Routine Use Training Workbook

CS-2400/CS-2500

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Contents

Disclaimer

Please note, the information contained in training resources provided by Sysmex should not be used as an alternative to your sites Standard Operating Procedure (SOP)/Contract. If you have any particular questions regarding any site specific use of reagents, consumables and/or equipment please contact your Management Team.

Revision History

Revised section	Alteration	Name	Date
New Document	New document to replace the following documents: - CS-2400/CS-2500 Onsite Training Workbook	J Hammersley	October 2020
Recording maintenance	Removal of missed maintenance icon from maintenance record.	J Hammersley	July 2021
Reagent information screen icons	Addition of uncalibrated reagent icon to reagent information screen icons	J Hammersley	July 2021
Explanation of symbols	Addition of section	J Hammersley	July 2021
All sections	Updated in line with new branding	N Thompson	August 2024
Reagents	Replacement of Siemens reagents with Sysmex	N Thompson	September 2024

Reference Documents

Document title	Version	Date
CS-2400/CS-2500 Instructions for Use	BN345704	December 2022
CS-2400/CS-2500 SOP – Maintenance	V2.0	September 2020
CS-2400/CS-2500 SOP – Loading Reagents	V5.0	September 2020
CS-2400/CS-2500 SOP – QC and Sample Processing	V2.0	September 2020

Explanation of Symbols

Symbol	Explanation
	**Risk of infection -** Always be aware of the dangers of infection, use caution and take appropriate measures
	**Risk of Injury -** Always be aware of the dangers of injury due to sharp objects, use caution and take appropriate measures.
	**Caution –** Potentially hazardous situation, use caution and take appropriate measures to avoid injury or harm.

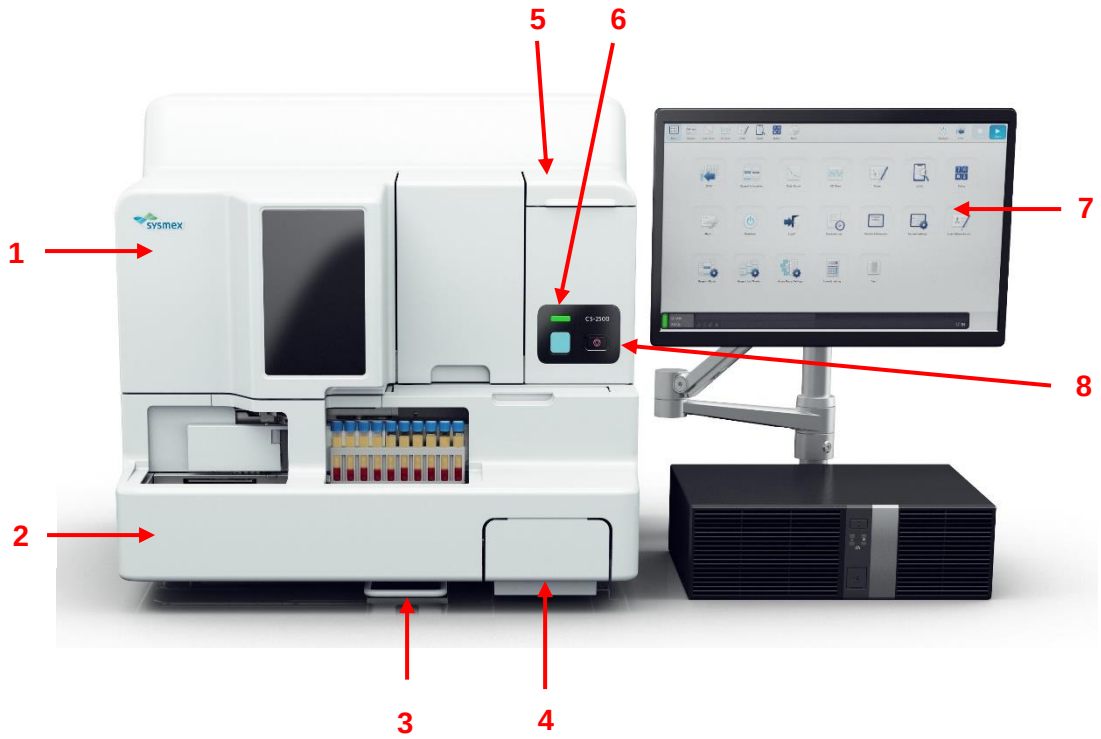
CS-Series Overview

The CS-Series analysers are fully automated blood coagulation analysers intended for in vitro diagnostic use to perform assays using clotting, chromogenic, immunoassay and aggregation methods. The primary sample for analysis is the plasma component of human blood with added anti-coagulant (sodium citrate).

Facts and figures	
Analysers	CS-2000i/2100i, CS-2400/2500 & CS-5100
Analytical Principles	Clotting assays Chromogenic Assays Immunoassay Aggregation
Detection Methods	Multi-Wavelength Detection System
Evaluation Methods	Percentage detection method – clotting assays only Rate method – Chromogenic assays, immunoassays and aggregation assays VLin Integral method – immunoassays only
Modes of Analysis	Normal Mode Micro Mode STAT Mode
Aspiration Methods	System Analysis (tracked integration, see specific analysers) Sampler Analysis Manual Analysis (Closed/Open/Micro)
Aspiration Volumes	PT: 50µl APTT: 50µl FibC: 10µl DDimer: 15µl
Throughput	CS-2000i/2100i mid volume market – 180 tests/hr CS-2400/2500 mid volume market – 180 tests/hr CS-5100 high-volume market – 400 tests/hr

CS-2400/CS-2500 Components

CS-2400/CS-2500 Components



1. **Main Unit** – This is where samples and QC material are processed.

2. **Sampler Unit** – Where the sample racks are placed for samples to be processed. Five racks can be placed on the right-hand side of the sampler unit at once, allowing for 50 samples to be loaded simultaneously. The CS-2400/CS-2500i will alarm if the left-hand side of the sampler unit is full to inform the user that racks need to be removed before further samples can be analysed. A barcode reader to the rear of the sampler unit scans each sample barcode first before it starts the rack (all 10 positions) and then each sample again individually before the sample is aspirated, for this reason DO NOT add or remove samples from the rack on the measurement line (the rack nearest the analyser).

3. **Condensation Tray (Tray No 48)** – Used to collect condensation depending on environmental conditions. Should be checked as part of daily maintenance.

4. **Cuvette Trash Draw** – For storage of used cuvettes, holding up to 500 at any time. CS-2400/CS-2500 will alarm at >400 and ask the user to empty the drawer the next time the analyser enters standby mode.

5. **Cuvette Hopper** – Storage of reaction cuvettes for use during QC/sample analysis. 500 cuvettes can be stored. If the cuvette hopper is overfilled, it can lead to cuvette hopper jams so avoid filling above the red line.

6. **Status Light** – Shows the status of the CS-2400/CS-2500:

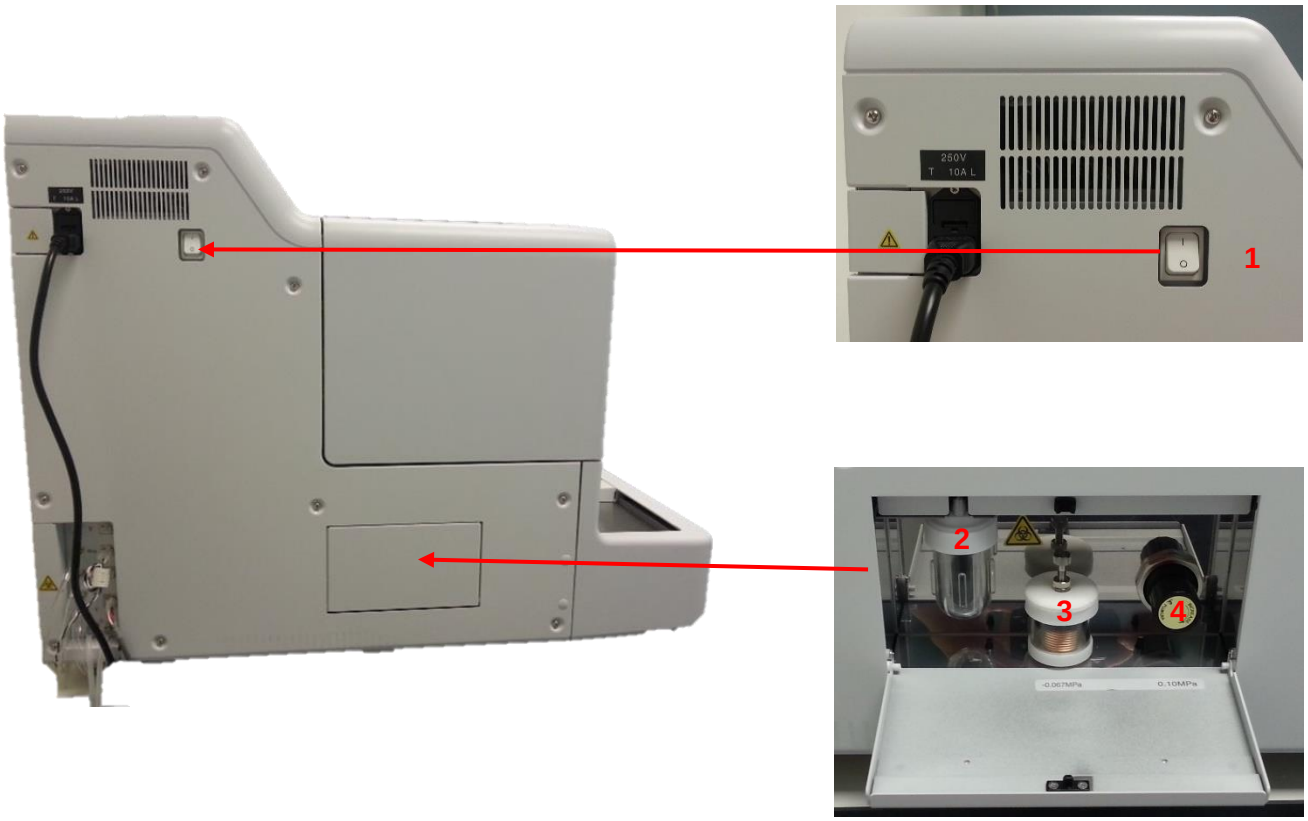
Colour	Status of Analyser	Message on IPU
Green	Ready to start analysis/ analysis interrupted by interruption operation	[Ready]/ [Int. Ready]
Flashing Green	Warming up/ analysing/ analysis is being performed or the instrument is being operated	[Warming up]/ [Processing]
Orange	Analysis has been interrupted and consumables have been used up/ The analysis can be started but the consumables are low	[Int. Ready]/ [Ready]
Flashing Orange	The analysis is being performed or the instrument is being operated, and the consumables are low	[Processing]
Red	The analysis has been automatically stopped by the instrument	[Int. Ready]
Long Flashing Red	The analysis cannot be started due to an error	[Not ready]
Grey	Main unit is not connected	[Off]

7. **Information Processing Unit (IPU)** – The IPU runs the operating software for the CS-2400/CS-2500 and acts as the user interface for the analyser. The IPU holds up to 10,000 complete sample records in its database and can be connected with a bi-directional interface to a hospital network allowing upload of test orders and patient demographics along with downloading of test results back to the host. All settings, calibration files, and flagging limits are also stored on the IPU.

8. **Start & Stop Buttons** – Blue and black buttons to start and stop the analyser, respectively. The start button will commence the automatic feeding of sample rack/s on the sampler unit. Racks will continue to feed through the analyser until no further racks remain on the right hand side of the sampler unit (status light turns green), when the next rack/s is placed onto the CS-2400/CS-2500 the start button will need to be pressed again. The stop button is a mechanical stop button which will halt the analyser and all tests currently being processed will be immediately aborted.

9. **Pneumatic Unit (Compressor) NOT DISPLAYED** – Supplies pressure and vacuum to the analyser. Also contains the 0.22 MPa pressure adjustment knob (top right). Following the IPU alarm indicating this pressure is outside of the desired range, loosen the screw on the end of the knob to allow adjustments to be made, when complete tighten the screw to keep the pressure stable.

CS-2400/CS-2500 Left Side Components



1. **Power Switch** – Used to turn the analyser ON and OFF.

2. **Pneumatic Trap Chamber** – The vacuum trap collects any fluid if a line becomes blocked therefore ensuring fluid cannot enter the pneumatic unit.

3. **Vacuum Adjustment Knob (-0.067 MPa)** – If the CS-2400/CS-2500 alarms warning of a vacuum error, adjustments are made using this knob. Before the vacuum can be altered the small nut needs to be loosened.

4. **Pressure Adjustment Knob (0.10 MPa)** – If the CS-2400/CS-2500 alarms warning of a pressure error (0.10 MPa) adjustments are made using this knob. Before the pressure can be altered the knob needs to be pulled out until 1 click is heard, following adjustment the knob should be pressed back into place.

5. **Air filter** - The instrument includes a filter to block the entry of dust. The filters should be cleaned regularly as part of the monthly maintenance.

CS-2400/CS-2500 Right Side Components

1. **Network Cable** – The network cable (blue), located top right, is used for communication between the CS-2400/CS-2500 and the IPU. It is essential for this cable to be connected correctly to allow the IPU to 'talk' to the CS-2400/CS-2500.

2. **Rear Air filters** - The instrument includes 3 rear air filters to block the entry of dust. The filters should be cleaned regularly as part of the monthly maintenance.

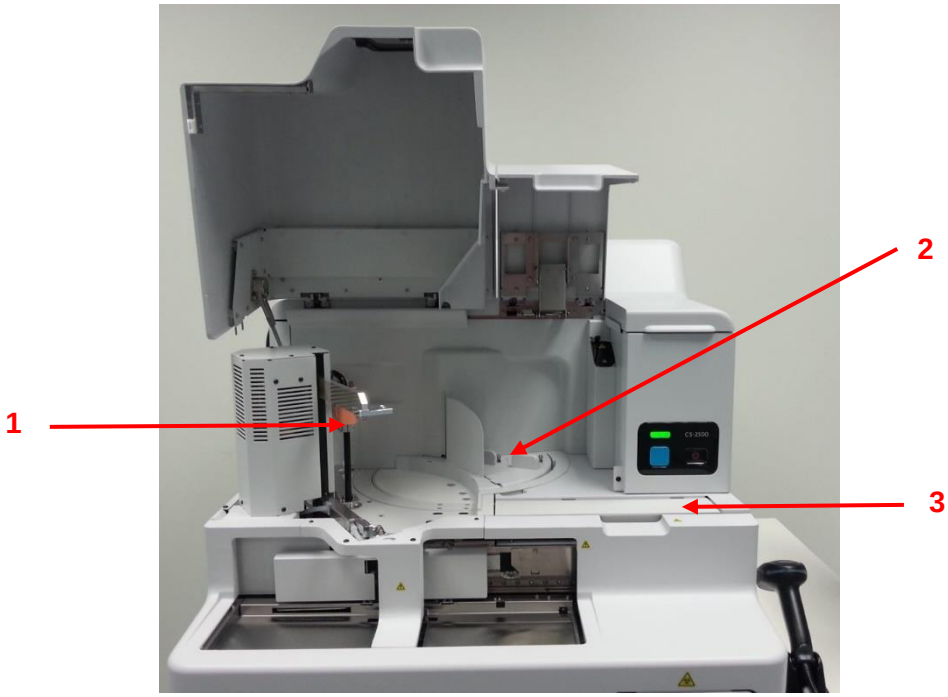
3. **Halogen Lamp** – The lamp is used during all sample analysis. A message will appear asking the user to change the lamp when it reaches 1000 hours (approx. 41 days).

CS-2400/CS-2500 Under Bench Components

1. **Waste Keg (Where applicable)** – Container for collection of waste (10 litre capacity).

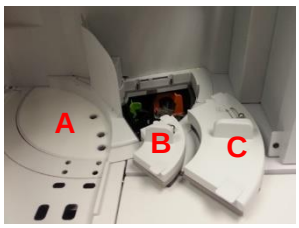
2. **Rinse Keg** – Holds the rinse (distilled or deionised water), this MUST be changed on a daily basis to prevent possible algae growth in the kegs (this can lead to contaminated lines which can affect QC/patient results) (20 litre capacity).

CS-2400/CS-2500 Internal Components



1. **Sample Arm** – Used for primary dispensing of capped (CS-2500 only) and uncapped samples. Aspirates and dispenses samples and controls.

2. **Reagent Table** – Main reagent storage area. In this compartment the reagents are kept at ~10ºC to maximise their onboard stability. The user can load up to 40 reagents at any time (depending on bottle size) and the reagents can be placed anywhere in the reagent table (no fixed reagent positions). There are 3 removable lids (A, B & C) in this section and a cuvette ring cover. LED lights indicate whether you can access each section when in operation.

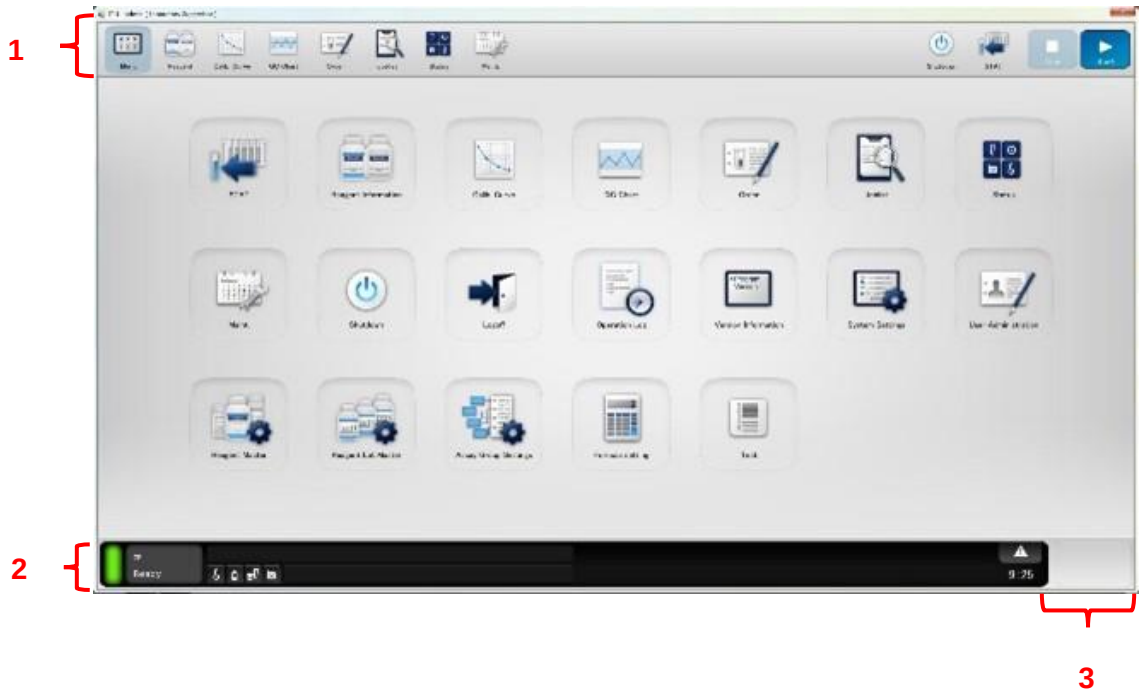


3. **Buffer Table/STAT Holder** – Storage area for up to 5 buffers and diluents, using the supplied bottle/cup holders (identified by the 2 metal prongs at the bottom of the holders). The buffers are kept at room temperature in this compartment. There are also 5 positions for STAT samples to the left of this compartment, where uncapped samples are placed and will be prioritised over other work.

4. **Reagent Arm (Not Shown)** – Hidden behind the cover. The reagent arm is responsible for aspirating onboard reagents and adding them to reaction cuvette.

IPU Software Layout

Menu Layout



1. **Toolbar** – The tool bar contains shortcut buttons for the main functions.

Displays the ‘Menu’ screen as pictured.

Used to view reagent information, add/remove reagents and load new lots.

Displays the ‘Calibration Curve’ screen.

Used to view QC results as well as load new lots of QC.

Displays the ‘Order’ screen. Used for ordering samples manually as well as QC and calibration curves.

Used to view patient results, print results and send results to host.

Displays ‘Status’ screen. Used to view cuvette, pressure and cuvette trash status as well as load cuvettes for aggregation studies.

Displays ‘Maintenance’ screen. Used to view maintenance performed and due, register maintenance being performed, view lamp hours etc.

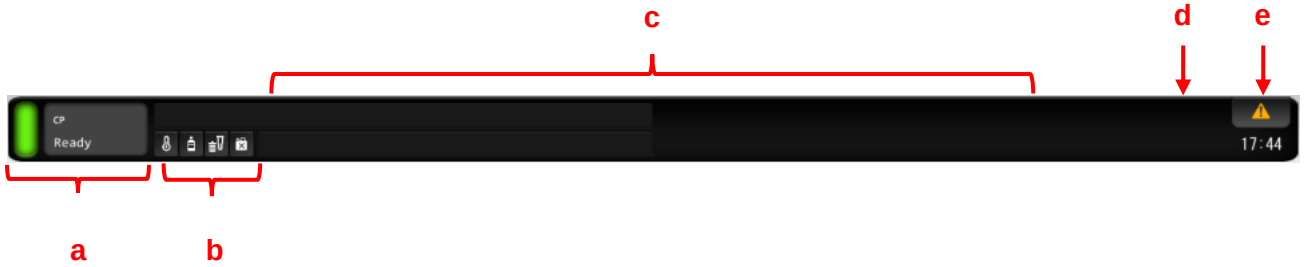
Used to shut-down CS-Series analyser.

Displays ‘STAT’ screen.

Interrupts analysis. Analyser will finish processing what has been started and then stop.

Starts analysis.

2. Status – Displays operating functions for the instrument.



a. Main Unit Status – Displays analyser status light, status message and nickname.

Colour	Status of Analyser	Message on IPU
Green	Ready to start analysis/ analysis interrupted by interruption operation	[Ready]/ [Int. Ready]
Flashing Green	Warming up/ analysing/ analysis is being performed or the instrument is being operated	[Warming up]/ [Processing]
Orange	Analysis has been interrupted and consumables have been used up/ The analysis can be started but the consumables are low	[Int. Ready]/ [Ready]
Flashing Orange	The analysis is being performed or the instrument is being operated, and the consumables are low	[Processing]

Red	The analysis has been automatically stopped by the instrument	[Int. Ready]
Long Flashing Red	The analysis cannot be started due to an error	[Not ready]
Grey	Main unit is not connected	[Off]

b. Indicator Icons – Further details on the status icons can be found in the 'Status' screen.

Indicator Icon	Colour	Meaning
 Indicates the temperature of reagent cooling unit, reagent probe, detector and sample incubator.	**Red**	Temperature outside normal
	Grey	Main unit not connected
 Indicates remaining reagent volume. **NOTE:** Does not specify which reagent is affected.	**Yellow**	Reagent running low
	Red	Reagent/detergent run out
	Grey	Remaining volume unknown as main unit not connected
 Indicates the remaining number of cuvettes or status of the cuvette trash box.	**Yellow**	Remaining cuvettes and/or trash box capacity are low
	Red	Set cuvettes or no remaining capacity in trash box.
	Grey	Main unit not connected
 Indicates the remaining rinse water.	**Yellow**	Rinse water is used up
	Red	There is no rinse water
	Grey	Main unit not connected

c. Messages – Displays analyser warning or error messages.

d. Remaining Time – displays the time remaining until light shield is unlocked when instrument status is [Int.Ready] or [Not Ready].

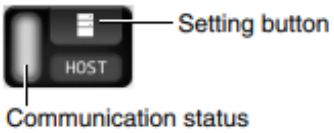
e. Help Button - Displays the status of an error/warning:

All errors have been corrected. Allows access to error log when error has not been triggered.

Error awaiting correction.

3. Host Connection (not shown):

Colour	Meaning
Green	Connected
Red	Error
Not displayed	Host not connected



Quick Guides

Maintenance

Detailed instructions for daily, weekly, monthly and as required maintenance can be found in CS-2400 CS-2500 SOP – Maintenance: SOPs | Caresphere Academy UK (caresphere-academy.com)

Daily Maintenance 

On a daily basis the following maintenance should be performed:

- Instrument shutdown
- Change water in the rinse keg. **IMPORTANT:** Do **NOT** top up rinse water.
- Discard waste fluid (if applicable)
- Check condensation Tray (No 48.)
- Check reagent trays for condensation
- Check the vacuum trap for fluid
- Instrument start-up. This includes an automatic ‘rinse probe’.
- Fill the cuvette hopper. **IMPORTANT:** Do **NOT** fill over the red fill line as this will cause cuvette jams.
- Discard used reaction cuvettes
- Perform additional manual ‘Rinse Probe’.

Weekly Maintenance 

On a weekly basis the following maintenance should be performed:

- Cleaning the instrument surfaces
- Cleaning the rinse tank

Monthly Maintenance 

On a monthly basis, the following maintenance procedures should be performed:

- System back-up
- Changing and calibrating the halogen lamp
- Cleaning the filters

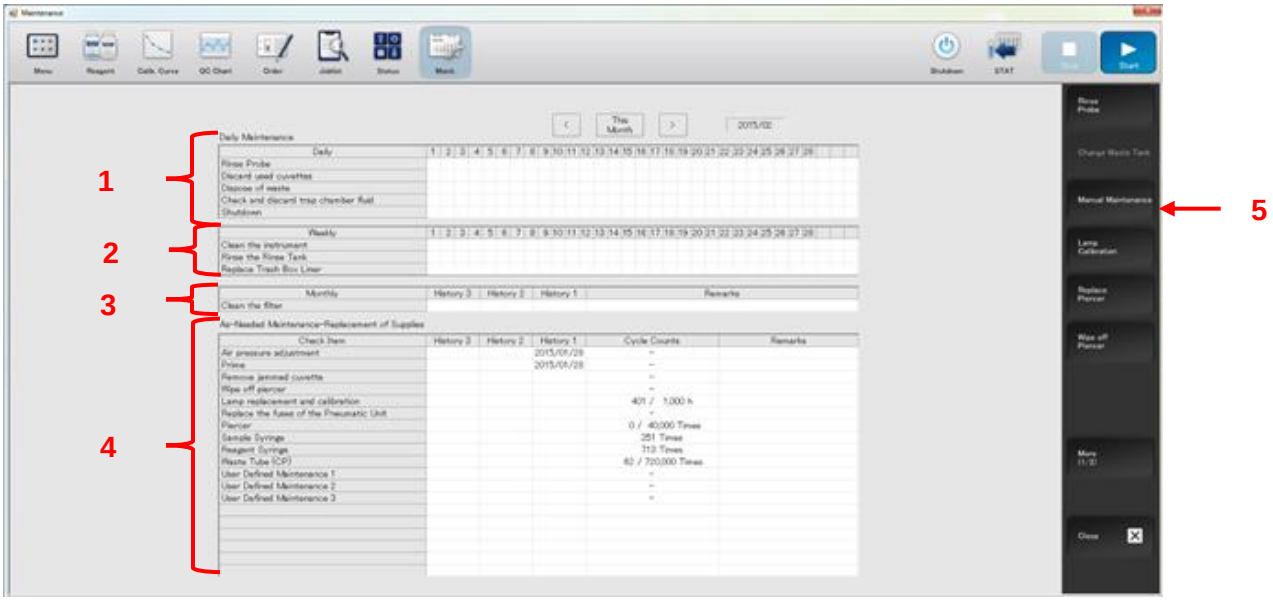
As Required Maintenance 

As required maintenance consists of:

- Probe decontamination. **IMPORTANT:** This should only be performed under the guidance of Sysmex Customer Support and never more than once a week.
- Removing jammed cuvettes
- Reset probe cycle counter. **NOTE:** This procedure is required when the maximum cycle count is reached and must be accompanied by a call to the Sysmex Customer Support Centre to book a service visit to change the probe in question.
- Wipe piercer. Only required if the piercer becomes dirty.
- Adjusting pressures

Recording Maintenance

All maintenance procedures should be recorded in the ‘Maintenance’ screen.



○ Task outstanding

● Maintenance task has been implemented

○ (yellow) Maintenance task has been missed

1. **Daily Maintenance Check List** – Lists daily maintenance to be performed and indicates the status of each action.

2. **Weekly Maintenance Check List** – Lists weekly maintenance to be performed and indicates the status of each action.

3. **Monthly Maintenance Check List** – Lists monthly maintenance to be performed and indicates the date of each action.

4. **As Need Maintenance** – Lists as required maintenance and indicates the date of each action. Also contains user definable maintenance.

5. **Manual Maintenance** – used to record any manual maintenance such as ‘Discard used cuvettes’, ‘Rinse the rinse tank’, ‘Clean the instrument’ or any user definable maintenance

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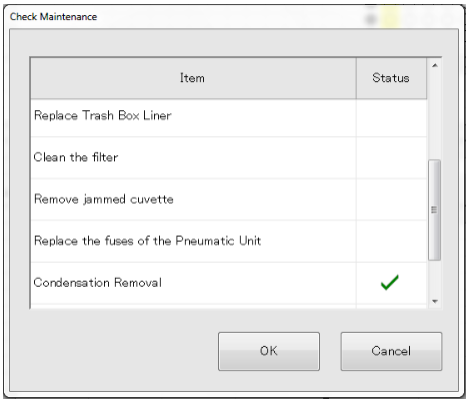
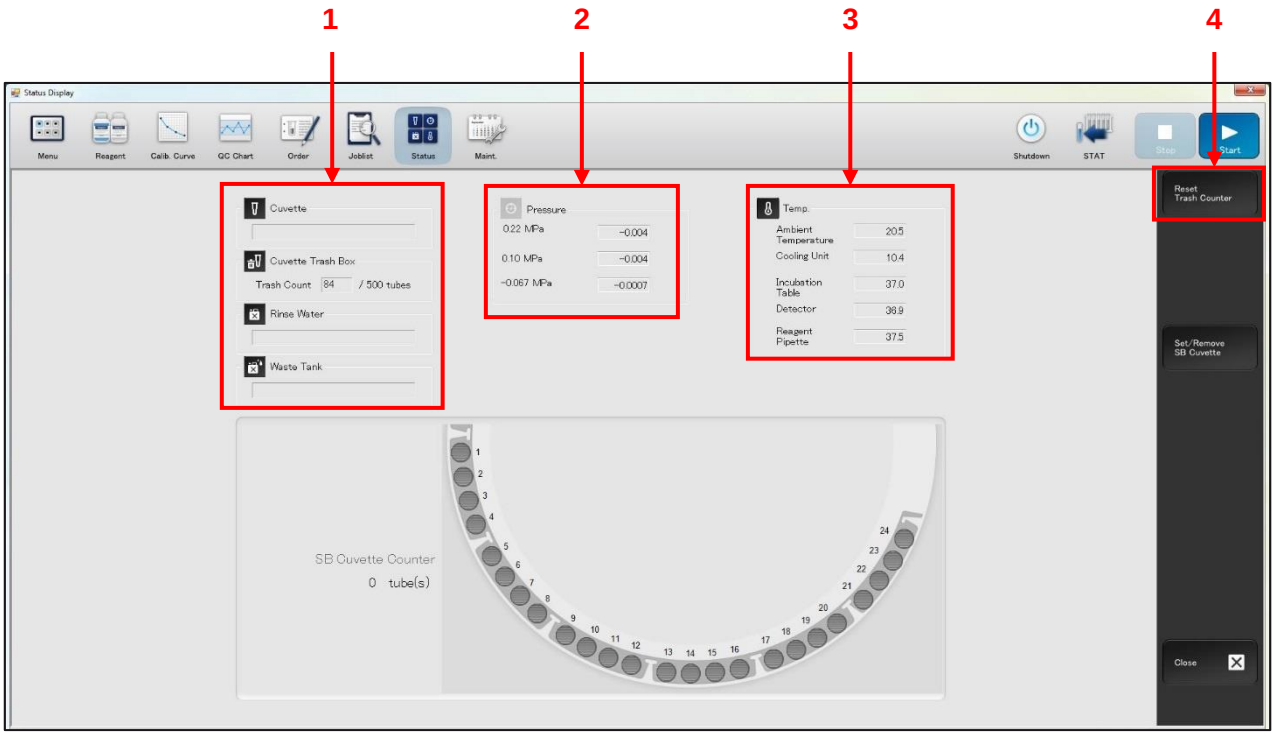


Checking the Analyser Status



1. **Cuvette/Rinse/Waste Status** – 'Cuvette' will turn yellow when running low and will turn red when insufficient. The number of cuvettes in the trash box can be seen below 'Cuvette Trash Box' and when this reaches >400 the analyser will alarm asking the user to empty the box. 'Rinse Water' will turn red when the rinse is empty and if the analyser has a waste keg attached (and the alarm is active) the 'Waste Tank' will turn red when the waste is full and requires emptying.

2. **Pressure Status** – Shows the current pressures and vacuum of the analyser.

3. **Temperature Status** – Shows the current temperatures of the various ambient/analyser components.

4. **'Reset Trash Counter'** – This button can be used to reset the 'Cuvette Trash Box' count to '0' manually. If the cuvette trash drawer is removed when the analyser is on, it will automatically detect that the drawer has been removed and replaced and then prompt the user to reset the count to '0'.

Reagents

There are numerous different reagents that can be used on the CS-Series analysers, the list below gives information on the basic reagents for the most common tests. The name of the test, reagent name, recommended quality controls and calibrators are given in the table. Reagent onboard stability can be increased by using evaporation caps. Please refer to appropriate reagent application sheet for further details.

Test	Reagents	Reagent Onboard Stability	QC material	Calibrator
PT	Innovin OR Thromborel S	96 hrs	CiTrol 1 & 2	PT Multi-Calibrator or in house Mean Normal PT
APTT	Actin FS OR Actin FSL OR Pathromtin SL and $CaCl_2$	96 hrs	CiTrol 1 & 2	Mean Normal APTT In House
Thrombin Time	Thromboclotin	96 hrs	CiTrol 1	None Required
Clauss Fibrinogen	Thrombin and OVB	96 hrs 60 hrs	CiTrol 1 & Control Plasma P or Dade Data-Fi Abn Fibrinogen Control	Standard Human Plasma
D-Dimer	Innovance Kit (4 reagents)	48 hrs	D-Dimer Control 1 & 2	D-Dimer Calibrator
Anti Xa	Biophen Heparin LRT Kit (2 reagents)	7 days	Control 1 to 4*	Related to the assay*

* 1 kit but different QC's and calibrators depending on type of heparin being measured, i.e. LMWH, UFH, Rivaroxaban, Apixaban and Edoxaban.

IMPORTANT: Always check the application sheets/reagent inserts for possible changes. Pink application sheets indicate something has changed, for example, onboard stability. Application sheets can be found in the 'Regulatory section' of Caresphere Academy.

Cleaning Reagents

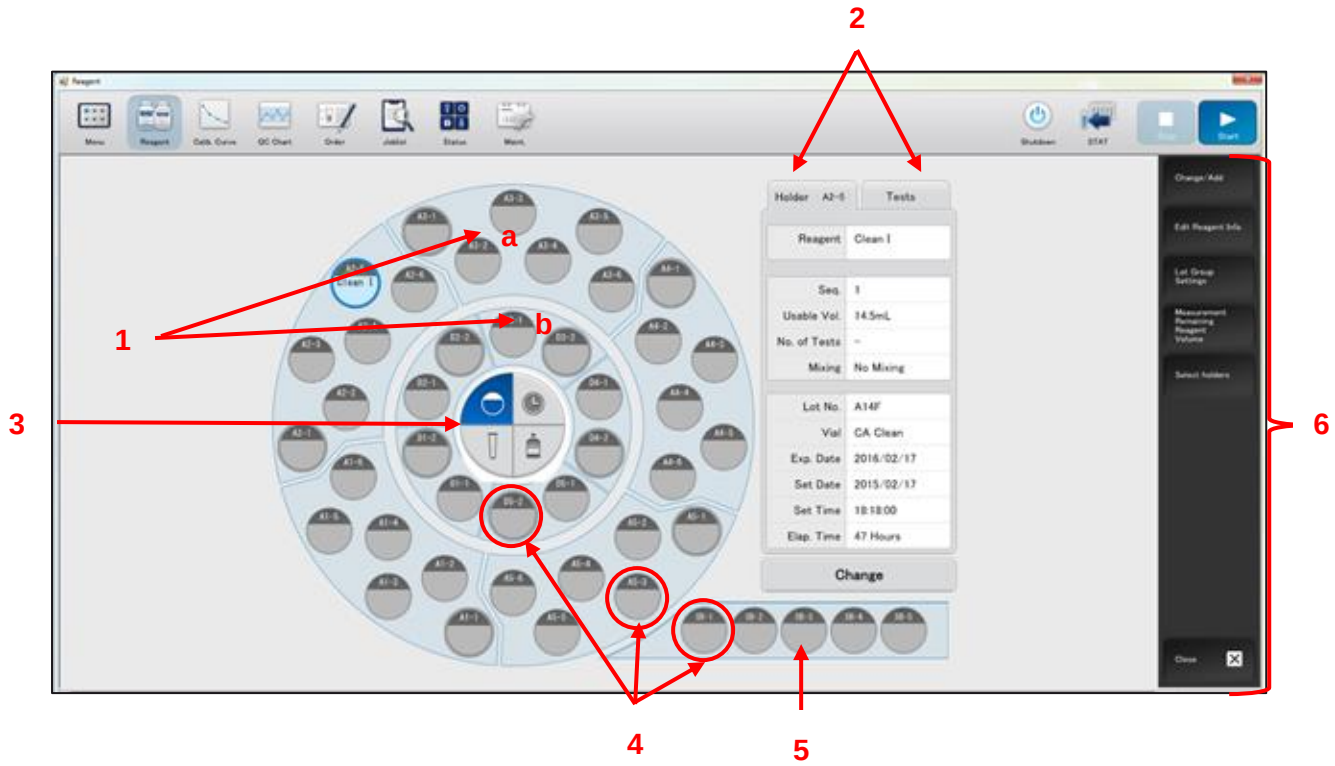
Two reagents are required for cleaning the lines in between samples, cleaning the probes and for the daily shutdown procedure:

1. **CA Clean I:** Bleach based solution used for general cleaning of the lines and used during daily maintenance. Must be replaced every 5 days. **NOTE:** CA Clean I is supplied in a similar bottle to CellClean which is a concentrated bleach used on the Sysmex Haematology analysers. Do **NOT** put CellClean on the CS-Series analysers.

2. **CA Clean II:** Acid based solution used to clean the probes inside and outside.

Reagent Information Screen

The ‘Reagent Information’ screen displays all information regarding reagents loaded on the to the CS-Series analyser and is used to load or remove reagents from the reagent table or buffer table as well as edit reagent information of lot group settings.



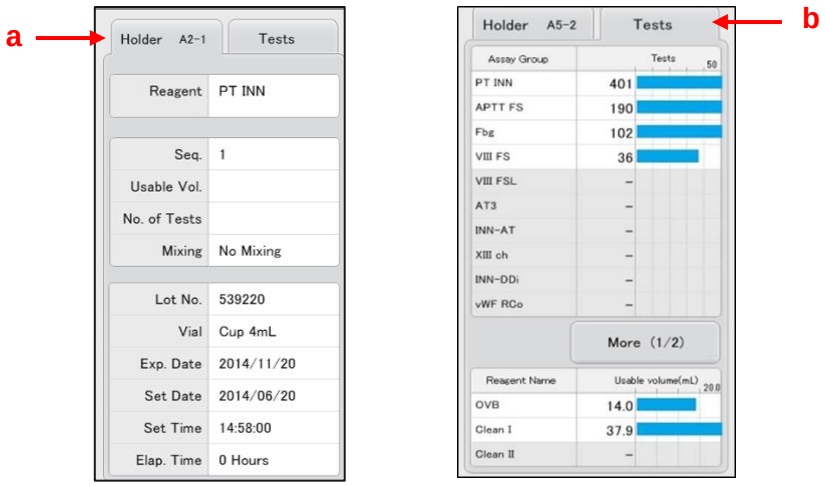
1. **Reagent Wheel –** The reagent wheel is composed of an inner and outer wheel in which up to 40 reagents with fixed position are kept at ~ 10ºC. All positions and reagents are barcode identified for positive reagent identification. Reagent bottles must be placed into segments with their lids OFF and barcodes facing forward or in cups with appropriate barcode placed on the adaptor**.**

    a. **Outer Wheel** – Consists of 5 segments labelled A1 to A5, with each segment containing 6 reagent positions.

    b. **Inner Wheel** - Consists of 5 segments labelled D1 to D5, with each segment containing 2 reagent positions.

IMPORTANT: When moving reagents between analysers move the reagent bottle and not the segment as each CS-Series analyser has reagent wheel segments labelled A1 to A5 and D1 to D5 and are unable to deal with duplicate segment labels.

2. **Holder/Test Tab** –



a. Holder Tab - provides the reagent information when a specific location in the reagent wheel is highlighted.

b. Test Tab – provides information on the number of tests that can be run at that time.

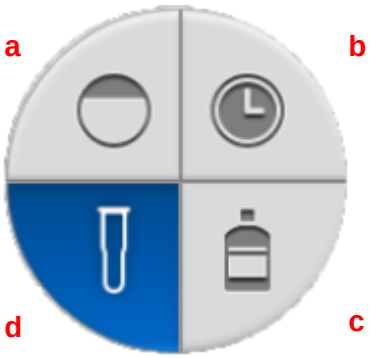
3. **Reagent Holder Display Options** – Allows the user to switch the reagent holder display information for each vial loaded onto the reagent and buffer tables.

a. Visual representation of reagent volume.

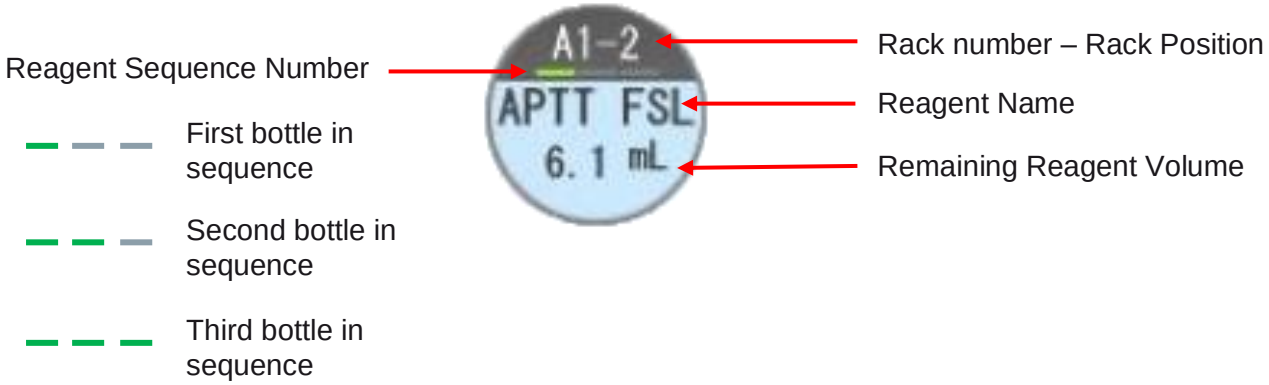
b. Indicates how long the reagent has been on board the analyser.

c. The volume of reagent onboard.

d. Number of tests available within each reagent bottle.



4. **Reagent Holder Display** – Displays information about the reagent in the selected position.



5. **Buffer Table** – The buffer table is kept at room temperature and has 5 reagent positions labelled SB1 to SB5. It displays information about the reagents loaded into the buffer table and is used to add or remove reagents. Reagent bottles must be placed into segments with their lids OFF and barcodes facing forward or in cups with appropriate barcode placed on the adaptor**.**

6. **Reagent Information Screen Options**

[Change/Add]	Used to change or add reagent.
[Edit Reagent Info]	Used to edit reagent information such as set date and time or enter expiry date the first time a new lot of reagent is placed on board the CS-Series.
[Lot Group Setting]	Allows the user to view which reagent lot is being used for each assay or assay group. One type of reagent can be used in multiple assays.
[Measurement Reagent Remaining Volume]	Used to measure the remaining volume of all reagents on aboard the analyser.
[Close]	Closes 'Reagent Information' screen to display last screen left open.

Other Reagent Information Screen Icons

A reagent that has been seen and used by the system before so the volume and number of tests can be displayed by using the reagent holder display options or by selecting the reagent followed by the holder tab.

A reagent that has been seen by the system but is yet to be used, so the remaining volume and number of tests available is unknown. The background will turn blue and this information will be updated after it's first use.

Empty reagent position.

Barcode not read. For example, if a reagent is placed in an adaptor without an attached barcode and thus cannot be identified. Other examples: no barcode on reagent or incorrectly formatted barcode.

A new batch/lot number of reagent has been placed onboard. The system will require an expiry date to be entered into the [Edit Reagent Info] option before it can be used.

Reagents have passed the expiry date stated on the reagent bottle. Replace with in-date reagent.

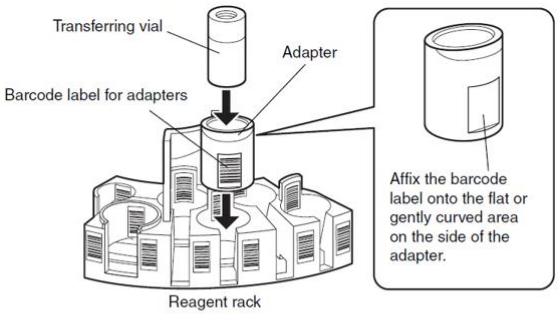
No calibration curve exists for reagent

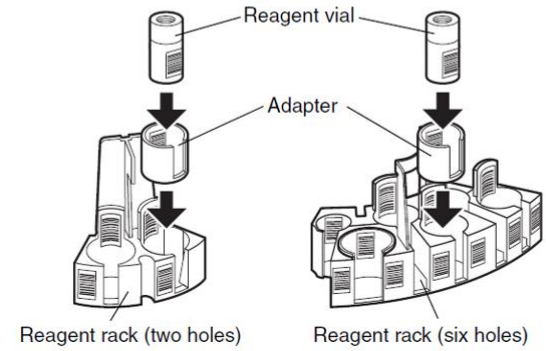
The reagent or buffer is in the wrong place. Remove buffer from the reagent carousel (10ºC) and place onto the buffer table (room temperature) or vice versa.

Third party reagent not set in ‘Reagent Master’ screen or new lot of Sysmex reagent where new reagent barcode ID has not been added to ‘Reagent Master’ screen. No reagent name is displayed behind the red X – Please contact the Sysmex Customer Support Centre (CSC).

Loading Reagents

1. Select [Reagent Information] from ‘Menu’ Screen or [Reagent] from the toolbar.
2. Select an empty reagent position in the reagent or buffer table as appropriate for the reagent(s) being loaded.
3. Select [Change/Add]. Reagent table will rotate so that selected position/segment is at the front of the reagent wheel access. If buffer table is selected, the buffer table will move underneath buffer table access lid.
4. When corresponding LED indicator is green, open section access lid and load reagent(s) with lid off (in adaptor if required) or in cup within appropriate adaptor. All barcodes must be facing forward.
5. Close section access lid and click [OK].





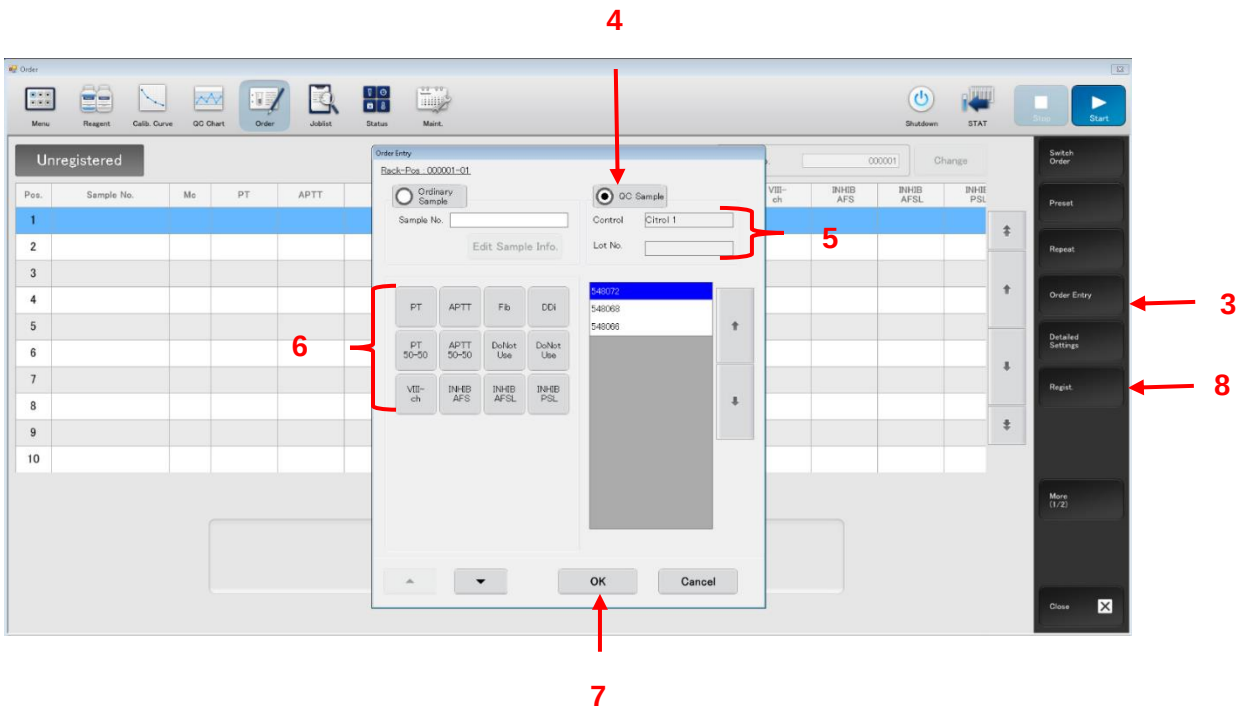
Detailed instructions for loading reagents can be found in CS-2400 CS-2500 SOP – Loading Reagents SOPs | Caresphere Academy UK.

Quality Control (QC)

QC can be run using 2 different methods, either from a sample rack or from within the instrument (in the reagent table). Detailed instructions for running QC can be found in CS-2400 CS-2500 SOP – QC and Sample Processing SOPs | Caresphere Academy UK (caresphere-academy.com).

Running QC from a Sample Rack

1. Select [Order] icon from 'Menu' or toolbar.
2. The 'Rack Order' screen will now be displayed. Select appropriate rack position.
3. Select [Order Entry].

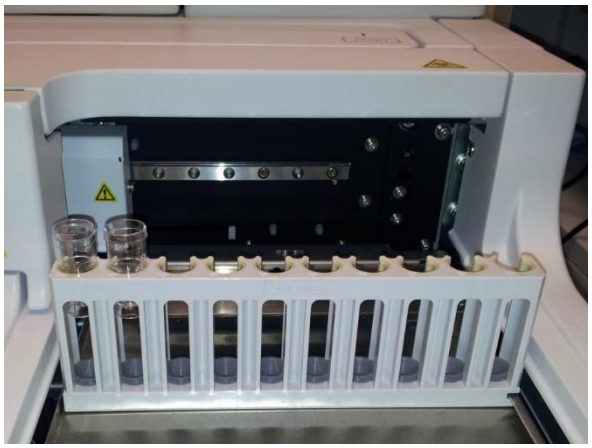


4. Select [QC Tab].
5. Select desired [Control] and [Lot number].
6. Select test that requires controlling. **TIP:** To enter further tests in the [Order Entry] screen press the down arrow ▼ to select rack position 2 and repeat the above procedure, therefore up to 10 controls can be ordered per rack.
7. Select [OK].

8. When all orders are complete press [Regist.]. **NOTE:** It is recommended that when QC is run from a sample rack that 'micro' mode is used to preserve the QC material. For each QC request (each line) select the [Micro-Sample Mode] box.

9. Place the QC material/s into the sample rack in an appropriate container, and place rack onto the sampler tray, ensuring they are in the correct rack position as requested above.

10. Press [Start] on the IPU or press the start button on the front of the instrument.



IMPORTANT: When running QC material from the reagent table, once reconstituted QC material must be either:

- Transferred into cups, inserted into the appropriate adaptor and loaded in 'A' (**orange**) or 'D' racks (**green**)

  OR
- Transferred into SLD mini vials, inserted into the corresponding QC vial and loaded in the appropriate 'C' rack (**yellow**) reagent table racks.

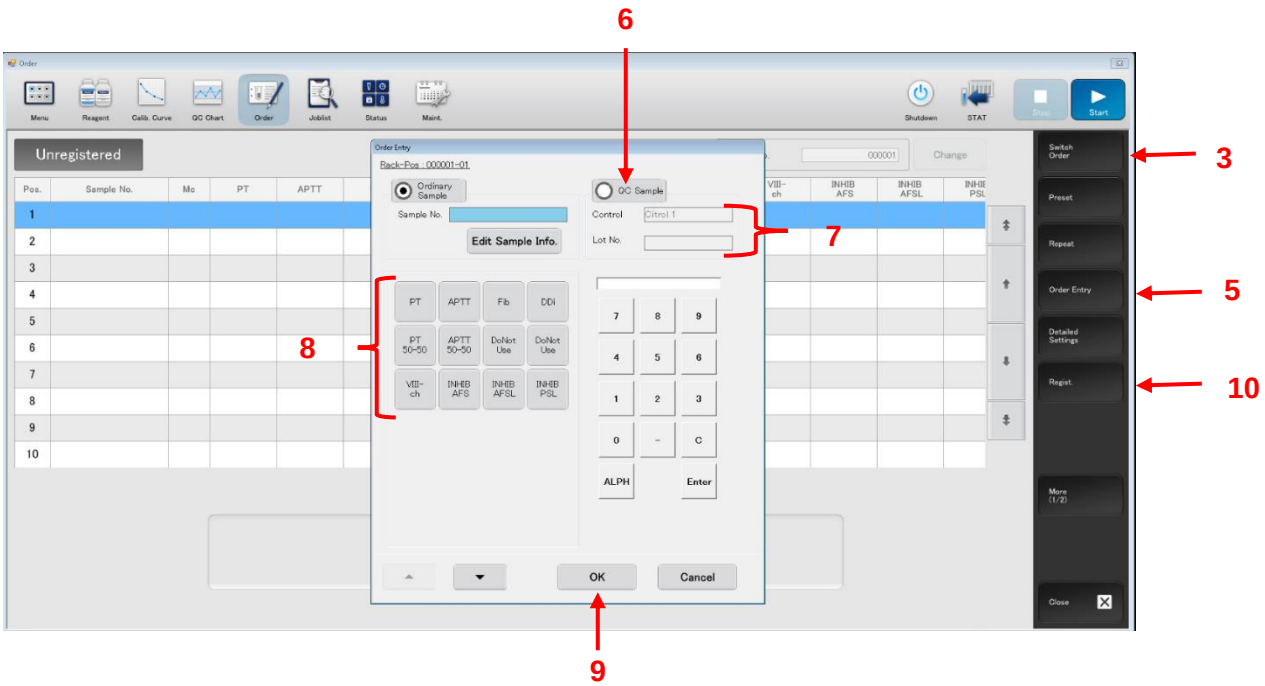
Please see CS-2400 CS-2500 SOP-Loading reagents for full details.

1. Ensure all QC material has been loaded on to the reagent table.

2. Select [Order] icon from 'Menu' or toolbar.

3. The 'Rack Order' screen will now be displayed. Select [Switch Order].

4. Select [QC Holder].



5. Select [Order Entry].

6. Select [QC Tab].

7. Select desired [Control] and [Lot number].

8. Select test that requires controlling. **TIP:** To enter further tests in the [Order Entry] screen press the down arrow ▼ to select rack position 2 and repeat the above procedure, therefore up to 10 controls can be ordered per rack.

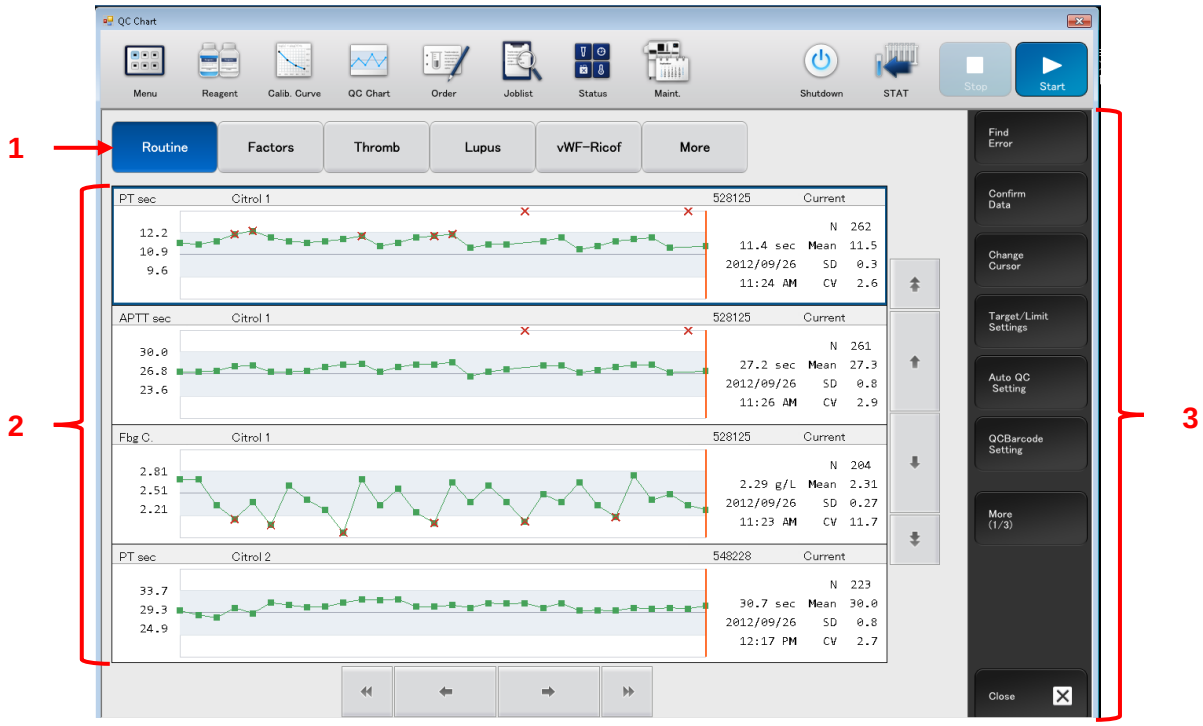
9. Select [OK].

10. When all orders are complete press [Regist.].

11. Press [Start] on the IPU or press the start button on the front of the instrument.

Viewing QC Results

QC results can be viewed in the [QC Chart].



1. **QC Option Tabs** – QC option tabs are customisable and allow QCs to be split into test types, for example, [Routine], [Factors] and [Thrombo]. Where the 'Routine' tab contains QC charts for PT, APTT, Fibrinogen, Thrombin Time and D-Dimer.

2. **QC Charts** - Individual charts display; test name, control, control lot number and statistics, number (N), mean, SD and CV. For the data point selected the result date and time are also displayed. Failed QC is marked with a x and is accompanied by a change in QC Chart background colour. QC results outside the upper/lower limit but within the stop limits (if different) will be highlighted in **orange**. QC results outside the upper/lower stop limits will be backlit in **red**. Sample analysis is paused, and the status light on the front of the analyser will turn red. **IMPORTANT:** Out of range QCs should be repeated before proceeding with further sample analysis. If a batch of reagent has changed, the cursor shape will change on the QC chart.

3. QC Chart Options

[Find Error]	Used to select the next chart with an error when errors have occurred in more than one test QC. When an error occurs QC chart background will turn **red** if stop condition is breached or **orange** if QC result is out of range but within stop condition limit.
[Confirm Data]	Allows the user to add comments to an individual QC result and if required remove the result from the statistics. It does NOT delete the QC point.
[Change Cursor]	Used to select a QC range to view range specific statistics or to be exported or printed.
[Target Limit Settings]	Used for setting QC targets and limits.
[Auto QC Setting]	Used when auto QC for a specific assay is not required for a specified period.
[QC Barcode Setting]	Used to set up QC barcodes. This allows QC analysis to be run via host query and QC results to be outputted to host.
[Delete]	Deletes selected QC point.
[Add Lot]	Used to add a new lot to the QC chart.
[Change Lot]	Used to change ‘New Lot’ to ‘Current Lot’.
[Change Scale]	Used to change the number of QC data points displayed on the QC chart.
[Switch Display]	Used to switch between ‘New Lot’, ‘Current Lot’ and ‘New + Current Lot’.
[Print Report]	Used to print multiple QC charts.
[More]	Allows the user to access a second page of options including [Print], [Export]. [Customise].
[Close]	Closes ‘QC Chart’ screen to display last screen left open.

Running Patient Samples

Sample Requirements

Citrated plasma samples are to be used on the CS-Series analysers and correct filling of the samples is essential as under filled and over filled samples can both have significant effects on the results gained from the analyser. The CS-Series analysers have sample fill level sensing capability, which generates a flag against the results to alert the user to incorrectly filled samples. If this feature is enabled this will alleviate the need to manually check sample volumes before loading them onto the analyser.

IMPORTANT: Ensure local laboratory procedures are followed with regards to sample volumes.

Adult and paediatric samples can both be loaded into the sample racks and placed on the sampler unit, although various rack inserts are required for use of certain tube types (paediatric specimens).

Modes of Analysis

There are 3 modes of analysis available on the CS-Series as summarised in the table below:

Mode	Sample Cap	Daughter Aliquot (Reflex Tests Available)
Normal 'Closed' Mode **(CS-2500 Only)**	ON	Yes
Normal 'Open' Mode	OFF	Yes
Micro Mode	OFF	No

All 3 modes of analysis involve sample aspiration from the sample racks. The only difference between normal 'Closed' and 'Open' mode is that the user leaves the cap pierceable lids on the sample tubes in 'Closed' mode (CS-2500 only), but they are removed in 'Open' mode. When in normal 'Closed' and 'Open' mode the daughter aliquot is used to perform haemolysis (H), icterus (I) and lipaemia (L) detection and if required any reflex testing without the need for re-aspiration of the sample. The CS-Series analysers have a cap sensor built into the sampler unit so the analyser can automatically detect if the sample caps have been removed.

For 'Micro' mode the user must order the test manually and request 'Micro Mode' so no daughter aliquot is taken, therefore reflex and HIL testing is not available. 'Micro' mode should be used wherever there is a small plasma volume, such as paediatric samples, or samples where plasma needs to be preserved, i.e. samples needing specialist testing or QC samples being run from a rack.

Running Patient Sample

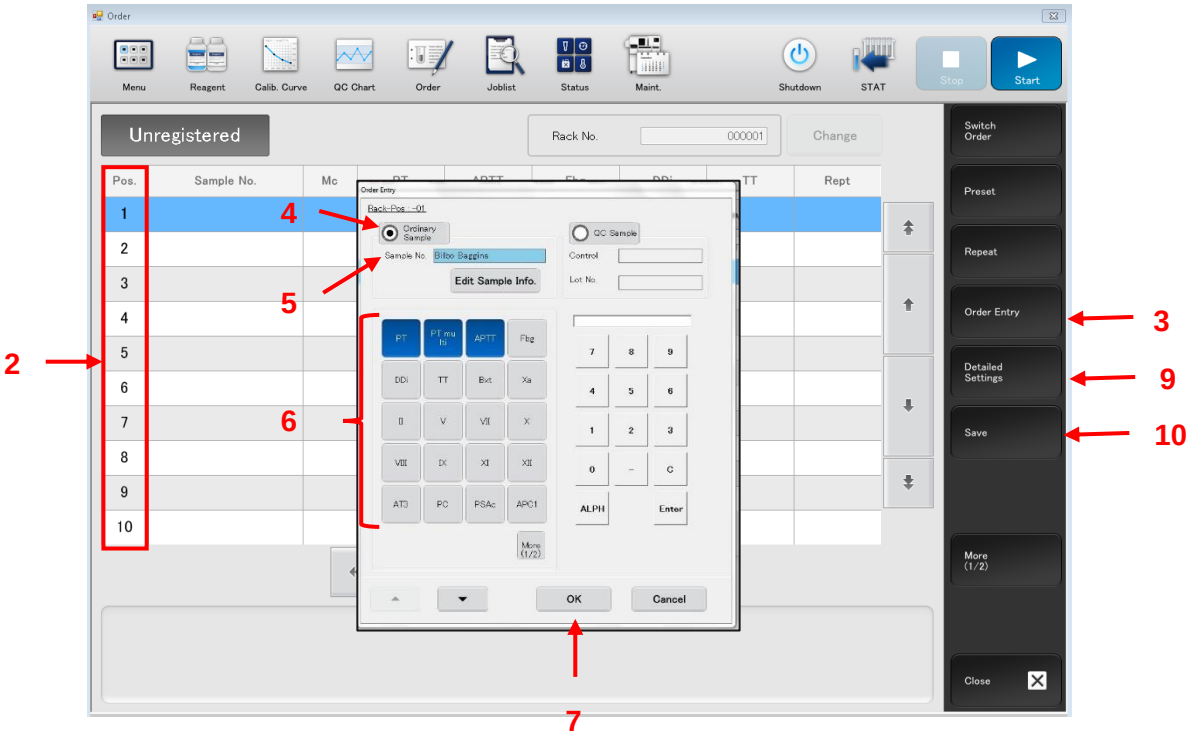
Patient samples are run in racks and can be ordered via host interrogation, ordered manually on the IPU screen or through 'STAT' mode. Detailed instructions for running patient samples can be found in CS-2400 CS-2500 SOP – QC and Sample Processing. SOPs | Caresphere Academy UK (caresphere-academy.com).

To run samples with host interrogation:

1. Place sample(s) into rack with the barcode facing forward.
2. Load rack onto the right-hand side of the sampler unit.
3. Press [Start] on the IPU or press [Start Button] on the front of the analyser.

To run manually ordered samples;

1. Select [Order] icon from 'Menu' or toolbar.
2. The 'Rack Order' screen will now be displayed. Select appropriate rack position. **NOTE:** If screen does not display the 'Rack order' screen indicated by rack numbers select [Switch Order], followed by [Rack Order].



3. Select [Order Entry].

4. Select the [Ordinary Sample] tab.

5. Click in the [Sample No.] box and enter the sample number/name required.

6. Select the appropriate tests. **TIP:** To enter further samples manually in the [Order Entry] screen press the down arrow ▼ to select rack position 2 and repeat the above procedure, therefore up to 10 samples can be ordered per rack.

7. Click [OK.].

8. Ensure that samples are placed in the rack in the same position that they are requested in the 'Order' screen.

9. If 'Micro Mode' is required, for example paediatric samples or samples with small plasma volume, select [Detailed Settings], followed by selecting the [Micro mode] box. Alternatively select the column labelled [Mc] for the appropriate sample. **IMPORTANT:** Ensure ALL lids are removed on samples placed into 'Micro mode'.

10. Select [Save].

11. Press [Start] on the IPU or press [Start Button] on the front of the analyser.

Running STAT samples

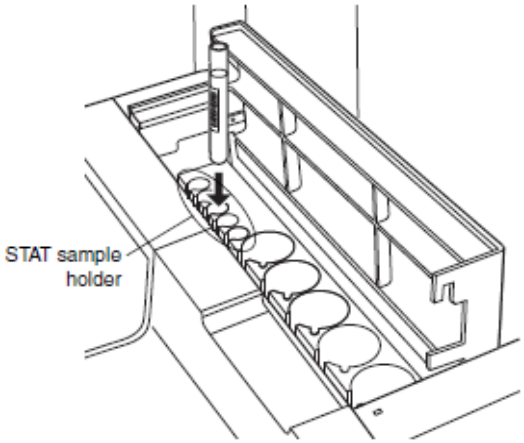
Running samples in ‘STAT mode’ allows samples to be placed into the buffer table and prioritised over samples being run in racks, QC analysis and calibration curve analysis. Samples run in ‘STAT mode’ can be ordered via host interrogation or ordered manually.

To run a ‘STAT mode’ sample with host interrogation:

1. Select STAT analysis from the ‘Menu’ screen or the toolbar.

2. Once buffer table indicator is solid green open buffer table and set sample. **IMPORTANT:** Samples MUST have lids REMOVED and barcode facing forward.

3. Close buffer table access lid.



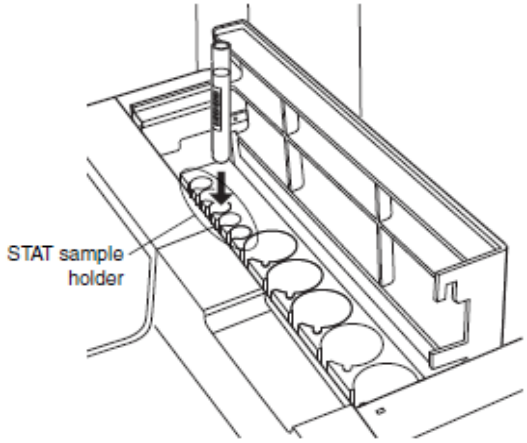
4. Press [Start] on the IPU or press [Start Button] on the front of the analyser.

5. Once processing is complete ensure sample is removed.

To run manually ordered ‘STAT mode’ sample:

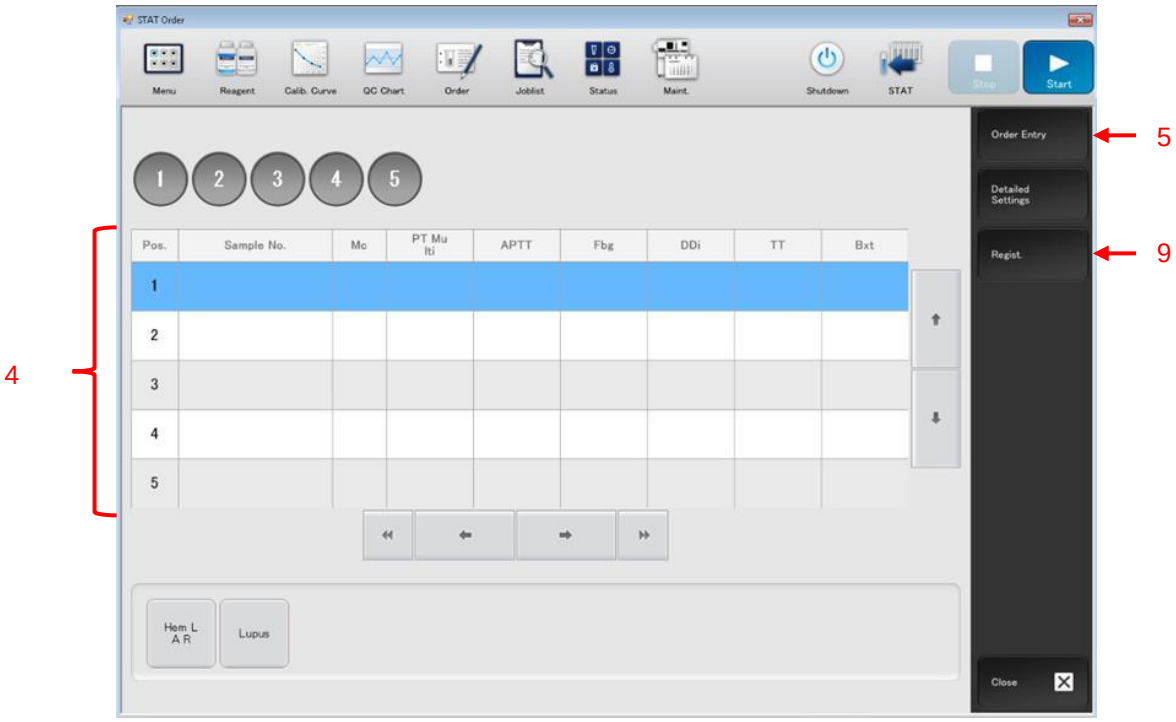
1. Select STAT analysis from the ‘Menu’ screen or the toolbar.

2. Once buffer table indicator is solid green open buffer table and set sample. **IMPORTANT:** Samples MUST have lids REMOVED and barcode facing forward.



3. Close buffer table access lid.

4. Select position that the STAT sample was placed in.



5. Select [Order Entry].

6. Select [Sample No.] and enter the appropriate sample number/name required.

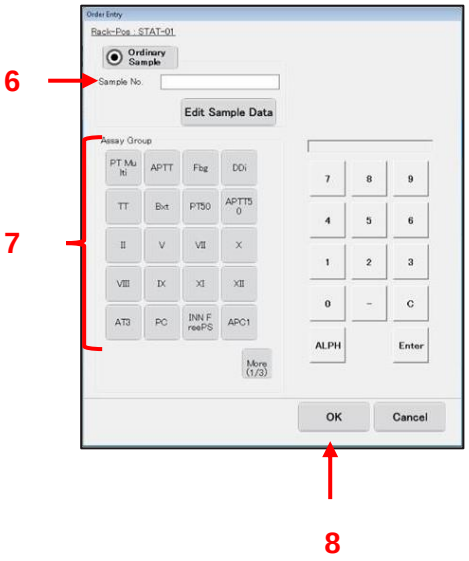
7. Select tests required.

8. Click [OK].

9. Select [Register] on the ‘STAT’ screen.

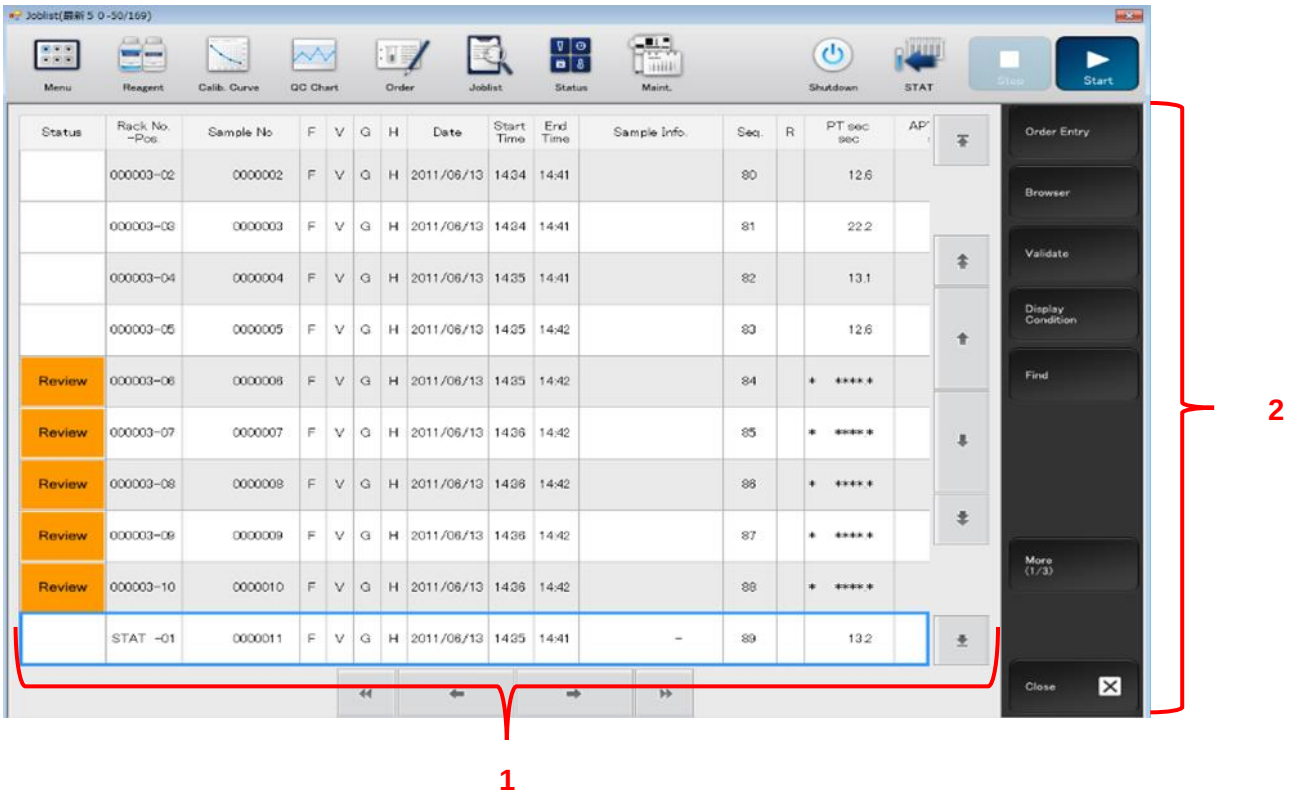
10. Press [Start] on the IPU or press [Start Button] on the front of the analyser.

11. Once processing is complete ensure sample is removed.

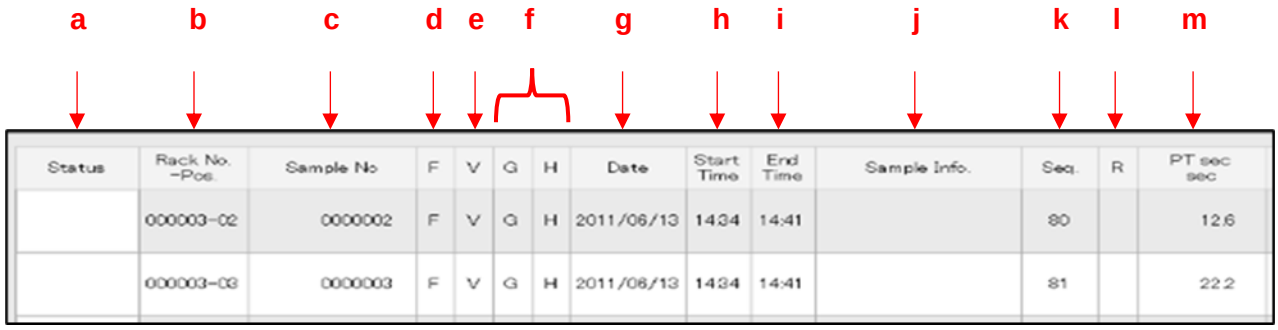


Checking Patient Results

The progress of patient samples, results and errors can be viewed in the ‘Joblist’ screen.



1. **Results Table** – this area is user customisable and can be filtered to display specific sets of data based on validation status, data etc using [Display conditions] in the screen options:



   a. **Status** – Analysis status of the sample displayed;

Pending	The order is registered but the analysis has not started.
Processing	One of the tests ordered is being analysed.

Review	Any sample that requires reviewing will be shown as a result with an asterisk next to it and the status bar on the left hand side will display a yellow box stating 'Review', thus informing the user that a flag/s is attached to that particular result. This may be an error such as slight coagulation, curve errors or a HIL flag.
On Hold	'On Hold' flags indicate that tests have been performed but put on hold as a new lot number of reagent has been used but not yet calibrated. Therefore, the only result available will be the optical density change (dOD) or time in seconds (the result will be displayed as XXX.XX).
Error	A 'result' with a red 'Error' box attached to it will not have a result displayed (numerical value). Instead asterisks will be displayed in place of the numerical values. Errors of this type could occur due to events such as a reagent/consumable running out, mechanical error etc.

b. Rack No & Pos - Displays the rack number of the sample and sample tube position.

c. Sample No. – Displays the sample/QC/background number.

d. F – Final analysis results. If analysis consists of multiple lines F will appear on the final line.

e. V – Validated analysis results.

f. Output – Presence of G and/or H indicates that the action has NOT occurred.

G	Analysis results that have **not** been printed out
H	Analysis results that have **not** been output to host computer

g. Date – Displays the date the analysis began

h. Start Time – Displays the start time the analysis began.

i. End Time – Displays the time when all analysis was finished or estimated end time if processing the sample.

j. Sample Info – Displays the results of the inhibitor check of the sample:

Hem	The haemolysis check results exceed the check level
H*	Prevention of accurate haemolysis check
Ict	The icterus check results exceed the check level
I*	Prevention of accurate icterus check
Lip	The lipemia check results exceed the check level
L*	Prevention of accurate lipemia check
Vol	The sample volume is outside the set range
-	The sample volume check is not performed on this sample

k. **Seq –** Displays the sequential number for each sample from after power was turned on.

l. **R –** Results of re-analysis**.**

m. **PT Sec –** From this point you can scroll along to view all tests. Test results are displayed or if the sample is still being analysed various icons can be displayed.

Sample ordered but not yet aspirated

Sample is being dispensed

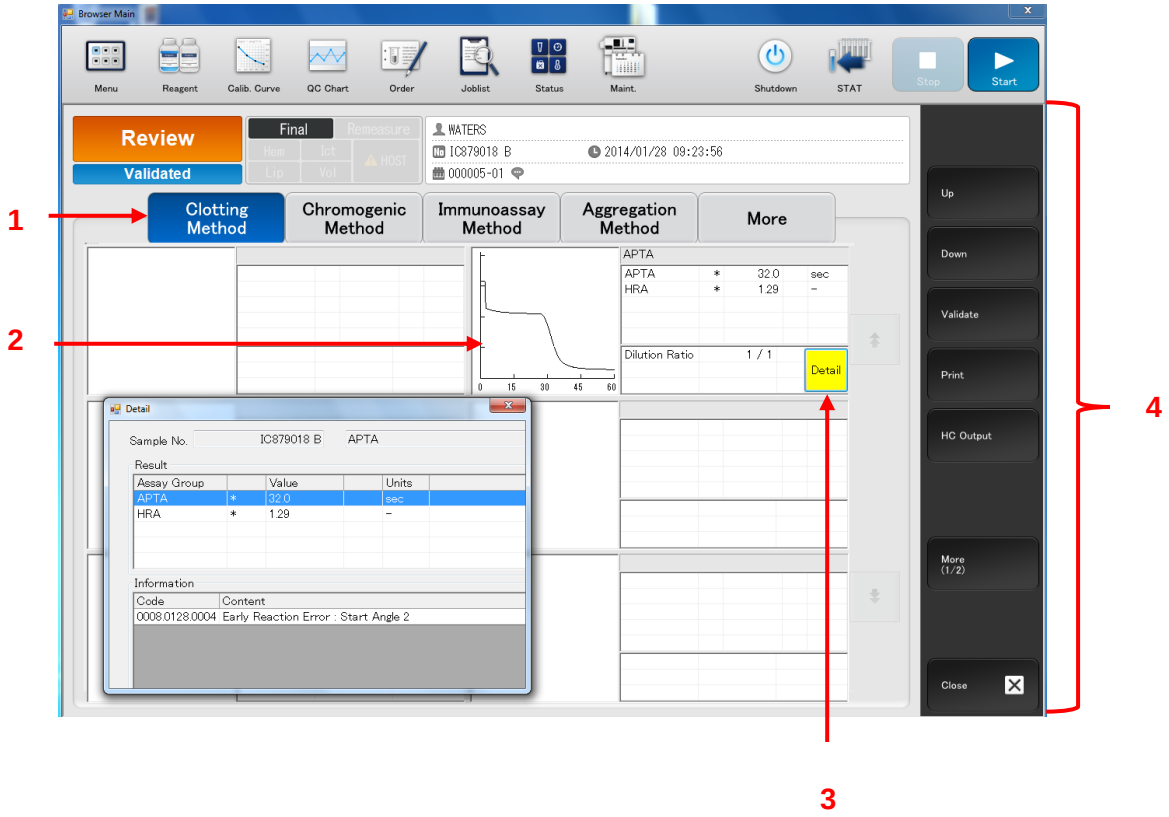
Sample is being incubated

Sample is being measured

2. **Screen Options –** There are 3 pages of 'Joblist' screen options, [More] can be used to switch between the three lists.

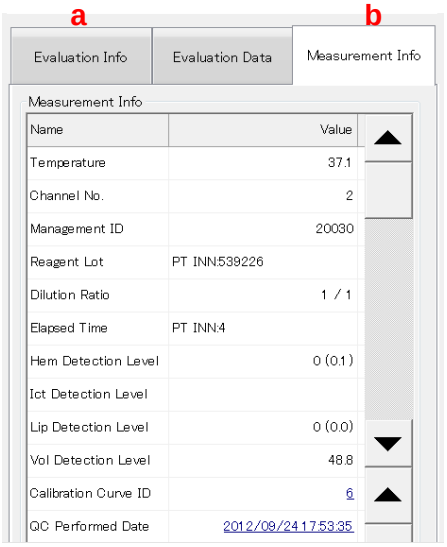
[Order Entry]	Allows direct access to the order screen form the 'Joblist' screen.
[Browser]	Browser screen displays assay curves, coagulation curve error information.
[Validate]	Used to validate results once further checks have been made to samples that have been held on the IPU screen.
[Display Conditions]	Allows the screen to be filtered to display a specific group of samples such as unvalidated results or results from a certain date(s).
[Find]	Allows the user to search for a sample.
[Mark]	Used to mark current result, results on same date or all, as well as releasing selected marked results. When results are marked, they are indicated by a green background to results.
[Print]	Used to print results from 'Joblist' screen.
[HC Output]	Used to send results to host.
[Delete]	Used to delete sample results **NOT RECOMMENDED.**
[Edit]	Allows the user to edit the order if analysis has not started.
[Recalculate]	Used to recalculate parameters where on analysis the relevant calibration curve was not available.
[Export]	Used to export analysis results list.
[Customise]	Allows user to customise the 'Joblist' screen.
[Data Integration]	Used for recalculating the aggregation % from PPP and PRP analysis results during aggregation studies.
More	Allows the user to toggle between the 3 lists of options.
Close	Closes the screen to display the last screen not closed.

Results with flags should be reviewed according to laboratory protocols. Further information can be found on a sample through the 'Browser' screen which can be accessed through the 'Joblist' options.



1. **Assay Method Tabs** – used to select the required assay method for the result being analysed.

2. **Coagulation Curve** - Double clicking on the curve opens the browser details screen. This screen allows the user to zoom in and out of the curve as well as access more detailed information about the assay including:



   a. **Evaluation Info** – bH and dH values.

   b. **Measurement Info** – Temperature, channel number, reagent(s) lot(s), haemolysis, icterus or lipemia level, calibration curve ID and QC performed detection date.

3. **Detail Button** – Any test that has an associated flag will have a 'Detail' button which can be used to view further information regarding the nature of the flags.

4. **Screen Options** – displays screen options. [More] can be used to switch between the two pages of options.

[Up]	Allows user to view the results on the 'Joblist' screen above the one selected.
[Down]	Allows user to view the results on the 'Joblist' screen below the one selected.
[Validate]	Used to validate results once further checks have been made to samples that have been held on the IPU screen.
[Print]	Allows the user to print out sample results.
[HC Output]	Allows the user to send results to host.
[Edit Sample Info]	Used to edit sample information **NOT RECOMMENEDED**.
[Export]	Used to export detailed information on analysis results.
[Superimposed Graph]	This displays the aggregation waveform graphs superimposed (Platelet aggregation results only).
[Customise]	Used to customise the 'Browser' screen.
[More]	Allows the user to access a second page of options including print, mark, output.
[Close]	Closes the screen to display the last screen not closed.

HIL Flags

A HIL flag occurs if the instrument detects haemolysis, icterus (bilirubin) or lipemia, if activated (not in micro mode). The CS-2400/CS-2500 tests each sample for these interfering substances before the analysis takes place.

If one or more of these flags are attached to a sample, then a 'Review' flag will be seen in the 'Joblist'. By entering the 'Browser' and selecting the [Measurement Info] tab the degree of the interfering substances can be seen, with levels ranging from 0 (not detected) to 5 (high level) and a '*' representing >5 for haemolysis and lipaemia or >3 for icterus.

Hem Detection Level	0
Ict Detection Level	*
Lip Detection Level	0

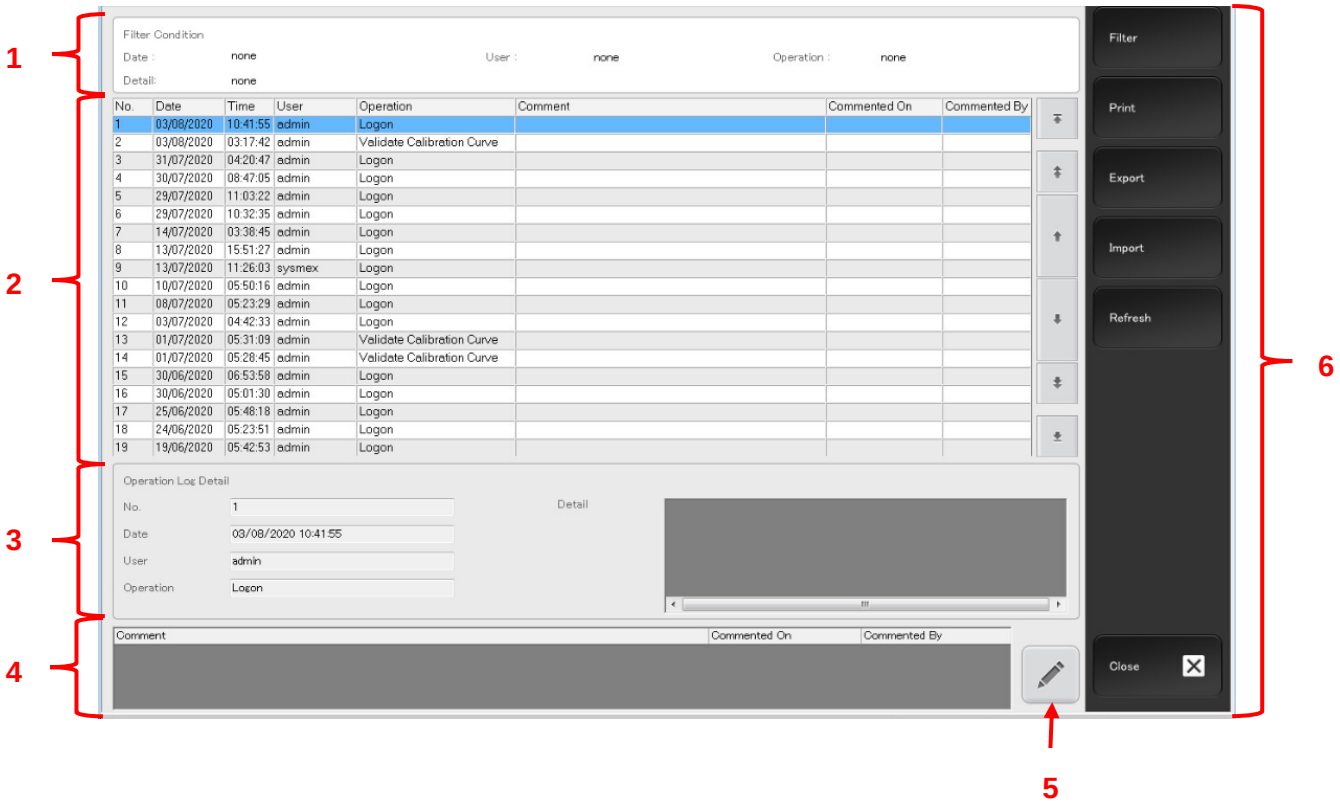
Action required for HIL flags:

As described above for HIL errors the system will flag if haemolysis, icterus and lipemia are present. If lipaemia occurs the system will perform a wavelength switch to minimise interference (if appropriate). This occurs without any further user intervention.

For both haemolysis and icterus the sample will need to be retrieved and visually inspected before the result can be validated. To validate the result, close the error dialogue box and then close the detailed sample 'Joblist' screen. Press the 'Validate' button on the right-hand side of the screen (this may not be required depending on individual analyser settings).

Operation Log

The ‘Operation Log’ screen details the operation carried out including date, time and user.



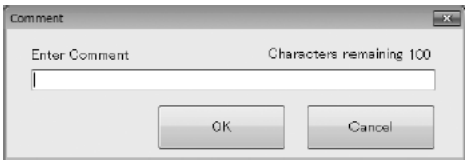
1. **Filter Condition** - displays filter conditions applied to the screen.

2. **Operation Log Display Area** – displays all operations carried out on the CS-Series analyser sequentially, including date, time, user performing the operation and any comments added to the operation.

3. **Operation Log Detailed Display** – displays detailed information about the operation selected in the operation log display area.

4. **Comments Display Area** – displays comments entered including date and time entered and the user who added the comment.

5. **Comment Button** – Used to add comments to the selected operation in the operation log display area. Comments have a maximum of 100 characters.



6. **Screen options –** displays screen options.

[Filter]	Used to perform a search within the operation log. Screen can be filtered according to start/end date, user, operation, or detailed content.
[Print]	Used to print operation log.
[Export]	Used to export the operation log. It is recommended this is done on a monthly basis. Exported files can only be opened within the operation log.
[Import]	Used to import exported operation log files.
[Refresh]	Used to update operation log.
[Close]	Closes the screen to display the last screen not closed.

Dealing with Errors

When an audible alarm sounds on the CS-2400/CS-2500 the following ‘Error Help’ screen appears to inform the user of the problem. To deal with errors:

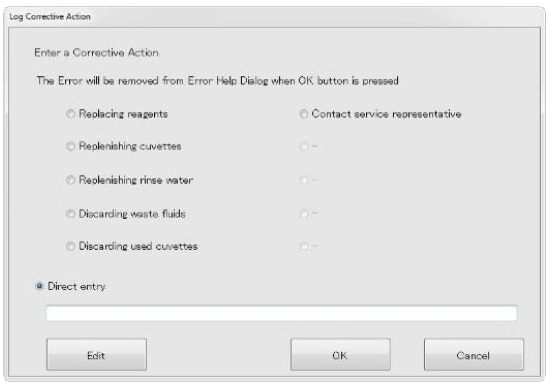
1. Press the [Stop Alarm] button to mute alarm.

2. Read the most recent ‘Error Message’ at the top of the list to determine which error has occurred.

3. Deal with the error as advised in the ‘Action Message’ area.

4. Select [Log Corrective Action].

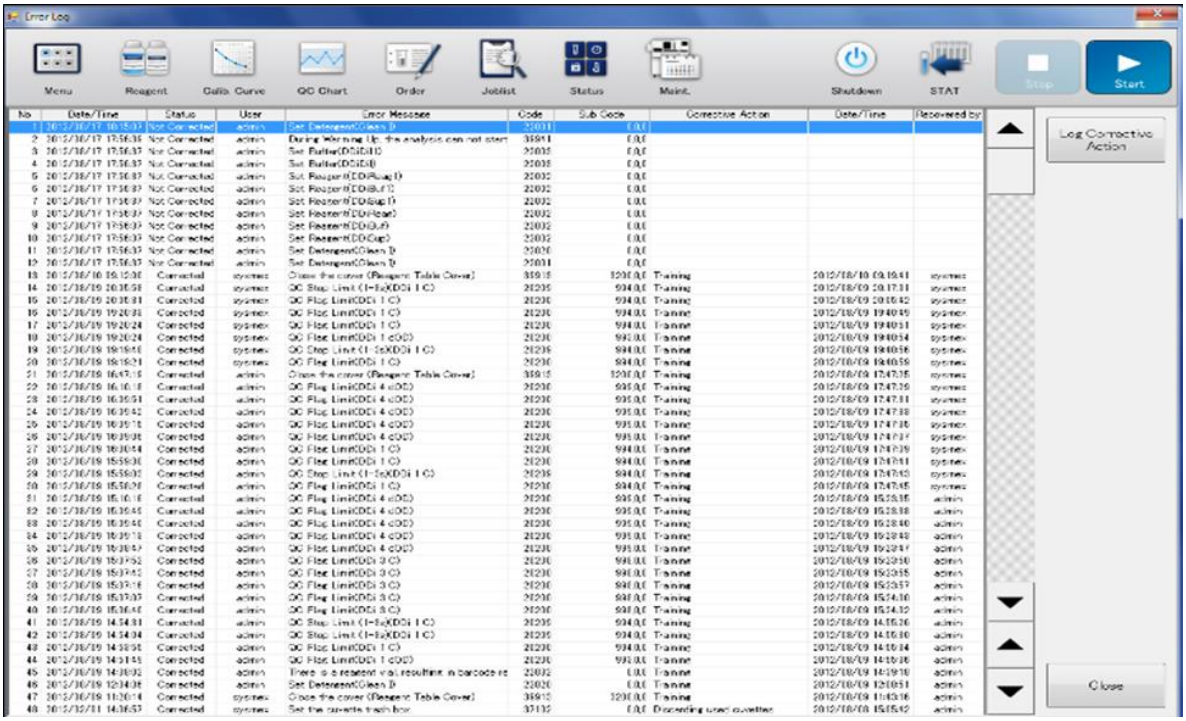
5. Select the most appropriate response from the pre-determined list or type a response in the direct entry box.



6. Click [OK]. The action will now be recorded on the error log and the warning triangle in the status bar will return to white.

NOTE: The warning triangle will remain yellow if errors have been acknowledged but no corrective action logged.

7. To view a more comprehensive error log, select [Error Log].



Final Task

1. Perform analyser shutdown and startup.

2. What other procedures need to be performed during daily maintenance?

   a _____
   b _____
   c _____
   d _____
   e _____
   f _____
   g _____
   h _____

3. What weekly maintenance is required?

   a _____
   b _____

4. What other routine maintenance is required?

   a _____
   b _____
   c _____

5. Where is the halogen lamp located?

6. What controls are used for?

   PT _____
   APTT _____
   FibC _____
   DDimer _____
   Anti-Xa _____

7. What is the temperature of?

Reagent Table _____

Buffer Table _____

8. Explain to your trainer how you would reconstitute a reagent?

9. What is the significance of a pink reagent package insert?

10. Load a selection of reagents onto the CS-2400/CS-2500.

11. What information is provided about the reagent selected in the icon below?

12. In the reagent screen where can you input the sequence number, expiry date and set date and time?

13. In the reagent screen what do the following icons indicate:

14. Order QC for the reagents available to you.

15. How do you add a comment to a QC point?

16. With the host connection off run a selection of samples for test profiles of your choice.

17. When would you run a sample in Micro mode?

18. What is the difference between the stop button on the front of the analyser and the stop on the IPU?

19. In the job list what do the following symbols indicate?

20. What does H, I, L stand for?

H _____

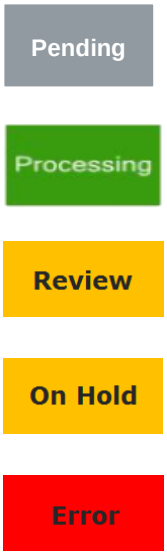
I _____

L _____

21. Where can the level of H, I or L be found?

22. Where can further information be found about the cause of a review or error flag?

23. What do the following job list flags indicate?



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www.sysmex.co.uk/company/contact/contact-us/