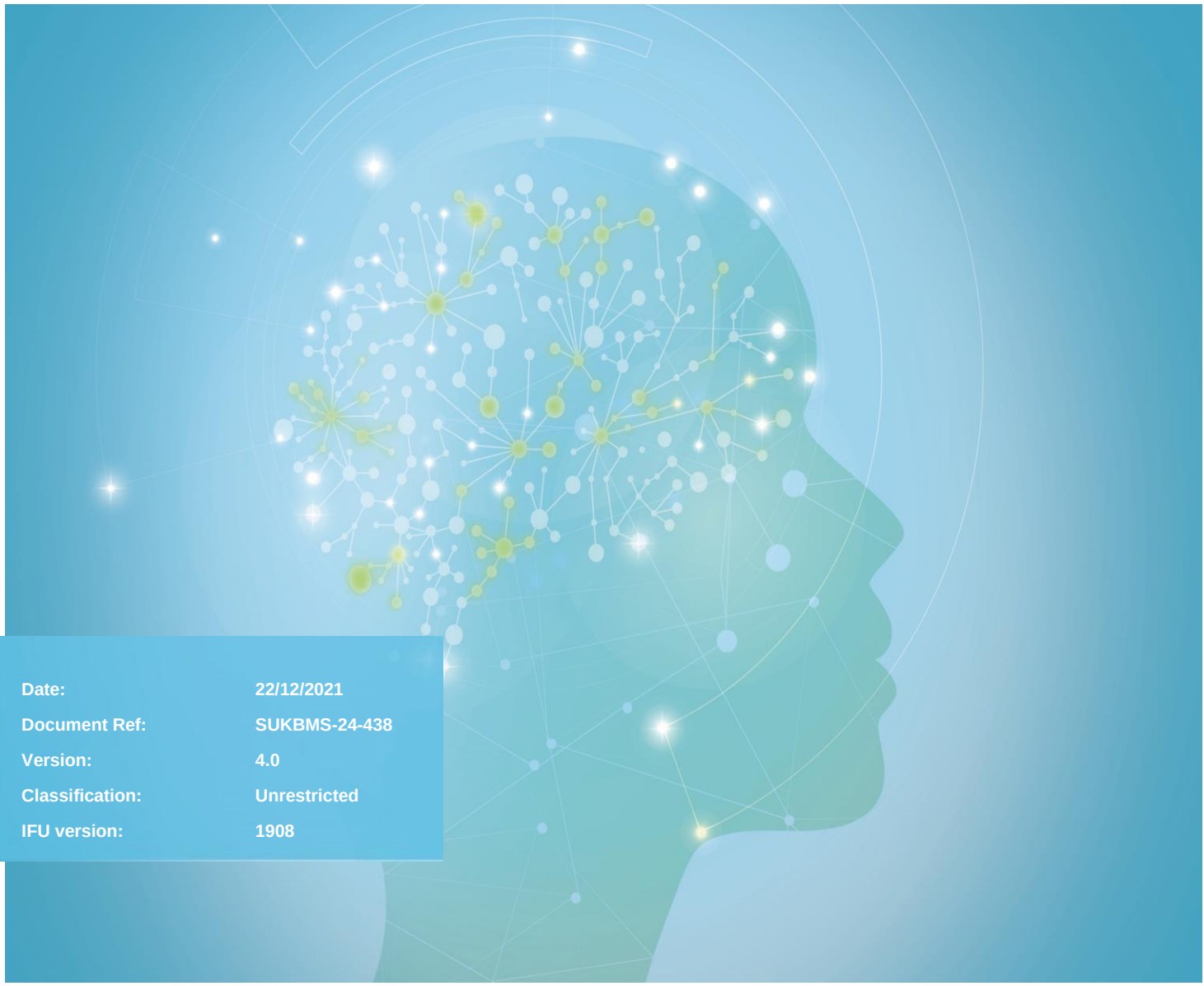
Routine Use Training Workbook

XN-Series



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Disclaimer

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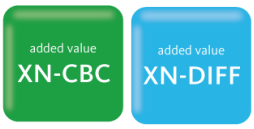
Revision History

Revised Section	Alteration	Name	Date
All sections	New document	J Hammersley	May 2020
Components	Internal components included	N.Bowen	August 2020
IPU Software Layout	Image of analyser control menu included	N.Bowen	September 2020
Data Browser	Layout of information altered	N.Bowen	September 2020
Quality Control	Addition of loading new lots of XN CHECK and the processing of EQA material	N Bowen	November 2021

Reference Documents

Document title	Version	Date
XN-1000 IFU	1908	August 2019
XN-2000 IFU	1908	August 2019
XN-3000 XN-3100 IFU	1908	August 2019
XN-9000 XN-9100 IFU	1908	August 2019

Overview of XN-Series

Facts and figures	
Analysers	XN-10 and XN-20
Configurations	XN-1000, XN-2000, XN-3x00, XN-9x00
Analytical components	Standard: 28 diagnostic parameters as standard  Optional: 16 optional diagnostic parameters 
Technologies	Spectrophotometry, Sheath flow (DC) detection and Fluorescence flow cytometry
Modes of analysis * If available	Whole blood (WB) mode Low WBC (LW) mode Pre-dilution (PD) mode Body fluid (BF) mode* HPC mode*
Aspiration methods	Sampler analysis Manual analysis (Closed/open/micro/raised bottom tube)
Throughput	100 samples per hour (CBC+DIFF)
Quality control	XN CHECK XN CHECK BF
Aspiration volumes * If available	88µl (WB, LW, BF* modes) 70 µl (PD mode)
Analysis range (whole blood mode)	WBC 0.00 to 440 $x10^3$/µL RBC 0.00 to 8.60 $x10^6$/µL Hb 0.0 to 260g/L HCT 0.0 to 75.0% PLT 0 to 5000 $x10^3$/µL NRBC# 0.00 to 20.00 $x10^3$/µl NRBC% 0.0 to 600.0/100WBC RET% 0.00 to 30.00% RET# 0.0000 to 0.7200 $x10^6$µL

Analyser Components

XN-Series Overview

1. **Main Unit –** The main unit or analyser is where samples and XN CHECK is processed.

2. **Status Indicator LED –** Shows the current status of the XN-Series analyser.

LED Indicator Light	Description
Green	Ready (Analysis or maintenance is possible)
Flashing Green	Starting up / Analysis in progress / Maintenance in progress
Orange	Sample analysis stopped / not possible
Flashing Red	Error (with alarm)
Red	Error (without alarm) / initialising system / Analyser ready to be turned off at the end of shutdown
Not Lit	Analyser powered Off

3. **Start Switch –** Press to start analysis for manual mode analysis.

4. **Mode Switch -** Press to switch between manual and sampler analysis. Also used to open and close the tube holder.

5. **Reflex Bay –** the reflex bay will hold sample racks until all results are processed and if any reflex/repeat tests are required the rack will automatically be reintroduced to the appropriate analyser. Only on XN-2000, XN-3000 and XN3100 configurations.

6. **Sampler Unit –** Where sample racks are placed for processing in closed mode. Load racks on the right pool and remove completed racks from the left.

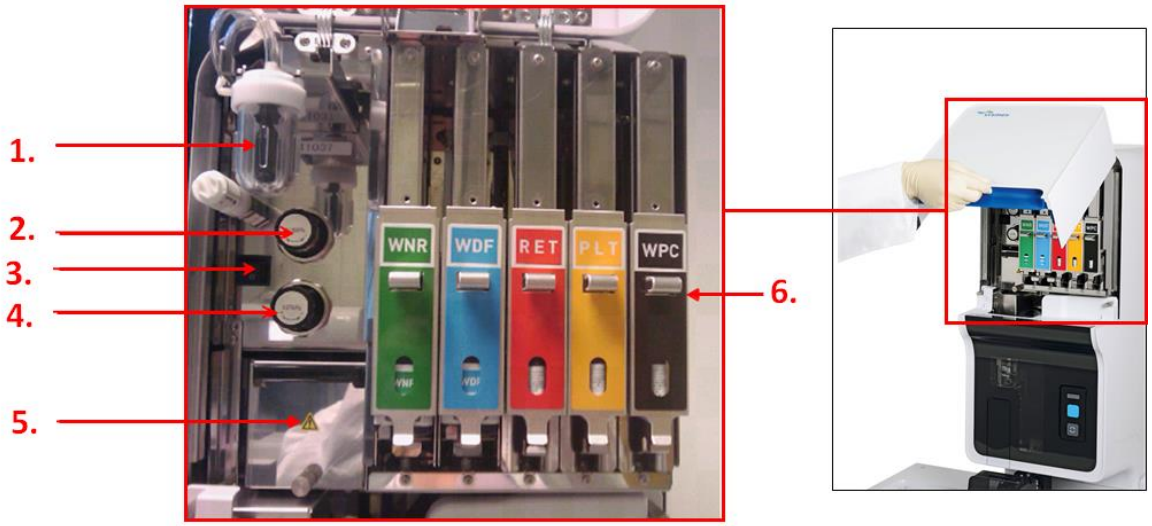
7. **Information Processing Unit (IPU) -** Runs the operating software for the XN-Series analyser and is the user interface for the analyser. The IPU holds up to 100,000 complete sample records in its database. All settings, calibration files and flagging limits are also stored on the IPU.

8. **Tube Holder -** The tube holder is used for samples processed in open/closed manual mode as well as samples requiring low WBC (LW) mode, Pre-dilution (PD) mode or body fluid (BF) Mode.

9. **Analysis Line** – When samples are introduced to the XN-Series in racks (closed mode), the barcodes are read, and the samples are resuspended and aspirated.

Inside the XN-Series

Under the front top cover



1. **Pneumatic Trap Chamber –** Prevents the reagent from flowing back into the pneumatic unit when the instrument malfunctions.

2. **0.16 MPa Regulator –** Regulates the pressure at 0.16 MPa.

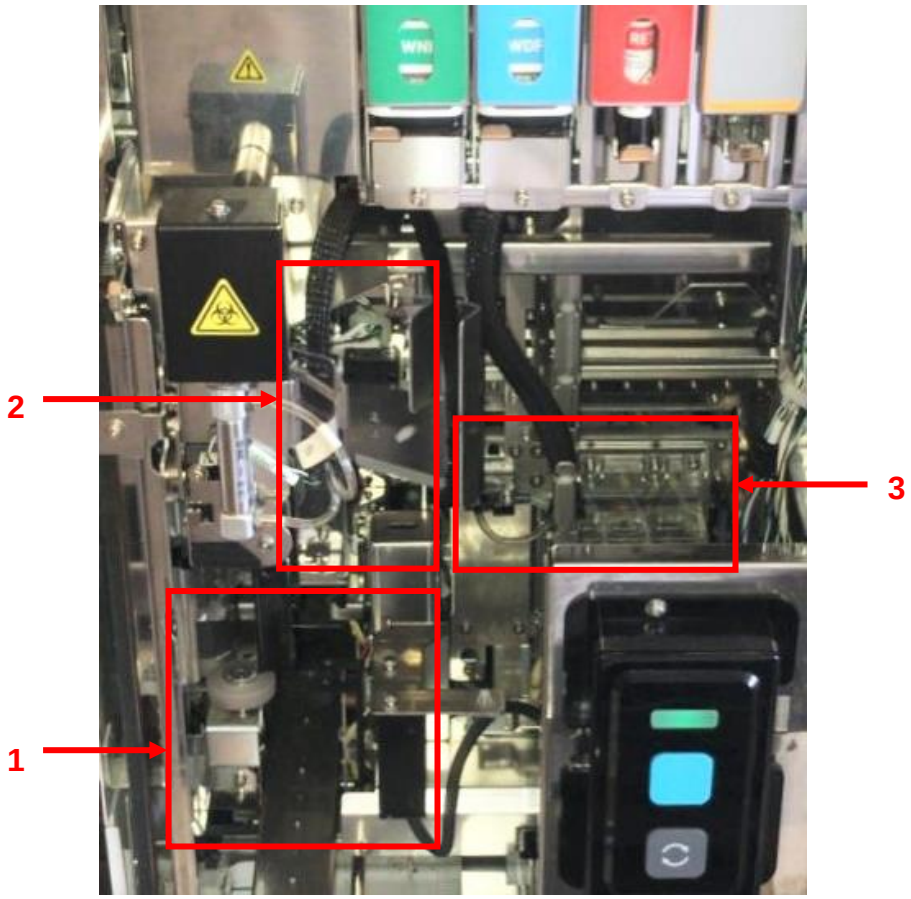
3. **Main Power Switch –** Turns the main power of the device ON/OFF.

4. **0.07 MPa Regulator –** Regulates the pressure at 0.07 MPa.

5. **RBC/PLT Detector Section –** For analysis of red blood cells and platelets using aperture impedance counting.

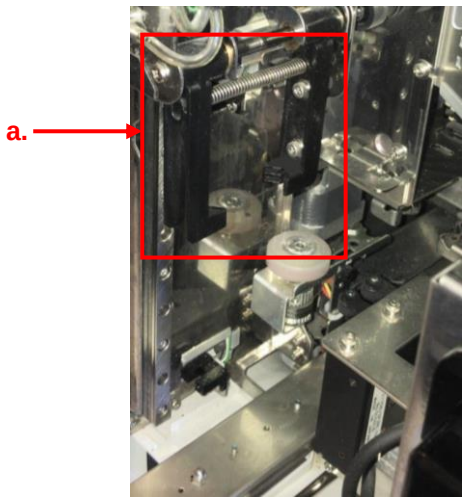
6. **Dye Cartridge Holder –** Holds the dye reagents. WPC position is unavailable on XN-10 analysers.

Under the front bottom cover



1. Tube Grabber, Tube Rotation Mechanism, Barcode Reader & Tube clamp

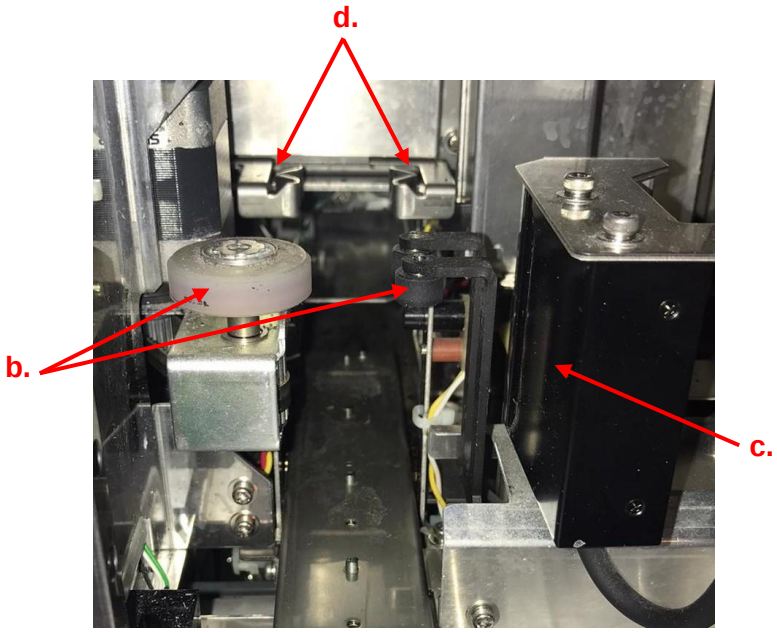
a. *Tube Grabber* - Removes the sample tube from the rack and resuspends it, before placing it in the normal sample tube holder position. After the analysis is complete it places the sample tube back in the rack. **NOTE:** Any errors relating to the tube grabber will refer to a 'hand error'.



b. *Tube Rotation Mechanism* - Rotates the sample tube within the normal sample tube holder to read its barcode.

c. *Barcode Reader* - Reads the barcode of the sample and queries to the host computer for relevant sample information.

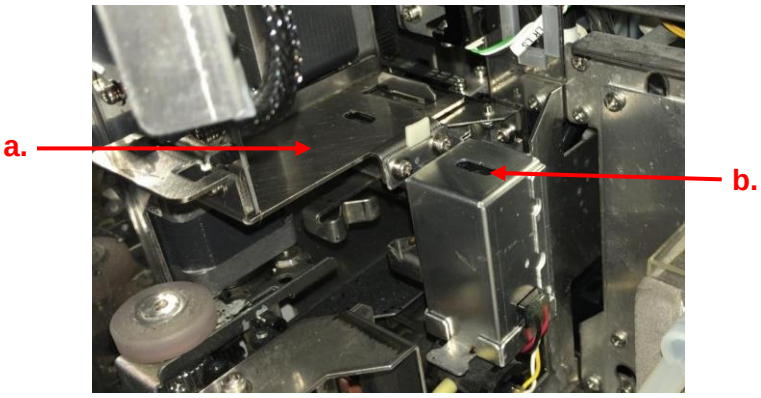
d. *Tube Clamp* - Holds the sample securely in place for aspiration by the sample piercer.



2. Piercer Cover & RBC/HB Chamber

a. *Piercer Cover* – Protector No.39 is an 'L' shaped cover that is located below the piercer. The piercer travels through the small hole present in the piercer cover before piercing the sample tube for aspiration.

b. *RBC/HB Chamber* – Red cell and haemoglobin aspiration sensor chamber cover. Sample and reagents are aliquoted here for RBC/PLT & Hb analysis.



3. Reaction Chambers & Rinse Cup

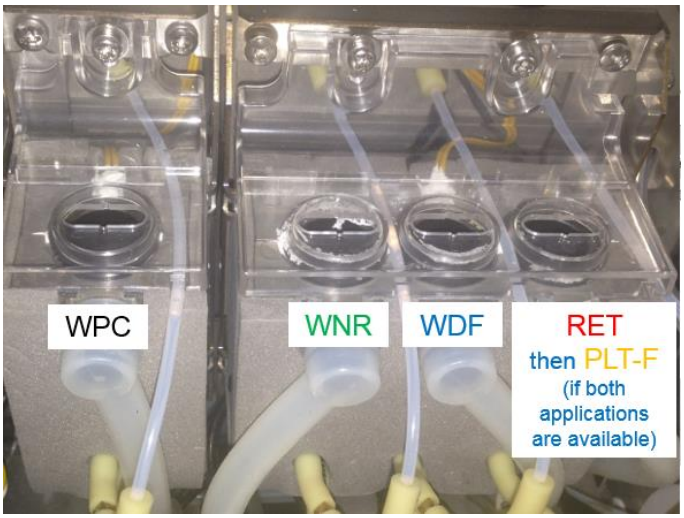
a. Reaction Chambers

[WPC Chamber] – Sample and reagents are aliquoted here for WPC channel analysis. **NOTE:** An XN-10 will not contain the WPC chamber, therefore, this area will be empty.

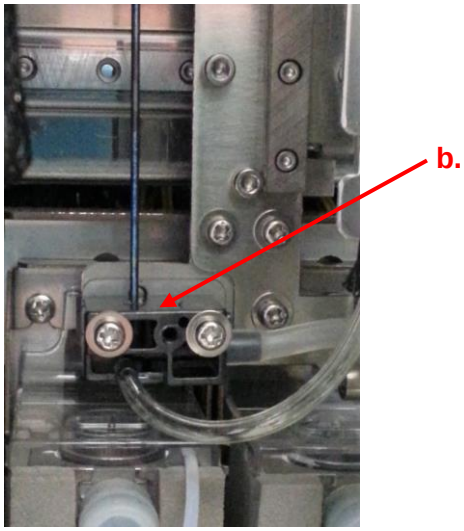
[WNR Chamber] - Sample and reagents are aliquoted here for WNR channel analysis.

[WDF/BF Chamber] – Sample and reagents are aliquoted here for WDF channel/body fluid mode analysis.

[RET/PLT-F Chamber] - Sample and reagents are aliquoted here for RET channel and PLT-F channel analysis.



b. *Rinse Cup* – The rinse cup supplies rinse to the aspiration probe.

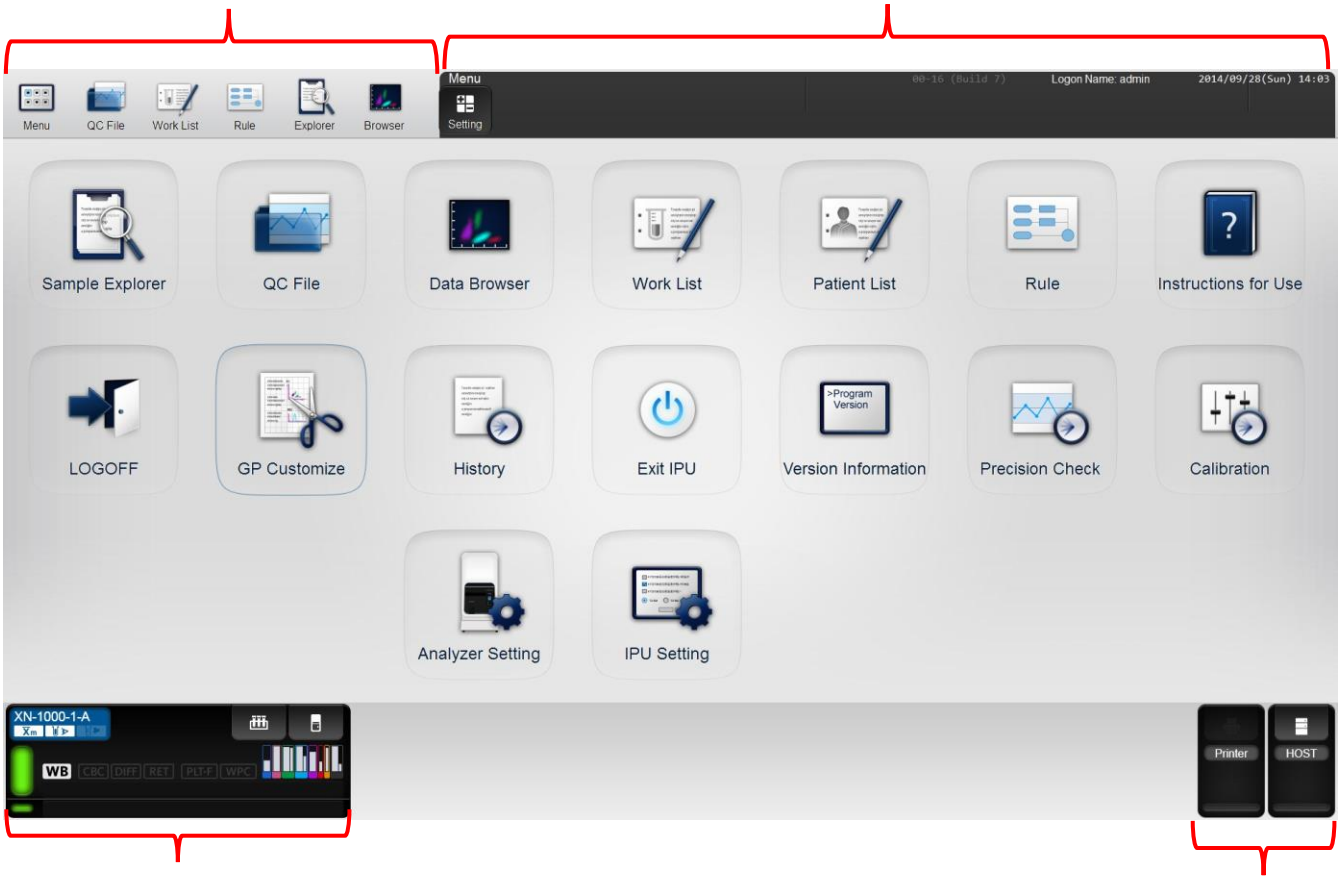


IPU Software Layout

Menu Layout

Fixed toolbar, where the above icons will always be present. Menu acts as a 'home' button, returning users to the below main screen.

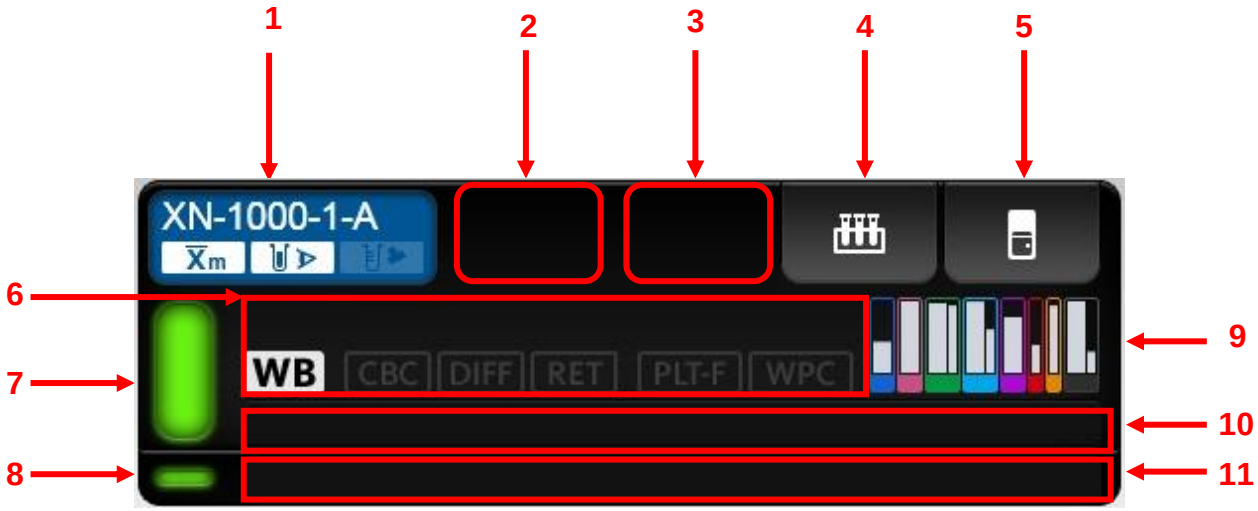
This is the changeable toolbar, where the icons alter depending on what screen is displayed. In the Menu screen, only the ability to alter the menu settings is displayed.



Analyser control menu

Printer and Host Menu

Analyser Control Menu



1. **Analyser information** – Displays the analyser's name and it's settings.

X̄m	Displayed when the X-barM function is ON
	Displayed when the blood aspiration sensor is ON
	Displayed when 'Cap Open' is ON.

2. **Help button** (not displayed above) – Displayed when there is an error. Click to display the Help dialogue box.

3. **Change Analysis Mode button** (not displayed above) - Displayed when performing manual analysis. Click to select analysis mode: Whole blood (WB), Low WBC (LW), Pre-Dilution (PD) and Body Fluid (BF).

4. Analysis button

   a. **Sampler Analysis button** (displayed above) – displayed when running samples in a rack. Click to define sample settings. Replaces change analysis mode button and manual analysis button.

   b. **Manual Analysis button** (not displayed above) – Displayed when performing manual analysis. Click to define sample setting.

5. **Analyser Menu button** – Click to open and close the analyser menu. Displays a submenu for performing QC, maintenance etc.

6. **Sample Information** – Displays information about the sample to be anlaysed.

   a. ***Sample number*** – Displays the number or prompts for a number to be entered.
   b. ***Discrete*** – Displays the selected discrete test (CBC, DIFF, RET, PLT-F, WPC).
   c. ***Analysis mode*** – The selected analysis mode is displayed (WB).

7. **Device status** – Indicates the status of the analyser and is linked to the status indicator LED on the analyser.

8. **Sampler status** – Indicates the status of the sampler unit attached to the relevant analysers.

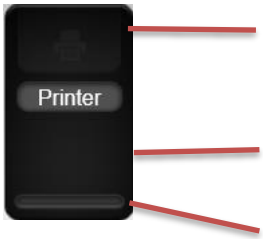
9. **Remaining reagent volume indicator** – Visually displays how much reagent is remaining. The colours indicate the colour of each reagent pack, with the thin bars representing the dye cartridges. **N.B**. If the reagent is not displayed, it has either not been registered or has expired.

10. **Analyser Error message** – Displays the highest priority error among all current errors.

Caution	Orange Background/Black text
Warning	Red Background/white text

11. **Sampler Error message** – Displays errors relating to the sampler. The display is the same as the [analyser error message].

Printer and Host Menu



Printer Menu button – opens/ closes menu & stops printing.

Number of print jobs- shows the number of jobs spooled to the printer.

Printer status – displays the status of the connection with the printer

Green = connected

Red = printing not possible

Host menu button- opens/ closes menu.

Host setting- displays the name of the connected host computer.

Host status – displays the status of the connection with the host computer.

Green = connected

Flashing Green = communicating

Red = cannot connect

Quick Guides to Using XN-Series

Daily Maintenance

Daily maintenance consists of:

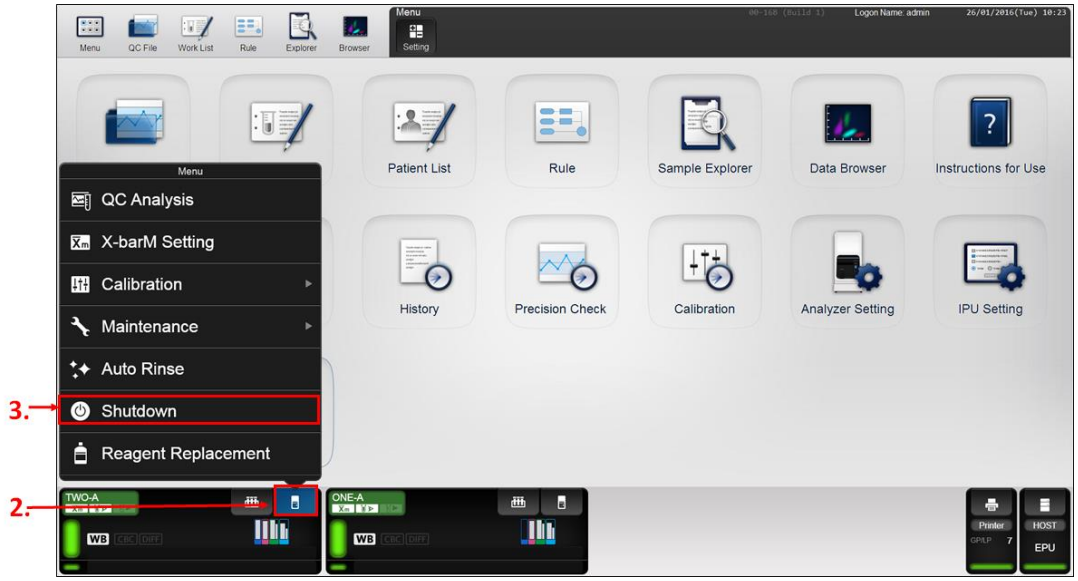
Daily shutdown

Daily Shutdown Procedure

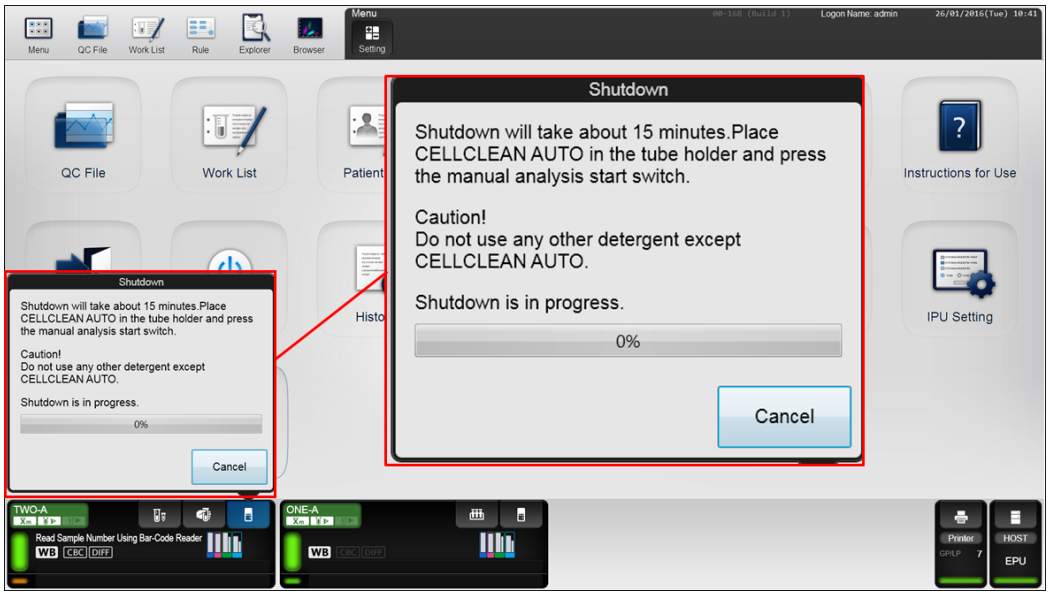
The shutdown procedure is recommended as daily maintenance and the analyser should be in a ready state with a green LED indicator light.

To perform a daily shutdown:

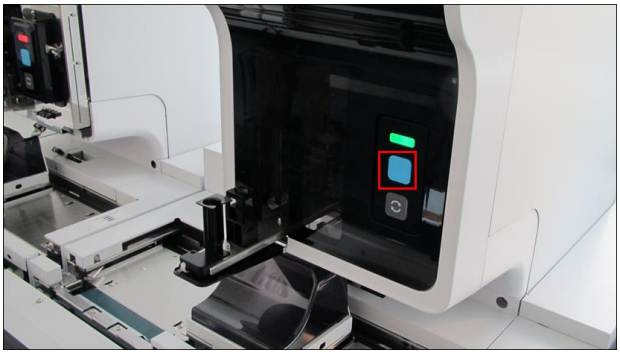
1. Locate the [Analyser Control] for the appropriate XN-Series analyser.
2. Select [Analyser menu].
3. Select [Shutdown].



4. Follow the instructions on the IPU - Place 4mL CELLCLEAN into a clean tube and place in the tube holder (cap removed).



5. Press the manual analysis start switch. The sample tube holder retracts into the analyser and aspiration begins. When aspiration is complete, the cleaning begins and the tube holder ejects. The tube used can be removed at this stage or it can remain in the tube holder until the start-up process is complete.



6. The shutdown procedure will take 15 minutes and on its completion the analyser should be switched off at the main power switch.

7. Allow the analyser to shut down completely before switching it back on at the main power switch.

8. The start-up procedure will take approximately 3-4 minutes. On start up the analyser will perform a series of self-checks including an auto rinse and background check. In event the event of the background check failing it will be repeated a maximum 3 times. If the results are still not within acceptable range, please perform an auto rinse as directed in the error message.

As Required Maintenance

As required maintenance consists of:

Auto rinse

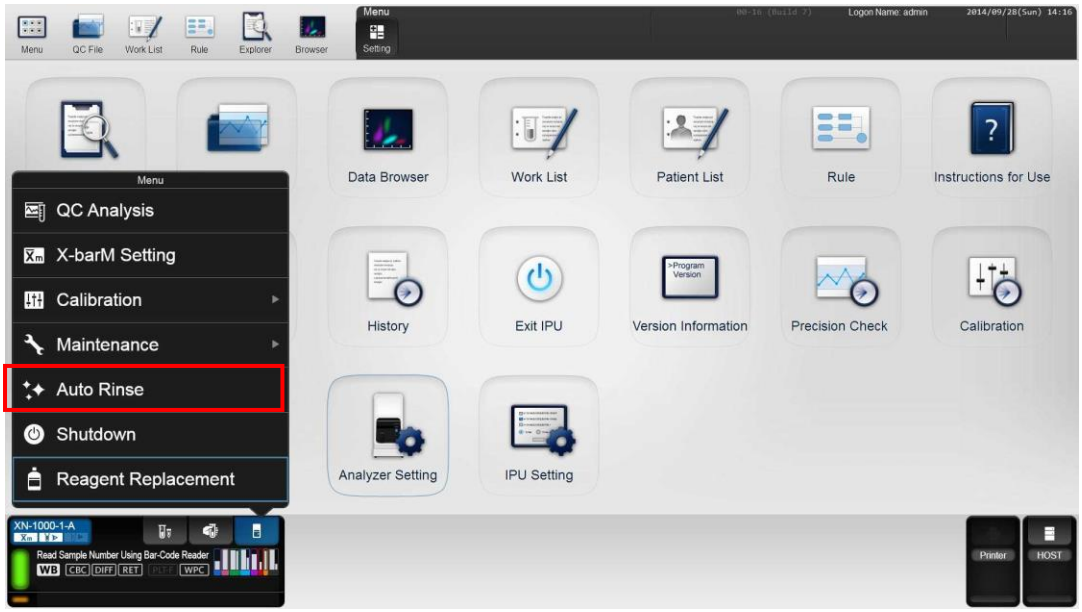
Cleaning Procedure

IPU Shutdown

Auto rinse

The auto rinse can be requested following operational errors such as background check failure or on request of the operator. If an error message requests an auto rinse, follow the instructions on the IPU. If a manual request of an auto rinse is required ensure the analyser is in the ready state with a solid green LED indicator light. To manually request an Auto rinse:

1. Select [Analyser menu] of the appropriate XN-Series

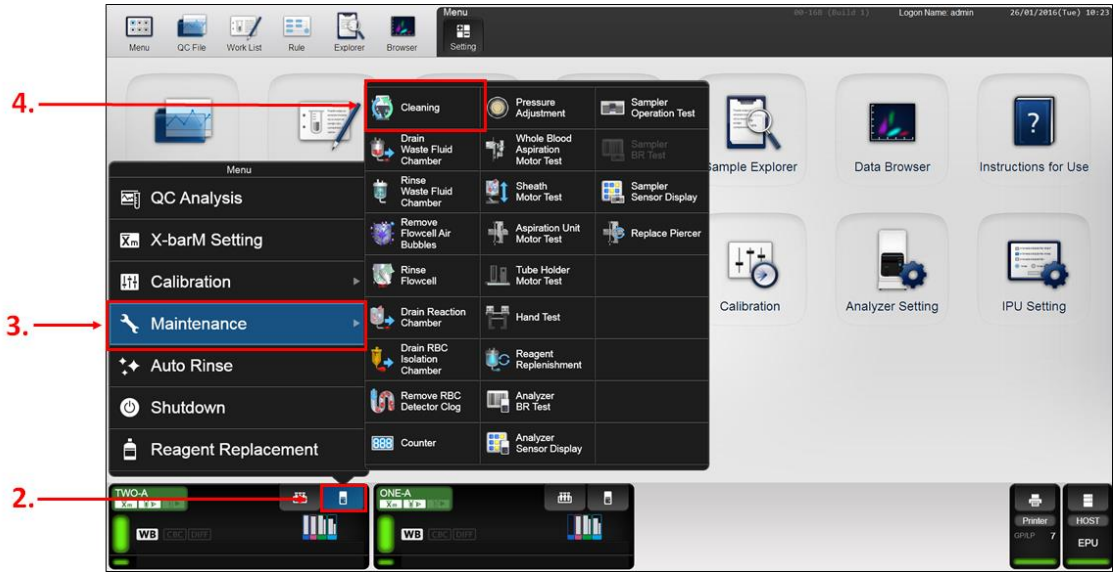


2. Select [Auto Rinse]

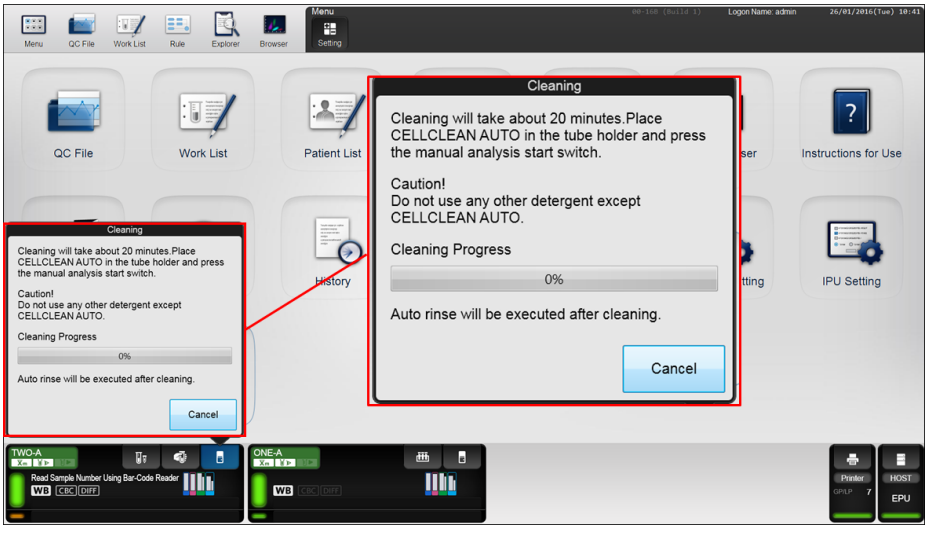
Cleaning procedure

The cleaning procedure is a longer clean than the daily shutdown procedure and can be performed if requested by the analyser or if following a daily shutdown the background check fails. If required, the analyser should be in the ready state with a solid green LED indicator light. To perform the cleaning procedure:

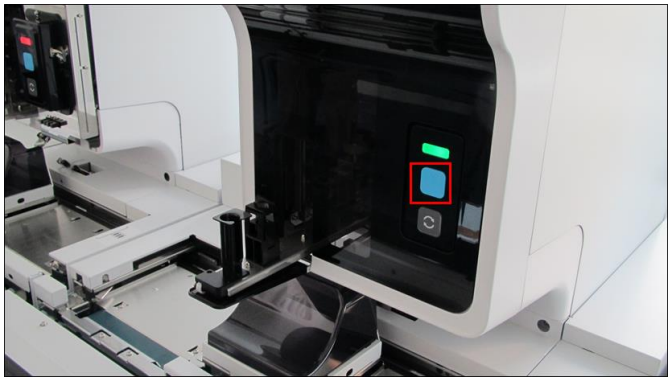
1. Locate the [Analyser Control] for the appropriate XN-Series analyser.
2. Select [Analyser menu].
3. Select [Maintenance].
4. Select [Cleaning]



5. Follow the instructions on the IPU - Place 4mL CELLCLEAN into a clean tube and place in the tube holder (cap removed).



6. Press the manual analysis start switch. The sample tube holder retracts into the analyser and aspiration begins. When aspiration is complete, the cleaning begins, and the tube holder ejects. The tube used can be removed at this stage or it can remain in the tube holder until the start-up process is complete.



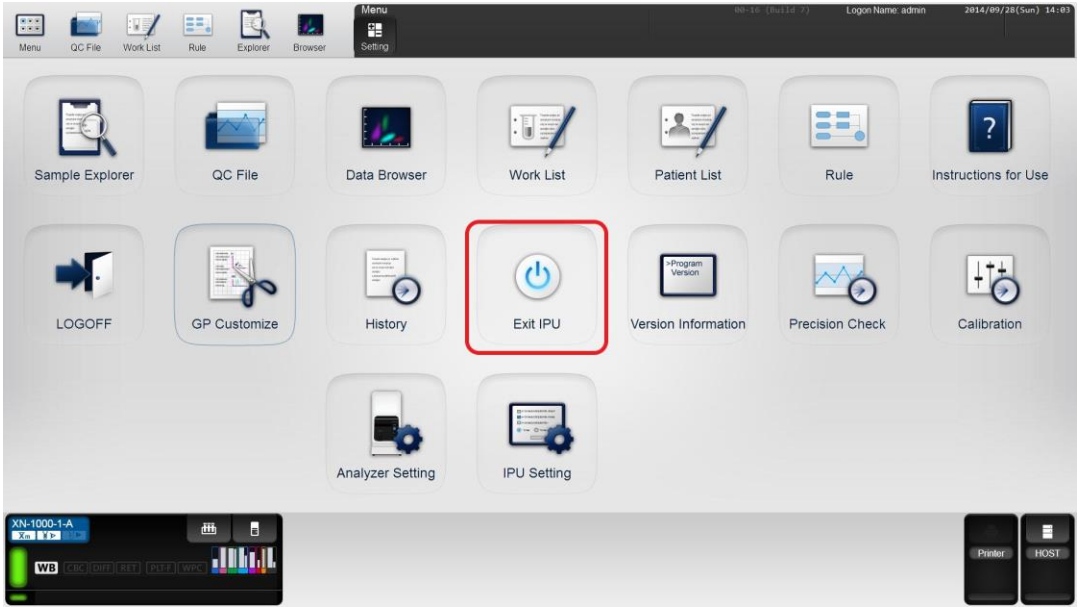
7. The shutdown procedure will take 20 minutes and on its completion the analyser will automatically commence an auto rinse and background check which will take approximately 3-4 minutes.

IPU Shutdown

To perform an IPU shut down:

1. Perform a shut down on all analysers attached to the IPU.

2. Once the analysers have been turned off at the main power switch select [Exit IPU] on IPU.



3. Using the windows key select [Shutdown].

4. Allow the IPU to shut down completely.

IPU Start-Up

To start the IPU back up it is important that the IPU is turned on first followed by the analysers.

To start up the IPU:

1. Turn on IPU at the desktop (computer).
2. IPU will go through the start-up process and preload the XN-Series software.
3. When the software loads up log in with the username ‘admin’, password ‘admin’.
4. Once IPU has restarted turn the analysers associated with that IPU on at the main power switch.
5. The analyser/s will commence the start-up procedure and will be ready for use when the LED indicator is solid green.

QC Material

The XN-Series uses QC material called XN CHECK, which comes in 3 levels:

Level 1 – Low Control

Level 2 – Normal Control

Level 3 – High Control

Overview of XN CHECK

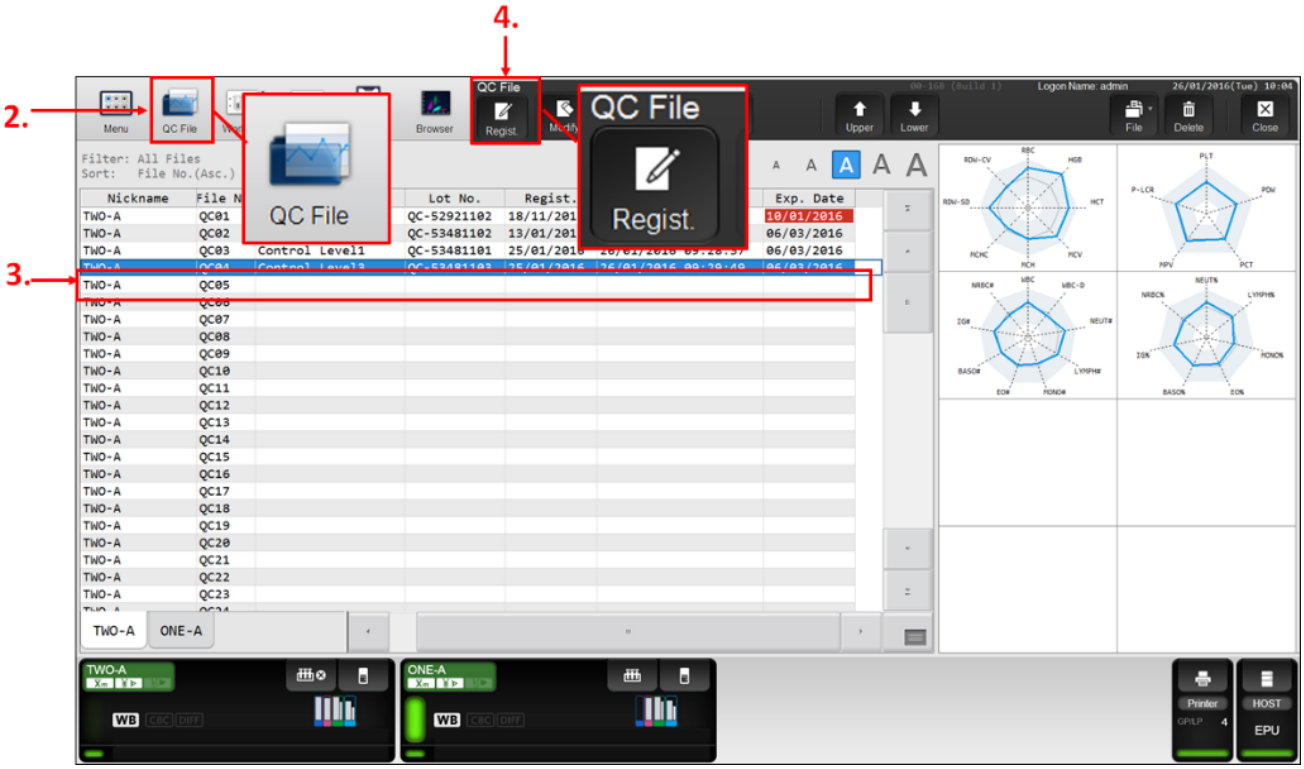
Information	Description
New Lot Numbers	New lots arrive in packs of 8 vials per level per analyser. Each lot lasts 8 weeks.
Stability	Once open XN CHECK is stable for 7 days.
Storage	XN CHECK should be stored at 2-8°C
Running XN CHECK	XN CHECK should be allowed to warm up to room temperature for a minimum of 15 minutes before use. XN CHECK should be manually mixed prior to analysis following the Sysmex guidance on mixing QC material. XN CHECK is only required to be run through a single mode of analysis.
Modes of Analysis	Sampler Mode Manual Mode

Registering New Lots of XN CHECK

New lots of XN CHECK will arrive approximately 2 weeks before the current lot of XN CHECK expires. Each lot and level received has a CD/USB attached, which contains all the lot and level information required to upload new lots on to the XN-Series analysers.

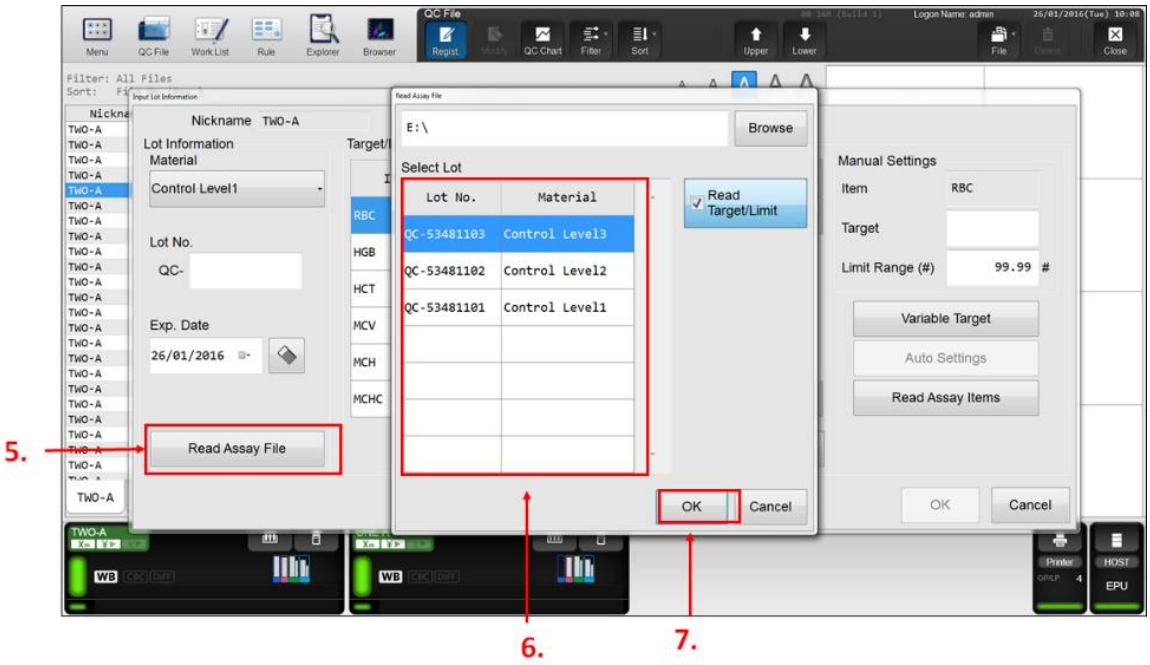
To register a new lot of XN CHECK:

1. Place the CD/USB received with the new lot/level into the CD drive/USB port of the IPU desktop.
2. Select [QC File].
3. Select an empty QC file.
4. Select [Regist.] which will open the 'Input Lot Information' Screen.



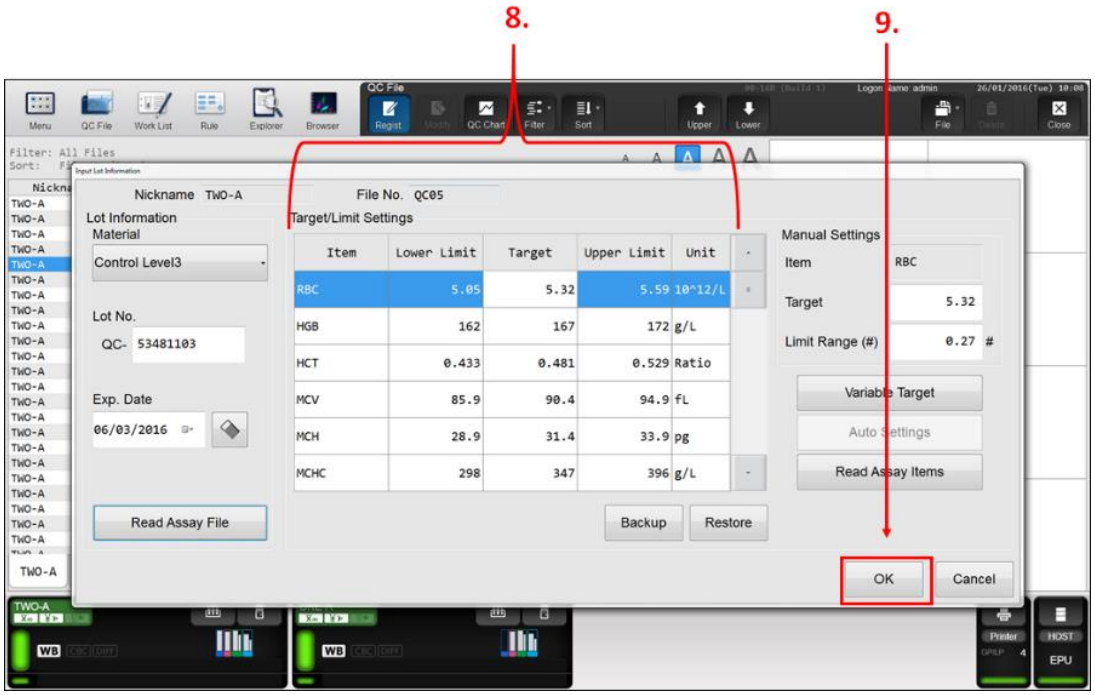
5. Select [Read Assay File]
6. The 'Read Assay file' screen displays all the levels and lots of QC present on the CD. Select the lot and level of QC to be registered and ensure the 'Read Target/Limit' box is checked.

7. Select [OK] to return to the ‘Input Lot Information’ screen.



8. The material level, lot number and expiry date will be present along with the ‘Lower Limit’, ‘Target’ and ‘Upper Limit’ for each parameter.

9. Select [OK]. Repeat process for each additional Lot/Level required and on each analyser.



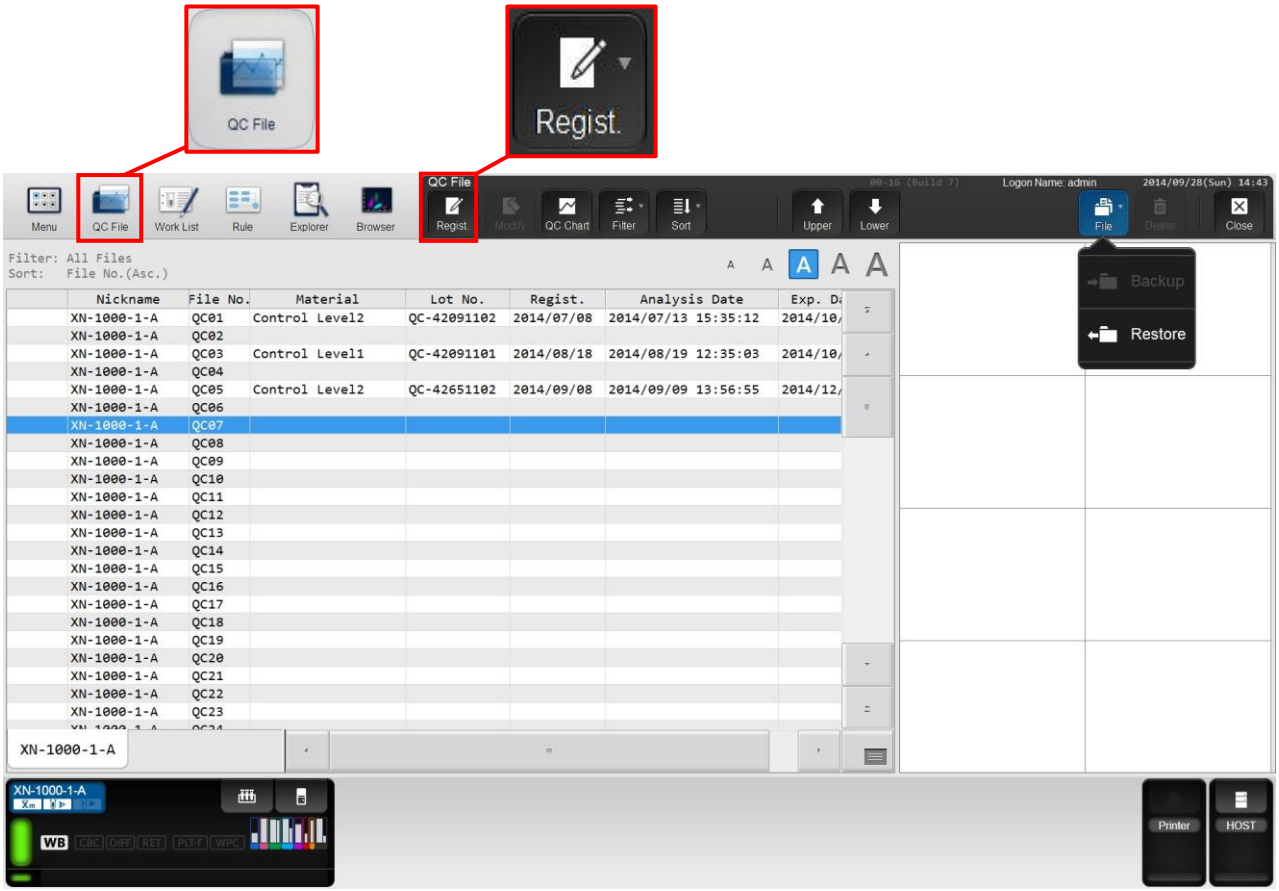
Setting up a NEQAS/EQA file

NEQAS samples should be processed as follows:

- Full blood count samples must be processed as patient samples.
- Automated Differential Leucocyte Count must be processed in QC Analysis mode.
- Reticulocyte samples must be processed as directed by NEQAS instructions.

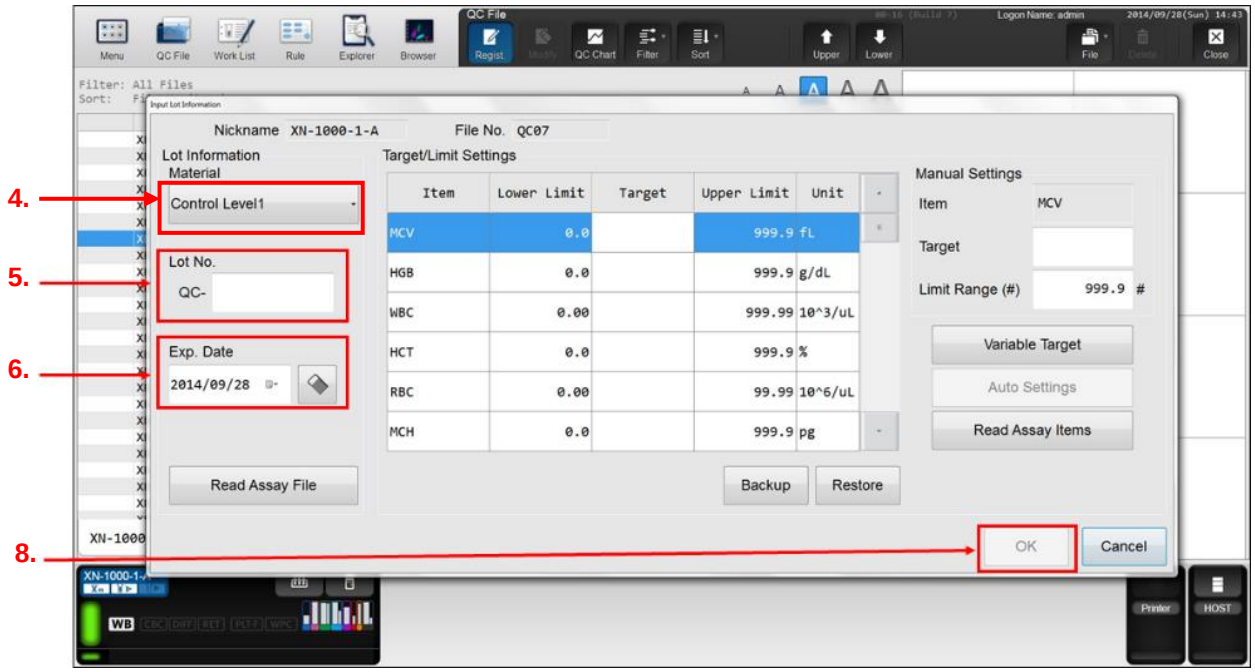
To set up a NEQAS/EQA file:

1. Select [QC File].
2. Select an empty QC file. It is recommended selecting a file towards the bottom of the screen to prevent accidental deletion of the file
3. Select [Regist.]



4. Ensure Material [Control Level 1/Control Level 2/Control Level 3] is selected.

IMPORTANT: Material [Other] changes the settings from QC settings to whole blood settings and this will result in incorrect NEQAS results, therefore, please ensure one of the [Control Levels] are selected.



5. Enter a file name under Lot No. QC - For instance NEQAS.

6. Select the Expiry Date for the file. It is recommended the expiry date is set for the end of the financial year

7. [Target/Limit Settings] should remain unaltered as NEQAS targets/limits are unknown.

8. Select [OK].

9. Repeat the process on each analyser.

Processing QC Material

Processing XN CHECK in Sampler Mode

QC material can be processed through all XN-Series analysers by running the QC material in sampler mode.

Processing QC material in Sampler Mode:

1. Place XN CHECK into a rack and load the rack onto the right hand side of the sampler unit in front of the XN-Series analyser.

2. XN CHECK will be processed on all XN-Series analysers.

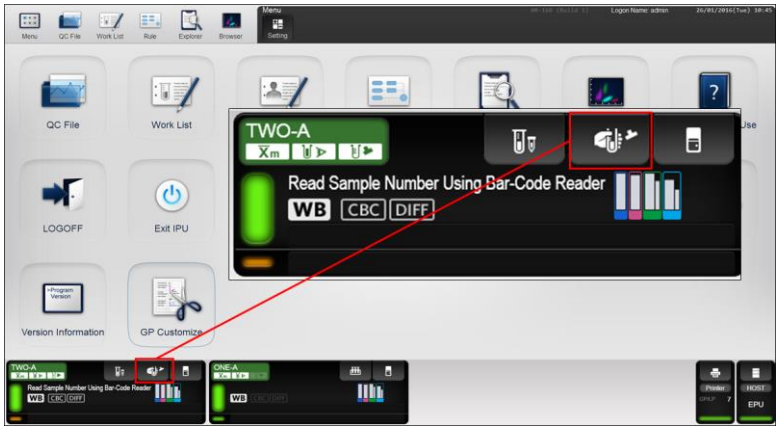
Processing XN CHECK in Manual Mode

QC material can be processed through individual XN-Series analysers by running the QC material in manual mode.

Processing QC material in Manual Mode:

1. Select the [Mode Switch] on the front of the XN-Series analyser to eject the manual tube holder.

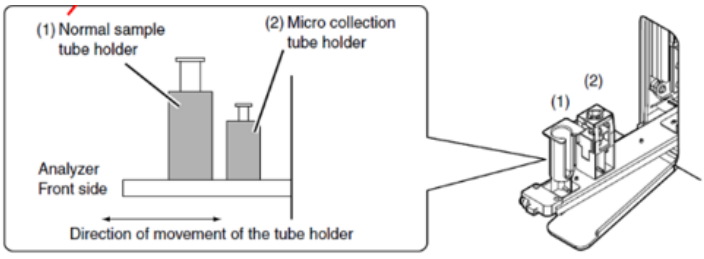
2. Once the manual tube holder has been ejected the [Manual Analysis button] will appear on the IPU in the corresponding analyser menu.

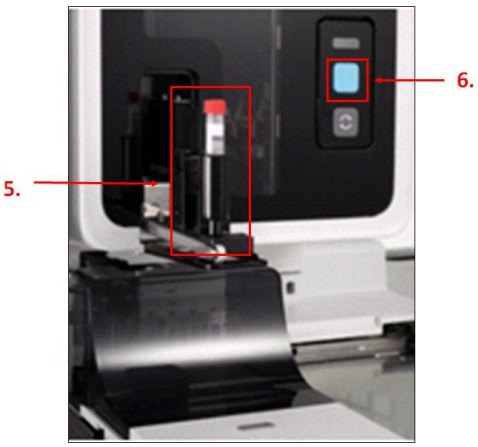


3. Select the [Manual Analysis button] and ensure that 'Read ID' and 'Aspiration Sensor' are both selected and 'Cap Open' is deselected.

4. Select [OK]

5. Manually mix the vial of XN CHECK and place it into the tube holder in the normal sample tube position and select [Start Switch]





6. Once the analysis is complete the manual tube holder will open allowing the XN CHECK to be removed.

7. Select the [Mode Switch] to close the manual tube holder.

Processing XN CHECK in QC analysis (EQA/NEQAS)

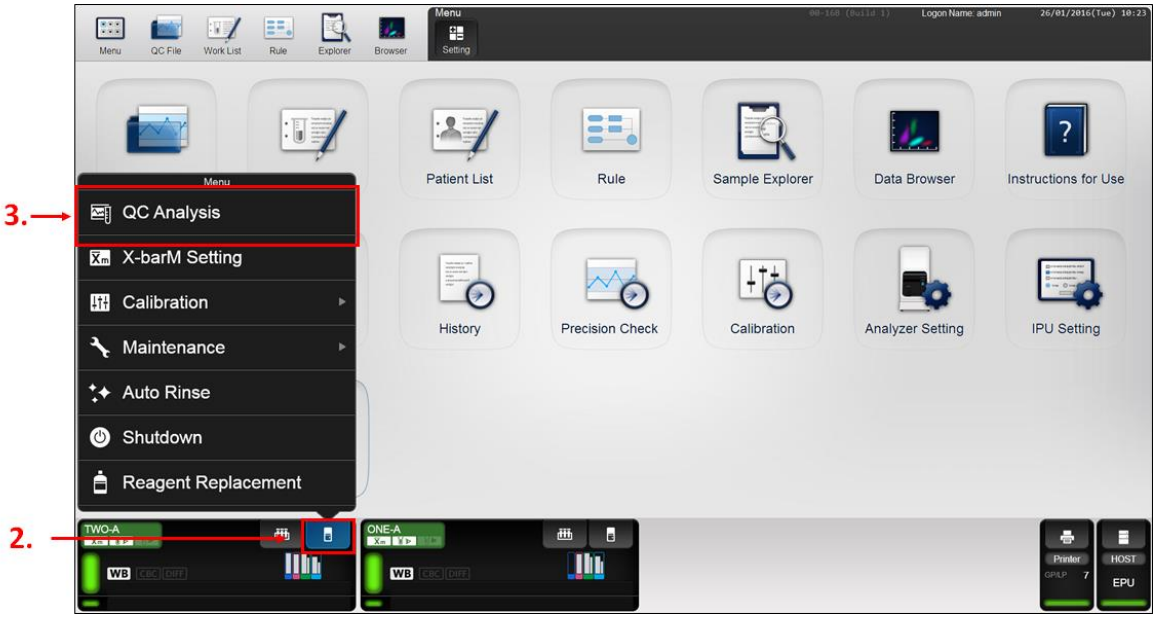
Running QC material in QC analysis mode requires the user to select the appropriate QC file and to accept QC before QC results are sent to the appropriate QC file.

NOTE: QC material run by this method does not have the QC material barcode read. This method of QC analysis is ideal for running External QC material such as NEQAS Automated Differentials, which require QC gating.

Processing QC material using QC analysis:

1. Select the [Mode Switch] on the front of the XN-Series analyser to eject the manual tube holder.

2. Select [Analyser Menu] on the appropriate XN-Series analyser.

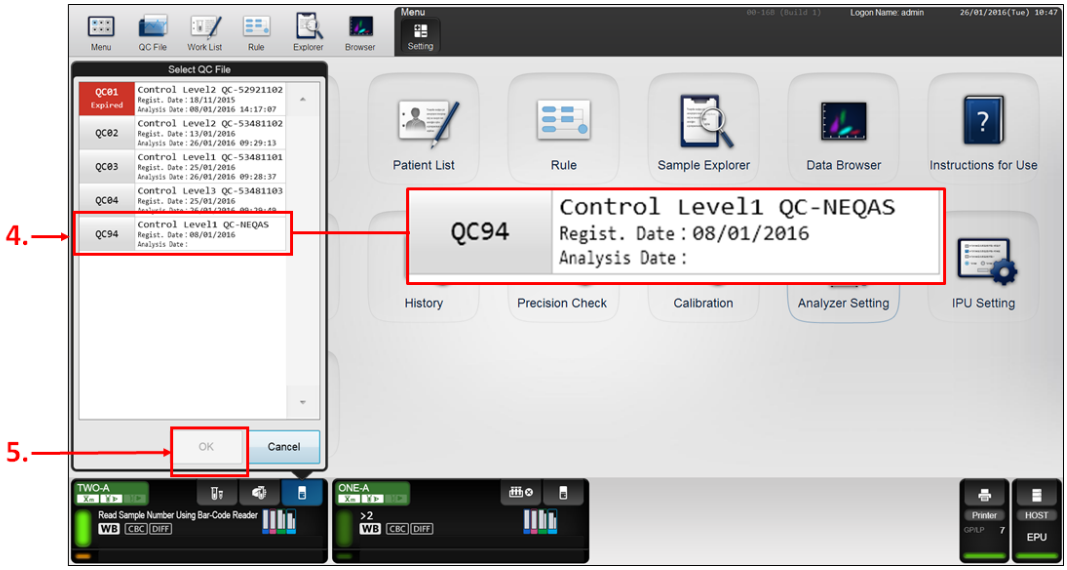


3. Select [QC Analysis] to display the [Select QC File] screen.

NOTE: QC analysis can **NOT** be selected if tube holder is **NOT** ejected.

4. Select the appropriate QC file, for instance NEQAS.

5. Select [OK]. When the QC File has been selected the Execute L-J tab will open.

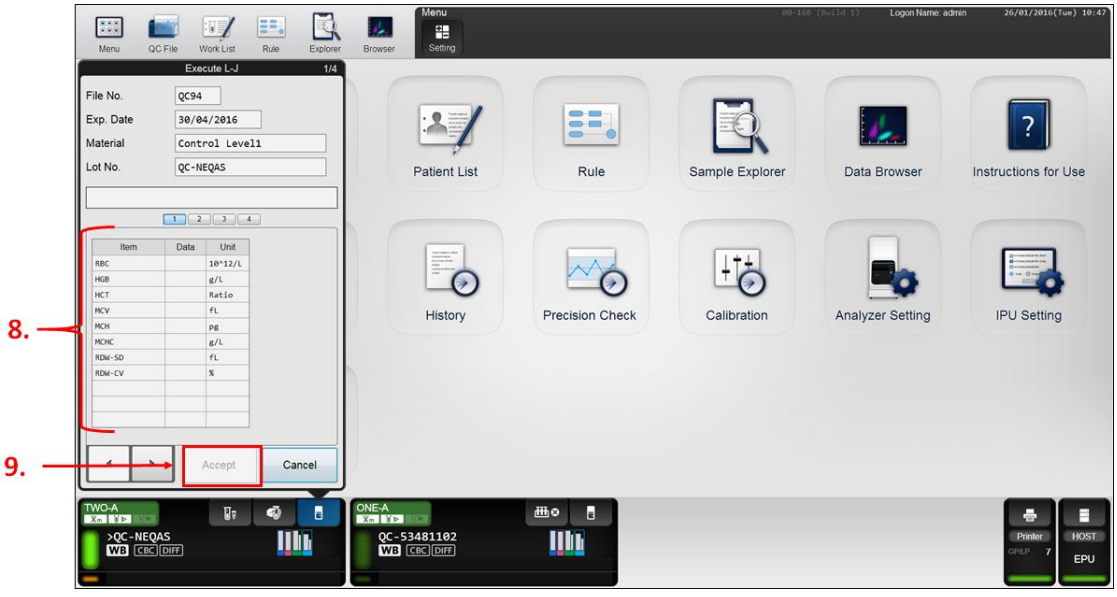


6. Run the NEQAS sample using the manual mode, ensuring the sample is manually mixed prior to analysis.

7. When analysis is complete the results will populate in the Execute L-J tab.

IMPORTANT: The 'Execute L-J screen will display the QC results. Any failed QC will be indicated by a red warning triangle. Different windows can be viewed by using the left and right arrows.

8. Check the results and select [Accept]. **NOTE:** If cancel is selected the QC results will be deleted ***(Not recommended).***

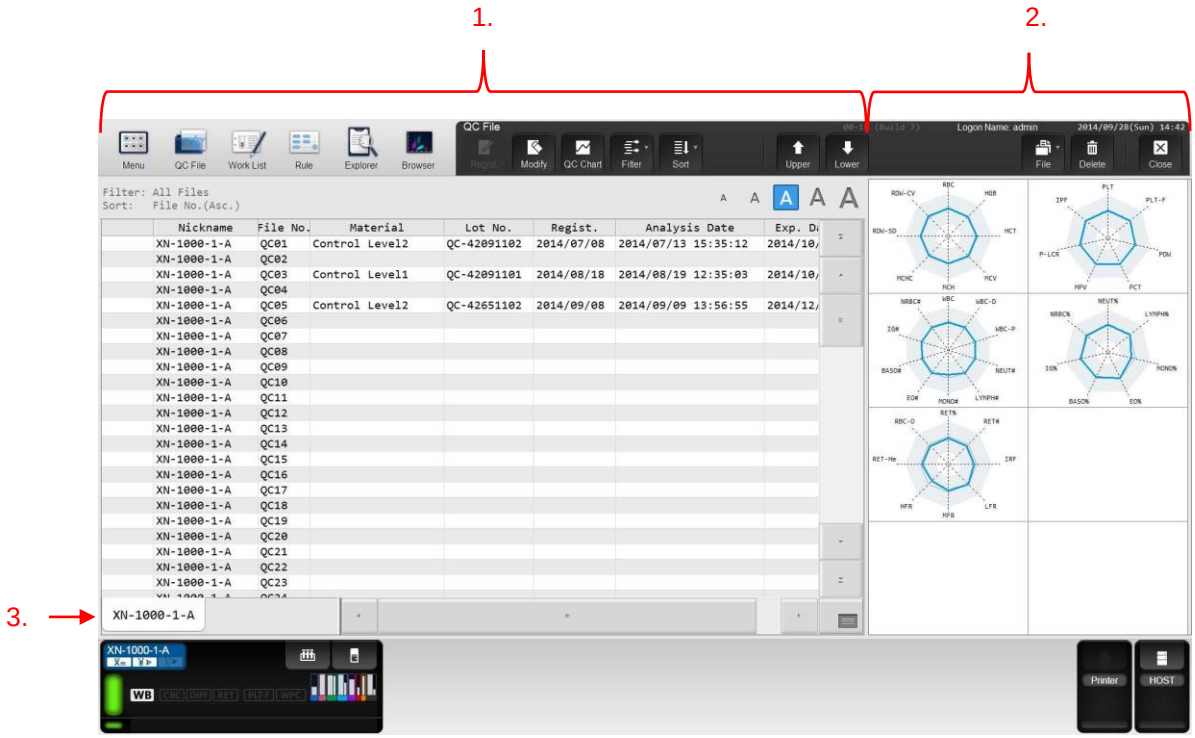


9. Once [Accept] has been selected the results will be filed in the Levy-Jennings Plot under [QC File].

Checking QC Results

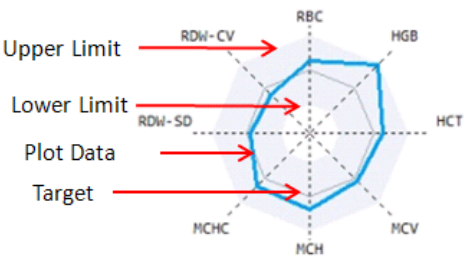
To check QC results, select [QC File] from the main menu on the IPU.

QC File



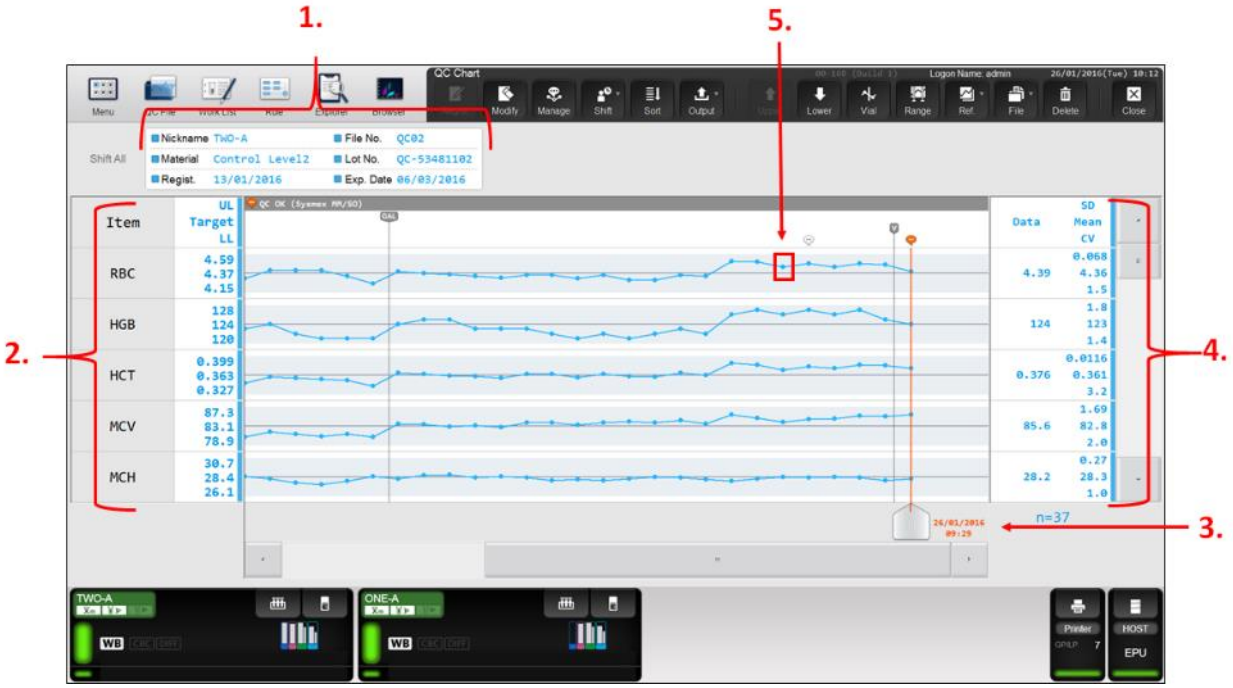
1. **QC File information**: includes file name, number, material, Lot No. register date, last analysis date/time and expiry date.

2. **Radar Plots -** Select the desired QC file and on the right hand side the last result will be displayed in radar plot format. Radar plots show the parameter names around the edge, the light grey area illustrates the target range for the QC (lower to upper limit) and the grey central line is the target value. **IMPORTANT**: Radar plots should not be used in isolation. L-J chart should always be checked in addition to check QC trends



3. **Analyser Tab –** When multiple XN-Series analysers are attached to a single IPU the QC data for each analyser is available in the relevant tab.

Levy-Jennings Plots



1. **Summary of QC File –** The summary section contains information such as material, lot number, expiry date and date registered.
2. **QC Parameters –** Parameters tested with target, upper limit and lower limit.
3. **Analysis Date –** Date and time of selected data point.
4. **Data Parameters –** Parameters for the QC point selected as well as the SD, mean and CV for all QC data points in this QC file.
5. **QC Plot –** Data points (within range ●, outside range ✕ or not managed ○).

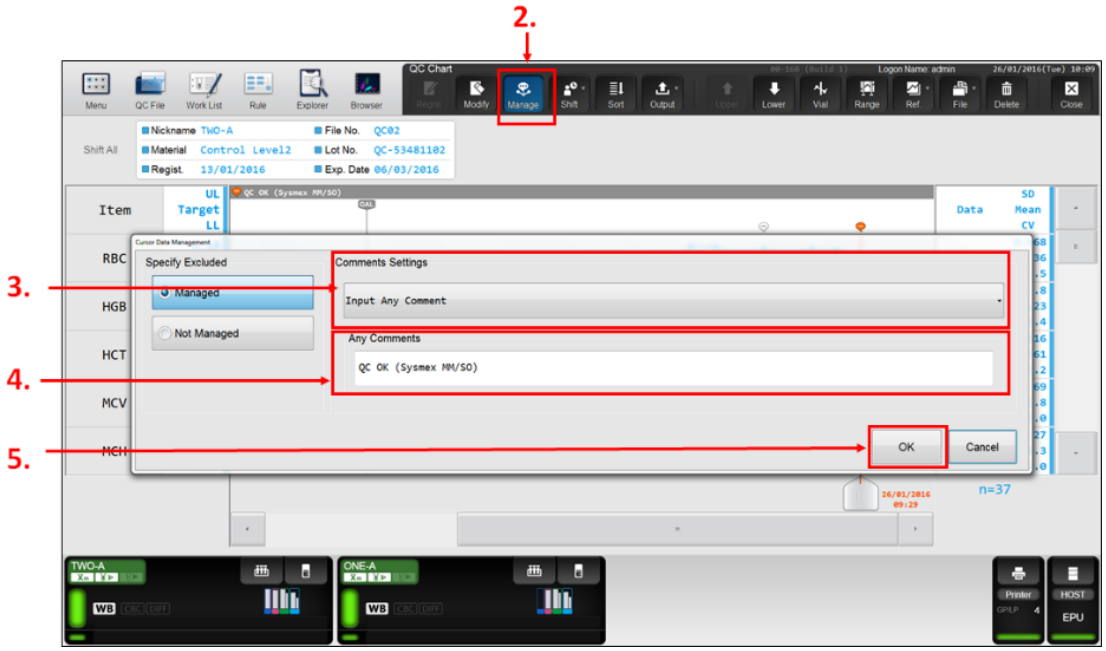
Managing QC points

'Manage' can be used to add QC comments and/or exclude a data point from QC file statistics. To add a comment to a data point;

1. Select the QC data point you wish to comment against.
2. Select [Manage].
3. Select the drop down menu and select [Input Any Comment].

4. Enter your comment into the ‘Any Comments’ box.

5. Select [OK]. The comment will be added against that QC point. The comment will appear in the comments section of the Levy-Jennings chart. If there is a comment present on a QC point a speech bubble will appear above the data point and the comment can be seen in the comment section on the top left of the Levy-Jennings chart.



To exclude or include a QC Point from statistical analysis:

1. Select the QC data point that requires management.

2. Select [Manage]

3. Select either include in statistics [Manage] or exclude from statistics [Not Manage] at the left hand side of the pop up box.

4. Select [OK].

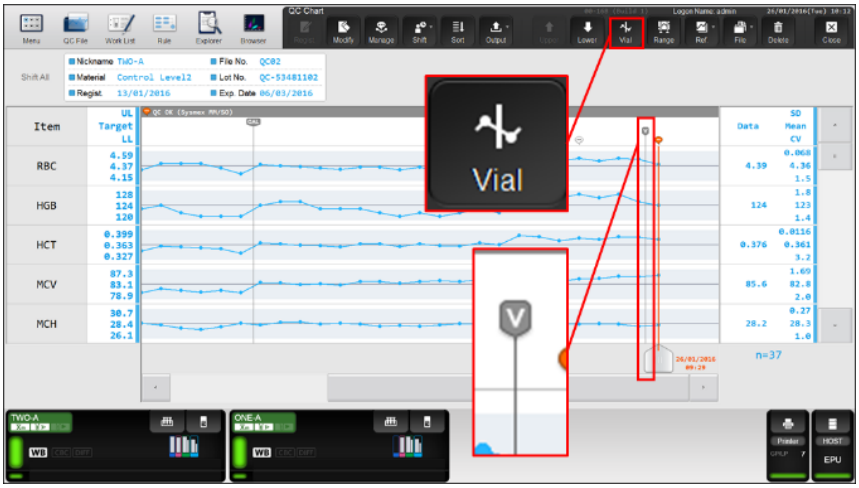
QC points may be ‘managed’ or ‘not managed’ as required. A QC point that is ‘managed’ is included in the statistical analysis on the right whereas a QC point that is ‘not managed’ will be excluded from the statistical analysis. All QC points will remain visible on the chart no matter the managed status

Adding a Vial Marker to the Levy-Jennings Chart

When a new vial of XN CHECK is opened a vial marker can be added to the Levy-Jennings chart to indicate this.

To add a vial marker:

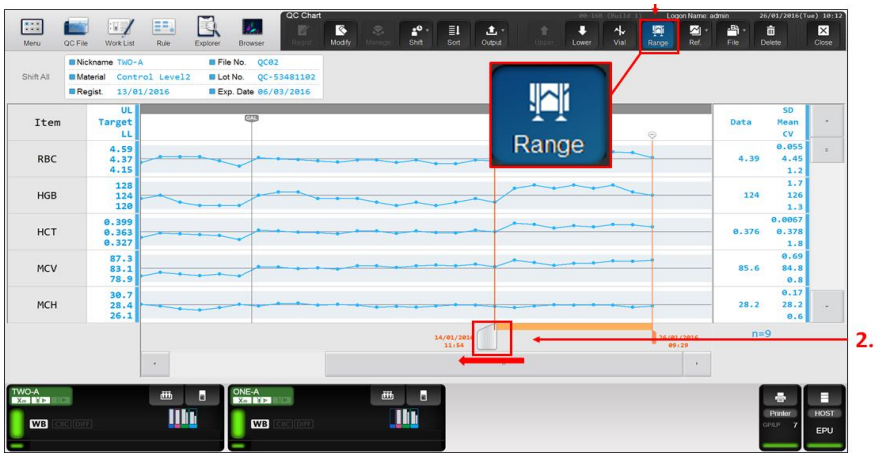
1. Run the new vial of XN CHECK through the XN-Series Analyser.
2. Select the QC data point of the new XN CHECK vial.
3. Select [Vial]. A vial indicator will appear on the Levy-Jennings plot to the left of the QC data point.



Selecting a Range of QC Data Points

A range of QC data can be selected by:

1. Select [Range].
2. Select and drag the cursor to select the range of QC points required.
3. To remove select [Range] again.



Comparing QC Files on XN-Series Analysers

It is possible to compare QC files between all XN-Series analysers connected to the same IPU or compare QC files on the same analyser.

To compare QC Files or analysers:

1. Select [Ref].
2. Select either [Compare QC files] or [Compare Analysers]:

[Compare QC Files]	Used to compare QC files on the SAME analyser
[Compare Analysers]	Used to compare QC files on DIFFERENT analysers connected to the same IPU

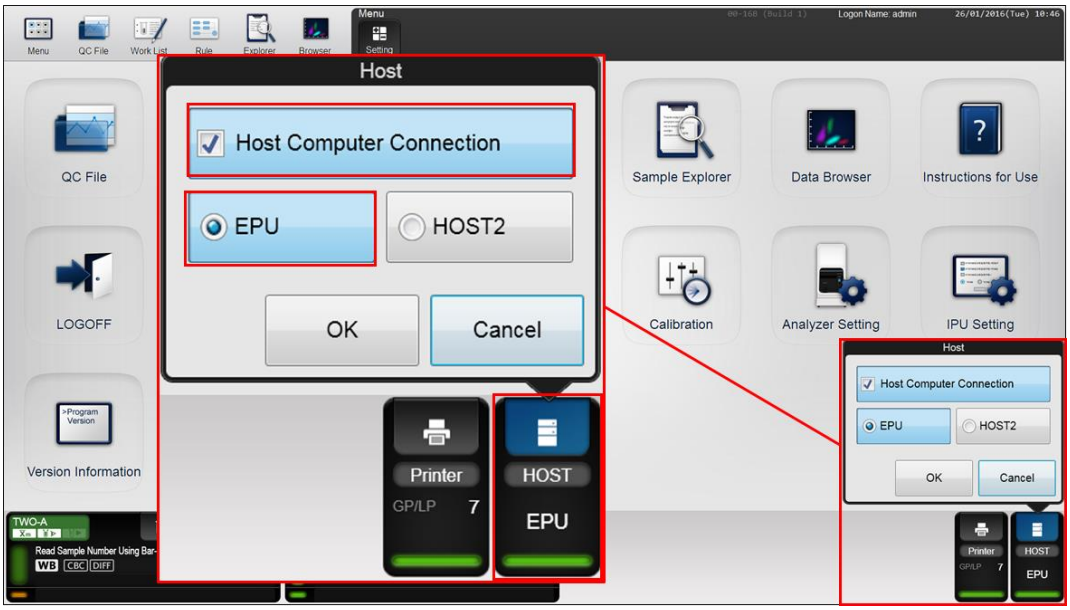
3. Select the Analyser or Lot No. for comparison.
4. To remove the comparison, select [Ref] then [None]

Connecting/Disconnecting Host

The analyser should always have host communication switched on. This enables the analyser to host query for required tests when presented with a sample barcode.

To Turn on Host Communication:

1. Select [HOST]
2. Select [Host Computer Connection]
3. Select the appropriate host connection and press [OK]



To Turn off Host Communication:

1. Select [HOST]
2. Deselect [Host Computer Connection]
3. Press [OK].

Running Patient Samples

Patient samples can be analysed using the following modes:

Mode	Description
Manual Closed Mode:	In this analysis mode, the operator loads the sample tubes individually by hand with lid **ON** (closed mode) The operator MUST mix the samples by hand. Use this analysis for STAT samples.
Manual Open Mode:	In this analysis mode the operator loads the sample tubes individually by hand with lid **OFF** (open mode). The operator MUST mix the samples by hand. Open mode should be used on any small volume samples in a normal tube type, pre-dilution mode or body fluid samples (if available).
Raised Bottom Tube (RBT):	In this analysis mode, the operator loads the sample tubes individually by hand with lid **ON** (closed mode) The operator MUST mix the samples by hand. The analysis is performed using raised bottom tubes to reduce dead volume.
Micro (Open) mode:	This is a type of manual analysis. In this analysis mode the operator loads the sample tubes individually by hand with lid **OFF**. The operator MUST mix the samples by hand. The analysis is performed using a micro tube, to further reduce dead volume.
Sampler/System mode	This type of analysis allows samples to be run in racks with lid on (closed mode). Racks can be placed on to the sampler unit (Sampler mode) or in the Start yard (XN-9x000 analysers only). Samples should be well mixed before placing in racks. Samples will be turned to locate sample barcode. The barcode will be used to query the host for patient ID and tests required. The sample is then re-suspended by the analyser before a second barcode and aspiration of the sample.

Insufficient Samples

IMPORTANT: The detection of insufficient samples is via the blood detector and the aspiration sensor.

The Blood Detector assesses the samples prior to aspiration by ‘looking’ through the bottom of the tube when in the rack. If no blood is detected in the tube the sample is not aspirated. This however will not work as designed if the samples have labels placed on the tube below the level of the manufacturer’s label.

The Aspiration Sensor monitors the aspiration status of whole blood in sampler and closed mode of analysis. There are two errors relating to sample aspiration; ‘Blood cannot be aspirated’ error and ‘Insufficient Blood Volume’ error. Samples with either of these errors should be checked for low blood volume and/or low Hb.

Sample requirements

Mode(s)	Analysis method	Support	Asp Volume	Minimum sample volume
 **Whole blood mode** Used for the analysis of whole blood.	Sampler	✓	88µl	1ml
	Manual closed	✓	88µl	1ml
	Manual Open	✓	88µl	300µl
	Raise Bottom Tube	✓	88µl	250µl
	Manual Open micro	✓	88µl	160µl
 **Low WBC Mode** Used for the analysing low WBC using whole blood. The count time of the WDF channel is set to 3 times that of whole blood mode to increase the WBC measurement accuracy.	Sampler	✓	88µl	1ml
	Manual closed	✓	88µl	1ml
	Manual Open	✓	88µl	300µl
	Raise Bottom Tube	✓	88µl	
	Manual Open micro	✓	88µl	160µl
 **Pre-Dilution Mode** 1:7 dilution (i.e. 50µl WB/300µl Cell pack DCL). Used for analysing small volumes of blood.	Sampler	-	-	-
	Manual closed	-	-	-
	Manual Open	✓	70µl	300µl
	Raise Bottom Tube	-	-	-
	Manual Open micro	✓	70µl	140µl (after dilution)
 **Body Fluid Mode** Used for analysing body fluids.	Sampler	-	-	-
	Manual closed	✓	88µl	1ml
	Manual Open	✓	88µl	300µl
	Raise Bottom Tube	✓	88µl	250µl
	Manual Open micro	✓	88µl	160µl

Processing samples in Sampler Mode

IMPORTANT: Please ensure that samples are mixed sufficiently before being placed on the analyser. Any delay in processing after mixing may lead to the production of incorrect results. This is especially important for samples from patients prone to high degrees of sedimentation or for samples that have been refrigerated/transported in a cool environment.

1. Place samples into a rack and load the rack onto the right hand side of the sampler unit in front of the XN-Series analyser. The rack will be automatically fed into the analyser(s) for processing.

2. When processing is complete the rack will become available on the left hand side of the sampler unit.

Note: On an XN-2000 and XN-3x00 racks may be held in the reflex bay for a short period until sample analysis has been completed. If any reflex/repeat tests are required the rack will automatically be reintroduced to the appropriate analyser.

Changing the Measurement Mode

Depending on the configuration of the XN-Series analyser there are up to four modes of analysis on board:

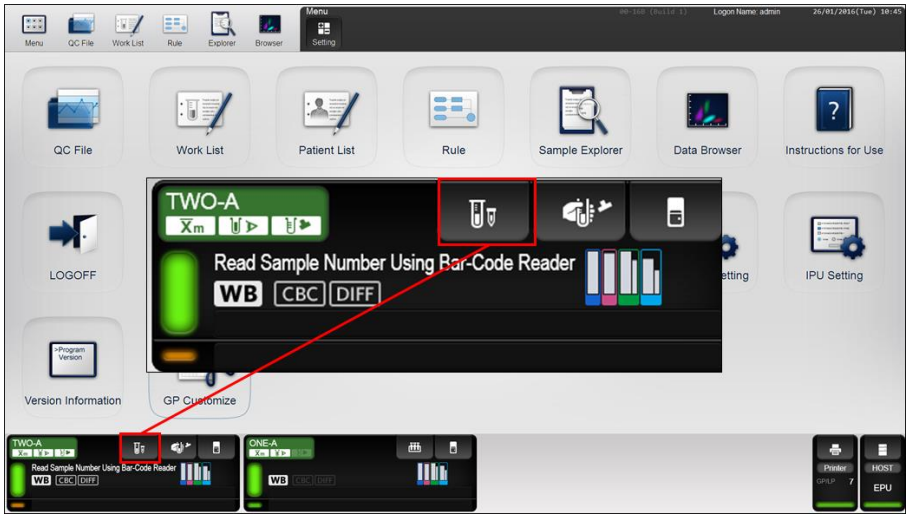
1. Whole Blood (WB)
2. Low WBC (LW)
3. Pre-Dilution (PD)
4. Body Fluid (BF) mode (if available)
5. HPC mode (if available)

To Change the Measurement Mode:

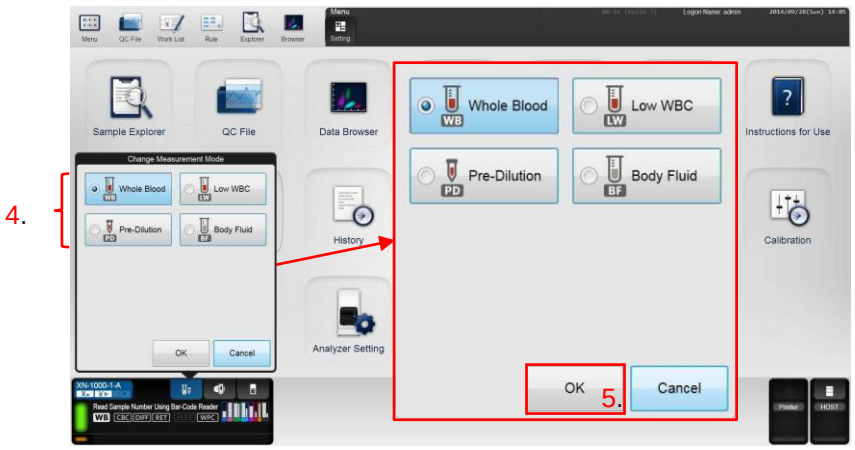
1. Select the [Mode Switch] on the front of the XN-Series analyser to eject the manual tube holder.

2. Once the manual tube holder has been ejected the [Change Analysis mode button] will appear on the IPU in the corresponding analyser menu.

3. Select [Change Analysis mode button].



4. Select the Measurement Mode required. If Pre-dilution mode is selected a 1:7 dilution must be performed manually prior to analysis. When Body Fluid and Pre-dilution mode are selected the analyser will perform a background check automatically.



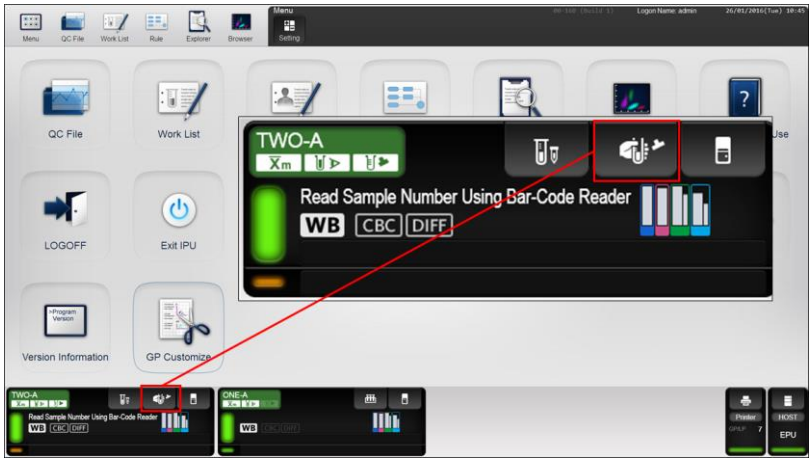
5. Select [OK]

Processing Samples in Manual Analysis (Open/Closed/Micro/Raised Bottom Tube)

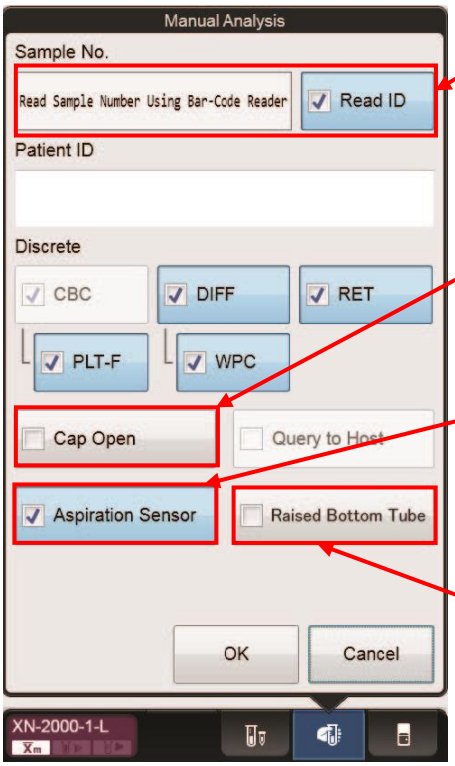
1. Select the [Mode Switch] on the front of the XN-Series analyser to eject the manual tube holder.

2. Once the manual tube holder has been ejected the Manual Input icon will appear on IPU in the corresponding analyser menu.

3. Select the [Manual Analysis button]



4. Ensure the manual mode is set up appropriately.



Read ID: When [Read ID] is selected the analyser will read the sample barcode. For samples loaded into the manual (micro) open position this option must be deselected and the barcode number MUST be manually entered.

Cap Open: Select [Cap Open] when running samples with caps removed. **NOTE:** All samples run in the manual (micro) open position MUST have the caps removed.

Aspiration Sensor: The aspiration sensor should always be selected, except in cases of severely low haemoglobins (Hb <50 g/L). Aspiration sensor is automatically turned off in Pre-Dilution (PD) and Body Fluid (BF) modes.

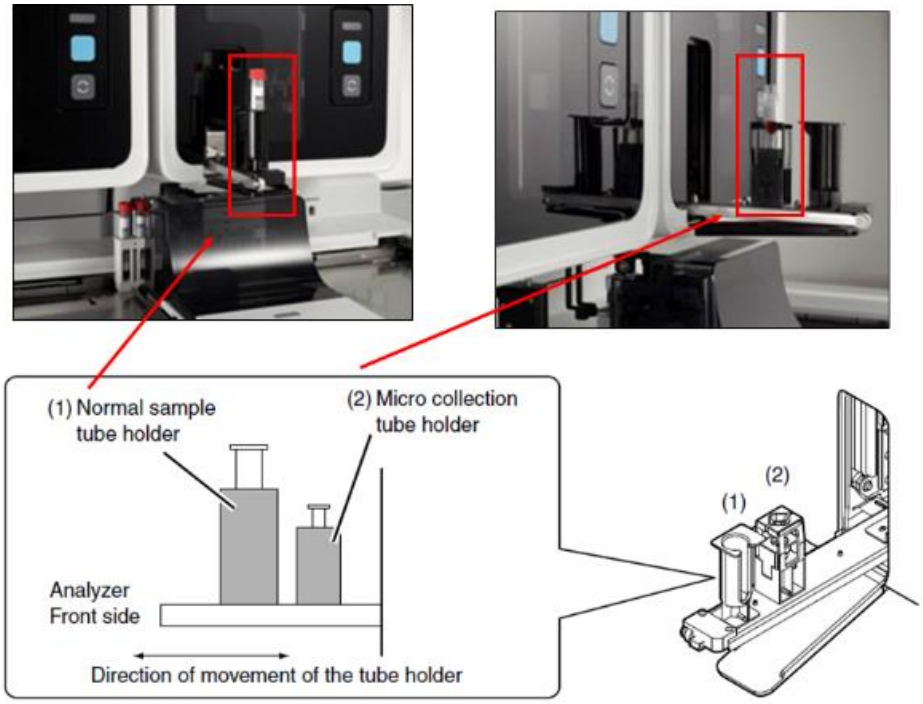
Raised Bottom Tube: Select [Raised Bottom Tube] when running samples with raised/elevated bottom tubes, to minimise dead volume. **NOTE:** Pre-dilution and body fluid mode cannot be utilised when using RBT samples.

6. Manually mix the sample and place it into the manual tube holder in the appropriate position.

IMPORTANT: Please ensure that samples are mixed sufficiently before being placed on the analyser. Any Delay in processing after mixing may lead to the production of incorrect results. This is especially important for samples from patients prone to high degrees of sedimentation or for samples that have been refrigerated/transported in a cool environment.

Analysis method	Tube holder position
Manual closed	Normal Sample tube holder (1)
Manual Open	Normal Sample tube holder (1)
Raise Bottom Tube	Normal Sample tube holder (1)
Manual Open micro	Micro collection tube holder (2)

When inserting a micro collection tube, insert the tube all the way in so that the bottom of the tube contacts the base of the holder (always remove cap when using manual (open) micro mode).

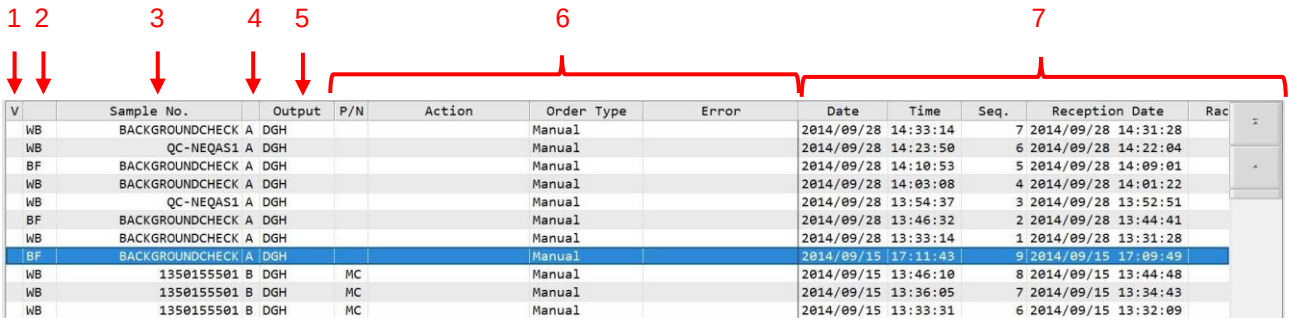


7. Press [Start Button]
8. Once the analysis is complete the manual tube holder will open allowing the sample to be removed.
9. Select the [Mode Switch] to close the manual tube holder.

Checking Patient Sample Results

Sample Explorer Screen

The Sample Explorer allows the user to display, validate and output patient results. The database can hold up to 100,000 sample results and also holds QC and background counts performed on the analyser.



V		Sample No.	Output	P/N	Action	Order Type	Error	Date	Time	Seq.	Reception Date	Rac
	WB	BACKGROUNDCHECK	A DGH			Manual		2014/09/28	14:33:14	7	2014/09/28 14:31:28	
	WB	QC-NEQAS1	A DGH			Manual		2014/09/28	14:23:50	6	2014/09/28 14:22:04	
	BF	BACKGROUNDCHECK	A DGH			Manual		2014/09/28	14:10:53	5	2014/09/28 14:09:01	
	WB	BACKGROUNDCHECK	A DGH			Manual		2014/09/28	14:03:08	4	2014/09/28 14:01:22	
	WB	QC-NEQAS1	A DGH			Manual		2014/09/28	13:54:37	3	2014/09/28 13:52:51	
	BF	BACKGROUNDCHECK	A DGH			Manual		2014/09/28	13:46:32	2	2014/09/28 13:44:41	
	WB	BACKGROUNDCHECK	A DGH			Manual		2014/09/28	13:33:14	1	2014/09/28 13:31:28	
	BF	BACKGROUNDCHECK	A DGH			Manual		2014/09/15	17:11:43	9	2014/09/15 17:09:49	
	WB	1350155501	B DGH	MC		Manual		2014/09/15	13:46:10	8	2014/09/15 13:44:48	
	WB	1350155501	B DGH	MC		Manual		2014/09/15	13:36:05	7	2014/09/15 13:34:43	
	WB	1350155501	B DGH	MC		Manual		2014/09/15	13:33:31	6	2014/09/15 13:32:09	

1. **V (Validate) -** A ‘V’ will appear for validated samples. If a sample has not been validated, nothing is displayed (as above).

2. **Analysis Mode -** This column shows the analysis mode for each sample.

   [WB]: Whole blood
   [LW]: Low WBC
   [PD]: Pre-diluted
   [BF]: Body fluid (if available)

3. **Sample No. –** Displays the sample/QC/background number.

4. **Sample Information –** Shows the source of the Sample No.

   [A]: Automatically incremented
   [B]: ID barcode scanned
   [M]: Manually entered
   [C]: Host computer queried

5. **Output -** Displays the output destination that has not been used to output the analysis result too. for example if results have been sent to host the H will be removed.

   [D]: Ticket printer (DP)
   [G]: Graphic printer (GP)
   [H]: Host computer (HC)

6. **Flagging**: Includes Positive/Negative flags, Action flags, Order type and errors.

   a. **P/N (Positive/Negative) -** Displays whether an analysis result is Positive or Negative (Positive indicates a flag has been generated).

   [D]: Diff. Positive
   [M]: Morph. Positive
   [C]: Count Positive

   b. **Action** – Displays a combination of the action message categories; Check, Review, Retest, for any relevant action messages that have been generated.

   c. **Order Type** – Displays the type of order of the analysed sample.

   d. **Error** – Displays the error type; Result or Func, relating to any errors that have occurred.

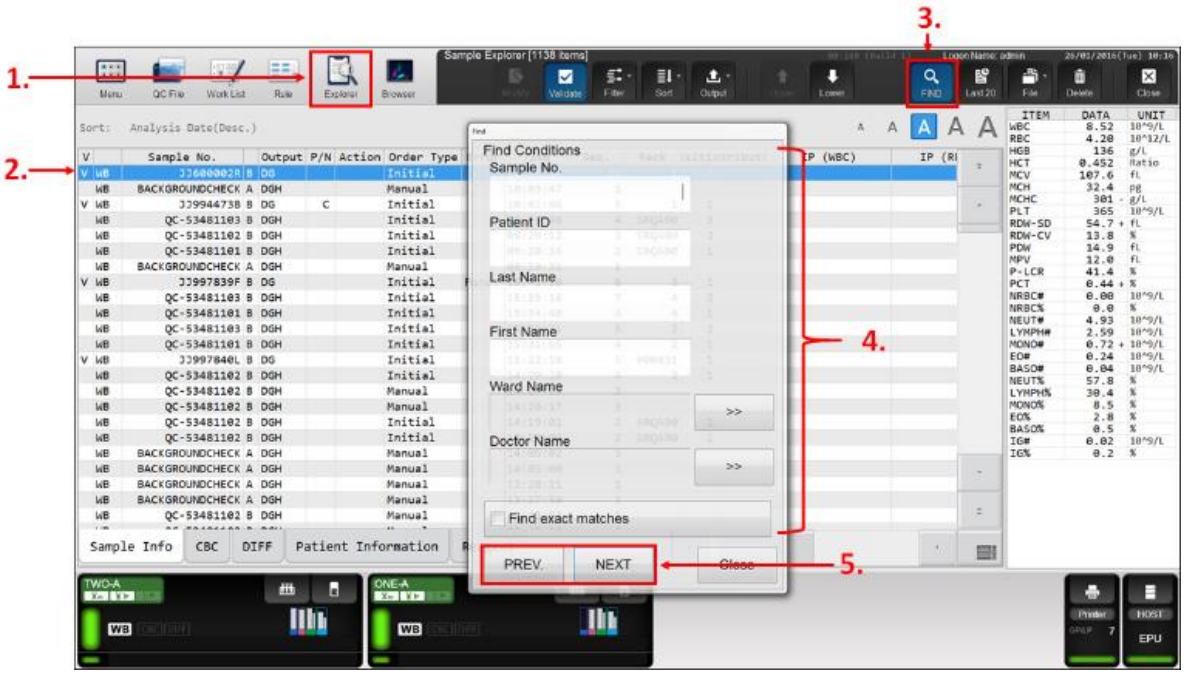
7. **Changeable display –** The display on the right hand side is changeable depending on the tab selected (lower left of the Sample Explorer Screen).

[Sample Info]:	Date and Time of analysis.
[CBC]:	Displays full blood count results for each sample.
[DIFF]:	Displays differential results for each sample.
[RET]:	Displays reticulocyte results for each sample
[Body Fluid]:	Displays body fluid results for each sample.
[Reagent]:	The lot number of each reagent used for the analysis of this sample.

Finding a Sample

To search for a patient sample in the sample explorer screen:

1. Open the [Explorer] screen
2. Select the most recent sample which will appear at the top of the screen. **NOTE:** If the most recent sample is not selected at the start of the search you will have to select [NEXT] to search below the sample highlighted in blue and [PREVIOUS] to search above the sample highlighted in blue.

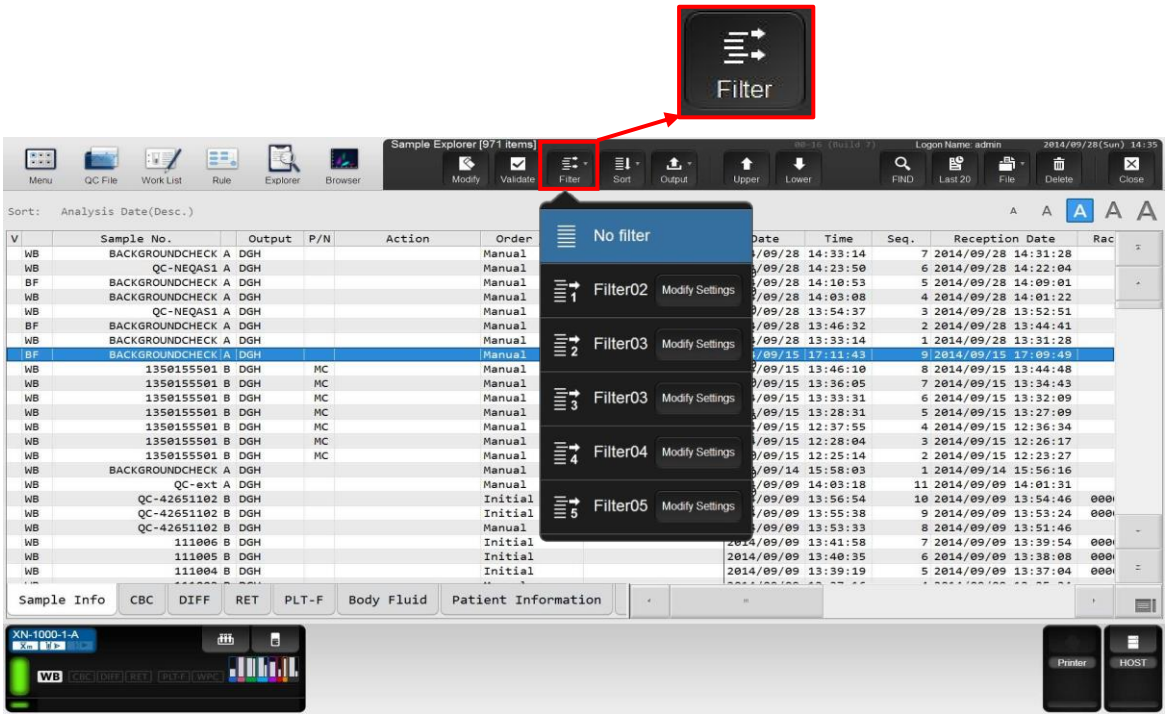


3. Select [Find]
4. Enter in the search criteria i.e. sample number, first or last name of the patient.
5. Select [NEXT]

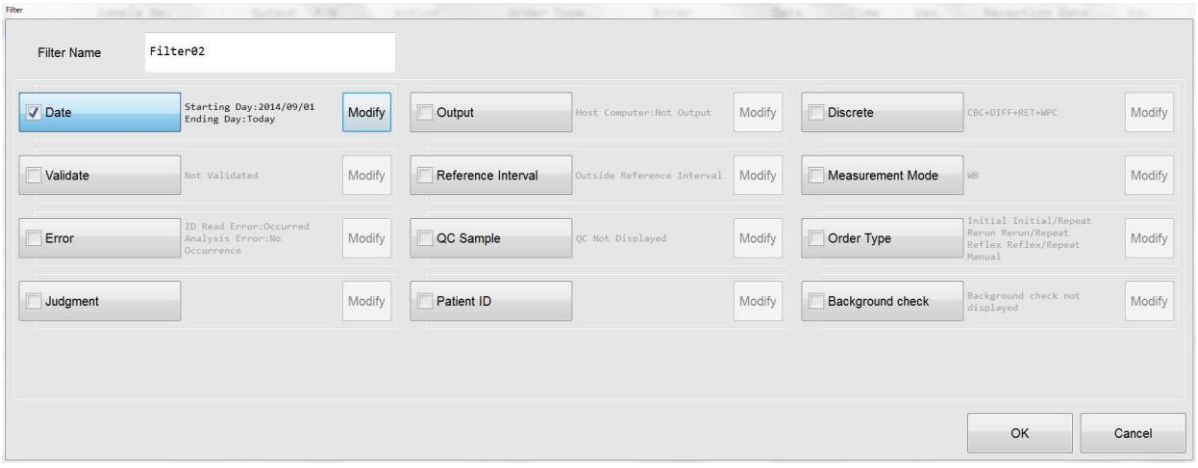
Applying a Filter to Sample Explorer

A filter can be applied to sample explorer such as date, analyser, order type etc. to display only specific samples. To Apply a Filter:

1. Select [Filter]



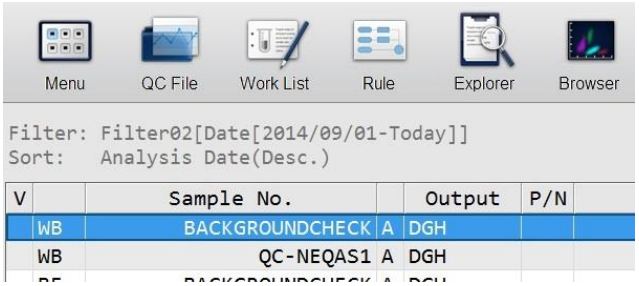
2. Select the Filter criteria.



3. Select [OK]

4. The results that match the filtered criteria will appear in Sample Explorer.

5. Once a filter is applied if a sample is searched for that does not meet the filtered criteria it will not be found. The filter being applied can be identified in the top left corner of the Explorer screen

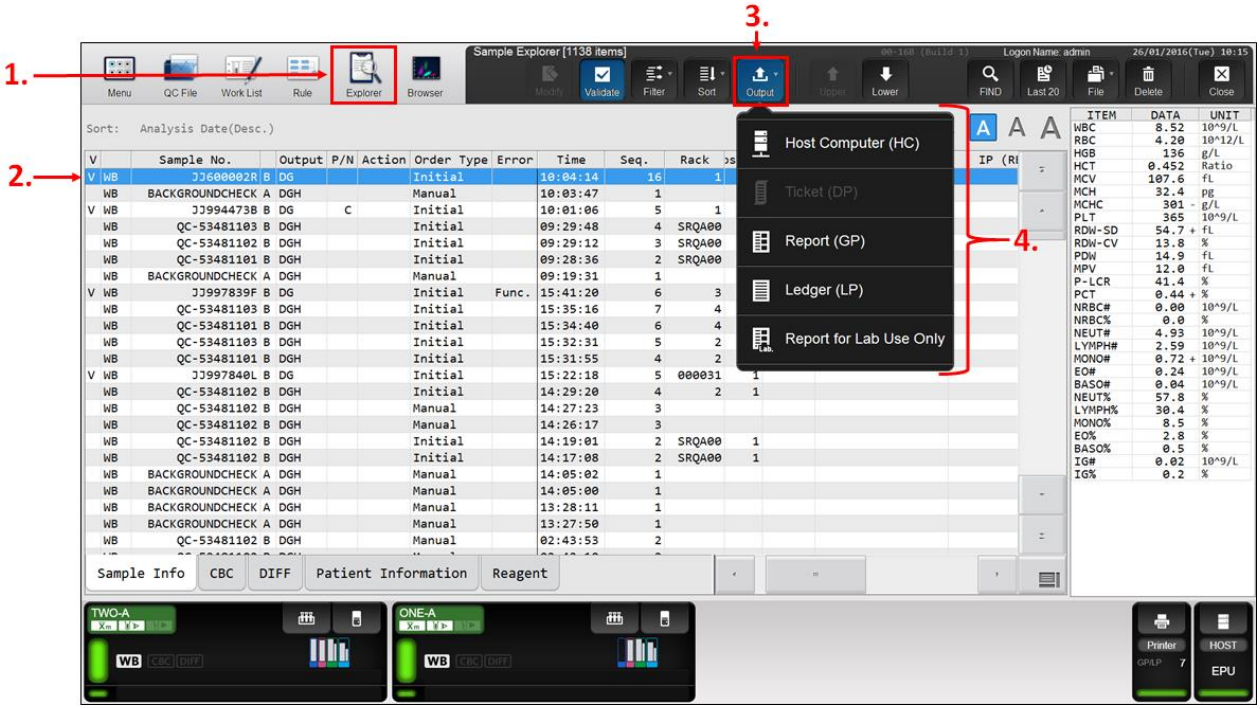


Outputting Sample Results

Sample results can be outputted to several destinations such as host and printed out. To output sample results from sample explorer:

1. Open the [Explorer] screen.

2. Select the result to be outputted (Sample will be highlighted blue). **TIP**: To select a block of results, select the first result, hold down [Shift] key and select the last result. To select random results hold done [Ctrl] key and select all results required individually



3. Select [Output]

4. Select the relevant output option

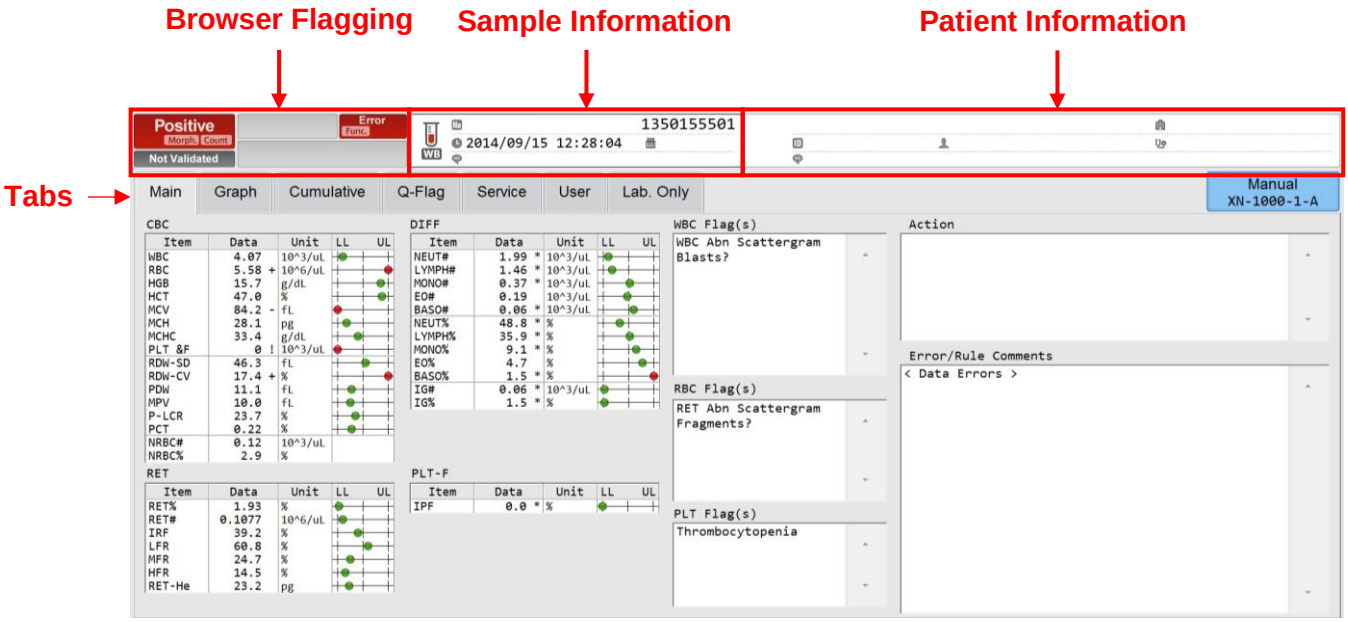
[Host Computer (HC)]:	Used to retransmit the result to HOST
[Ticket (DP)]:	Ticket printer (not in use)
[Report (GP)]:	Customisable printout
[Ledger (LP)]:	Ledger print out
[Report for Lab Use Only]:	Print out contains a whitewash in the background stating for Laboratory Use Only.

Data Browser Screen

The Data Browser Screen is a detailed display of the patient information including results, scatterplots, histograms, action and error messages and interpretative flags.

To view the Data Brower Screen:

1. Select the patient sample in Sample Explorer.
2. Select [Browser] or double click the sample in Sample Explorer.



Patient Information – Displays the patient information

Sample Information – Displays the sample information

Browser Flagging – Shows whether an analysis result is Positive or Negative.

No abnormality

One or more positive IP message

Positive/Negative Flags – Negative indicates no flags were generated, whereas, Positive indicates that one or more interpretive messages have been generated. Further information on the 'Positive' flag can be seen highlighted.

The positive flags are categorised as either:

[Diff]:	Abnormal blood cell differential value
[Morph]:	Abnormal cell morphology
[Count]:	Abnormal blood cell count

With further information on which 'Diff', 'Morph' or 'Count' flag has been generated being found in the 'IP Messages' section of the 'Main' tab of the browser screen.

Action Flag – The 'browser flagging' area also shows whether any 'Action', 'Error' or 'Rule' flags have been generated (not show in image above).

Check – Check the sample
Review – A channel difference has occurred
Retest – Displays mode and order (to prompt analysis)

Further information on these flags can be seen in the 'Action messages' section on the 'Main' tab of the browser screen.

Error Flag – The 'browser flagging' area also shows whether any errors have occurred during the analysis and are categorised as either:

Result – Blood can't be aspirated, insufficient volume or low count error
Func. – Other error (NOT a result or barcode reader error)

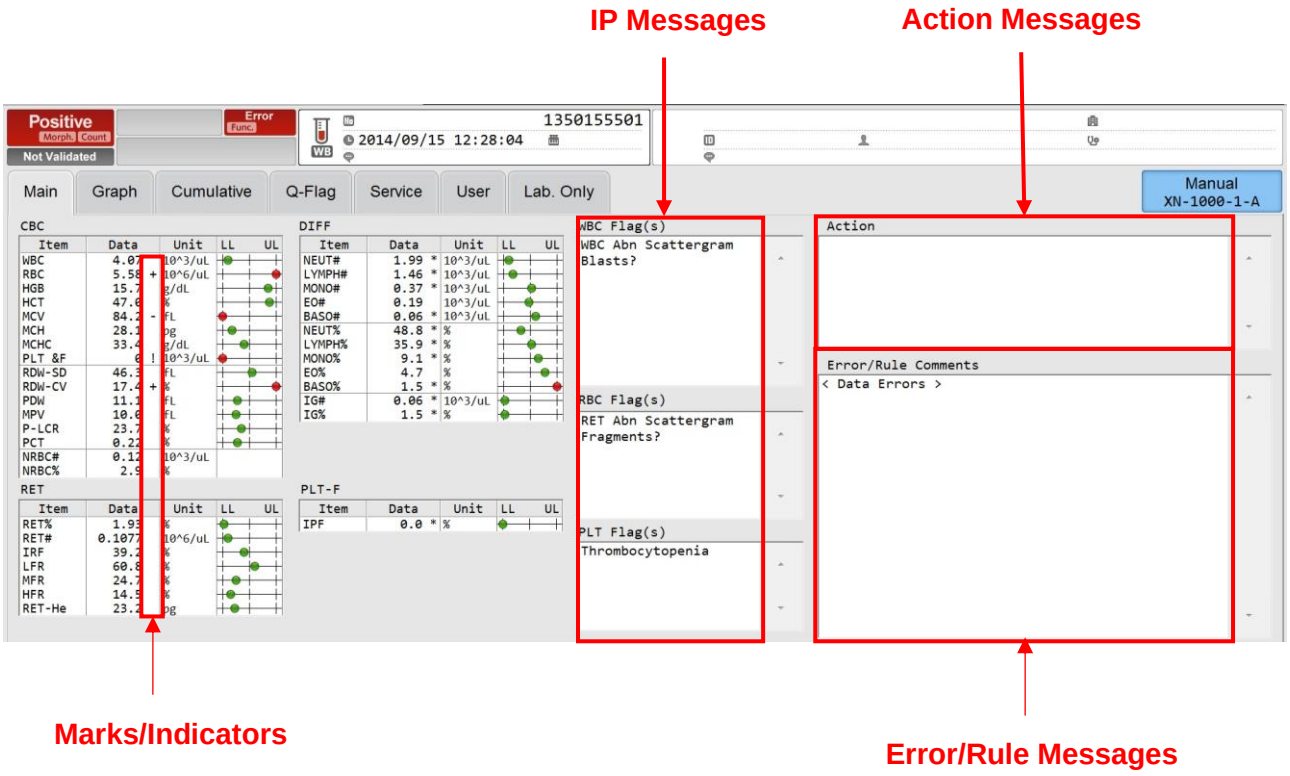
Further information on which 'Error' flag has been generated can be found in the 'Error/Rule message' section of the 'Main' tab of the Browser screen.

Rule Flag – The 'browser flagging' area also shows when a 'Rule' has been triggered. Rules are categorised as either:

[Reflex]:	Automatic reflexing of a new order to be run in another channel, the order is dependent on the first results (e.g. low platelets = reflex RET channel analysis).
[Rerun]:	Run the sample again and compare to the previous result (e.g. extremely low or high values).
[Repeat]:	Run the sample again due to an error (e.g. WNR channel error message).

Further information on which 'Rule; has been triggered can be found in the 'Error/Rule message' section of the 'Main' tab of the Browser screen.

Main Tab



Marks/Indicators

The following symbols may be seen in the ‘Parameter Indicator Column’ alongside the results:

+/-	Data Exceeding Reference Interval
!	Outside ‘Critical/Panic’ Limits
@	Data Outside Linearity Range
*	Data is Unreliable
“----”	Analysis can’t be done
“++++”	Data exceeds display capability
“ “	No order given
&	Corrected Data

CBC

Item	Data		Unit
WBC &	5.26		10^3/uL
RBC	3.68		10^6/uL
HGB	11.4		g/dL
HCT	39.4		%
MCV	107.1		fL
MCH	31.0		pg
MCHC	28.9	-	g/dL
PLT &	14	*	10^3/uL
RDW-SD	64.7	+	fL
RDW-CV	16.8	+	%
PDW	17.7	*	fL
MPV	12.7	*	fL
P-LCR	47.2	*	%
PCT	0.24	*	%
NRBC#	0.02		10^3/uL
NRBC%	0.4		%

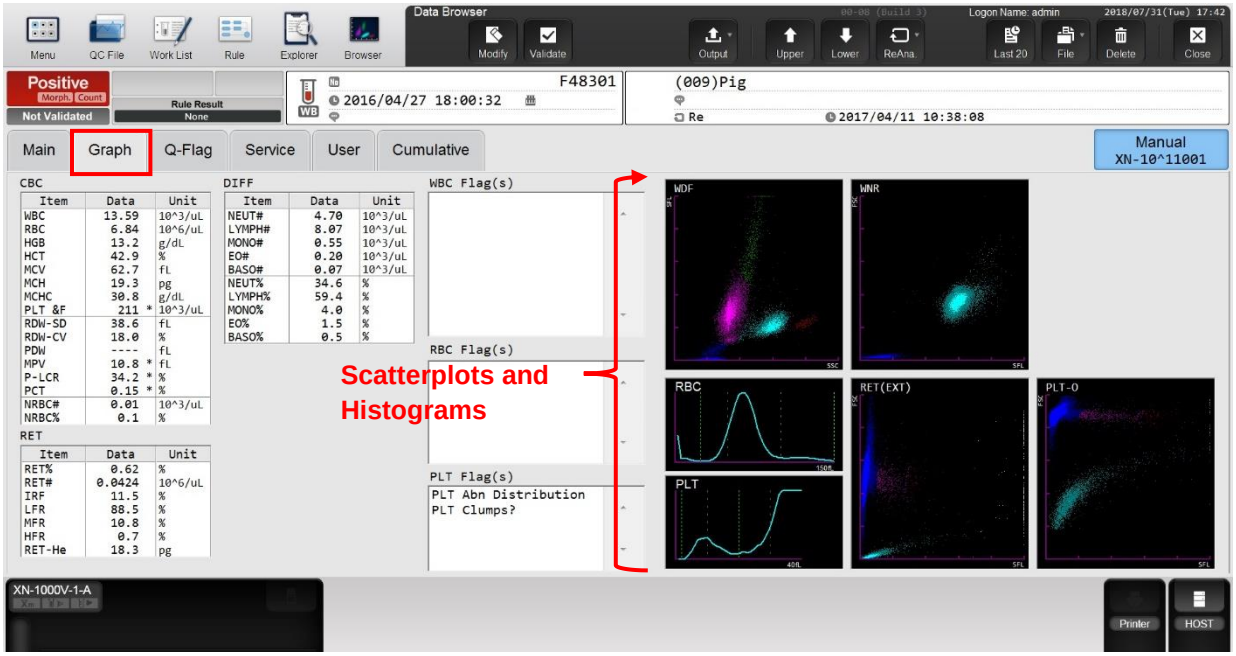
IP Messages

Further information on which 'Diff', 'Morph' or 'Count' flag has been generated can be found in the 'IP Messages' section of the 'Main' tab of the Browser screen where they are further split into:

[WBC Flag(s)]:	Flags associated with White Blood Cells	Example: WBC abnormal scattergram, neutrophilia, Blast/Abn lymph?
[RBC Flag(s)]:	Flags associated with Red Blood Cells	Examples: Abnormal RBC distribution, Anaemia, hypochromia, microcytosis
[PLT Flag(s)]:	Flags associated with Platelets	Examples: Plt Clumps?, Abnormal PLT distribution, thrombocytopenia

Graph Tab

Scatterplots and histograms can be viewed in the 'Graph' tab of the data browser screen. Should there be a need to enlarge the plots, place the mouse cursor over the scatter plot of interest and double click.



Service Tab - For use by Sysmex staff

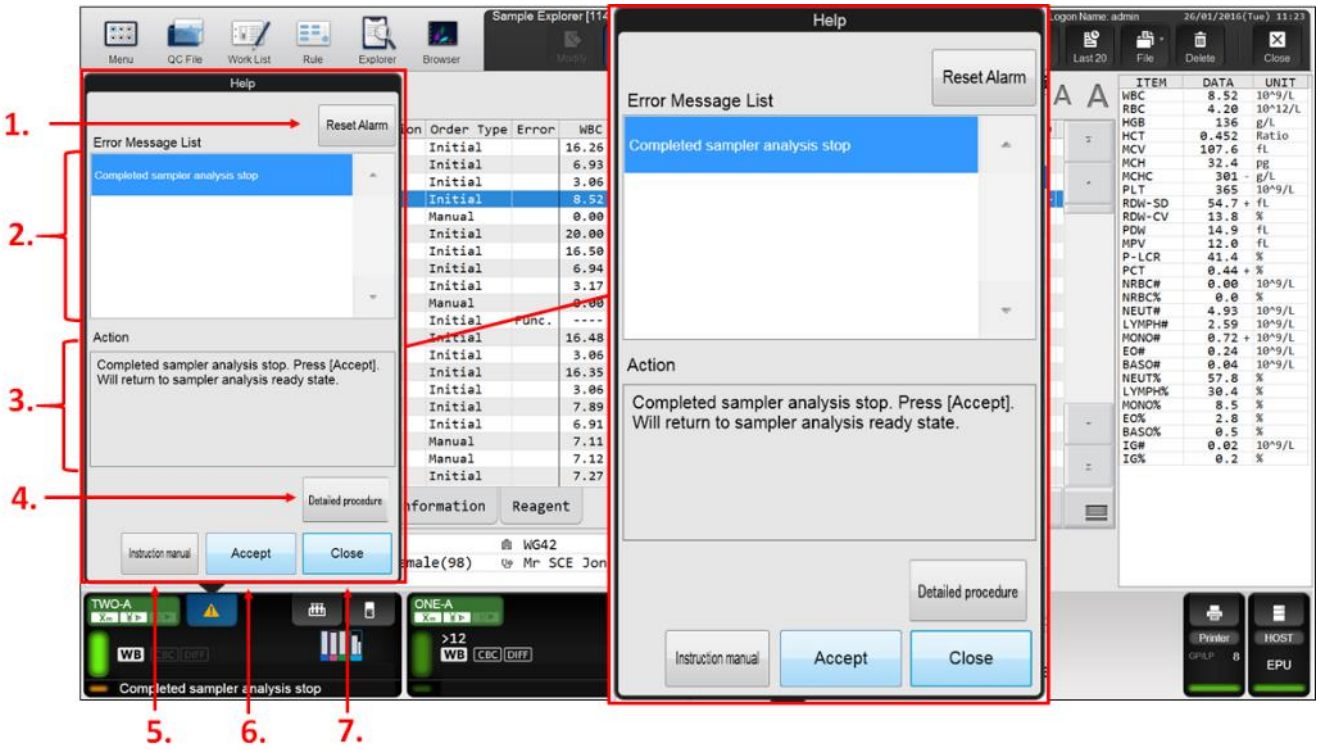
Lab Only Tab - User customisable

The 'Lab only' tab is user customisable. It can be used to view research parameters and compare the same parameter obtained from different channels. For example;

- Comparing the impedance platelet count (PLT-I), optical platelet count (PLT-O) obtained from the RET channel and fluorescent platelet count (PLT-F) obtained from the PLT-F channel.
- Comparing primary total WBC obtained in the XN-CBC channel (WBC-N), WBC-D obtained from the XN-DIFF channel and WBC-P obtained from the WPC channel.

Responding to Alarms

When there is an error, an audible alarm will sound and a help box will be displayed.



1. **Reset Alarm -** Selecting reset alarm will silence the audible alarm.

2. **Error Message List –** Displays the list of current errors. If there are multiple errors the error messages are displayed in order of priority.

3. **Action –** This area displays the corrective action required to resolve the error.

4. **Detailed Procedure –** Selecting [Detailed Procedure] will take the user to the Instructions for Use manual to the specific troubleshooting section outlining the procedure required to resolve the error.

5. **Instruction Manual -** Selecting [Instruction Manual] will take the user to the Instructions for Use manual to the specific troubleshooting section relating to the error message displayed.

6. **Accept –** Select [Accept] or [Execute] to execute any actions outlined in the error message and to clear the error message list.

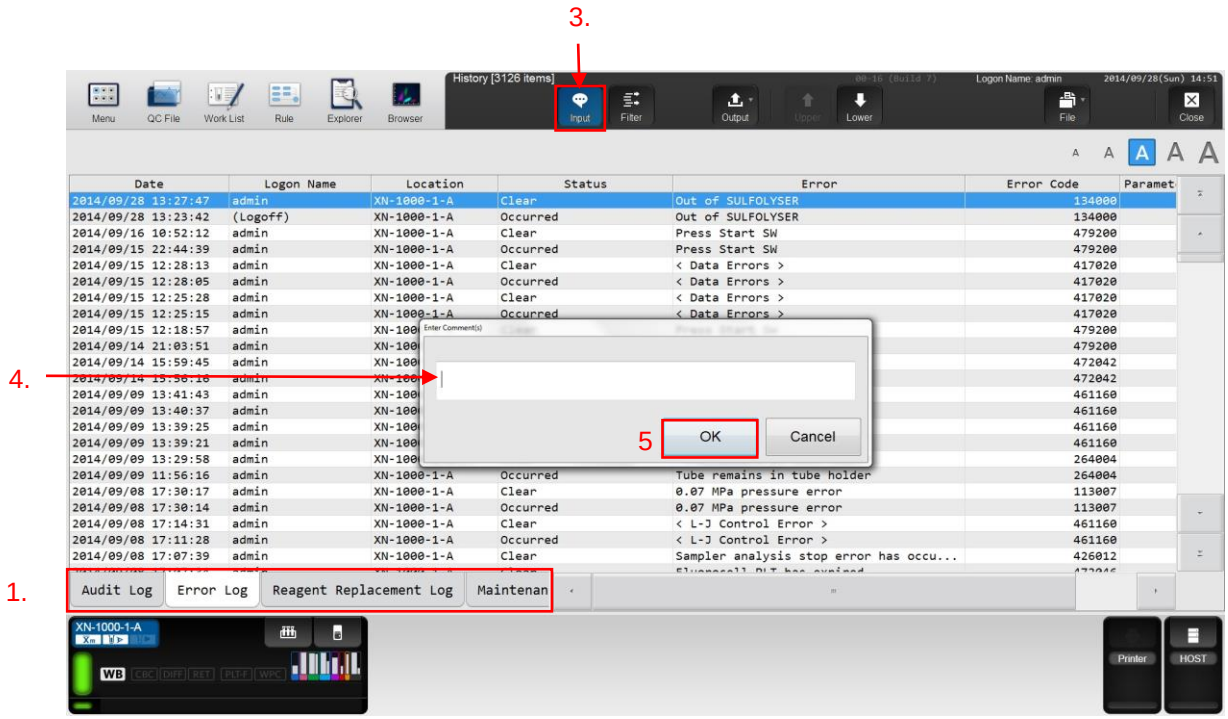
7. **Close –** Select [Close] to close the Help Box.

History

A full audit history including error logs, reagent replacement logs and maintenance logs can be found in [History]. User details and comments can be added to any of the history logs at any point.

Adding comments and user details to the History Log:

1. Select the log required
2. Select the entry of interest
3. Click on [input] or double click on the corresponding entry in the ‘comments’ column.
4. Add the relevant comment.
5. Select [OK]



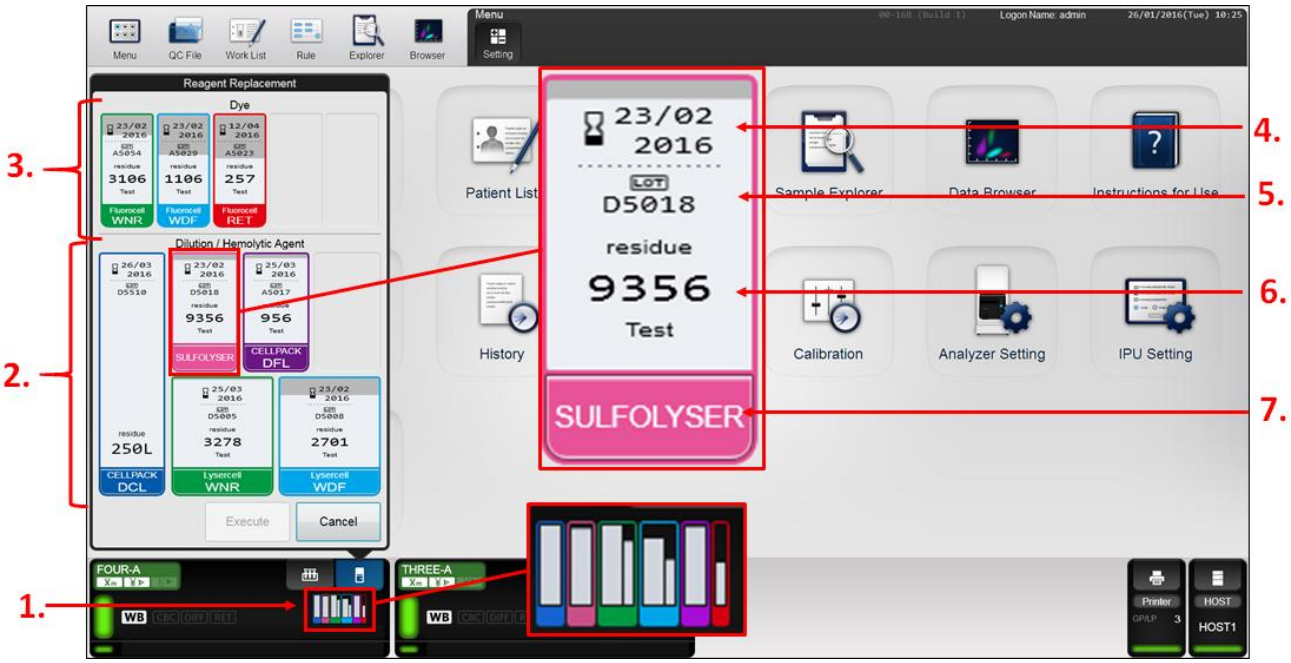
Reagents

There are a total of 12 different reagents that can be used on the XN-Series analysers (varies due to configuration), each having a different purpose. A summary can be found below describing the reagent name, pack volume, cycle counts, on board stability and the parameters produced using the reagent.

Reagent Name	Cycles Per Container (approx.)	On board Stability (Days)	Parameters Produced
CellPack DCL (10L)	200	60	Red cell and platelet parameters*
CellPack DST (10L)	5,000	60	
Sulfolyser (5L)	10,000	90	Haemoglobin
Lysercell WNR (5L)	2,000	60	Total white cell count, basophil count and nucleated red cell count
Fluorocell WNR (82ml)	4,000	90	
Lysercell WDF (5L)	3,333	90	Neutrophils, lymphocytes, monocytes, eosinophils and Immature granulocytes
Fluorocell WDF (42ml)	2,000	60	
Lysercell WPC (1.5L)	1,000	90	Blast? and Abnormal Lympho? flags
Fluorocell WPC (12ml)	500	90	
CellPack DFL (1.5L)	1,500	60	Used in conjunction with Fluorocell RET and Fluorocell PLT
Fluorocell RET	500	90	Reticulocytes and optical platelet count
Fluorocell PLT	500	90	Fluorescent platelet count and immature platelet fraction

* CellPack DCL/CellPack DST are also used in all channels for hydrodynamic focussing of cells and for rinsing the lines between samples.

Reagent Menu



1. **Reagent Menu –** Each analyser menu has an individual reagent menu. Selecting the reagent menu will open up the reagent replacement screen which shows all current reagents on-board including number of tests/volume remaining, lot number and on-board stability.

2. **Dilution/Haemolytic reagents –** Shows CellPack DCL, CellPack DFL, Sulfolyser and Lysercell reagents on-board.

3. **Dye –** Shows Fluorocell reagents on-board.

4. **On-board Stability –** On-board expiry date of reagents. **NOTE**: this is not the same as the Lot expiry on reagent box.

5. **Lot Number –** Reagent lot number.

6. **Tests/Volume Remaining –** Number of tests or volume remaining.

7. **Reagent Name -** Name of reagent.

Replacing Dilution/Haemolytic Reagents

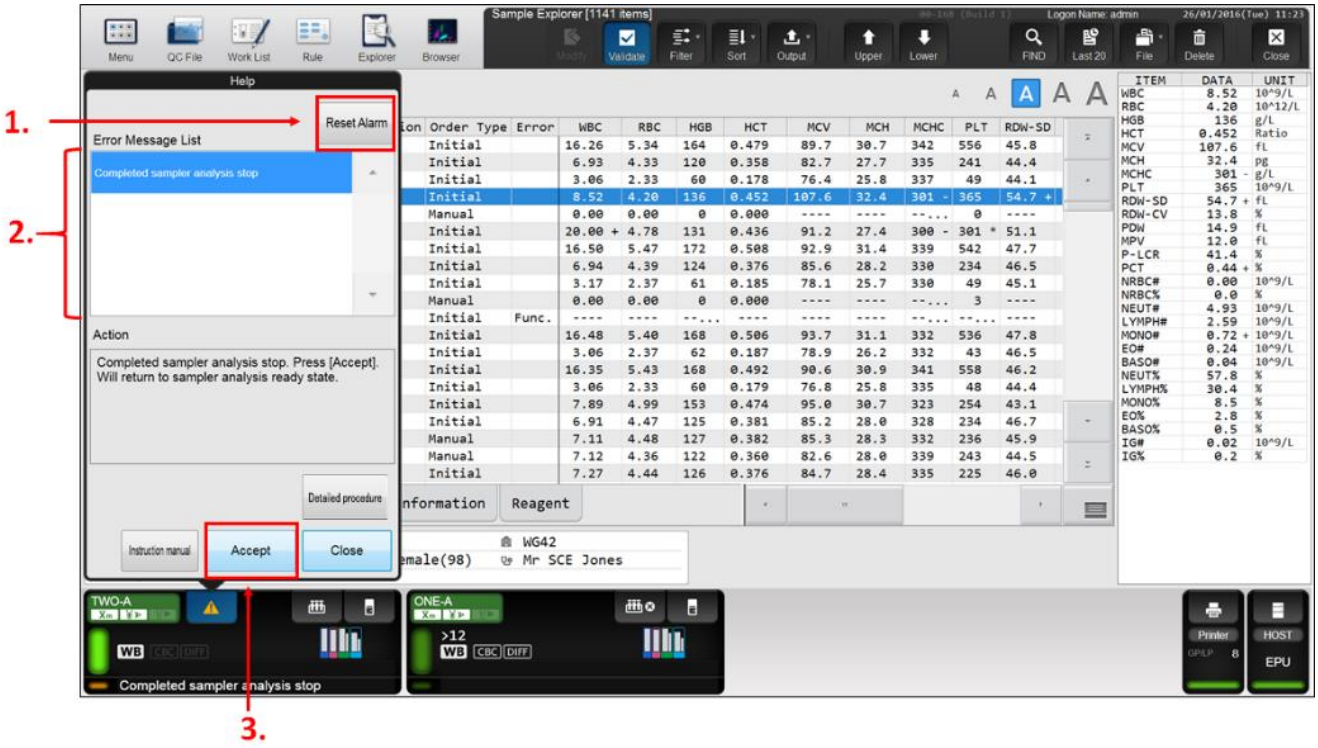
When a diluent or haemolytic reagent needs replacing an audible alarm will sound and the help box will appear detailing the reagent to be replaced. This alarm can also be caused by bubbles in the lines. If this happens perform a ‘Reagent Replenishment’ NOT ‘Reagent Replacement’.

To replace Dilution/Haemolytic Reagents:

1. Mute the alarm by selecting [Reset Alarm]

2. The reagent that requires replacement will appear in the Error Message List.

3. Select [Execute] on the help box to open up the Reagent Replacement Menu.



4. The [Reagent Replacement Menu] will open indicating which reagent requires replacement with a red warning triangle.

5. Using the barcode reader wand in the XN-Series Reagent Barcode.

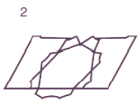
6. Once successfully barcoded the reagent will be marked as received.

7. Change probe from old reagent keg to new reagent keg. **DO NOT** place probe on the floor. The carton boxes of the Sysmex reagents have been designed to assure best stability after opening by protecting the reagent from being exposed to daylight. In addition, smart perforations allow the easy opening of the box.

It is recommended to apply the following opening procedure for Sysmex reagent boxes (e.g. Lysercell WDF, Sulfolyser and CellPack DCL). Please note: Be aware of paper cuts, protect your fingers!

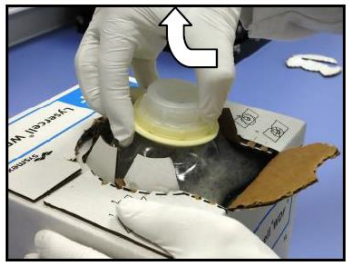
a. Remove both the middle and upper cardboard sections. Fold the front support tab forwards.

b. Fold upwards and outwards all the other support tabs.

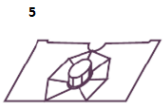


c. Grasp the connection nozzle below the support tabs and lift and angle forwards.

d. Push the connection nozzle backwards pulling firmly upwards at the same time.



e. Arrange all the support tabs under the collar of the connection nozzle. Now, the container can be connected to the analyser.



8. Select [Execute] and reagent replacement will commence. When this process is complete the analyser will continue testing patient samples. If a part box is loaded onto the analyser it will assume it is full.

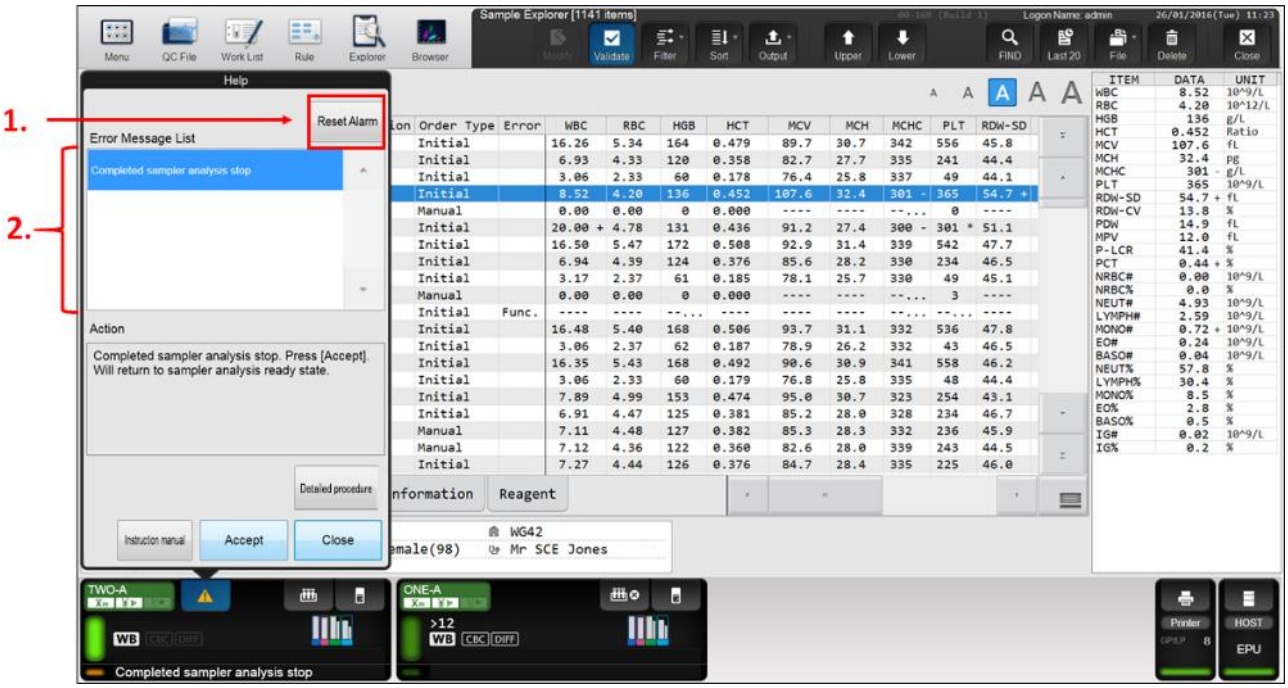
Replacing Fluorocell Reagents

When a Fluorocell dye needs replacing the help box will appear detailing the Fluorocell dye to be replaced and an audible alarm will sound.

Dye cartridges contain a Radio Frequency Chip (RF-ID) that the analyser will read as the cartridge is introduced. This chip contains all relevant information such as reagent type, lot number, expiry, on-board stability etc.

To replace Fluorocell reagents:

1. Mute the alarm by selecting [Reset Alarm]
2. The reagent that requires replacement will appear in the Error Message List.

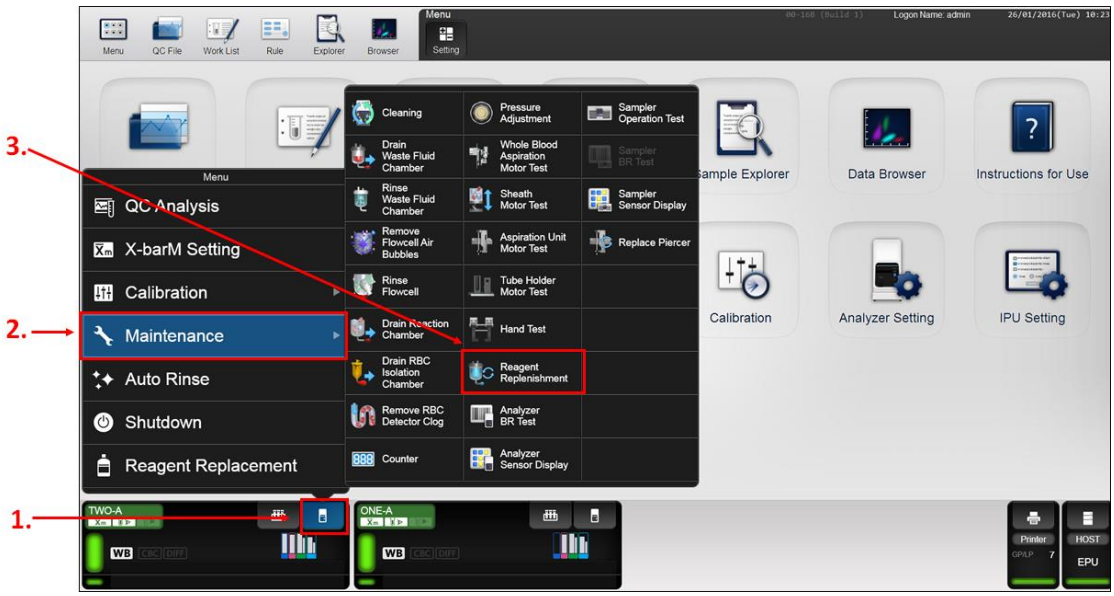


3. Open the front cover and push up the dye cartridge cover allowing access to the dye cartridge area.
4. Remove the old dye cartridge and replace it with the new. When placing the new cartridge in it is essential it's placed in with the pierceable cap to the back and the name of the cartridge facing the user.
5. When the cartridge is replaced the analyser will beep as it registers the RF-ID chip.
6. Close the dye cartridge cover and front lid.

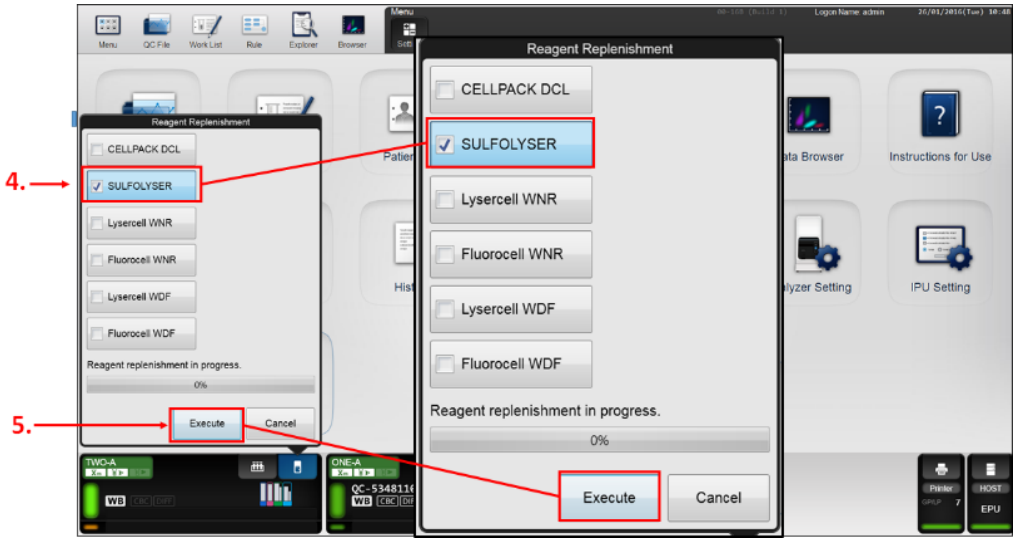
Reagent Replenishment

If you encounter any errors such as bubbles in the system performing a reagent replenishment will prime the reagent through the system removing the bubbles. To perform a Reagent Replenishment:

1. Select [Analyser Menu]
2. Select [Maintenance]
3. Select [Reagent Replenishment]



4. Select the reagent for replenishment



5. Select [Execute]

6. Reagent Replenishment will take a few minutes to complete. The progress is shown with a progress bar and when complete the dialog box will automatically close.

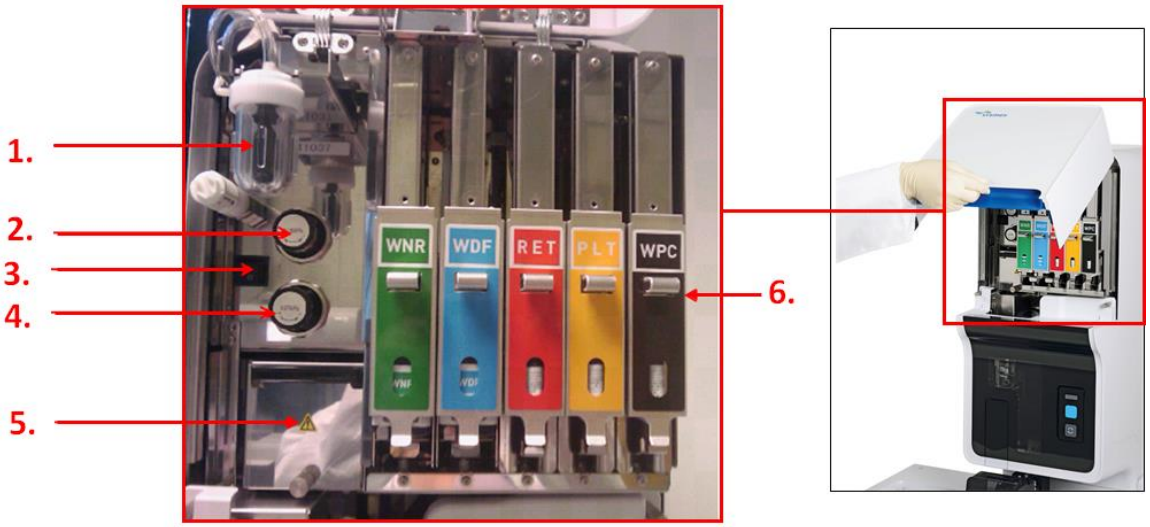
Tasks

Task 1: XN-Series Analyser Components

1. Perform a daily shutdown of an XN-Series analyser.
2. From the list below, label the external parts of the XN-2000 with it's corresponding number

Change analysis mode button	Information Processing Unit (IPU)	Manual sample holder location
Status indicator LED	Sampler Barcode reader	Start button
Reflex Bay	Upper Front cover	Sampler Unit

3. From the list below, label the internal components of the XN-Series



Dye Cartridge Holders	Main power swtich	0.16 MPa Regulator
Pneumatic Trap Chamber	0.07 MPa regulator	RBC/PLT Detector

Trainee _____ Date _____

Trainer _____ Date _____

Task 2: XN-Series Routine Use

1. How long does the shutdown procedure take?

2. What other procedures aside from an auto rinse are included in the ‘as required’ maintenance?

   - _____
   - _____

3. When may an auto rinse be required?

4. Give 2 examples of when the ‘Cleaning’ procedure may need to be performed?

   - _____
   - _____

5. Show your trainer where you go to perform the cleaning procedure.

6. What are the two main differences between the cleaning procedure and the shutdown procedure?

   - _____
   - _____

7. Explain to your trainer how you would register a new lot of XN CHECK.

8. Please run the QC in:

   - Manual closed mode
   - Sampler mode

9. Once open how long is a vial of XN CHECK stable?

10. How long should the XN CHECK be at room temperature before analysis?

11. Making sure you have identified the relevant analyser add the comment **'Checked'** indicating that you have run and checked the QC.

12. Show your trainer how to exclude the QC result from statistical analysis.

13. Select a range of QC data (the last 5 QC data points).

14. Indicate a new vial of XN CHECK has been opened.

15. Compare QC files for the current XN CHECK lot between all analysers connected to the IPU or compare different QC lots on the same analyser.

16. When creating a QC File for EQA (NEQAS) material, what should be input for the following (use the IPU for guidance if required):

a. Control Material:

b. Lot Number:

c. Expiry Date:

d. Targets and Ranges:

17. When processing NEQAS material on the XN-Series analyser, what analysis method should be used for the following (circle the correct answer):

a. Full blood count samples

Processed as a patient sample *Processed using QC Analysis mode*

b. Automated Differential Leucocyte Count samples

Processed as a patient sample *Processed using QC Analysis mode*

18. If performing Task 2 on a system which is NOT live please identify the host communication and if it's connected please disconnect.

19. How do you know the status of the HOST connection?

20. Using old patient samples;

- Run 3 samples in sampler mode.
- Run a sample in Manual open mode, letting the analyser read the barcode.
- Run a sample in Low WBC mode.
- Run a sample in manual mode, giving the sample ID **12345.**
- Run a sample in manual (open) micro mode

21. What dilution is required for Predilution mode?

22. Filter the database to show the last 2 days and set to show all analysers.

23. Find and select 12345, and GP print.

24. How would you resend results to host?

25. Find the sample run in low WBC mode.

26. Select a sample and open 'Browser' screen.

27. Where are the following located on the main browser screen:

- Flags
- Action messages
- Error messages

28. Locate the WDF scattergram and enlarge.

29. Where would you locate all platelet counts performed by the analyser?

30. Locate reagent replacement menu. What information is provided in the reagent replacement screen.

- _____
- _____
- _____

31. Explain to your trainer how you would change a diluent reagent.

32. Locate the reagent replenishment menu.

Trainee _____ Date _____

Trainer _____ Date _____

Contact Us

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SCAN ME