communicated by an appropriate tone.

	Platinum Message	Action
ERROR MESSAGES	"Z motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"X-Motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Y-Motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Rack load motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Finger motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"CE motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Cup motor position cannot be reached, please restart the V8"	Restart instrument, if problem persists contact service.
	"Pressure leak – Servicing required"	Contact Service Department.
	"Method is not OK"	Restart instrument, if problem persists contact service.
	"Sample handling error - please restart the V8"	Restart instrument, if problem persists contact service.
	"Inlet lift or CE process error – please restart the V8"	Restart instrument, if problem persists contact service.
	"Waste pump stopped too early, trying again"	Restart instrument, if problem persists contact service.
	"Sample rack loading system re-initialising"	Restart instrument, if problem persists contact service.
	"Error occurred in high voltage unit"	Restart instrument, if problem persists contact service.
	"Error in temperature control"	Restart instrument, if problem persists contact service.
MESSAGES REQUIRING ACTION	"Unknown liquid, please scan bottle barcode"	Scan barcode of bottle in identified location.
	"Liquid missing"	Load required liquid, outstanding tests will begin with no further intervention.
	"Servicing required"	Contact service department.
	"Please replace the waste bin"	Replace waste drawer.
	"Please empty the waste bin"	Empty the waste drawer and replace onboard.
	"Please replace the waste bottle"	Replace fluid waste bottle and check bottle cap is detected by system (led illuminated).
	"Please empty and reconnect the waste bottle"	Empty waste bottle and replace.
	"Cup load tower empty, please load sample cups"	Refill sample cup load tower immediately
	"Sample cup load tower nearly empty"	Refill sample cup load tower soon
	"Sample tray missing"	Place sample tray onboard the V8 UltraCE
	"10% liquid remaining in bottle"	Place additional buffer onboard the V8 UltraCE to prevent system stopping due to insufficient reagents
	"Unachievable dilution without a sample tray"	Reduce override dilution
	"Max number of tests achieved – please load a new bottle"	Replace container with a new container
	"Fluid out of expiry date – please load a new bottle"	Replace with an in date product
	"Method is not OK, Big wash and Sample tray can't be used at the same time"	Remove the sample tray from the system to allow access to the big wash station

	"Duplicate barcodes in rack"	Barcodes will need to be manually entered as all barcodes will be removed from the rack. Remove one of the duplicate barcodes to allow all barcodes in the rack to scan
	"Rack barcode has not been scanned"	Reload the rack, or try a different rack if it fails again
Sensor Messages	"Front cover open"	Close cover
	"Top cover open"	Close cover
	"Rack cover open"	Close cover
	"Empty sample tray required"	Place a new sample tray onboard the V8 UltraCE.
	"New sample tray"	Enter sample tray ID to enable positive patient ID of samples loaded

	Platinum Message	Action
STATUS MESSAGES	"V8 and Platinum connected"	No action required
	"Starting V8"	No action required
	"Preconditioning Capillaries"	No action required
	"Postconditioning Capillaries and shutting down"	No action required
	"Starting analysis"	No action required
	"Asking for reflex tests"	No action required
	"Starting V8"	No action required
	"Purging outlet"	No action required
	"Purging needle"	No action required
	"Purging inlet"	No action required
	"Conditioning capillaries"	No action required
	"Waiting for front cover to close"	No action required
	"Waiting for top cover to close"	No action required
	"Waiting for rack cover to close"	No action required
	"Waiting for front cover to open"	No action required
	"Waiting for top cover to open"	No action required
	"Waiting for rack cover to open"	No action required
	"Sample rack found, preparing samples"	No action required
	"Liquid not available"	No action required
	"Empty sample tray required"	No action required
	"Saving tests for later"	No action required
	"Returning racks"	No action required
	"Applying pressure"	No action required
	"Applying voltage"	No action required
	"Setting reagent bay temperature"	No action required
	"Setting capillary temperature"	No action required
	"Change of method, need preconditioning"	No action required
	"There are capillaries disabled"	No action required
	"Filling remaining cups with buffer"	No action required
	"No liquid detected in reagent bay"	No action required
	"No liquid detected in sample tray"	No action required
	"Waiting for unknown liquids"	No action required
	"Waiting for conditioning to finish"	No action required
	"Carrying out saved tests"	No action required

	"Immediate reflex tests starting"	No action required
	"Starting re-conditioning"	No action required
	Platinum Message	Action
	"Cancelling all queued tests"	No action required
	"Unknown analytical method"	No action required
	"Adding queued tests to the worklist"	No action required
	"Max idle time reached - shutting down"	No action required
	"Picking up next cup"	No action required
	"Buffer cup loaded"	No action required
	"Sample cup loaded"	No action required
	"Asking for immediate reflex tests"	No action required
	"Inlet filled with liquid"	No action required
	"Outlet filled with liquid"	No action required
	"Applying current"	No action required
	"Adding queued tests to worklist"	No action required
	"Purging buffer lines"	No action required
	"Delay Shutdown"	No action required
	"System about to shutdown"	No action required