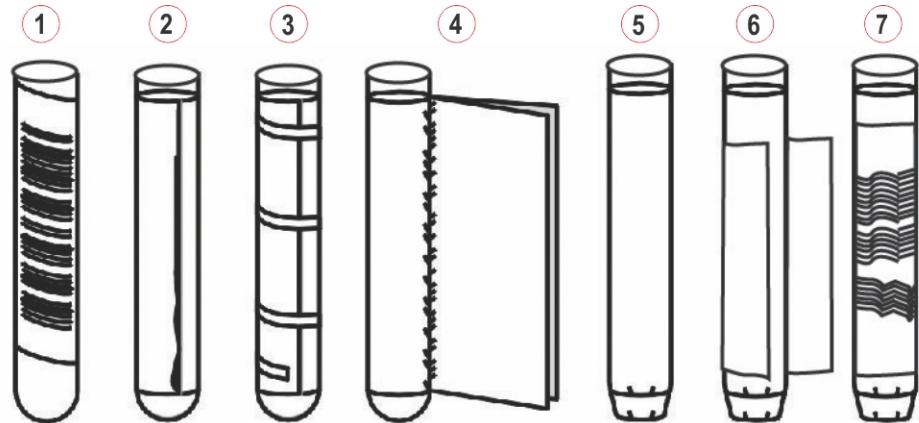


**Figure 5:** Correctly labeled sample tube

- The barcode label shall be oriented along the length of the tube. Do not wrap the label horizontally around the tube.
- The barcode label shall no overlap the top or bottom of the tube.
- The barcode label shall be vertically as straight as possible.
- The barcode label shall not touch the tube cap.
- The barcode label shall be free of excess moisture.
- The barcode label shall be placed at the top of the sample tube to ensure the barcode to read.
- The barcode label shall not extend beyond the top of the tube carrier.
- The barcode label shall be well stuck to the sample tube.

**Figure 6:** Incorrectly labeled sample tube

1. Angled placement
2. Edges peeled loose
3. Clear tape over label
4. Flap extends from label
5. Label extends beyond bottom of tube
6. Label partially detached from tube generates flap
7. Label is creased

**NOTICE**

Load to the Automation System only sample tubes compliant with the above indications on labeling.

### 3.4.3 Sample ID maximum length

The maximum allowable length for sample IDs to be used on the Automation System is 23 characters.

### 3.4.4 Not allowable Sample IDs

The following sample IDs shall not be used for sample tubes:

- Unreadable#(nnn)
- Invalid-SID#(nnn)

where (nnn) is a number from 000 to 999.

### 3.4.5 Sample ID allowable characters

The allowable character set for sample barcode IDs consists of all printable ASCII characters, except the characters listed below.

The following printable ASCII characters cannot be used in a sample ID.

Character name	Symbol	ASCII Hex	ASCII Decimal
Ampersand	&	26	038
Backslash	\	5C	092
Caret	^	5E	094
Pipe		7C	124
Tilde	~	7E	126
Semicolon	;	3B	59

The following ASCII character cannot be used for sample ID of secondary tubes.

Character name	Symbol	ASCII Hex	ASCII Decimal
Pound/Number Sign	#	23	35
Semicolon	;	3B	59

Examples of valid sample IDs include:

- 001040
- 001040A
- 001040-B
- 001040/C1
- 001040?D
- 001040\*
- ABCDEFG/10H
- 001040A

Examples of invalid sample IDs include:

- 001040&A
- 001040\A
- 001040^B
- 001040|B
- 001040~A

Sample tubes with an invalid sample ID are automatically sorted to a Priority output rack without processing.

Samples with duplicate sample IDs loaded on the Automation System will not be processed (until the original sample has been removed from the System) and, therefore, will be sent to PO racks. Aliquot duplicate tubes can be recapped or sealed, or sorted to IOM/ROM racks.

For Automation Systems with a Storage and Retrieval Module, do not re-use sample IDs until the Storage Disposal Timeout has expired. Follow your Laboratory Good Practices to avoid loading samples with duplicate sample IDs on Automation System and manually into connected analyzers at the same time.

### 3.4.6 Secondary tubes - allowable barcode symbologies

Secondary sample tube labels can be printed using sample barcode symbologies allowed onto Automation System, with the following restrictions:

- Code 128: maximum 12 characters.
- Code 39 (only without check digit): maximum 9 characters.

#### **NOTICE**

It is not possible to enable check digit for "Code 39" symbology on the Aliquoter Module printer.

- Interleaved 2 of 5: maximum 20 characters.
- USS Codabar: maximum 13 characters.

#### **NOTE**

Contact the Service Assistance to customize the configuration.

Each field of the Aliquoter label has a different length. For each type of barcode, the fields Patient Name, Birth Date, Patient ID, Destination and Test Codes have different values:

**Table 2:** Aliquoter label fields length

Field	Code 128	Code 39	Interleaved 2 of 5	USS Codabar
Patient Name	30	30	30	30
Birth Date	10	10	10	10
Destination	30	30	30	30

**Table 2 Aliquoter label fields length (cont'd.)**

Field	Code 128	Code 39	Interleaved 2 of 5	USS Codabar
Test Codes	30	30	30	30
Patient ID	13	17	17	17

**NOTICE**

Take precautions when entering values to prevent fields truncation.

## 4 User Interface

### 4.1 Description

UI – User Interface – allows the User to manage automation, tests results and data analytics with a unique user interface, because it combines DMS, FlexLab, DAS and Automation Map interfaces.

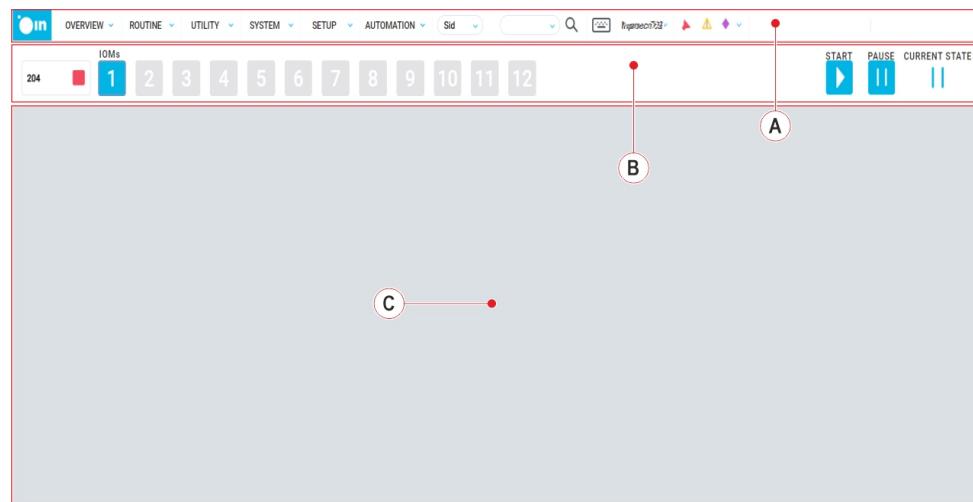
UI can be accessed by browser on multiple clients, using IP address of DMS server, depending on the network from which client is opened.

UI supports interaction on touchscreen devices and allows the possibility to interact through swipe action to switch between tabs and scroll among elements.

UI is divided into the following areas:

- A Multifunctional toolbar always visible at the top (Figure 7 – A)
- A Overview bar always visible below the multifunctional toolbar (Figure 7 – B).
- A central workspace to display the Automation Map or the Module Cards (Figure 7 – C).
- A lower panel – always accessible by means of a special indicator – that contains numerical summary tables relating the System status, the processing and the Instruments.
- Side panels – accessible by means of a special indicator and visible only in Validation screen – that contain additional information regarding the patient and the samples that the User is consulting.

**Figure 7:**



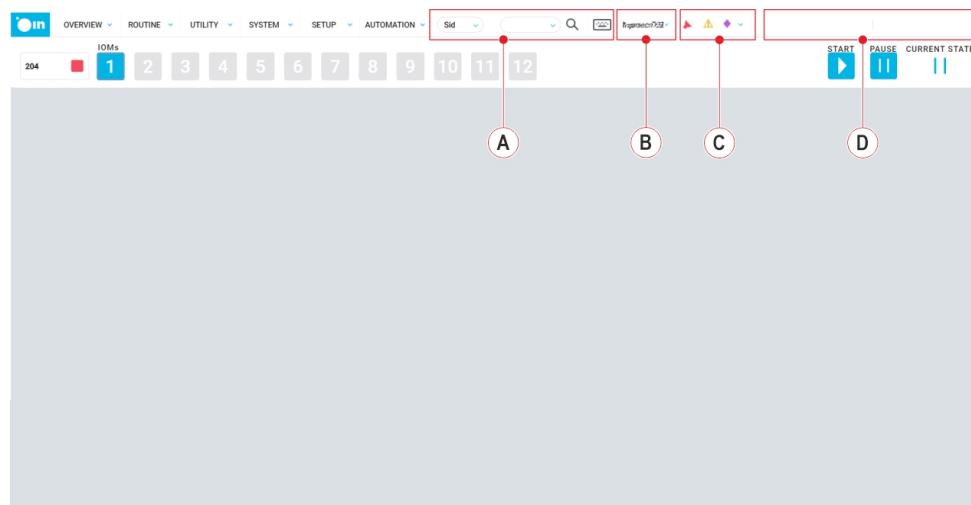
## 4.2 Multifunctional toolbar

The Multifunctional toolbar is always visible at the top of the User Interface and allows the User to access functions and settings of the Automation System.

The Multifunctional toolbar consists of:

- Overview menu.
- Routine menu.
- Utility menu.
- System menu.
- Setup menu.
- Automation menu.
- Rapid search bar for the data relating to the samples (Figure 8 – A).
- User menu button that displays the name of the logged-in User (Figure 8 – B).
- Icon area button (Figure 8 – C).
- Message area (Figure 8 – D).

**Figure 8:**



### 4.2.1 Rapid search bar

Rapid search is composed of the following parts.

Part	Description
Dropdown menu	Allows to search data by SID (Sample ID), Order (Order ID), Patient Last-name, Patient ID.
Search box	Allows to enter the text to be searched. It displays a dynamic pre-view of the matches found.
Search icon	When selected, it displays the Validation screen for the matches found. <ul style="list-style-type: none"><li>• If the entire Order ID has been keyed in, the software will open the Validation screen containing all the information of that order (all samples and tests related to the order).</li><li>• If the entire Sample ID has been keyed in, the software will open the Validation screen related to that specific sample.</li><li>• If no value is keyed in, the software will open the Validation screen for all patients included in the worklist.</li></ul>
Keyboard icon	Allows to enter data to be searched through a pop-up keyboard.

## 4.2.2 User menu

The User menu displays the name of the User that has logged in.

By the User menu, additional functions are available.

Part	Description
Logout	Allows to logout the current logged-in User. <sup>1</sup>
Lock session	Allows the current logged-in User to temporarily lock the one's own session. To unlock the session, the User can log in again by entering the one's User name and Password or logout.
Operation Manual	Allows to display the Operations Manual (PDF file).
Display notifications	If checked, it enables the pop-up notifications that display System communication events and errors occurring during the use of the software
List of Sites	It is displayed only when the Multisite option is enabled): list of all Sites where the User has permissions. The checkboxes near each Site name allow to enable/disable viewing the specific information and to activate user actions on the related Site.
Software versions	It displays the current DMS, SMS and DAS versions.
License	It displays the End-user license agreement.
Serial number	It displays the serial number of the current System in use.

1. If the User has performed more than one login simultaneously, the logout from one of the login session implicates the termination also from the other sessions opened in the tabs of the same browser window, while it does not terminate other login in progress in other different browser windows.

### 4.2.3 Icon area

The Icon area provides an overview of the communications status (external and internal) of DMS and notifies exceptions messages, recent enabling/disabling of Tests on Instruments and Quality Control results coming from Instruments.

In the dropdown list, each row item represents a single communication channel between DMS and the item itself. The item can be either an Analyzer, an Automation System, a Host/LIS System, or one of the internal DMS components (i.e. kickstart, scheduler and dispatcher). An icon next to the item name describes the communication status of the channel, along with the Instrument driver version number (only for supported drivers), and an internal identification number of the communication process (for technical support use). Additional icons are displayed when exceptions, recent tests enabling/disabling activities, Quality Control results relating to an Instrument and low level reagents are present. When the User selects an icon, further actions are performed, or a related screen with more information is opened, depending on the icon selected. When the pointer is left over the item name, a pop-up opens, giving more details about the item configuration and (for analyzers only) its status.

The icons displayed are the followings.

Part	Description
Connection Status summary icon	It summarizes the general status of the communications.
Exceptions summary icon	It notifies the presence of unread exceptions coming from Instruments.
Recent tests enabling/disabling summary icon	It notifies if any test has been enabled/disabled on any Instrument in the last 5 minutes.
Quality Control summary icon	It notifies an alarm about Quality Controls.
Low Level Reagents summary icon	It notifies the presence of tests with low level reagents.

#### 4.2.3.1 Connection Status summary icon

The Connection Status summary icon depends on the connection of individual Instruments, according to the rules hereafter.

**Table 3:** Connection Status summary icon

Icon	Description
	At least one Instrument is not connected, all of the other Instruments are connected and communicating.
	At least one Instrument is connected but is not communicating due to physical connection problems.

**Table 3 Connection Status summary icon (cont'd.)**

Icon	Description
	At least one Instrument is connected but is not communicating.
	All Instruments are connected and communicating.

For each instrument, the following icons can be displayed.

**Table 4: Instrument Connection Status icon**

Icon	Description
	Disconnected, switched off or deactivated instrument (disabled connection).
	Instrument connected but lacking communication due to physical connection problems. The deactivation/reactivation of this icon is restricted to technical assistance staff.
	Instrument connected but lacking communication (connection enabled but not working). Indicates a malfunction in the communication.
	Instrument connected and communication functioning (communication enabled and functioning correctly).

#### 4.2.3.2 Exceptions summary icon

The Exceptions summary icon is displayed if there are unread Exceptions from the Instruments. If the Exception has been configured as Warning or Error type event, the icon is displayed with a yellow or red background, respectively.

The Exceptions can be consulted by means of the [Exceptions list](#) button in the [System](#) menu.

For each instrument, the following icon is displayed in case of Exceptions.

**Table 5: Exceptions icon**

Icon	Description
	A new unread Exception related to the Instrument is present.

#### 4.2.3.3 Recent tests enabling/disabling summary icon

The Recent Tests Enabling/Disabling summary icon is displayed if at least one test has been enabled/disable on any instrument in the last 5 minutes.

The notification, if not acknowledged, lasts 60 minutes. Clicking on the icon, a popup asks if the User wants to acknowledge and immediately remove the icon or not. Then, the System events screen with the relevant details about the test enabled/disabled will be displayed.

For each instrument, the following icon is displayed in case of tests enabled/disabled recently on the instrument.

**Table 6:** Recent Test Enabling/Disabling icon

Icon	Description
	One or more test have been enabled/disabled on the instrument in the last 5 minutes.

#### 4.2.3.4 Quality Control summary icon

The Quality Control (QC) summary icon depends on the following criteria.

**Table 7:** Quality Control summary icon

Icon	Description
	Displayed if no QC has been performed during the current period.
n/a	No icon is displayed if at least one QC has been performed on at least one instrument, and all QC results are valid in the current period.
	Displayed If the worst QC status is warning and not all QC have been performed in the current period.
	Displayed if the worst QC status is warning and all QC have been performed in the current period.
	Displayed if the worst QC status is failed and not all QC have been performed in the current period.
	Displayed if the worst QC status is failed and all QC have been performed in the current period.

If all the cases above should be managed for the configured instruments, DMS displays the icon  as Quality Control (QC) summary icon (i.e. the worst status).

For each instrument, the following icons can be displayed.

**Table 8:** Quality Control icons

Icon	Description
	All online QC results for each Control ID are valid and all tests enabled for performing QCs on the current instrument have been processed in the current period.
	All online QC results for each Control ID are valid, but not all tests enabled for performing QCs on the current instrument have been processed in the current period.
	There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as failed. All tests enabled for performing QCs on the current instrument have been processed in the current period.
	There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as failed. Not all tests enabled for performing QCs on the current instrument have been processed in the current period.
	There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as warning, no one is failed. All tests enabled for performing QCs on the current instrument have been processed in the current period.

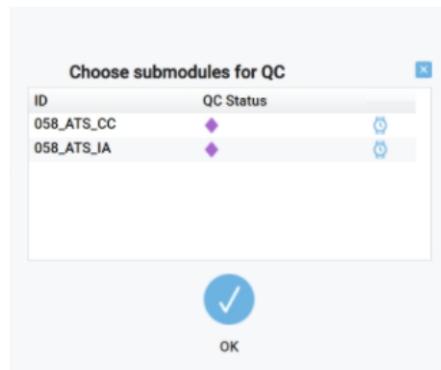
**Table 8 Quality Control icons (cont'd.)**

Icon	Description
	There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as warning, no one is failed. Not all tests enabled for performing QCs on the current instrument have been processed in the current period.
	No Quality Control has been run in the current period for the related instrument. It is possible that at least one test on instrument has QC results produced in a previous day, or used for the pre-period or QC results moved in the historical area.

By clicking on the QC icon of an instrument that does not have submodules, DMS opens the [Quality Control](#) screen with tests list filtered by instrument equal to the selected one.

By clicking on QC icon of an instrument that has submodules (the QC icon related to an instrument with submodules is the sum of status of all submodules), an additional window is opened and allows user to choose one or more submodules for which filters the tests list in [Quality Control](#) screen.

Multiple selection is allowed using CTRL keyboard button and clicking on the desired rows. After having selected all desired items, click on [OK](#) and the [Quality Control](#) screen opens with tests list filtered by chosen instruments.



Moreover, it is possible to manually reset the [QC expiration date](#) of a specific Instrument as described in the following table:

**Table 9:**

Icon	Access Level	Description
	Lab Supervisor	Clicking on the icon, a popup asks user to confirm the reset the QC expiration date. If confirmed, a warning popup will be displayed on the bottom right of the screen.

#### 4.2.3.5 Low Level Reagents summary icon

The Low Level Reagents summary icon notifies that one or more tests have a low level of reagents and have reached the value configured as **Warning Threshold**. Clicking on the icon, the **Inventory** table screen opens and only the tests with the **Test quantity** lower than the **Warning Threshold** are displayed.

For each instrument, the following icon is displayed in case of tests with low level of reagents.

**Table 10:** Low Level Reagents icon

Icon	Description
	One or more tests have a low level of reagents and have reached the value configured as <b>Warning Threshold</b> .
<b>NOTE</b>	
<p>It is possible to configure the <b>Warning Threshold</b> for the reagent level and the <b>Limit Threshold</b> in the <b>Inventory</b> table. Functionality reserved to FSE only.</p>	

In case of Instruments with sub-modules, the Low Level Reagents icon is shown for the Main Module when at least one of its sub-module has tests with **Test quantity** lower or equal to **Warning Threshold**. Clicking on the icon, the **Inventory** table opens and only the tests of the sub-module with the **Test quantity** lower than the **Warning Threshold** are displayed.

## 4.2.4 Message area

The Message area displays specific warnings/errors that may require the intervention of the technical assistance.

The messages displayed can be the followings.

Message	Description
Raid Disk WARN	<p>One of the server RAID disks could be damaged and require substitution.</p> <p>By clicking on the message, a popup will show technical information useful for the technical assistance staff.</p>
Sample Database Error	<p>The Automation System database is not correctly configured and does not work properly.</p>
DB Replication WARN	<p>The database replication process on the standby server is not properly working.</p> <p>By clicking on the message, a popup will show technical information useful for the technical assistance staff.</p>
LAS Communication Error	<p>LAS Communication Error.</p> <p>By clicking on the message, the User can access the recovery.</p>
Duplicate Carrier	<p>A carrier with an RF-ID duplicate of another carrier RF-ID has been detected on Track.</p> <p>By clicking on the message, the User can access the recovery.</p>
High Computer Resource Usage	<p>The memory threshold has exceeded the value set in the item <a href="#">Memory Threshold (MB)</a>, refer to <a href="#">4.10.4.4 Computer, page 281</a>.</p> <p>By clicking on the message, the User can access the recovery.</p>
Maintenance overdue or Maintenance due	<p>Warnings about preventive maintenance activities to be done. By clicking on the notifications, the <a href="#">4.10.3.3 Maintenance, page 269</a> is shown.</p>
Telegram is not running	<p>The Instant messaging functionality is configured.</p> <p>DMS Software restarts automatically the Telegram service, if not running.</p>
Communication Error	<p>There are problems in communication with the Automation Software on IUI channel.</p> <p>A non-blocking pop-ups notify the User of the specific error; subsequently, after a configured timeout, the <a href="#">Overview</a> screen is disabled (covered by a grey stripe) and the</p>

Message	Description
Communication Error message is displayed.	
Dream Queue OverFlow	The Q-size exceeds the value configured. The Automation System pauses automatically.
Communication Error with Connected Automation System	There is a communication problem with an Automation System connected via Track Overpass/Underpass Module. Neither sample Tubes nor carrier are sent to the Overpass/Underpass Module in communication error condition.
Insufficient disk space	<p>The disk space occupancy reaches the threshold set.</p> <p>By clicking on the message, it is possible to display for which partition(s) the disk usage threshold has been reached.<sup>2</sup></p>
Sample Database not responding	<p>Message displayed in case a query/insert to the Sample Database is taking more than 45 seconds.</p> <p>The Automation System is automatically paused.</p>
DMS database not responding to Automation System queries	<p>Message displayed in case a query/insert to the DMS Database is taking more than 45 seconds.</p> <p>The Automation System is automatically paused.</p>
Message Broker Down	Message displayed when the sending of results to Host via Message Broker is enabled but the Message Broker is not available for more than a certain amount of attempts <sup>3</sup> .
Automatic Archive Error	<p>Message displayed in case the archiving procedure exceeds the tolerance configured by technical assistance staff.</p> <p>Click on the message to mute the notification.</p>

2. Depending on the options configured in “General Settings” screen by technical assistance staff, the “Critical Hard Drive usage percentage” pop-up is displayed to run the compression procedure of log files.

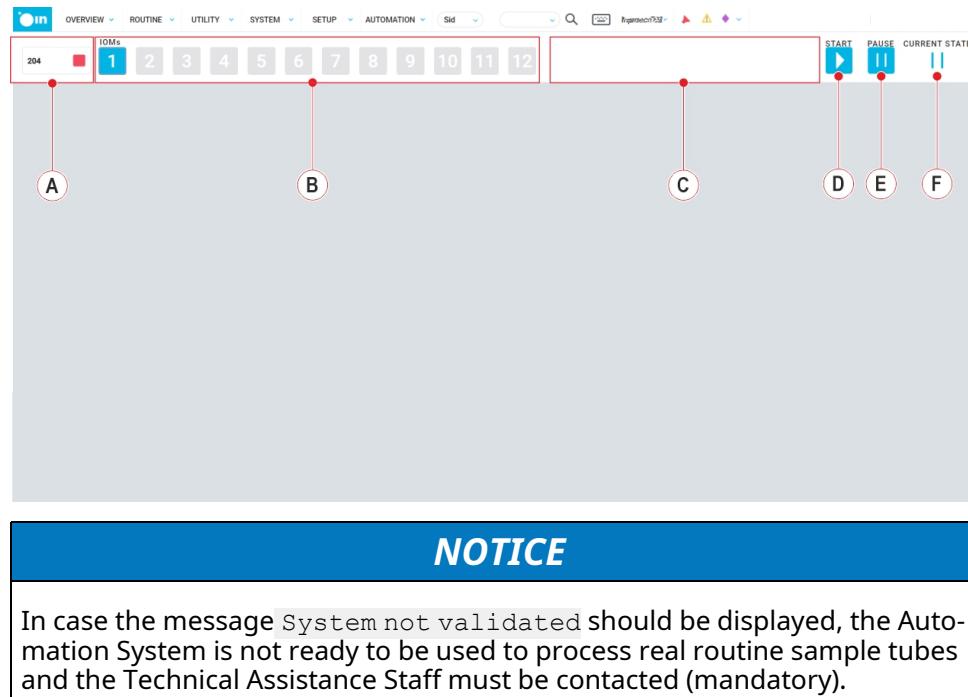
3. The option can be enabled in “General Settings” screen and configured through DMS services.ini file by technical assistance staff.

## 4.3 Overview bar

The Overview bar is always visible below the Multifunctional toolbar.

The Overview bar consists of the following information.

Components	Description
Automation button (Figure 9 – A)	Displays the name and the status of the current Automation System selected. If pressed, a pop-up allows the User to show a different Automation System (only if multiple Automation Systems are installed).
IOM buttons (IOMs) (Figure 9 – B)	Lists all the Input Output Modules configured on the current Automation System and allows to switch between them.
Message area (Figure 9 – C)	Displays a message when the Automation System is in Pause, Shutting Down, in Exercise mode, or needed to be validated. The area can also display a warning message with the number of rules to be validated. Only if all the rules are accepted, the warning message will disappear.
Start (Figure 9 – D)	Allows to start the Automation System. Restores the motion of the carriers on the track if the Automation was previously paused. Confirm the pop-up window to start the Automation System.
Pause (Figure 9 – E)	Allows to pause the Automation System. When <code>Pause</code> button is selected, a pop-up window appears to advise the User that pausing the Automation System may lead to delayed patient results and/or waste of reagents. Confirm the pop-up window to pause the Automation System.
Current State (Figure 9 – F)	Indicates the operating status or pause of the entire Automation System.

**Figure 9:**

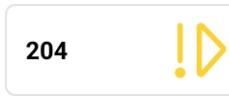
### 4.3.1 Automation button

The Automation button displays the name and the status of the selected Automation System.

If there are multiple Automation Systems configured, it is possible to switch to a different Automation System by pressing the Automation button. A pop-up will appear presenting a list with all the configured Automation Systems that can be selected.

The color of the icon in the Automation button depends on the overall status of Automation System.

**Table 11:** Automation button status

Automation button	Icon Color	Automation System – overall status
	None	All Modules are in non-error condition or in Off-line Mode (but at least one is not in Off-line Mode).
	Pink	At least one Module is in Full status and its Mode is not Off-line and there are no other Modules in Warning or Error status.
	Yellow	At least one Module is in Warning status or in Exercise Mode and its Mode is not Off-line and there are no other Modules in Error status.
	Red	At least one Module is in Error or Unknown status and its Mode is not Off-line.

### 4.3.2 IOM buttons (IOMs)

A IOM button is displayed for each Input/Output Module currently installed on the Automation System. Each button is identified by a progressive number.

When a IOM button is selected, the related IOM Lanes are displayed.

**Table 12:** IOM button status

Icon	Button Color	IOM - overall status
	Blue	IOM selected. This IOM has not lanes full of samples.
	Pink	IOM with at least a lane full of samples.
	Grey	IOM installed on the Automation System but not selected.

## 4.4 Overview – Automation Map

The Automation Map is displayed by clicking on the *Overview / Automation Map* button of the Multifunctional toolbar.

### 4.4.1 General information

Automation Map nodes can be represented in the following way:

- Textured, with a png image, available in the Automation Map assets, representing the module top view
- Outlined, the bounding box according the nodes dimension width and height, in case related texture is not available
- Label Only, the Node Type of the automation nodes

The Automation Map rendering is generated according the following criteria:

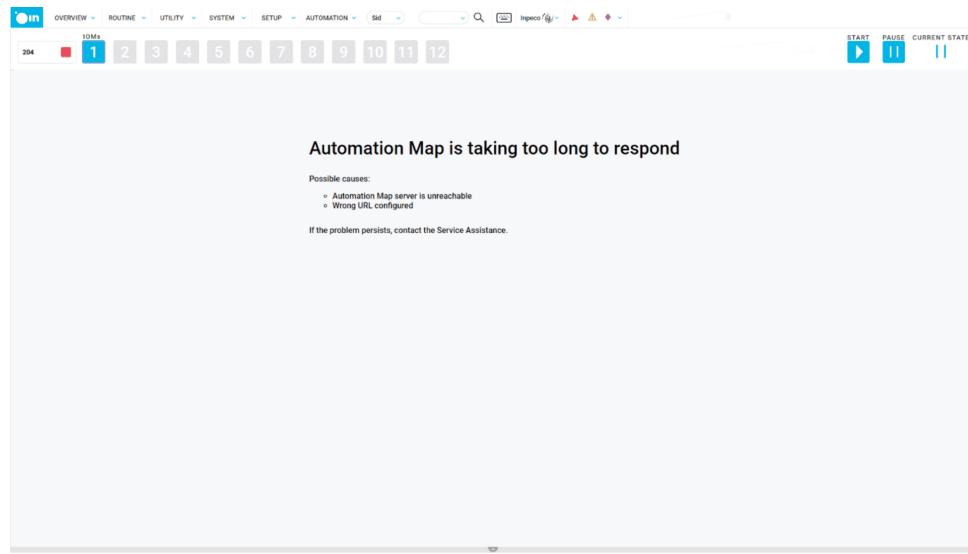
- Module's textures must be recognizable by the shape and colors
- Module's textures must be proportioned to the module's dimensions according to the global laboratory scale
- Module's status online/offline or warning/error must be distinguishable and not ambiguous.
- Add a default placeholder for each Node Type not defined

#### **NOTE**

For each module instance is displayed in the labels.

#### 4.4.1.1 Automation map communication error

In case of missing communication with Hosting service, after a loading indicator Automation Map is not displayed and a failure message appears indicating possible causes.

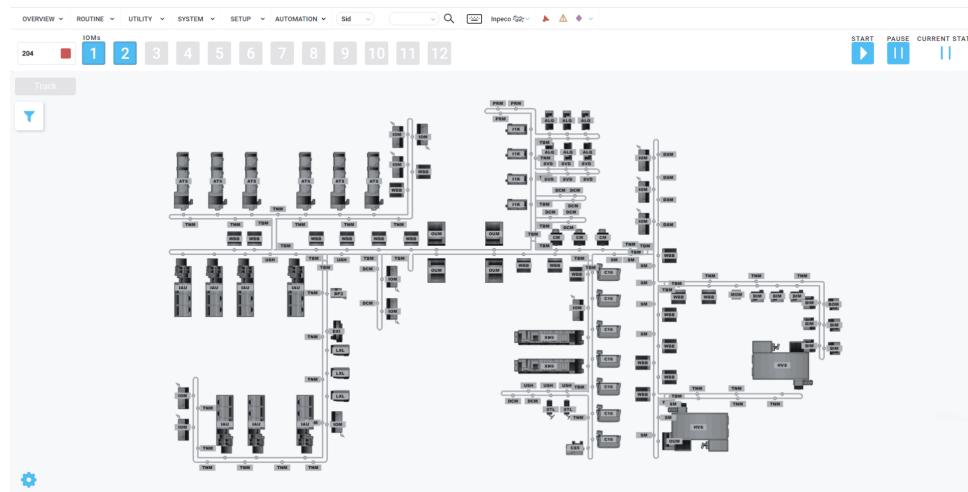
**Figure 10:**

#### 4.4.1.2 Communication error with automation system

Automation Map shall handle communication error with automation system.

In case of error communication:

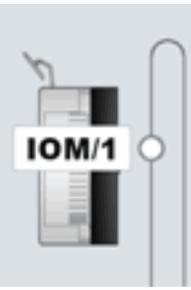
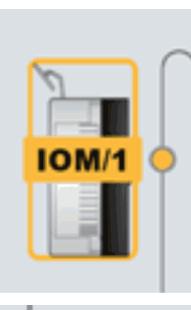
- All modules are displayed as offline.
- Traffic is not displayed (grey).
- All the actions on module card are disabled.
- The Track button is disabled.

**Figure 11:**

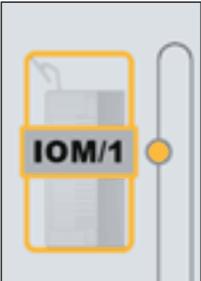
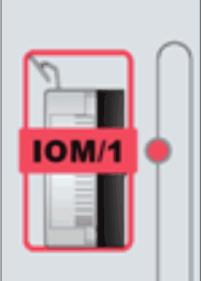
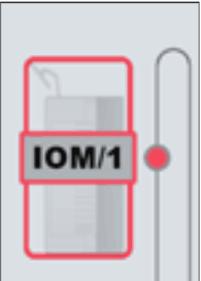
## 4.4.2 Automation Map status

Automation Map is connected by websocket channel to DMS to show the status of automation's modules. There are 4 available status:

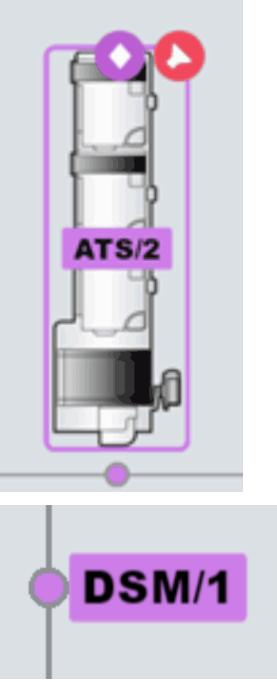
**Table 13:** Status of automation's modules

Icon	Description
Online/Run 	The node is represented with texture and Node Type label background colored in white.
Offline 	The node is represented with texture and Node Type label in grey scale. Offline modules have an increased transparency compared to online ones.
Warning status (Module Online): Yellow state (Initializing / Exercise):  	The node is represented with light texture and Node Type label background colored in yellow.
Warning status (Module Offline):	The node is represented with texture and Node Type label background in grey scale, both outlined in yellow.

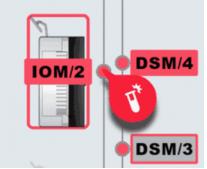
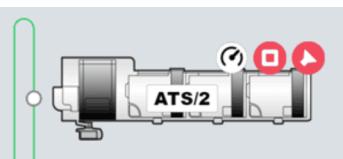
**Table 13 Status of automation's modules (cont'd.)**

Icon	Description
	
	
<p>Errors status (<b>Module Online:</b>)</p> 	<p>The node is represented with light texture and Node Type label background colored in red.</p>
	
<p>Errors status (<b>Module Offline:</b>)</p> 	<p>The node is represented with texture and Node Type label background in grey scale, both outlined in red.</p>
	

**Table 13 Status of automation's modules (cont'd.)**

Icon	Description
<p>Pink error (<b>Module Online:</b>)            Pink state (<b>Stand-by status / Going to offline status:</b>)</p> 	<p>The node is represented with light texture and Node Type label background colored in pink.</p>
<p>Pink error (<b>Module Offline:</b>)</p> 	<p>The node is represented with texture and Node Type label background in grey scale, both outlined in pink.</p>

**Table 14:** Automation Map status icons

Icon	Description
Stop Loading status 	The Stop Loading status notifies the user about the warning SC06C on BIM and RIM modules, if available, and this notification indicates that it is not possible to load other tubes on module. Warning representation is preserved. Stop Loading icon is displayed inside BIM/RIM module card.
Track Jam notification / NSD error 	In case of NSD error Automation Map notifies the user about the possibility of a Track Jam. Track Jam notification is represented by a floating red pin with a "tube" icon in correspondence to the module whose NSD is in error, in order to make this notification more visible. The Track Jam caused a red error on the module affected by NSD error. Once error is recovered, both manually and automatically, Track Jam icon is removed from Automation Map.
Overload module 	In case of an Overload module, the warning that there are too many full carriers foreseen to be processed by a specific analyzer class, a white icon is displayed in the upper part of the module. Overload icon is displayed inside module module card.

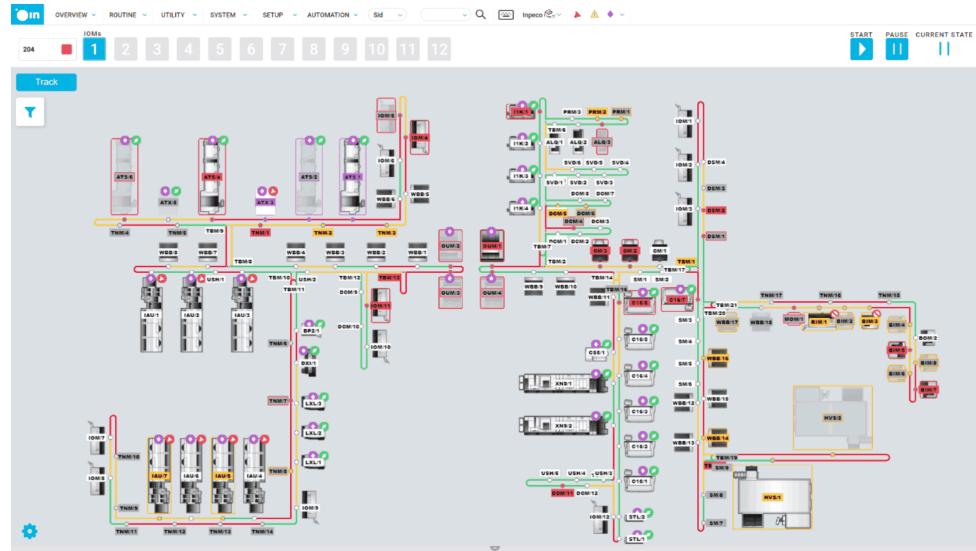
In case of the automation layout configuration changes, the map will show a warning notification at the top right with the modification date inside and that the layout configurations have been updated.

In case traffic level on track is enabled, track is colored according to current traffic on the Automation System in relationship to the configured thresholds.

In case carriers' density is lower than Moderate threshold, track is displayed as green. In case it is greater and equal than Moderate and lower than High threshold, track is displayed as yellow. While in case carriers' density is higher and greater than High threshold, track is displayed as red.

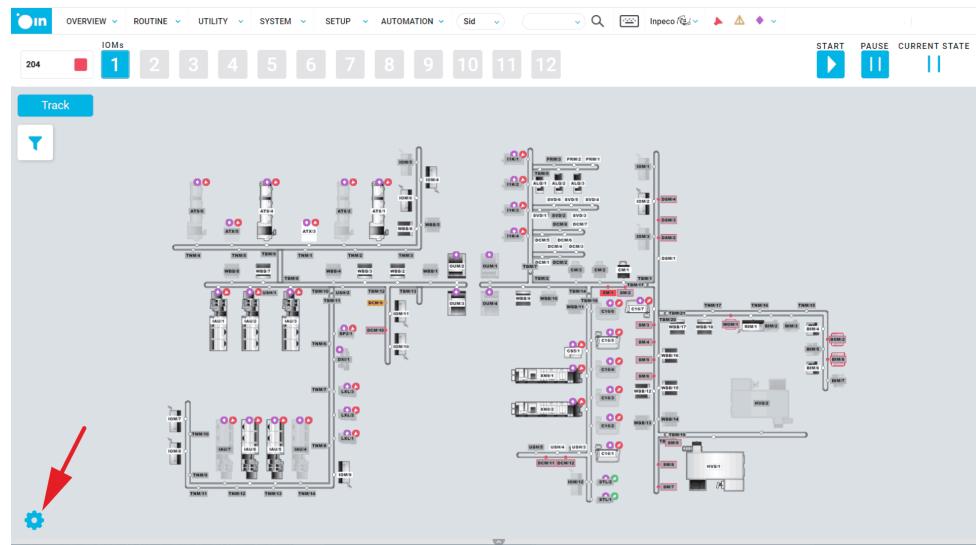
### NOTE

In this status the automation may not be correctly represented, please contact the system administrator.

**Figure 12:**

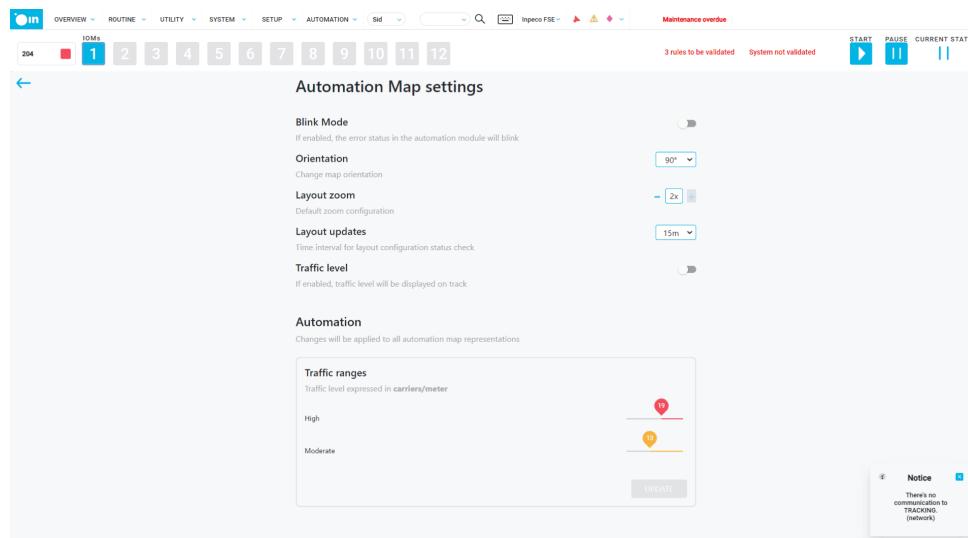
### 4.4.3 Automation Map Settings

Automation Map settings are accessible through the settings icon In the left bottom corner of the Automation Map page.

**Figure 13:**

**Table 15:** Automation Map Settings

Function	Description
Blink mode	The Blink Mode toggle switch, if disabled the node status in the automation module will not blink.
Orientation	Orientation, Layout map shall be rotated with 4 steps of 90 degrees related to cad drawing (0,90,180,270 degrees).
Layout zoom	Layout Zoom, set the default zoom configuration during start up or after Automation Map refresh (from 0.2x to 2x).
Layout updates	Layout Updates, Layout configuration status check every minutes options (1,5,10,15,30,60 minutes).
Traffic level	Traffic Level toggle switch, if disabled the traffic is not displayed on the track. <b>NOTE:</b> This setting must be performed only by FSE.
Automation	Automation section (this section requires confirmation on updates): <ul style="list-style-type: none"> <li>Traffic ranges sliders, set the High and Moderate traffic level thresholds, expressed in carriers/meter and referred to the module queue.</li> </ul>

**Figure 14:**

Selecting one of these options a spinner and a subsequent icon confirm that the operation has been auto-saved (in case of failure to save the icon will be different).

Clicking on the back icon in the left bottom corner, Automation Map can be visualized with updating settings.

#### 4.4.4 Interacting with the map

Automation Map can be explored using the mouse, or by performing standard gestures on the touchscreen to zoom or move the track. Interacting with the map is possible even if the Filter or the IOM's lane panel are open.

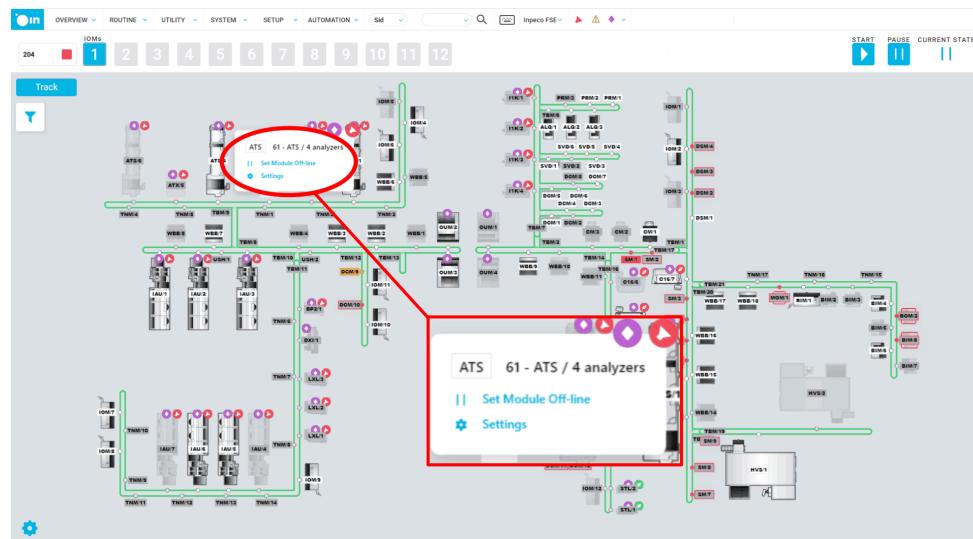
**Table 16:** Type of interaction

Type	Interaction descriptions
Desktop	<ul style="list-style-type: none"> <li>• Pan Around: click and drag.</li> <li>• Zoom: mouse wheel.</li> </ul>
Touchscreen	<ul style="list-style-type: none"> <li>• Pan Around: hold two fingers on the screen.</li> <li>• Zoom: pinch with two fingers.</li> </ul>

By clicking or tapping on a module, a module card is displayed in proximity to execute common actions, like Set Module Online/Offline, open the Settings modal or perform other actions depending on module type (e.g. interact with the IOM's lane configuration).

NOTE
Node type, node ID, instance and module category are displayed inside module card.

**Figure 15:**

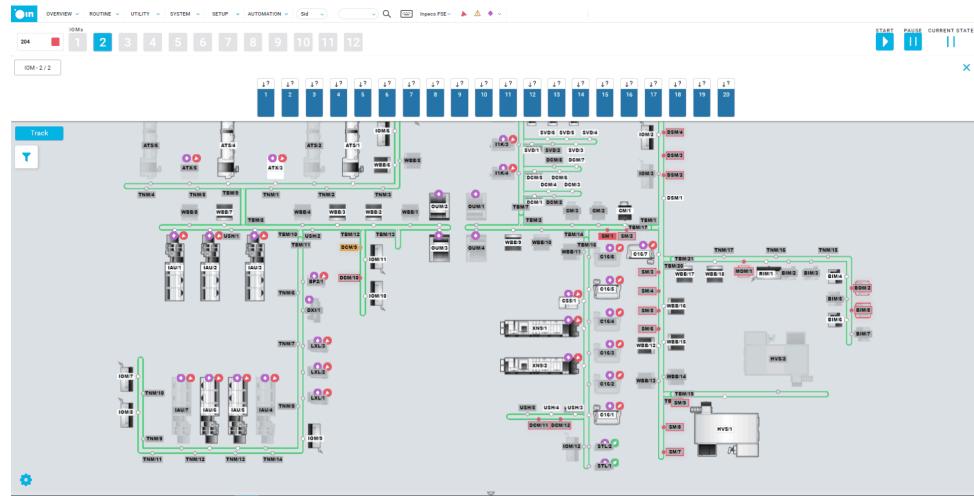


On Automation Map it is possible to click a specific IOM and select "Lanes Configuration" option, in order to visualize configuration and status of its lanes. After the selection, a dedicated panel is opened reporting information

related to the selected IOM and its lanes. It is possible to interact with the lanes for changing configuration or verify rack content.

Selected IOM, zoom and map position are preserved, in case of navigation to another screen.

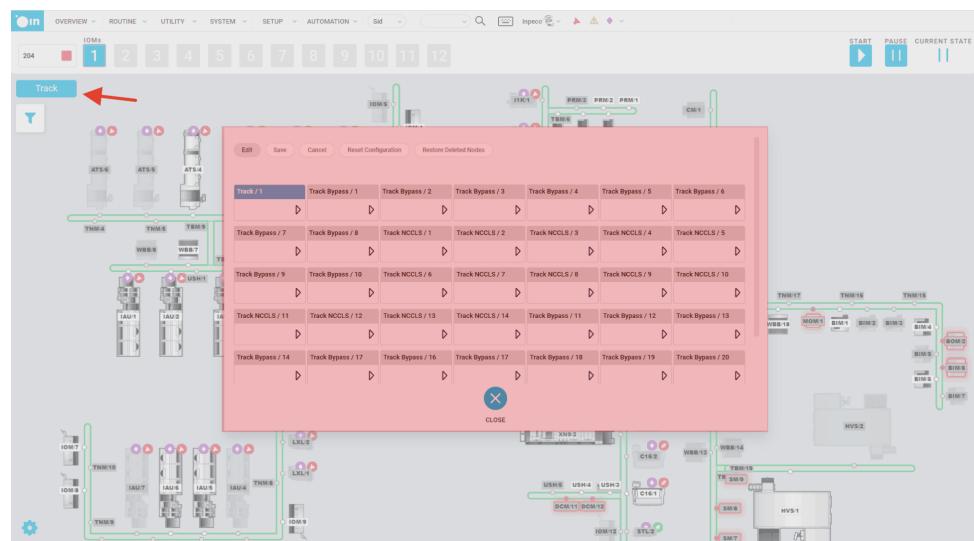
**Figure 16:**



#### 4.4.4.1 Track button

By clicking on **Track** button, all the track modules are displayed. Refer to [Table 22 Track status, page 68](#) for more information.

**Figure 17:**



## 4.4.5 Filters

Filter feature allows to view only some modules on the map, to reduce distractions and cognitive load while focusing on a specific activity.

Filters are activated by clicking the blue funnel icon located in the top left corner of the Automation Map overview page.

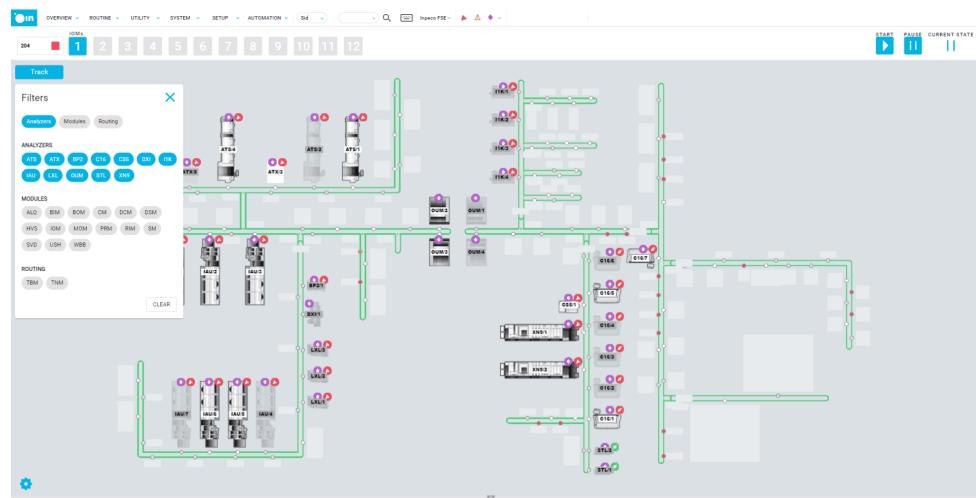
Modules to be shown can be selected by:

- Single node type, by clicking on one or more node types (e.g. ATS).
- Category, using the **Analyzers**, **Modules** and **Routing** presets on top of the section. Also in this case it is possible to select multiple categories (e.g. Analyzers and Routing).

Only node types that are present on the layout are displayed in the filter panel.

When filters are active, a little blue dot icon appears on top of the funnel button. The modules status not selected to be shown is still visible by looking at the module gateway, however the texture of the module is replaced by a gray area indicating its size and no other visual hint about module status will be visible on the module.

**Figure 18:**



Active filters can be removed by using the **Clear** button. Once the filters have been removed, all modules will be visible again on the Automation Map and the little blue dot on the funnel icon will be no longer be visible.

### NOTE

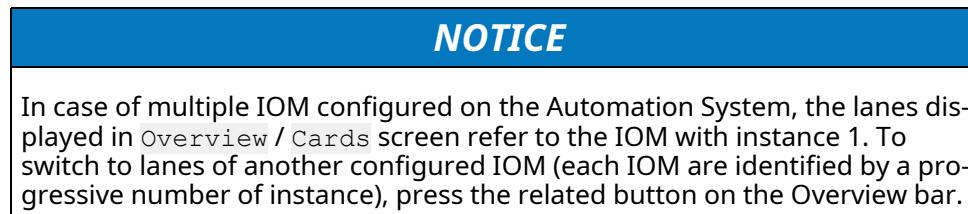
IUX shall preserve applied filters once user changes page and then comes back to Overview screen.

## 4.5 Overview – Cards

The Module Cards are displayed by clicking on the [Overview / Cards](#) button of the Multifunctional toolbar.

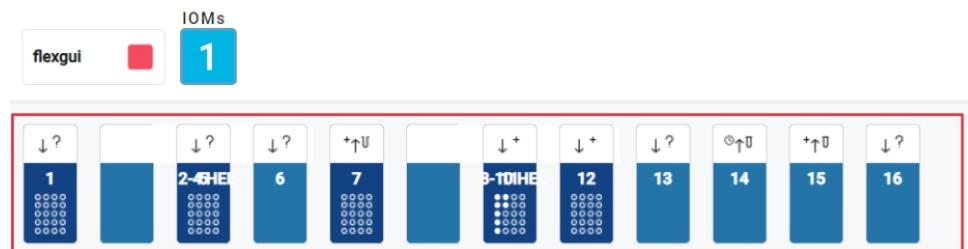
### 4.5.1 IOM lanes

The 16 lanes of the Input/Output Module (IOM) are displayed in [Overview / Cards](#) screen.



In case of Input/Output Module configured as GPI, the [Overview](#) screen provides a clear representation of the lane occupation based on the configured trays.

**Figure 19:** IOM lanes



The color of each lane button identifies its status. Selecting the lane button, it is possible to perform various actions depending on the lane status.

**Table 17:** Lane status – User Interface

Icon	Button color	Lane status description	Action when the lane button is selected
	Blue	No Rack is currently inserted in the lane.	A pop-up is displayed to allow the User to change the lane configuration.
	Dark Blue	An empty Rack is currently inserted in the lane	A pop-up with the list of the samples currently located in the Rack is displayed.
		A Rack with at least one sample tube inside (but the Rack is not full) is currently inserted in the lane.	A pop-up will be displayed in case an Sorting Lane is changed to another configuration.
	Pink	The Rack currently inserted is full.	
	Red	Lane to be identified.	A pop-up is displayed to ask the User to insert the Rack ID.

The icon on each lane button identifies its configuration.

**Table 18:** Lane configuration – Input lanes

Icon	Lane configuration	Description
	Dynamic	Lane used for routine input and, after being emptied, for incomplete output.
	Lowest Input	Lane used to load sample tubes with lowest priority.
	Routine Input	Lane used to load sample tubes not centrifuged for routine processing. Sample tubes will be automatically detected as capped or uncapped by the Vision System. Sample tube is considered as centrifuged if no Centrifuge Module is installed.
	ASAP Input	Lane used to load sample tubes not centrifuged with ASAP priority.
	STAT Input	Lane used to load sample tubes not centrifuged with STAT priority.
	Skip Centrifuge Lowest Input	Lane used to load pre-spun and capped sample tubes with lowest priority.
	Skip Centrifuge Routine Input	Lane used to load pre-spun and capped sample tubes for routine processing.
	Skip Centrifuge ASAP Input	Lane used to load pre-spun and capped sample tubes with ASAP priority.
	Skip Centrifuge STAT Input	Lane used to load pre-spun and capped sample tubes with STAT priority.
	Uncapped Lowest Input	Lane used to load uncapped sample tube with lowest priority.
	Uncapped Routine Input	Lane used to load uncapped sample tube for routine processing.

**Table 18** Lane configuration – Input lanes (cont'd.)

Icon	Lane configuration	Description
	Uncapped ASAP Input	Lane used to load uncapped sample tube with ASAP priority.
	Uncapped STAT Input	Lane used to load uncapped sample tube with STAT priority.
	Sealed Lowest Input	Lane used to load sealed sample tubes with lowest priority.
	Sealed Input	Lane used to load sealed sample tube for routine processing.
	Sealed ASAP Input	Lane used to load sealed sample tube with ASAP priority.
	Sealed STAT Input	Lane used to load sealed sample tube with STAT priority.
	Long Term Storage Input	Lane used to load sample tubes for Long Term Storage only.
	Shaken Uncapped STAT Input	Lane used to load shaken uncapped tubes with STAT priority.
	Shaken Capped STAT Input	Lane used to load shaken capped tubes with STAT priority.

**Table 19:** Lane configuration – Output lanes

Icon	Lane configuration	Description
	Sorted Output	Lane used to unload sample tubes with sorting tests or with configured error codes.
	Generic Sorted Output	Lane used to unload sample tubes with test orders configured as Generic Sorted Output in IOM Generic Sorting Tests (Settings screen).
	Incomplete Output	Lane used to unload incomplete sample tubes (for parking tubes, i.e.

**Table 19 Lane configuration – Output lanes (cont'd.)**

Icon	Lane configuration	Description
		sample tubes that did not complete their processing on the Automation System; if the rack remains locked on the lane, sample tubes will be automatically re-loaded on track as necessary).
	Complete Output	Lane used to unload complete tubes or, if configured, to unload tubes routed to Storage Module or ROM when they are unavailable or in case <code>IOM Helps Storage to Unload Tubes</code> is configured as Yes.
	Priority Output	Lane used to unload sample tubes with error codes or sample tubes requested by the User.
	Dynamic	Automatically selected when the <code>Dynamic Input Lane</code> is selected.

In case of anomalies, the following icon is displayed:

**Table 20: Icon for anomalies**

Icon	Description
	Lane not configured.

In case of anomalies, the following icons are displayed:

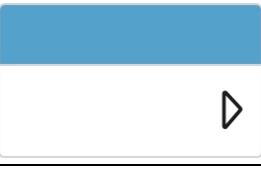
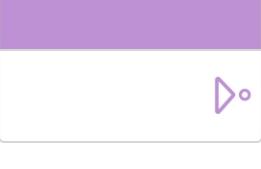
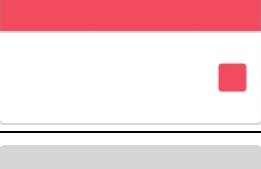
## 4.5.2 Automation Modules and Interface Module

### 4.5.2.1 Cards

Under the IOM lanes, each card corresponds to a connected Interface Module or Automation Module – with its instance – except the card for Track that groups all the Track Modules.

The header color of the cards and the icon correspond to the Module (or Interface Module) status.

**Table 21:** Automation Modules and Interface Modules status

Card	Module Status	Header Color – Icon Color	Description
	On-line	Blue – Black	The Module is On-line and in non-error condition.
		Pink – Pink	<ul style="list-style-type: none"> <li>The Module is in Full status (i.e. it may accept only Empty Carriers if necessary for its functioning) and On-line, or the node is in Stand-by status (e.g. Storage Module).</li> <li>The Analyzer is remotely disabled by the Automation Software.</li> </ul>
		Yellow – Yellow	The Module is in Warning or Initializing status or in Exercise Mode and On-line.
		Red – Red	The Module is in Error status and On-line.
	Off-line	Gray – Black	The Module is in non-error condition and Off-line.

**Table 21 Automation Modules and Interface Modules status (cont'd.)**

Card	Module Status	Header Color - Icon Color	Description
		Gray - Pink	The Module is in Full Status (i.e. it may accept only Empty Carriers) and Off-line (or, in case of CM, it is Off-line with Sample Tubes inside).
		Gray - Yellow	The Module is in Warning status or in Exercise Mode and Off-line.
		Gray - Red	The Module is in Error status and Off-line.
		Yellow - Black	<p>The Module is automatically set Off-line for inactivity.</p> <p><b>NOTE:</b> The Module is automatically restored to on-line condition when a sample tube to be routed to the Module:</p> <ul style="list-style-type: none"> <li>• is loaded on the Automation System;</li> <li>• comes out from the Centrifuge Module.</li> </ul>

The color of the Track card corresponds to the overall Track Modules status.

**Table 22: Track status**

Header Color	Description
	All Track Modules are in Normal status or Off-line (but not all Off-line).
	At least one Track Module is in Full status and its Mode is not Off-line and there are no other Track Module in Warning or Initializing or Error Status.

**Table 22 Track status (cont'd.)**

Header Color	Description
	At least one Track Module is in Warning or Initializing Status or in Exercise Mode and its Mode is not Off-line and there are no other Track Module in Error status.
	At least one Track Module is in Error status or in Unknown Status and its Mode is not Off-line.

Only on Analyzer cards, additional icons display the Quality Control status and the Connection status for the current instrument.

**Table 23: Additional Analyzers icons**

Icon	Description	Meaning
	Quality Controls	All online QC results for each Control ID are valid and all tests enabled for performing QCs on the current instrument have been processed in the current period.
		All online QC results for each Control ID are valid, but not all tests enabled for performing QCs on the current instrument have been processed in the current period.
		There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as failed. All tests enabled for performing QCs on the current instrument have been processed in the current period.
		There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as failed. Not all tests enabled for performing QCs on the current instrument have been processed in the current period.
		There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as warning, no one is failed. All tests enabled for performing QCs on

**Table 23 Additional Analyzers icons (cont'd.)**

Icon	Description	Meaning
		the current instrument have been processed in the current period.
		There is at least one test related to the current instrument with at least one Control ID with last QC result evaluated as warning, no one is failed. Not all tests enabled for performing QCs on the current instrument have been processed in the current period.
	LIS Connection (between Analyzer and Data Management Software)	No Quality Control has been run in the current period for the related instrument. It is possible that at least one test on instrument has QC results produced in a previous day, or used for the pre-period or QC results moved in the historical area.
		Communication enabled, Analyzer correctly connected and communicating.
		Communication enabled, but Analyzer is not correctly connected or not correctly communicating.
		Analyzer connected but lacking communication due to physical connection problems.
		Communication with Analyzer is disabled.

### 4.5.2.2 Common Function buttons

Pressing a Module card (except for the Track card), a pop-up is displayed to select the appropriate Status, Settings, Gates or Diagnostics screen for that Module. Pressing the Track card, the screen that groups all the Track Modules is displayed.

The Common Function buttons are buttons in common to many modules that are displayed when accessing the Module and Analyzer cards through the Status, Settings, Gates and Diagnostics screens of the Module or Analyzer.

**Table 24:** Common Function buttons

Function button	Access Level	Description
On-line	Operator	Sets the Module to On-line.
Off-line	Operator	Sets the Module status to Off-line.
Going Off-line	Operator	Completes the current work on the Module, then automatically transitions to Offline when complete.
Explain	Operator	Allows to show details about possible error cause that occurred and its recovery.
Reset	Operator	Resets a Module after an error recovery.
Reboot	FSE	Restarts the Module.
Backup	FSE	Backups the Module firmware configuration.
Restore	FSE	Restores of Module firmware configuration.
Stand-by	Operator	Sets the Module to stand-by. Module will not accept any further tubes for processing, but will maintain its other functions similar to the On-line status.
Recovery	Operator	Provides a direct link to the appropriate Diagnostics screen where it is possible to recover from the last error.

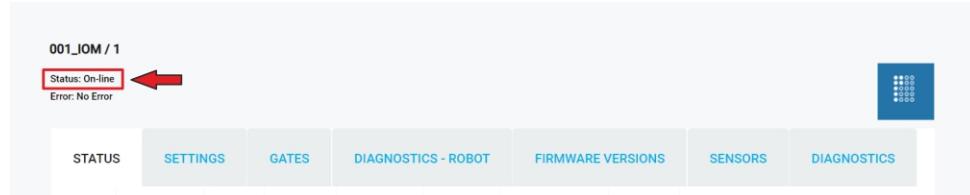
**Table 24 Common Function buttons (cont'd.)**

Function button	Access Level	Description
Print	Operator	Allows to print the content of the list box.
Export CSV	Operator	Allows to export the content of the list box to file. It is necessary to add the extension to the exported file.

### 4.5.2.3 Modules and Interface Modules status

Every Module (or Interface Module) can assume various statuses.

The status is displayed in the top left part of the Module/Interface Module card.



Modules can assume the following status.

**Table 25:** Module Status

Status	Description	Comments
Unknown	Temporary status: occurs during Automation System power on procedure	The Module is not ready to process samples.
On-line	On-line button selected. It is the status where the samples are processed.	The Module is ready to process samples.
Stand-by	Stand-by button selected. New samples are not routed to the Module. Empty carriers routed to the Module to allow sample tubes loading on Track.	Module stays in Stand-by Mode until User intervention. <b>NOTE:</b> Storage and Retrieval Module in Standby Mode will continue disposing tubes and retrieving tubes.
Going to Off-line	Going to Off-line button selected. Module completes processing samples currently inside the Module and then passes to Off-line status. New samples are not routed to the Module. It is possible to schedule when the Module status will be changed to Going off-line. A popup allows choosing the time: immediately (selecting the Now button) or at a specific time (selecting the time in the popup and then Scheduled time button)	Module completes processing samples currently inside the Module. <b>NOTE:</b> Status leading the Module to transitioning to Off-line and then to Off-line status.
On-line (Off-line command sent)	The Module is On-line but the Off-line button has been pressed.	Status leading to transitioning to Off-line status.

**Table 25 Module Status (cont'd.)**

Status	Description	Comments
On-line (Exercise command sent)	The Module is On-line but the Exercise button has been pressed.	Status leading to exercise status.
Transitioning to Off-line	Off-line button selected. Temporary status: it leads to Off-line status.	<p>The Module is transitioning to Off-line status.</p> <p>New samples are not routed to the Module.</p> <p><b>NOTE:</b></p> <p>If the Module is not configured with NSD device, the Automation track must be in running so that the Module can transition to Off-line status. If the Module is configured with NSD device, the transition can occur with the Automation track in Pause mode.</p>
Stopping	<p>Off-line button selected with the flush carriers option.</p> <p>Temporary status: when Off-line command is being executed and was asked to flush the Module buffer from the present carriers and tubes.</p>	<p>The Module is not ready to process samples.</p> <p><b>NOTE:</b></p> <p>The Module buffer is emptied from all carriers and tubes.</p>
Stop	The Module is stopped.	The Module is not ready to process samples.
Off-line	Off-line button selected. It is the status where the samples are not processed.	<p>Required status to perform Module Diagnostics.</p> <p>The samples are not routed to the Module.</p>
Off-line (On-line command sent)	The Module is Off-line but the On-line button has been pressed.	Status leading to initializing status.
Off-line (Exercise command sent)	The Module is Off-line but the Exercise button has been pressed.	Status leading to exercise status.
Initializing	<p>On-line button selected.</p> <p>Temporary status: when On-line command is being executed.</p>	<p>The Module is not ready to process samples.</p> <p><b>NOTE:</b></p> <p>The Module buffer is emptied from all present carriers and tubes.</p>
Transitioning to Exercise	Temporary status: it leads to Exercise status.	The Module is transitioning to Exercise status.
Exercise	The Module is in exercise status.	Carrier and tubes routed to the Module will not be processed. Functionality used by FSE to check gates activation.

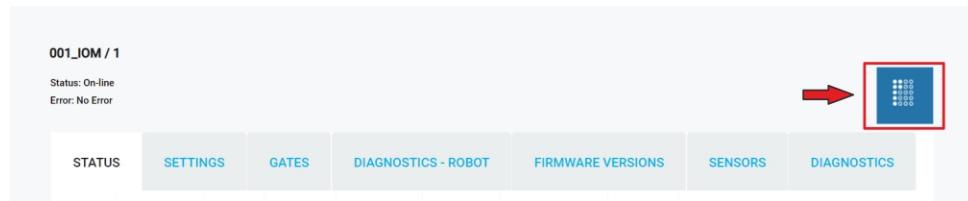
**Table 25 Module Status (cont'd.)**

Status	Description	Comments
Transitioning to Shutdown	Temporary status leading to shut down status.	The Module is not ready to process samples.
Shutdown	The Module has been shut down.	The Module is not ready to process samples.
Transitioning to Pause	Temporary status leading to pause status.	The Module is transitioning to pause status.
Paused	The Module is in pause status.	The Module is not ready to process samples.
Undefined	Undefined firmware node status.	The Module is not ready to process samples.

#### 4.5.2.4 Snapshot button

In the Module/Interface Module card, the Snapshot button allows to search the list of tubes located in the Module (or Interface Module) through the Snapshot window.

The Snapshot button is displayed in the top right part of the Module/Interface Module card.



The Snapshot button is displayed for:

- “Pick and Place” Analyzers
- Automation Modules for which the change in position is communicated (e.g. Input/Output Module, Centrifuge Module, Storage and Retrieval Module, etc).

#### 4.5.2.5 Layout configuration buttons

The Layout configuration buttons allow to change the visualization of Modules and Analyzers cards.

The Layout configuration buttons are displayed in the bottom part of **Overview / Cards** screen.

Button	Description
Edit	<p>Press this button to activate the Layout configuration mode. This mode allows the current User to move each button to a different position by dragging and dropping the button to the new position. Besides, the following icon will appear on each button permitting the user to hide the button from the <b>Overview</b> screen.</p> 
Save	<p>Allows the user to save the changes made to the visualization of the layout.</p> <p>Each User can save his own layout configuration. Modifications made by an User are visible only to the User himself.</p>
Cancel	<p>Allows the user to exit the configuration mode without saving the changes.</p>
Reset Configuration	<p>Allows the user to reset the initial positions and visualization of the Module/Analyzers cards.</p>

Button	Description
Restore Deleted Nodes	Displays a list of the previously hidden nodes. It is possible to select the nodes that need to be visualized again by selecting them and then pressing the <code>Restore</code> button.
Show IOM Labels	Displays all labels and configurations of the IOM lanes.

## 4.6 Routine

The **Routine** menu contains functions relating to the main operations used in the laboratory routine.

The menu is made up of the following items.

Screen	Access Level	Description
Search	Laboratory Technician	Allows to search of tubes (with the option of filtering in accordance with various criteria), display of test processing status, results validation and management of doubtful cases.
Historic Archive	Laboratory Technician	Allows a search for tubes with tests already completed and allows archiving.
Admission	Laboratory Supervisor	Allows the manual input of a new patient and orders, or the amendment of an existing patient's anographic data and orders.
Instrument Worklist	Laboratory Technician	Allows a work order list to be sent manually to a selected Analyzer.
Patient Results Report	Laboratory Technician	Allows to print a check list of patients on the worklist of one or more Instruments.
Medical Reports	Laboratory Supervisor	Allows the creation and printing of medical report.
Send to Host	Laboratory Technician	Allows test results to be manually resent from DMS to the Host.

## 4.6.1 Search

The Search screen allows the User to search sample tubes (with the option of filtering in accordance with various criteria) and clinical information about the orders that match the filters criteria, display the status of test processing status, and results validation.

It consists of two sections:

- Extended Search
- Validation screen (Patient detail screen).

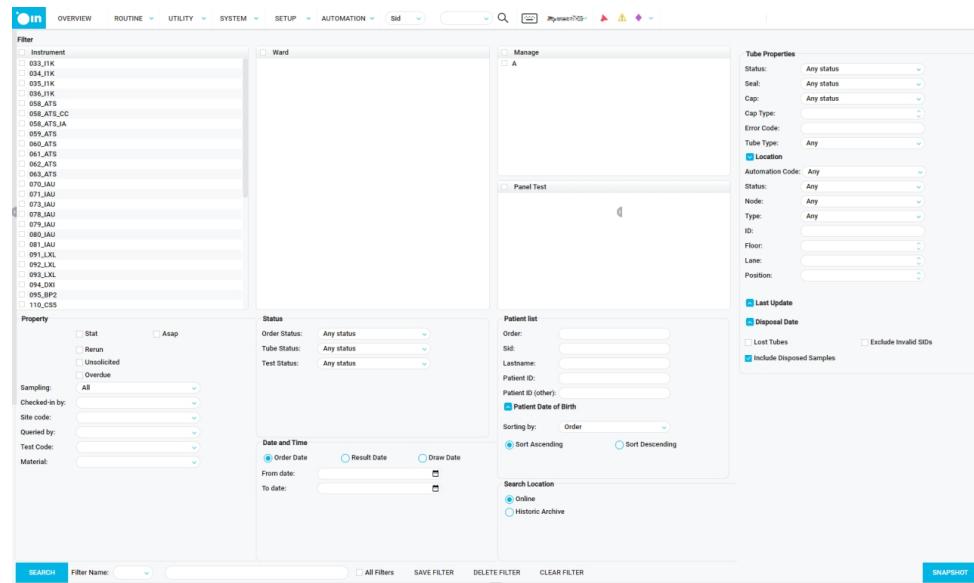
### 4.6.1.1 Extended search

Allows to search for patients and tests on worklist, with additional filtering options compared to those on the quick search bar.

The screen is divided in different sections that provide all the tools to define:

- filter parameters to refine the research criteria;
- choice of a specific search location: On-line, Pre-admission, Historic Archive.

**Figure 20:** Search screen



Area	Description
Filters	<p>The various filters, which can be combined, can be used to select required tube characteristics.</p> <p>Refer to <a href="#">Table 26 Available filters, page 80</a>.</p>
search location	<p>Allows to choose where executing the research among the type of order present in DMS. There are three choices:</p> <ul style="list-style-type: none"> <li>• <b>Online:</b> orders currently present in the Laboratory workflow;</li> <li>• <b>Pre-Admission:</b> orders received from the LIS and not yet present in Laboratory</li> <li>• <b>Historic Archive:</b> orders processed and already archived</li> </ul> <p><b>NOTE:</b> Some filter options will be disabled according to the location chosen to help the User to keep the research criteria consistency.</p>

The available filters are reported hereafter.

**Table 26:** Available filters

Filter	Description
Instrument	Allows the User to search for patients with tests linked to one or more Analyzers that performed the analysis.
Ward	Allows the User to search for patients with tests relating to one or more wards.
Manage	Allows the User to search for patients with tests relating to one or more laboratory code managements.
Panel Test	Allows the User to search for patients with tests relating to one or more panel tests (i.e. set of tests to be ordered together using a single test code).
Property	Allows the User to search for tubes with Priority (Stat or Asap), Rerun, Unsolicited and Overdue tests. Using the drop-down menus, it is also possible to search for the Sampling status of the Patient samples, the Instrument or Automation System where the check-in of the samples has been performed, the possible Site where the tube is present, the Instrument that performed the query, a specific test code and the Analyzer used to test the tube, the location of the Sample on the Automation System, and the sample Material.

**Table 26 Available filters (cont'd.)**

Filter	Description
Status	Allows the User to search for patients with orders, tubes and tests fulfilling a specific status via a drop-down menu.
Patient list	<p>Equivalent to the quick search box on the multi-function bar. The filter contains different boxes (Order ID, Sample ID, Patient last name and Patient ID) for searching specific tests based on patient data. In this panel, the box <b>Patient ID (other)</b> allows to enter optionally an additional search criterion for patient identifier (e.g. SSN - Social Security Number) as per record sent from Host (field 08.01.05). Besides, it is also possible to conduct a search by using a time range based on the patient's date of birth.</p> <p>Results may be sorted by ascending or descending order in accordance with a criterion selectable from the drop-down menu.</p>
Date and Time	Allows the User to specify the range of date and time for Orders, Results or Draws in which search the results to be displayed. The start and/or end dates can be selected from a calendar that appears when the button next to the date box is pressed. In this popup that shows the calendar, it is possible to specify the time by clicking on the <b>Change...</b> button. Click on <b>Now</b> to set the current time. Press <b>Done</b> to confirm.
Result	Allows filtering of test results according to actual value or setting search ranges by using mathematical symbols and logical operators (AND/OR). The filter <b>Result</b> is displayed only if it has been enabled in General Settings (feature allowed to technical assistance staff only).
Tube Properties - Status	<ul style="list-style-type: none"> <li><b>Complete:</b> tube is in complete status when S025/C message is received.</li> <li><b>Incomplete:</b> tube is in incomplete status when S025/I, or L001, or L005, or L006 messages are received.</li> <li><b>Expected:</b> tube is in expected status.</li> <li><b>Deferred:</b> tube is in deferred status when S025/D message is received.</li> </ul>
Tube Properties - Seal	<ul style="list-style-type: none"> <li><b>Sealed:</b> tube is sealed when S005/SEALED message is received</li> <li><b>Unsealed:</b> tube is not sealed when S005/UNSEALED message is received.</li> </ul> <p>By default, when a tube is loaded on Automation, it is considered to be unsealed.</p>
Tube Properties - Cap	<ul style="list-style-type: none"> <li><b>Capped:</b> tube is capped when L00x messages (L001, L002, L003, L004, L005, L006) are</li> </ul>

**Table 26 Available filters (cont'd.)**

Filter	Description
	<p>received with Cap Type value equal to "C" or a number greater than 0.</p> <ul style="list-style-type: none"> <li>Uncapped: tube is not capped when L00x message (L001, L002, L003, L004, L005, L006) is received with Cap Type value equal to "N" or S005/DECAPPED is received</li> </ul>
Tube Properties - Cap Type	<ul style="list-style-type: none"> <li>When Cap-type value greater than "0" or cap-type value equal to "C" are received, tube is capped.</li> <li>When Cap-type value equal to "N" is received, tube is not capped.</li> </ul> <p>Cap type is set when L001 message is received.</p>
Tube Properties - Error Code	<p>Error Code associated to the Sample Tube is set when S004 message is received.</p>
Tube Properties - Tube Type	<ul style="list-style-type: none"> <li>Any</li> <li>Automation Tube Type 1 (Tube Type 1)<sup>4</sup></li> <li>Automation Tube Type 2 (Tube Type 2)<sup>5</sup></li> <li>13x75 mm (Tube Type 3)</li> <li>13x100 mm (Tube Type 4)</li> <li>16x75 mm (Tube Type 5)</li> <li>16x100 mm (Tube Type 6)</li> <li>Sarstedt 15x75 (Tube Type 7)</li> <li>Sarstedt 13x90 (Tube Type 8)</li> <li>Aliquot Tube (Tube Type 9)</li> <li>Sarstedt 15x90 (Tube Type 10)</li> <li>Sarstedt 13x75 (Tube Type 11)</li> <li>13x82mm (Tube Type 12)</li> <li>Greiner MiniCollect 13x75mm (Tube Type 13)</li> <li>GBD Microtainer MAP Chemistry (Tube Type 14)</li> <li>BD Microtainer MAP (Tube Type 16)</li> <li>Sarstedt Microvette APT (Tube Type 17)</li> <li>Sarstedt S-Monovette 11x66mm (Tube Type 18)</li> <li>Sarstedt Microvette Capillary Cap (Tube Type 19)</li> </ul> <p>Tube type is set when L001 or S015 messages are received.</p>

4. unknown diameter x 75 mm

5. unknown diameter x 100 mm

**Table 26 Available filters (cont'd.)**

Filter	Description
Location - Automation Code	Allows to choose one of the available Automation System (e.g. FLEXLAB1, FLEXLAB2). All tubes that have been loaded on the chosen automation are retrieved. If <b>Any</b> value is selected, all samples available in the system are retrieved.
Location - Status	<ul style="list-style-type: none"> <li>On-Track: when this filter is set, all tubes on track or inside any module of the automation system are retrieved</li> <li>Off-Track: when this filter is set, removed or disposed tubes, or all tubes that have never been loaded on Automation are retrieved</li> <li>Removed from Rack: tube is considered as "Removed from rack" when S005/REMOVED or R001/REMOVED messages are received</li> <li>Disposed: tube is disposed when S005/DISPOSED or R001/DISPOSED messages are received</li> </ul>
Location - Node	<p>When this filter is set, all tubes loaded on the selected module (or Node) are retrieved. This filter depend on the filter Automation Code.<sup>6</sup></p> <p>The location Node is set when S001 message is received.</p>
Location - Type	<ul style="list-style-type: none"> <li>Rack-Tray: all tubes located on rack (or tray in case of IOM upgraded to GPI) are retrieved. The location type Rack-Tray is set when S001 message is received.</li> <li>Carrier: all tubes located on Carrier are retrieved. The location type Carrier is set when L00x, or S003 or S005 messages are received.</li> <li>Any.</li> </ul>
Location - ID	Rack ID or carrier ID based on choice done in the filter Type.
Location - Floor	<p>Rack floor (for SRM) where the tube is located. The location Floor is set when S001 message is received with information related to floor.</p> <p>This field is visible only in case the filter Type is set to Rack or Any.</p>
Location - Lane	<p>Rack lane (for SRM or IOM) where the tube is located. The location Lane is set when S001 message is received.</p> <p>This field is visible only in case the filter Type is set to Rack or Any.</p>
Location - Position	Rack position (for SRM or IOM). The location Position is set when S001 message is received.

6. For example, if the filter "Automation Code" is set to "FLEXLAB1", the filter "Node" will display all modules (nodes) belonging to "FLEXLAB1". If "Node" is set to "IOM", all tubes loaded to IOM of the Automation System "FLEXLAB1" are retrieved.

**Table 26 Available filters (cont'd.)**

Filter	Description
	This field is visible only in case the filter <b>Type</b> is set to <b>Rack</b> or <b>Any</b> .
Location - Temporary Parking Rack	Checkbox displayed only if: <ul style="list-style-type: none"> <li>The Storage Module is configured.</li> <li>Location - Status is <b>On-Track</b>.</li> <li>Location - Node is the Storage Module.</li> </ul>
Last Update	Allows to filter tubes by date and time of the last event (L001, S004, S006, S007, S014, S015, S021, S022) occurred on the sample.
Disposal Date	Expected date and time (Y-m-d H:m:s) on which the tube will be disposed.
Lost tubes	If checked, all tubes with error code SC01E are retrieved. It is not checked by default.
Exclude invalid SIDs	If checked, invalid Sample IDs (i.e. Unreadable, Invalid, Duplicate SIDs) are excluded from the search. It is not checked by default.
Include disposed samples	If checked, all disposed samples are retrieved with the search. It is checked by default.

In the bottom of the Extended Search screen, the following buttons are available.

**Table 27: Extended Search screen – Function buttons**

Function button	Description
Search	Starts the search based on the set filters, displaying the corresponding patient detail screens (Validation screen). If the search gives no results, a pop-up message notifies the User, who is returned to the search page in order to change the settings and start a new search. Selecting the <b>Search</b> button, with no filter active, the data of all patients present in the worklist are displayed (this operation is equivalent to a search carried out from the quick search bar with the text box empty).
Snapshot	Opens a pop-up to consult the list of samples with the related tests that match the filters criteria; summary information is displayed for quick consultation. The lists may be sorted

**Table 27 Extended Search screen – Function buttons (cont'd.)**

Function button	Description
	based on various criteria (using the column headers to group by different criteria).
Filter Name	Displays the list of saved filters by the logged User.
All Filters	If checked, displays all the available filters (including filters created by other Users) in the Filter Name drop-down menu.
Save Filter	Allows to create a private library of filters.
Delete Filter	Deletes the saved filter.
Clear Filter	Resets the search criteria set.

#### 4.6.1.1.1 Snapshot screen

The Snapshot screen reports a list of samples with the related tests that match the filters criteria.

Depending on the type of Search location chosen, different snapshots screen are displayed.

**Table 28: Snapshot screen with Online option**

Function button	Description
Refresh	Allows to reload the list of samples in the Snapshot screen. Wait for the operation to finish (i.e. until the progress bar disappeared) before refreshing the screen.
Export CSV	Allows to export the information to file.
Print	Allows to generate a printable PDF with the content of the filtered order informations.
Go to Sample	Allows to open the Validation screen related to a sample.
Rerun <sup>7 8</sup>	Allows to execute the rerun of the tests selected from the list.
Validate <sup>7</sup>	Allows to validate the selected tests.
Command	Contains all the operation applicable to the selected tests/samples. Refer to <a href="#">Table 41 Command buttons, page 104</a> . In particular, the commands Complete sends to the Automation

7. Displayed if the option "Enable result displaying on snapshot" in General Settings has been checked.  
8. FSE can order a rerun only if the test is in "Final" status.

**Table 28 Snapshot screen with Online option (cont'd.)**

Function button	Description
	software the notification of Complete (message S002) for the whole tube regardless of the test selected; the Complete Test sends the notification of Complete (message S002) only for the test selected.
Collapse All Expand All	Used to collapse/expand the group content display.
Close	Closes the Snapshot screen.

**Table 29: Snapshot screen with Pre-Admission option**

Function button	Description
Refresh	Allows to reload the list of samples in the Snapshot screen. Wait for the operation to finish (i.e. until the progress bar disappeared) before refreshing the screen.
Command	Contains all the operation applicable to the selected tests/samples. <ul style="list-style-type: none"> <li>Move On-line and Move On-line All: this command moves the selected orders (or all orders) into the online laboratory workflow.</li> <li>Delete and Delete All: this command removes the pre-accepted orders from DMS Software.</li> </ul>
Grouping criteria buttons: <ul style="list-style-type: none"> <li>Clear Grouping</li> <li>Group by Test</li> <li>Group By Oid</li> <li>Group By Sid</li> <li>Group By Last Name</li> </ul>	Those buttons changes the grouping criteria for the list visualization.
Collapse All Expand All	Used to collapse/expand the group content display.
Close	Closes the Snapshot screen.

**Table 30:** Snapshot screen with Historic Archive option

Function button	Description
Refresh	Allows to reload the list of samples in the Snapshot screen. Wait for the operation to finish (i.e. until the progress bar disappeared) before refreshing the screen.
Export CSV	Allows to export the information to file.
Print	Allows to generate a printable PDF with the content of the filtered order informations.
Go to Sample	Allows to open the Validation screen related to a sample.
Collapse All Expand All	Used to collapse/expand the group content display.
Close	Closes the Snapshot screen.

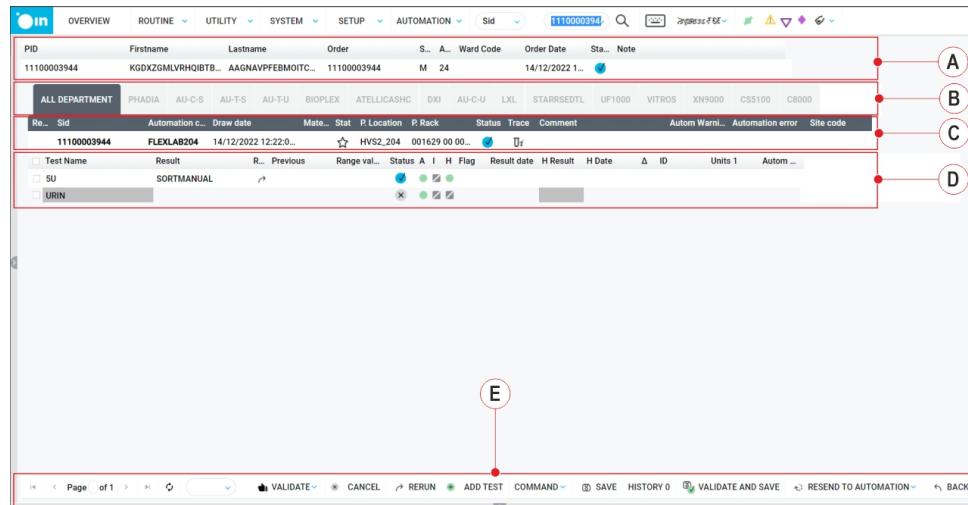
Note that:

- The `Historic Data Visualization` label is shown in the Snapshot window for historic archive search location.
- The button `Snapshot Pre-Admission` is displayed only if configured.
- To use the `Snapshot Pre-Admission` pop-up and functions, the option to put new orders in pre-admission must be enabled in the Host/LIS communication parameters, otherwise the list will be empty (no orders in pre-admission, all orders are considered on-line).

#### 4.6.1.2 Validation screen (Patient detail screen)

The Validation screen summarizes all orders, tubes and tests currently associated to a patient, and allows test results to be managed and validated.

**Figure 21:** Validation screen



The Validation screen is structured as follows:

- Patient Anographic Details ([Figure 21 Validation screen](#) – A)
- Departmental Tabs ([Figure 21 Validation screen](#) – B)
- Details of tubes (SIDs) ([Figure 21 Validation screen](#) – C)
- Details of Tests and Results for each SID ([Figure 21 Validation screen](#) – D)
- Navigation and Validation Bar ([Figure 21 Validation screen](#) – E)
- Sides Panels (Right panel, Left Panel) – normally closed, can be displayed by clicking on the arrows on the side of the screen

##### 4.6.1.2.1 Patient Anographic Details

Only one patient is displayed at a time on each Validation screen. The first row of the page shows the patient anographic and details of the order received from the Host.

**Table 31:** Patient Anagraphic Details parameters

Parameter	Description
PID	<p>Patient ID, a unique code that identifies the Patient.</p> <p><b>NOTE:</b></p> <p>If LIS sends orders leaving blank the <i>Lab Assigned Patient ID</i> (or <code>PID</code>) field of the Patient Record (08.01.04 field in DMS Host Interface Specifications document), DMS software will automatically generate a unique PID identifier using an internal algorithm.</p>
<code>Firstname</code> <code>Lastname</code>	<p>Patient's name and surname. When this field is selected, the right Patient Detail side panel is opened.</p>
Order	<p>Order number received from the Host. If the Host does not send this code, Data Management Software uses the first barcode received in relation to the patient as an order number. When this field is selected, the right Order Detail side panel is opened.</p>
Sex	<p>possible values are <code>M</code> (Male), or <code>F</code> (Female), or <code>U</code> (Unknown)</p>
Age	<p>Calculated as the difference between Admission Date and Birth Date.</p>
Ward Code	<p>Name of the hospital ward that carried out the patient admission.</p>
Order Date	<p>date of order sent by the Host.</p> <p><b>NOTE:</b></p> <p>If LIS sends orders leaving blank the <i>Order Date</i> field of the Patient Record (08.01.24 field in DMS Host Interface Specifications document), DMS software will set as <i>Order Date</i> the date and time of order receiving.</p>

**Table 31 Patient Anagraphic Details parameters (cont'd.)**

Parameter	Description
Status	Patient status is identified by an icon. For an explanation of statuses, refer to <a href="#">Table 32 Meaning of the status relating to patients and tubes, page 90</a> .
Note	<p>Single line field showing comments received from the Host with regard to the order, or allows manual entry of notes (max 255 characters).</p> <p><b>NOTE:</b></p> <p>In case the Host amended the anagraphic data of a patient already existing in the database, the message PATIENT DEMOGRAPHIC HAS BEEN CHANGED will be displayed in this field. Host can update demographics data only if the related option is enabled in <a href="#">Setup / Configurator /General Settings</a>. The option <a href="#">Update demographics</a> can be enabled in <a href="#">Setup / Instrument screen (Instrument Option Editor panel)</a> only for Instruments whose Class = HOSTASTMmCH.</p>

The status of Patients and tubes is identified as reported hereafter.

**Table 32: Meaning of the status relating to patients and tubes**

Icon	Description
	Requested (initial phase): all patient (or sample) tests are Requested
	Cancelled: all patient (or sample) tests are Cancelled
	Received: at least one of the patient (or sample) tests is Received but no test is Pending yet
	Pending: at least one of the patient (or sample) tests is Pending
	Hold: at least one of the patient (or sample) tests is Held and none of the other tests is Requested, Received or Pending (or, all of the patient/sample tests have been completed or cancelled and at least one test is Held)

**Table 32 Meaning of the status relating to patients and tubes (cont'd.)**

Icon	Description
	Validated: all of the patient (or sample) tests are Validated, Cancelled or Final, but at least one test is in the Validated state (or, all of the tests have been completed or cancelled, at least one result is Validated and there are no Held tests)
	Final: all of the patient (or sample) tests are Final or Cancelled, but at least one test is in the Final state

#### 4.6.1.2.2 Departmental Tabs

The Department tabs group tests based on the Laboratory Departments (for example, Hematology, Clinical Chemistry, Immunology, etc).

Only Department tabs for wards where the patient has effectively carried out the tests are listed.

Some Departmental tabs with particular tests could have a different layout from the standard one, for example, to allow the visualization of charts, graphics, results of plates analysis, etc.

#### 4.6.1.2.3 Details of tubes

When a Departmental tab is selected, a list of tubes relating to the selected ward is displayed.

Each tube is represented by a row containing the following details.

**Table 33: Detail of tubes parameters**

Parameter	Description
Restraint	Displays a biohazard icon if the sample tube is considered blocked as a consequence of error messages coming from the Automation System. In this case, any further test result coming from the Instrument will be discarded and not associated to tests or sent back to Host/LIS.
Sid	Tube code. When this field is selected, the right Tube Detail side panel is opened.
Automation Code	Indicates the code of the last Automation System that processed the sample tube
Draw Date	Indicates the date on which the tube was drawn. <b>NOTE:</b>

**Table 33 Detail of tubes parameters (cont'd.)**

Parameter	Description
	<p>If LIS sends orders leaving blank the <i>Specimen Collection Date and Time</i> (or <i>Draw Date</i>) field of the Order Record (09.04.08 field in DMS Host Interface Specifications document), DMS software will set as Draw Date the date and time of order receiving. When LIS sends an update with the field blank, DMS will not update the Draw Date information. Each update from LIS with a valid value set in 09.04.08 field, will be evaluated in respect to Check-in Date: if tube is not running (Check-in Date not set), DMS will accept every update from LIS. If tube is still running (Check-in Date set), DMS will update Draw Date only if the value coming from LIS is in the past in respect to the Check-in Date. Check-in Date is set when a tube is physically checked by Automation OR when a Query is received from Instrument OR when a result is received. The first event occurred will set the Check-in Date for all the tube life.</p>
<i>Preparation Date</i>	<p>It is displayed only for analysis on plates.</p> <p>Displays the date of preparation of the plate.</p>
<i>Material</i>	<p>Material making up the tube (S = SERUM, P = PLASMA).</p>
<i>Stat</i>	<p>Indicates the tube priority (refer to <a href="#">Table 34 Sample priority icons, page 94</a>).</p>
<i>P. Location</i>	<p>Position of tube on Automation System.</p> <p>In particular, for samples located in IOMs, the reference to the IOM is displayed in the field <i>P. Location</i>.</p>
<i>P. Rack</i>	<p>Position of tube on an rack of the Automation System.</p> <p>In particular, for samples located in IOMs, the reference to Lane, Rack, Position and Rack ID is displayed in the field <i>P. Rack</i>. The "R" prefix in the Rack ID means that it is an Inpeco Rack (e.g. R123456789). For IOMs configured as GPI, the tray type is directly specified along with the Rack ID (e.g. DXI1_123456789).</p>

**Table 33 Detail of tubes parameters (cont'd.)**

Parameter	Description
Status	Tube status is identified by an icon. When the mouse is hovered over the icon, a text pop-up describes its meaning. If the tube is Held or Validated, the text pop-up shows the sublevel of the hold (from H1 to H4) or validation (from V1 to V4). For an explanation of statuses, refer to <a href="#">Table 32 Meaning of the status relating to patients and tubes, page 90</a> .
Trace	A pop-up appears that displays the history of all messages and events concerning the tube, from the Host order to post-analytical work, and results management. Anagraphic data modifications of an already existing patient are also logged in this popup. Refer to <a href="#">Table 43 Trace pop-up window, page 111</a> .
Comment	<p>Shows any comments received from the Host concerning the tube. When this field is selected with the mouse, it is also possible to insert personalized comments by opening a special pop-up allowing text editing and input.</p> <p><b>NOTE:</b></p> <p>Unlike notes, comments consist of several rows of text, of which only the first one is displayed. To read a comment in full, select the comment field to open the comment pop-up.</p>
Autom Warning	Displays any warnings from Automation System.
Autom Error	Displays any errors from Automation System.

**Table 33 Detail of tubes parameters (cont'd.)**

Parameter	Description
Plates	<p>Optional value for tests that required plate analysis.</p> <p>If <b>Yes</b>, indicates that some plates have been prepared for the SID sampled. Selecting <b>Yes</b>, a popup displays the list of the prepared plates, with additional details. If <b>No</b>, no plates are yet available for the SID.</p> <p><b>NOTE:</b></p> <p>The Plates field is displayed only for tests that require plates analysis and are properly configured with the appropriate Validation template.</p>
Site Code	Indicates the name of the last Site where the sample tube has been processed.

The priority of samples is identified as following.

**Table 34: Sample priority icons**

Icon	Description
	No priority, routine samples.
	ASAP priority, samples to be executed as soon as possible.
	STAT priority, urgent samples to be executed with high priority.

#### 4.6.1.2.4 Details of Tests and Results

A list of all tests performed on that sample and belonging to the active department is displayed. For each test, all the information configured as visible in the related Template will be displayed.

**Table 35: Detail of Tests and Results**

Parameter	Description
Test Code <sup>9</sup>	Test code.
Test Name	name of the Test ordered for the Tube. When this field is selected, the right Test Detail side panel is opened. An icon will be displayed near the test name in case a comment is received for the specific test.

9. It is displayed if enabled by FSE in the Template table.

**Table 35 Detail of Tests and Results (cont'd.)**

Parameter	Description
	<p><b>NOTE:</b> Hovering your mouse cursor over the test name, a popup with additional information is displayed (test code, test code on Automation, test code on Analyzer, Analyzers name on which the test is enabled).</p> <p><b>NOTE:</b> when the Multisite option is enabled, the Site code where the test has been performed will be additionally showed, between parenthesis, near the test name.</p>
Result	<p>shows the latest test result sent by the Analyzer. The left side displays the first result received from an Instrument (1st result). The right part displays the second result received (2nd result).</p> <ul style="list-style-type: none"> <li>The results values displayed in this box can be showed or hidden by checking or unchecking the appropriate options <code>Display 1st result</code> and <code>Display 2nd result</code> in the test configuration panel (see <a href="#">4.9.4.1 Test, page 234</a>). Also the type of values displayed for each test (interpreted, numerical, etc.) can be configured in the test configuration panel (using the <code>Config Instruments</code> button of the Laboratory Test list).</li> </ul> <p><b>NOTE:</b> The Result column has overlapping text when the field contains <code>SortManual</code>; to avoid the overlap in Setup / Configurator / Test select only <code>Display 1st result</code> for the sorting test.</p> <p><b>NOTE:</b> Hovering your mouse cursor over the Result, a popup with raw results (R1 Raw Result and R2 Raw R2) received by the Analyzer is displayed (results before truncation or rounding).</p> <ul style="list-style-type: none"> <li>If configured, it is possible to see all the values of the extra aspects of the result for the specific test, with the relative aspect units, by right-clicking on the Result cell. To have a complete view of the extra aspects associated to the test,</li> </ul>

**Table 35 Detail of Tests and Results (cont'd.)**

Parameter	Description
	click on + symbol beside the test name to expand the nested grid: the previous results (Previous) and the historic results (Historic) are displayed, if available, in addition to the Aspect value and Aspect Unit related to the specific Aspect ID. In case of multiple result values for the same Aspect ID, only the first result value is displayed and a numbers, in brackets, identifies how many result values are available for the specific Aspect ID: hovering the mouse over the result value, a tooltip displays the other result values. <sup>10</sup>
Rerun <sup>11</sup>	shows an icon that allows performing the rerun of the test.
Previous	<p>shows the value of the previous result of the test (if present). If several previous results are available, the total number of results is shown in brackets. The following actions are available on the Previous value:</p> <ul style="list-style-type: none"> <li>Swap results : double click with the mouse on the Previous result box to display a drop-down list with all the available previous results and the related details. From this list, it is possible to choose an alternative result to be moved to the Result box (replacing the current result). After selecting an alternative result, press the Save button in the validation bar to confirm the swapping of results.</li> </ul> <p><b>NOTE:</b></p> <p>If a swap action is requested for the main test, DMS Software performs the swap action for all replicate tests together with the main test.</p> <ul style="list-style-type: none"> <li>Display of rerun graph: select the Previous result box with the right mouse key to display a pop-up with a graph showing the results trend.</li> </ul>

10. In order to have a complete view of the extra aspects associated to the test, it is possible to configure a specific Department with the template "Aspect" (features allowed to technical assistance staff only) and link the test to this specific Department.

11. FSE can order a rerun only if the test is in "Final" status.

**Table 35 Detail of Tests and Results (cont'd.)**

Parameter	Description
Range Value	indicates the range of normal reference values (if configured) for the test. If the result is outside the range, the reference value is shown in purple.
Status	<p>The status of test is identified by an icon, refer to <a href="#">Table 36 Meaning of the test status, page 100</a>. When the mouse is hovered over the icon, a text pop-up describes its meaning. If the test is Held or Validated, the text pop-up shows the sublevel of the hold (from H1 to H4) or validation (from V1 to V4).</p> <p>Clicking on the icon, a pop-up opens to display the status of the tests related to the specific tube (SID) on the Automation System, refer to <a href="#">Table 37 Meaning of the test status on Automation System, page 101</a>.</p> <p>Also refer to <a href="#">4.11.2 Tube Status, page 316</a> for further information.</p>
A I H	in columns A (Automation), I (Instrument) and H (Host), the meaning of the symbols, is described in <a href="#">Table 38 Operation icons, page 102</a> .
Flag	displays the exceptions and flags related to the test. Double click on this field to open a pop-up with the list of all the exceptions/flags received and the extended description (if configured) of each one.
Result Date	date on which the current result was obtained.
H Result (Historical Result)	If the patient on the work list has already carried out the test previously, this shows the most recent stored result obtained. When the mouse is moved to the box, a pop-up automatically shows another 2 results from the history (if available). Select the box with the right mouse key to display a pop-up with a graph showing the trend of all previous results in the history. Double click on the field to display a pop-up with the details of the tests.
H Date (Historical Result Date)	if there is an H Result, this shows the date on which it was obtained. Select the box with the right mouse key to display a pop-up with a graph

**Table 35 Detail of Tests and Results (cont'd.)**

Parameter	Description
	showing the trend of all previous results in the history.
$\Delta$ (Delta Check)	<p>change in current result compared to latest result obtained. It is calculated as the minimum between:</p> <ul style="list-style-type: none"> <li>the percentage difference between the Current Result (CR) and the H Result (HR) normalized to the Current Result (CR), based on the equation <math>[(CR-HR)/CR]*100</math>;</li> <li>the percentage difference between Current Result (CR) and Historical Result (HR) normalized to the Historical Result (HR), based on the equation <math>[(CR-HR)/(HR)]*100</math>.</li> </ul> <p><b>NOTE:</b> it is possible to view which are the delta check configurations applied on the specific test, by clicking on the field <math>\Delta</math>. This feature is available also when the test has no results yet.</p>
	<p><b>NOTE:</b> If a test has been held by a Delta Check rule (online or offline), the related cell in <math>\Delta</math> column is highlighted in orange. By clicking on the cell, the column related to the delta that has held the test is highlighted in orange.</p> <p><b>NOTE:</b> If there is no offline result, but the test is held by online Delta Check, the related cell in <math>\Delta</math> column is highlighted in orange.</p> <p><b>NOTE:</b> <math>\Delta</math> cell is highlighted in orange only when the test is in held status and the last applied rule is Delta Check. The last rule that has been applied is displayed in Rule field of the Roll-away right panel that can be opened by clicking on the Test Name.</p>
ID	<p>Name or code of the Instrument that performed the test and delivered the result.</p> <p><b>NOTE:</b> In case the result is output from a instrument composed of sub-modules, hovering your mouse cursor over the</p>

**Table 35 Detail of Tests and Results (cont'd.)**

Parameter	Description
	<p>ID row value, a tooltip with additional information is displayed.</p> <p><b>NOTE:</b> If the test is in Overdue, the ID Analyzer field will be highlighted in orange.</p>
Sub-Module ID <sup>12</sup>	<p>Sub-module that generated the result.</p> <p>It is applicable only for Instrument with sub-modules.</p>
Units 1	<p>Indicates the measurement unit of the current first result (Id1 field of Setup / Configurator / Test / Laboratory Tests / Config Instruments parameters). When the pointer is left over the value, a pop-up opens and displays the Units 2, i.e. the measurement unit used for the second result (Id2 field).</p>
Autom W (Automation Warning)	<p>Shows any messages and warnings from Automation related to the test.</p>
IM (Instant Messaging) <sup>12</sup>	<p>Shows message transmission status sent via Telegram; the meaning of the icons is described in <a href="#">Table 39 Instant Messaging status, page 102</a>.</p> <p><b>NOTE:</b> User can open the Instant Message pop-up by clicking on the IM icon and edit the message. Hovering your mouse cursor over the IM icon, a tooltip with the notification of the Decision Making rule that has triggered the sending (or not) of the Instant Message via Telegram is displayed. The notification is also registered in the Trace details panel of the sample tube.</p>
User name <sup>12</sup>	DMS User.

The status of tests is identified as following:

12. It is displayed if enabled by FSE in the Template table.

**Table 36:** Meaning of the test status

Icon	Description
	<p>Requested (initial phase of the test): order for a test has been received by Data Management Software (invited by Host or entered by means of Data Management Software manual acceptance). The test must still be carried out and the sample for which the test is carried out must still arrive at the Laboratory (or has arrived but has not yet been uploaded onto the Automation)</p>
	<p>Cancelled: The test will not be carried out due to it being cancelled by the Host or by the User</p>
	<p>Received: the test ordered has yet to be carried out, but the tube has arrived at the Laboratory and has been uploaded onto the Automation</p>
	<p>Pending: the tube is loaded onto the Automation and has been sent to the Analyzer. The test is in progress and results are expected</p>
	<p>Hold: test completed. The results are sent to Data Management Software but are not accepted because they are considered invalid according to the automatic validation rules. The results must be manually rechecked by an User (manual validation), to decide whether they are accepted, whether they are permanently discarded, whether to repeat the test (rerun) or whether to perform other additional tests (reflex)</p>
	<p>Deferred: a deferred result is held with level H1. Data Management Software checks deferring conditions every time a change occurs on an attribute of the order the deferred result belongs to. When a result is in deferred status, DMS will not apply any validation rules. Once deferring conditions are no more verified, validation process will be started and the configured validation rules are applied. Deferring status can be manually skipped, by manual validation (refer to Validate button in <a href="#">Table 41 Command buttons, page 104</a>). A popup that notifies user is displayed.</p>

**Table 36 Meaning of the test status (cont'd.)**

Icon	Description
	Validated: test completed, the results are sent to Data Management Software and have passed the rules of automatic validation. The results are ready to be sent to the Host
	Final: test completed. The results are validated and sent to the Host

The status of tests on Automation System is identified as following:

**Table 37: Meaning of the test status on Automation System**

Automation Test Status	Description
To Do	Test to be performed
Scheduled	Test has been scheduled to be run on an Analyzer (or on an Automation Module for a Sorting Test, or on an Aliquoter Module for an Aliquot Test)
Sampled	Test has been sampled on a Point of Space Analyzer
Processed	Test has been processed on a Pick and Place Analyzer
Sorted	Test has been sorted to an Automation Module (e.g. Input/Output Module, Storage, etc.)
Completed	Test has been completed by DMS or set as complete by the User.
Aliquoted	Test has been aliquoted on an Aliquoter Module
Canceled	Test has been cancelled by DMS
Deferred	Test deferred following the unavailability to perform the test on Instrument.

The status of the sending operation to Automation, Host or Instrument is identified as following:

**Table 38:** Operation icons

Icon	Description
	The operation has not yet been carried out (results not sent to Host <sup>13</sup> , order not sent to Automation, order not sent to Instrument)
	The operation is in progress (results being sent to Host, order being sent to Automation, order being sent to Instrument)
	Operation completed (Results sent to Host, order sent to Analyzer, order sent to Instrument)

The status of message transmission sent via Telegram is identified as following:

**Table 39:** Instant Messaging status

Icon	Description
	Telegram Instant Message held (not sent). Sending Instant Message via Telegram is in held status and can be unlocked only when the test will be validated.
	Instant Message sent via Telegram.
	Telegram Instant Message received by the Telegram client. Telegram client has sent feedback upon the receiving of the Instant Message via Telegram.

#### 4.6.1.2.5 Navigation and Validation bar

The Navigation and Validation bar is present in the lower part of the Patient detail screen.

**Table 40:** Navigation and Validation parameters

Parameter	Icon	Description
Dual navigation arrows	n/a	to access the first and last detail page
Single navigation arrows	n/a	to access the previous and next page

13. The sending to Host of a test in “cancelled” status (only if the action “Send Test Cancel to Host using comment” is configured using GEM rules) will be represented using the grey icon for the column “H”.

**Table 40 Navigation and Validation parameters (cont'd.)**

Parameter	Icon	Description
Page number box	n/a	shows the current page and total number of pages. A new current page number may be entered manually, and displayed by pressing the Return key on the keyboard
Refresh		reloads the current patient details screen
Quick Search	n/a	bar to conduct a quick search among listed patients
Command	n/a	<p>see explanation in <a href="#">Table 41 Command buttons, page 104</a>.</p> <p><b>NOTE:</b> Some of the commands will be immediately executed just after the button selection (immediate effect), while others will be added to a temporary command queue (<a href="#">History</a>) and will not be executed until the User selects the <a href="#">Save</a> button.</p> <p><b>NOTE:</b> If the Multisite option is enabled (feature allowed to technical assistance staff only), only the Users linked to a set of test associated to a specific Site can perform the actions listed in <a href="#">Table 41 Command buttons, page 104</a>. If an actions can not be performed, a popup will inform the User that the action is not permitted. See <a href="#">4.9.4.3 Site Editor, page 242</a> for further details on Multisite and permission configuration.</p>

**Table 41:** Command buttons

Button	Effect	Select	Icon	Function
Validate (Validate drop-down button)	Queued in History	At least one test with result that is not yet Final or in Held/Validated status with level less than or equal to that of the current User.		Validate selected tests.
Hold (Validate drop-down button)	Queued in History	At least one test with result that is not yet Final or in Held/Validated status with level less than or equal to that of the current User.		Hold selected tests.
Cancel	Queued in History	At least one test with requested or received status		Change status from requested/received to cancelled.
Rerun <sup>14</sup>	Queued in History	At least one test held, validated or final (function can be used only if the option of carrying out reruns is configured)		Perform a rerun of the tests selected and the action is queued in the History list of the Validation bar. If the test is configured so that it can be carried out on more than one Instrument, Data Management Software shows a pop-up to select the Instrument on which the rerun should be carried out (Any as default Instrument) and, if available, the dilution parameters and the number of replicates.
Add Test	Queued in History	Always available		Opens a pop-up from which it is possible to add one or more tests to the patient, selecting the available tubes and tests from the drop-down lists.

14. FSE can order a rerun only if the test is in "Final" status.

**Table 41 Command buttons (cont'd.)**

Button	Effect	Select	Icon	Function
				<p><b>NOTE:</b> Sample type consistency (Material) is checked when a new test is added to a tube. Using this command, it is also possible to manually re-add (re-open) a test that is in Cancel status.</p>
Command 15	Queued in History	At least one tube		<p>Complete: changes the To Do tests on the sample tube to Complete. The notification of Complete (message S002) is sent to the Automation software and the tube will be processed accordingly by the Automation System.</p> <p><b>NOTE:</b> The command Complete can be performed on a single test or the whole tube (by selecting all tests of the tube).</p>
Command 15	Queued in History	At least one tube		<p>Delivery: marks the sample tube with the message SC001 (User Sample Delivery Request) and sends the sample tube to the User Delivery rack (if configured), or to PO rack (if not configured).</p> <p><b>NOTE:</b> In case more than one IOM is configured for Sample Delivery (SC001),</p>

15. When the arrow is selected, a menu opens from which one of the messages may be sent to Automation System software.

**Table 41 Command buttons (cont'd.)**

Button	Effect	Select	Icon	Function
				the Delivery button allows to select which IOM (or any IOM) the sample will be delivered to.
Command <sup>16</sup>	Queued in History	At least one tube	! U	Error : marks the sample tube with the message SC00C (Sample Delivery Request) and sends the sample tube to the Automatic Deliver Sorted Output rack (if configured), or to PO rack (if not configured).
Command <sup>16</sup>	Queued in History	At least one tube		Keep: marks the sample tube with the message SC00D (Deliver to Long Term Storage) and keeps the sample tube in the Storage Module until the disposal timeout elapses, then sends the tube to Long Term Storage Sorted Output rack (if configured), or to PO rack (if not configured).
Command <sup>16</sup>	Queued in History	At least one tube		Dispose: asks the Storage Module to immediately dispose the sample tube.
Command <sup>16</sup>	Queued in History	At least one tube		Remove: removes the sample tube from the Automation System. This command allows to reset its location on the Automation software.
Save	Immediate	Always available		Makes effective the actions saved in the History

16. When the arrow is selected, a menu opens from which one of the messages may be sent to Automation System software.

**Table 41 Command buttons (cont'd.)**

Button	Effect	Select	Icon	Function
				queue (except for buttons that have immediate effect)
History	Immediate	Available if at least one Validation/ Hold operation has been selected	n/a	<p>Automatically updated panel: every non-immediate action is queued in the History (the number of actions in the queue is shown in brackets). When the button is selected, a pop-up shows a list of queued actions.</p> <p><b>NOTE:</b> Actions in the History are applied only after pressing the <b>Save</b> button.</p>
Validate and save	Immediate	At least one test with Held status is available		<p>Combines 3 functions:</p> <ul style="list-style-type: none"> <li>• Validates selected tests if at least one test is selected, or validates all Held tests if no test is selected.</li> <li>• Makes the changes immediately effective (as selecting the <b>Save</b> button)</li> <li>• After saving, automatically shows the next patient.</li> </ul>
Resend to Automation (Resend to Automation drop-down button)	Immediate	At least one test with Requested, Received or Pending status		Changes the status of selected test to Received and resends the order to the Automation System

**Table 41 Command buttons (cont'd.)**

Button	Effect	Select	Icon	Function
Resend to Host (Resend to Automation drop-down button)	Immediate	At least one test with Validated or Final status	n/a	<p>Resend Results to Host for the selected test.</p> <p><b>NOTE:</b></p> <p>This command is performed on the selected test result even if the test belongs to a specific department for which the result grouping option is enabled (the configuration of Department table is reserved to FSE only).</p> <p>The Host Resending make sense only for real test with results. If the User selects Sorting Tests, Aliquot Tests and/or Printable Tests, DMS sends only real tests with a numeric result.</p>
back to Filter	Immediate	Always available	←	Return to Extended Search page to re-filter data (equivalent to selecting Search button in Routine menu)

#### 4.6.1.2.6 Right panel

The right panel is divided into 4 tabs, containing more detailed information on:

- Patient
- Order (additional comments to send back to Host/LIS can be added here)
- Sample (and Tube Trace)
- Test

These information are not modifiable and are extracted from the order sent to DMS by the Host/LIS or are retrieved from the sample tube processing status on the Automation System. Only comments can be edited by the User.

**Table 42:** Right panel information

Information	Description
Patient Details	<p>Anag ID (internal reference code assigned to the patient) - Ethnic Code - Diagnosis Code - Physician Code - Address - Birth place - Mother's Maiden name - Telephone - Height - Weight - Height units - Weight units - Alternative Diagnosis - Birth date</p> <p><b>NOTE:</b> If LIS sends orders leaving blank the <i>Birth Date</i> field of the Patient Record (08.01.08 field in DMS Host Interface Specifications document), DMS will set the <i>Birth date</i> to a default value (0000-00-00).</p>
Order Details	<p>Order - Practice - Patient ID (other) - Discharge - Comment</p> <p><b>NOTE:</b> Additional comments can be added here by the User. To add a comment:</p> <ul style="list-style-type: none"> <li>• <i>Edit</i> button: opens a pop-up to insert, modify and format a comment.</li> <li>• Text is modified (and pop-up is closed) when the <i>Close</i> button is selected.</li> <li>• To confirm saving the comment, use the <i>Save</i> command from the Navigation and Validation bar on the bottom of the screen.</li> </ul>

**Table 42 Right panel information (cont'd.)**

Information	Description
Sample Details	Order - Sid - Location code - Physician Code - Type - Weight - Volume collected (µL) - Spun - Capped - Sealed - Disposed - Removed - #Seals - Collector - Specimen Source - Runs on - Shaken - Tube type code - Expected volume - Automated QC Sample - Input Lane - High Serum Level - Low Serum Level - Hemolitic index - Icteric index - Lipemic index - Dilution value - Cap type - Automation Node ID - Top - Diameter - Internal Diameter - Previous warn automation - Draw Date - Check-in Date - Checked-in by. Clicking on Trace button, the <a href="#">Table 43 Trace pop-up window, page 111</a> opens to view details about sample processing history (i.e. tube traceability). Clicking on MVS images button, the MVS images window opens to provide images and information related to sample processing retrieved from Vision System.
Test Details	Action Code - Parameter Code - Dilution Value - Num Dilution - Replicates number - Analyte name - P. Location - P. Rack - P. Row - P. Column - Result Date - Result - R2 - User Name - ID query - Query time - Stat - Host - Host Type - Host Test - Validated - Rule

**Table 43:** Trace pop-up window

Tab	Description
Trace	<p>contains the events generated by DMS that occurred on the specific tube (Event Date - Event Code - Description).</p> <p>In the event the User had configured some messages to be excluded in the Excluded Trace Events box (see <a href="#">4.9.3 Users, page 230</a> or <a href="#">4.9.1 Personal Settings, page 220</a> screens), the <b>Ap-</b> <b>ply Filter</b> button is displayed. Click on the <b>Clear Filter</b> button to re- store the standard view with all events occurred on the related sam- ple tube.</p>
Tube Log	<p>contains the events sent by the Automation System that occurred on the specific sample tube (Event Date - Automation (Automation ID where the event on tube happened) - Node ID - Node (Node where the event on tube happened)<sup>17</sup> - Event Code - Error Code - Parameters).</p> <p>Tube Log tab is displayed and popu- lated only if an Automation System is configured and connected to Data Management Software.</p>
Details	displays further details on the specific tube

In Table 43 *Trace pop-up window, page 111* some buttons are present:

Button	Description
Export CSV	allows to export the information to file
Close	closes the pop-up

#### 4.6.1.2.7 Left panel

The left panel is divided into 3 blocks, containing the following information.

---

17. If the event has been generated on the same Automation System selected by User, the Node is identified by its extended name and the instance number (e.g. Decapper / 1); if the event has been generated on an Automation System different from the one selected by User, the Node is identified by three specific letters of the Node and the instance number (e.g. DCM/1).

**Table 44:** Left panel information

Information	Description
Correlated Tests	when a Department chart and a test are selected on the detail page, this section shows any tests performed by other Departments correlated with the selected test as a support for the User during Validation. The result, result date and test data are shown for each correlated test. The correlated tests to be displayed can be configured by technical service staff.
Unsolicited	displays any Unsolicited results for known sample tubes (only if the option of auto-linking of Unsolicited results is disabled). See <a href="#">4.8.3 Unsolicited, page 143</a> for additional details.
Quality Control	shows all QC Controls concerning tests and Instruments selected on the detail page. When a row is selected, a Levey-Jennings graph is displayed with the QC trend

### 4.6.1.3 Validation screen (Patient detail screen) – Historic data visualization

If the search is performed among orders processed and already archived, the [Figure 22 Historic validation screen, page 113](#) is displayed instead of [Figure 21 Validation screen, page 88](#). The Historic Validation screen is organized as the Validation Screen, but:

- The rows for tubes have a different header.
- The Navigation and Validation bar only allows to navigate among different patients.
- The **HISTORIC DATA VISUALIZATION** label is shown in the Navigation and Validation bar.
- In the Test and Result rows, the columns **Result**, **Rerun** and **STAT** are inactive.
- In the Test and Result row, the values in the columns **H Result**, **H date** and **Δ** are hidden.

**Figure 22:** Historic validation screen

Re...	Sid	Automation c...	Draw date	Test Name	Result	R...	Previous	Range value	S...	A...	H...	Flag	Result date	H Result	H Date	Δ...	ID	Units 1	Autom...
	6000001	FLLEXLAB	25/05/2021 10:57:07	BP2_ANA	194	194	194	11:44:36 ...	11:44:36 ...	11:44:36 ...	11:44:36 ...	11:44:36 ...	11:44:36 ...	11:44:36 ...	095_BP2	IU/mL			
				BP2_CENB	933	933	933								095_BP2	IU/mL			
				BP2_CHR	520	520	520								095_BP2	IU/mL			
				BP2_CMVM	908	908	908								095_BP2	IU/mL			
				BP2_DSDNA	1	1	362								095_BP2	IU/mL			

#### 4.6.1.4 Validation screen (Patient detail screen) – Duplicated samples

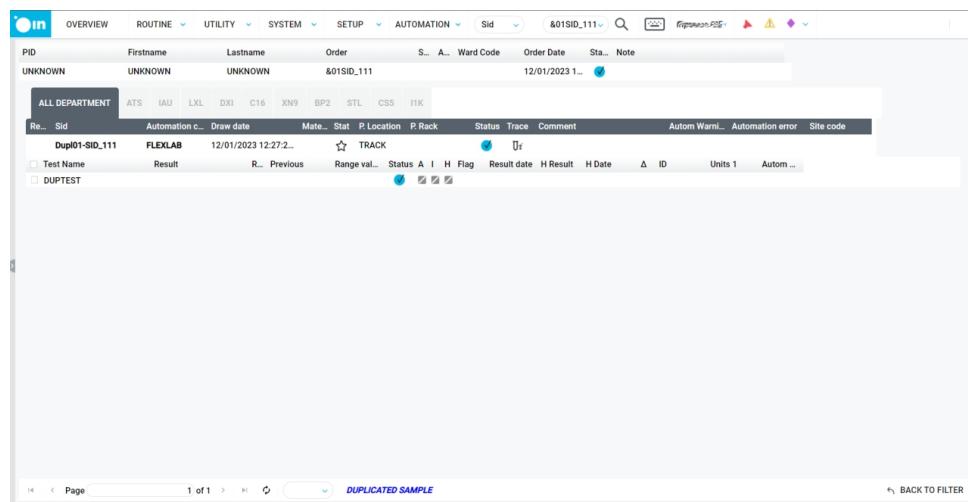
When DMS receive from the Automation System a message (e.g. L001, L005) for a duplicate sample, a new order for the specified sample is automatically created with the following characteristics:

Patient ID	UNKNOWN
Order ID = Sample ID	<p>&amp;+duplicate+SampleID</p> <p>where:</p> <ul style="list-style-type: none"> <li>“duplicate” is the received Duplicate Tube Number, always two digits (e.g. “02”)</li> <li>“SampleID” is the original sample (e.g. “SID123”)</li> </ul> <p>E.g. &amp;02SID123</p>
Test name	<ul style="list-style-type: none"> <li>Only one test linked to the sample</li> <li>The default test for duplicate sample is “DUPTEST”<sup>18</sup></li> <li>Configured as Printable in Laboratory Test Editing Panel, with no communication channel configured in Config Instruments.</li> </ul>

Duplicate samples can be displayed both in Validation screen and in **Snapshot** view, but User is not allowed to perform any actions on duplicate samples.

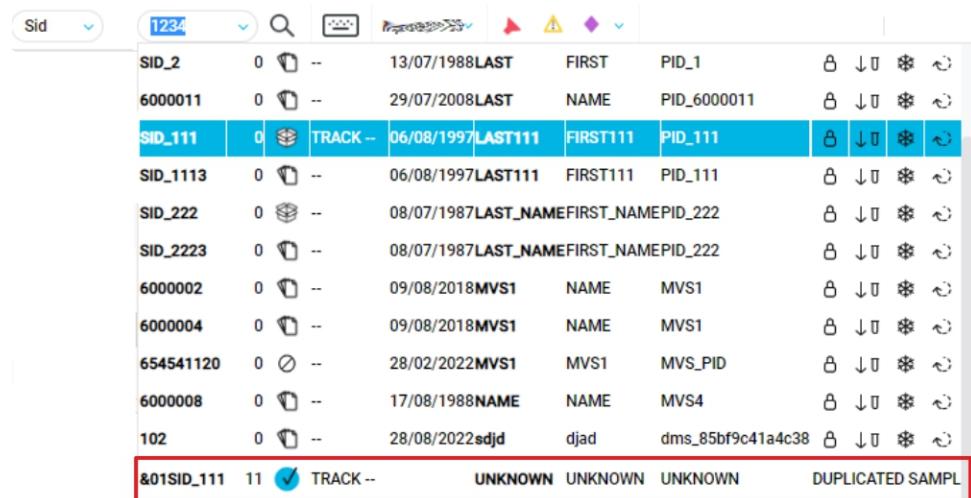
In Validation screen, the label **DUPLICATED SAMPLE** notifies of the visualization of a duplicate tube to the User.

**Figure 23:** Validation screen for duplicate samples



Actions on duplicate samples are not allowed.

18. Test code that is automatically added to duplicate sample can be configured in “General Settings” (feature allowed to technical assistance staff only).

**Figure 24:** Quick Search for duplicate samples

Sid	1234	SEARCH	LAST	FIRST	PID_1	Actions
SID_2	0	--	13/07/1988	LAST	FIRST	PID_1
6000011	0	--	29/07/2008	LAST	NAME	PID_6000011
SID_111	0	TRACK	06/08/1997	LAST111	FIRST111	PID_111
SID_1113	0	--	06/08/1997	LAST111	FIRST111	PID_111
SID_222	0	--	08/07/1987	LAST_NAME	FIRST_NAME	PID_222
SID_2223	0	--	08/07/1987	LAST_NAME	FIRST_NAME	PID_222
6000002	0	--	09/08/2018	MVS1	NAME	MVS1
6000004	0	--	09/08/2018	MVS1	NAME	MVS1
654541120	0	--	28/02/2022	MVS1	MVS1	MVS_PID
6000008	0	--	17/08/1988	NAME	NAME	MVS4
102	0	--	28/08/2022	sdjd	djad	dms_85bf9c41a4c38
&01SID_111 11		TRACK	UNKNOWN	UNKNOWN	UNKNOWN	DUPLICATED SAMPL

## 4.6.2 Admission

The **Admission** screen consists of four panels to be filled sequentially.

### 4.6.2.1 Patient Demographics

This panel allows to enter the Patient's personal data.

Parameter	Description
Lastname	Patient's surname (mandatory)
Firstname	Patient's name (mandatory)
Birth day	Patient's birth day (mandatory)
Age	Patient's age (automatically calculated)
Patient ID	Unique ID automatically assigned to the Patient when saving. The Patient ID generated shall be in the format <i>DMS_xxx</i> , where <i>xxx</i> is an univocal number.
SSN	Social Security Number or National Identify Number or Fiscal Code (depends on the Country)
Team Code	Also called EHIC - European Health Insurance Identity Number
Male	Patient's gender
Female	
Undefind	
Hold Validation	If checked, all test results for the Patient will be automatically flagged as Held and a manual action is required to validate all the test results connected to the Patient.
Note	Personal notes and comments on the Patient.
Comment	

The following commands are displayed:

Command	Description
Refresh	Allows to refresh the screen
Patient Details	Allows to add additional Patient personal data
Save	Allows to save the information

### 4.6.2.2 Order

This panel allows to enter the data about the Patient's order.

Command	Description
New	Allows to insert a new Patient's order.
Save	Allows to save the information

#### 4.6.2.3 Tubes

This panel allows to enter the data about the Tube order linked to the Patient's order.

Command	Description
New	Allows to insert a new tube to the order.
Delete	Allows to delete a non-saved item.
Multitube	Allows to configure different draw quantity for the specific test linked to the tube.

## 4.7 Utility

The **Utility** menu contains accessory functions for the Laboratory routine.

The menu is made up of the following items.

Screen	Access Level	Description
Barcode	Laboratory Technician	Consists of functions for printing additional labels and for printing new barcodes.
Data Backup	Laboratory Supervisor	Allows the backup of data on the Data Management Software server. Allows you to choose the type of data to be backed-up (log, processing data, report, attachments and complete programme) and the backup mode (on an external disc, on the hard disc of the Data Management Software server, or on a shared network folder).
Quality Control	Laboratory Technician	Allows to manage and export to file the data related to the Quality Controls (QC) of the Analyzers.
List Print	Laboratory Technician	Displays the list of all printings carried out.
Print Configurations	Laboratory Supervisor	Displays a PDF file with the Test Map, Normal Values, GEM rules or Decision Making rules configured.
Export configuration changelog	Head Physician	Allows to export a report with the changes done to the DMS configuration by Users.

## 4.7.1 Barcode

The **Barcode** screen is divided into two submenus:

- **Free Barcode** for creating and printing labels with a new code.
- **Barcode Re-print** to reprint a label with a code that is already in progress.

## 4.7.2 Data Backup

The **Data Backup** screen allows various parts of the Data Management Software to be saved and subsequently recovered. Saving and recovering data can be achieved by using different types of storage devices.

The available saving options are the following:

- **Log**
- **Data Backup**
- **Reports**

**Table 45:** Log

Parameter	Description
Instrument Logs	Log of communications between Data Management Software and the Instruments.
Audit	Log registering the operation sequence carried out on Data Management Software by every User, in addition to errors, exceptions and significant events that occurred on the System.

**Table 46:** Data Backup

Parameter	Description
Data Backup	Data Management Software database with configurations, data of samples in progress and archived samples.
Programs	Data Management Software files.

**Table 47:** Reports

Parameter	Description
Medical Reports	Saves previously created medical reports.
Attachment	Saves all attachments (images, files, reports, etc.) received from the Instruments.

The **DM server hard disk folder** tab allows to backup and recovery using a local hard disk folder (for example: /temp) in the Data Management Software server.

**Table 48:** DM server hard disk folder

Parameter	Description
Hard disk folder:	Folder used to save the backup.
Available Backups:	The drop-down menu shows any previous backup files, already in the periphery, which can be selected and restored with the <b>Restore</b> button.

**Network shared hard disk folder:** allows backup and recovery by using a shared network folder on a different PC, for which it is possible to specify the parameters for connection. The configurable parameters and available buttons are:

**Table 49:** Network shared hard disk folder

Parameter/Button	Description
workgroup/domain	Workgroup/domain of the PC, for example WORKGROUP.
Computer and sharing folder	Network path written with the syntax <code>\PC_IP_address\shared_folder_name</code> (for example: <code>\192.168.1.106\sharedFolder\</code> ).
destination folder (not needed)	Allows to specify a sub-folder of the shared folder (for example: backup2014).
User name User password	Credentials for the identification and access to the shared folder.
Available Backups	The drop-down menu shows any previous backup files, already in the periphery, which can be selected and restored with the <b>Restore</b> button.
Save	In every peripheral card, the button creates a backup file containing the data previously selected in the <b>Log</b> , <b>Data Backup</b> and <b>Reports</b> panels.
Reset	The button cleans the contents of the boxes to allow new backup/restoration options to be set up.
Restore	The button restores a backup.
Save Configuration	The button saves the values configured in this pages.
Test Backup	The configuration can be tested using this button: a popup will confirm if the backup will be successfully done or if it will fail.

***NOTE***

The Network shared folder PC must be already properly configured with existing folders and credentials before entering the relevant data in the Network shared hard disk folder page.

### 4.7.3 Quality Control

The Quality Control (QC) screen allows the User to configure the rules used by DMS to validate the Quality Control Results received from the Analyzers and to show a graphical representation of them.

This menu is organized in submenus:

- Quality Control : for configuration and displaying of QC results;
- Export Quality Control : for exporting the QC data into a specific directory.

In the Quality Control submenu, the User can configure the QC behavior defining the controls and the control charts for each couple constituted by a Quality Control test and the specific Analyzer where the QC test is performed.

- Each QC test can have one or more Controls (for example, some tests can require 3 controls: one for results considered in the High range, one for the Medium range and one for the Low range).
- Each Control can have many associated Control Lots.
- When a Control and a Control Lots are selected, the list of the related results is displayed in the QC Results list.

The User, for each Control, can also define the method to interpret, create the graphs, and validate the QC results. These methods are based on Westgard rules (default method) or Margins rules. The FSE can change the default algorithm for Westgard rules by composing of the available rules described in [4.7.3.1 Westgard rules, page 123](#).

If, for a given Control, the User configures the expected statistical values of mean and standard deviation, then these values will be used by DMS to evaluate the QC validation rules (using Westgard rules or Margins rules) and to display the Levey-Jennings charts of the QC result sequence for that specific control.

On the other hand, if the statistical values are left empty, then DMS will automatically calculate them any time a new QC result is processed, using the whole sequence of known result for that control and control lot. Westgard rules (or Margins rules) will be checked against the calculated statistical values.

This feature should be used as a temporary means to determine the expected statistical values for a given control and once the calculated values can be considered statistically stable and sound, they should be manually inserted in the mean and standard deviation fields of the QC control configuration.

When DMS works in "calculated statistics" mode, standard deviation and mean may vary at each new result, and this may lead to misleading Levey-Jennings charts as the yellow and red bands of the charts are drawn using the latest calculation of standard deviation and mean, so older results that were evaluated as invalid may now appear inside the white area of the charts (and vice versa). Levey-Jennings charts can be toggled to display calculated statistical values even for controls where theoretical values are configured, in order to allow comparisons between the expected behavior and the real trend of the test inside the Laboratory.

Some Analyzers are able to transmit the information related to these statistical values and DMS is able to acquire them automatically, in this case there is no need to manually fill these values.

If the Pre-Period management is configured, the User can use calculated statistical values to be applied on QC result evaluation (refer to [4.7.3.5 Pre-Period Management, page 135](#)).

- When using validation rules, after receiving QC results from an Analyzer, DMS warns the User with different colors associated to the Analyzer (refer to [Table 8 Quality Control icons, page 42](#) and to the result itself (in the [QC Display](#) window) if the results are not valid, or require further attention.
- The green color is associated to valid results, the yellow color is associated to a Warning, and the red color is associated to a rejected result.
- The warnings are calculated and displayed only for the QC Results related to the current period.
- If DMS receives a QC result containing a comma in its value (example: 32,4 instead of 32.4), this value will be handled as a string and the Westgard rules (or Margins rules) will not be evaluated. The result is anyway displayed on the UI, in the [QC Results](#) list and duly sent to Host/LIS.
- In the [QC Results](#) section, the User can see the list of QC results received from analyzers, or manually add additional results.
- It is possible to insert a comment about each result and modify the active status of the result, accepting or not accepting it by checking/unchecking the [Accepted](#) options (refer to [4.7.3.3 QC Results, page 129](#)). The evaluation status icon displays the outcome of the automatic evaluation of the QC result made by the system when each result is processed and can not be manually changed but only accepted or rejected .
- To display a graph of the results in Levey-Jennings graphical format, at least two results must be present and accepted in the [QC Results](#) section.
- The User can select a particular date or a time range that will be used to create the graph.
- The User can also select the number of results (points of the graph) to be used to create the graph.

#### 4.7.3.1 Westgard rules

When using the Westgard rules to validate the Quality Control results, DMS uses a pre-defined set of Westgard rules (refer to [Figure 25 Westgard flow chart, page 124](#)).

Each rule, for convenience, is written using a short hand notation to abbreviate the different decision criteria. For example, 1:2s indicates 1 control measurement exceeding the 2s control limits (where 2s stands for "two times the standard deviation (s) " ).

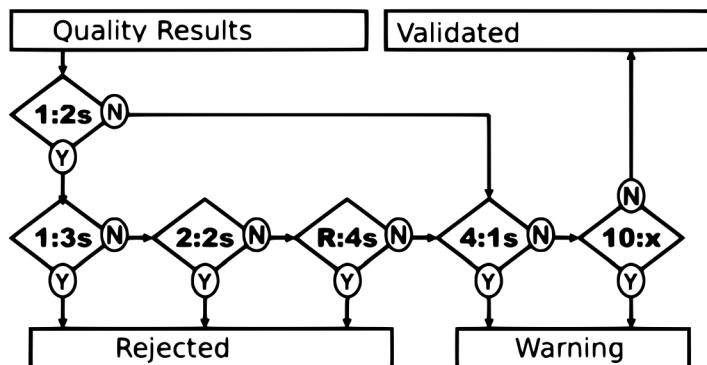
#### NOTE

For some Analyzers (Architect / Centaur XP / Vista / Sapphire / Liaison XL) the content of the various fields of the couple Control/Control Lot is automatically configured with the data sent by the Analyzer when the first quality result arrives. By default, the validation method configured for these data is "Westgard". Some Analyzers (for example, the Architect family) can also send the specific values to populate the Mean and the Standard Deviation (SD) fields.

#### 4.7.3.1.1 Evaluation

DMS evaluates the series of Quality results received for a Control/Control Lot couple using the flow chart below. The series of Quality Results coming from an Analyzer can be either Validated, Rejected, or giving a Warning regarding to the possible combinations of rejection rules triggered, as displayed in the diagram.

**Figure 25:** Westgard flow chart



The individual rules are defined below. The graphic reported after the rule shows an example of control results that violate that rule.

- $1_{2s}$  refers to the control rule that is commonly used with a Levey-Jennings chart when the control limits are set as the mean plus/minus  $2s$ . In the original Westgard multi-rule QC procedure, this rule is the first step of the evaluation, and is used as an alarm rule to trigger a careful inspection of the subsequent control data (second step), in order to establish if the series of results are to be validated or not. After a  $1_{2s}$ , DMS evaluates if any new result is positive to the other rejection rules following in the diagram.

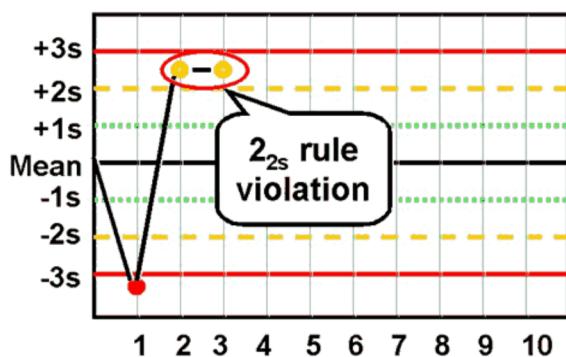
For example: a  $1_{2s}$  followed by a  $1_{3s}$  or  $2_{2s}$  or  $R:4s$  gives "Rejected" ;  $1_{2s}$  followed by  $4:1s$  or  $10x$  gives a "Warning" ;  $1_{2s}$  followed by an acceptable value (i.e. no additional rule triggered) gives a "Validated" result.



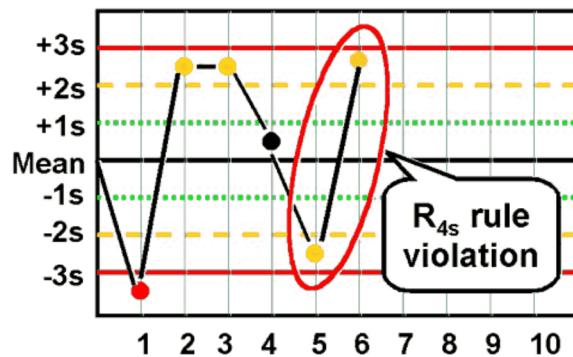
- $1_{3s}$  refers to a control rule commonly used with a Levey-Jennings chart where the control limits exceed the mean plus  $3s$  or the mean minus  $3s$ . A run is rejected when a single control measurement exceeds the mean plus  $3s$  or the mean minus  $3s$  control limit.



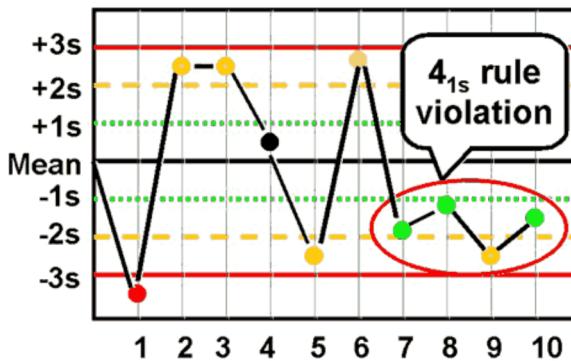
- $2_{2s}$  rejects when 2 consecutive control measurements exceed the mean plus 2s or the mean minus 2s control limit.



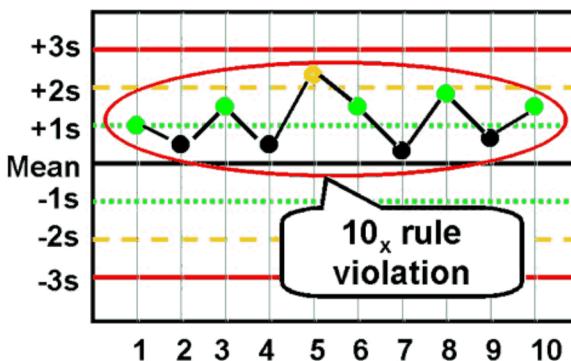
- $R_{4s}$  rejects when 1 control measurement in a group exceeds the mean plus 2s and another exceeds the mean minus 2s (i.e. the 2 results differ for more than 4s).



- $4_{1s}$  rejects when 4 consecutive control measurements exceed the mean plus 1s or the mean minus 1s control limit.



- **10<sub>x</sub>** rejects when 10 consecutive control measurements fall on one side of the mean.



### NOTICE

Use the expected statistical values for mean and standard deviation (either values declared by Analyzer vendor or calculated values that are considered statistically stable).

#### 4.7.3.2 Margins rules

In addition to default Westgard rules, it is possible to evaluate QC results using Margins rules.

##### 4.7.3.2.1 Evaluation

When QC result is received from an Analyzer and its value is greater or equal of **High** value or lower or equal of **Low** value, DMS considers result as failed. A QC result is valid only if its value is between **Low** and **High** values (excluded limits).

Also the first QC result received for a Control already configured to work with Margins evaluation is evaluated and rejected in case it is outside the configured margins.

**Low** and **High** values shall be filled manually or from analyzer; otherwise, if both are equal to "0", all QC results are set as valid by Margins evaluation.

### 4.7.3.3 East area

This area reports information related to Quality Controls, Quality Control Lots and Quality Control results are displayed, based on the selected QC tests from the list displayed in [4.7.3.4 West area, page 133](#).

#### 4.7.3.3.1 Controls

In the **Quality Control** panel, the **Controls** panel allows to manage Controls for the specific pair Test-Instrument. Each Control is composed of the following items.

Item	Description
Bind	Not used.
Description	Optional information for identifying the Quality Control
Control ID	Sample identifier of the Quality Control
Alarm	<p>Possible values are:</p> <ul style="list-style-type: none"> <li>Westgard (default): refer to <a href="#">4.7.3.1 Westgard rules, page 123</a></li> <li>Margins: refer to <a href="#">4.7.3.2 Margins rules, page 126</a></li> </ul>
Low	<p>Low value used for statistical values calculations. It can be:</p> <ul style="list-style-type: none"> <li>received from the Instrument</li> <li>inserted manually by the User</li> <li>calculated automatically after Mean and SD values update</li> <li>calculated after clicking on the button Close in <a href="#">4.7.3.3.2 Control Lots, page 128</a>.</li> </ul> <p>If the low value is already set for a specific Control, it will not be automatically updated with the new value received by the instrument.</p>
High	<p>High value used for statistical values calculations. It can be:</p> <ul style="list-style-type: none"> <li>received from the Instrument</li> <li>inserted manually by the User</li> <li>calculated automatically after Mean and SD values update</li> <li>calculated after clicking on the button Close in <a href="#">4.7.3.3.2 Control Lots, page 128</a>.</li> </ul> <p>If the high value is already set for a specific Control, it will not be automatically updated with the new value received by the instrument.</p>

Item	Description
Mean	Mean value can be: <ul style="list-style-type: none"> <li>calculated with <b>Low</b> and <b>High</b> values</li> <li>inserted manually by the User.</li> </ul>
SD	Standard deviation value can be: <ul style="list-style-type: none"> <li>calculated with <b>Low</b> and <b>High</b> values</li> <li>inserted manually by the User.</li> </ul>

The panel is composed of the following buttons.

Button	Description
Add	Adds new Controls.
Save	Saves the configuration of the selected Control.
Show Closed	Displays information on closed Quality Controls (historical data). To return to the online QC data, click on Hide Closed.
Hide Closed	
Delete <sup>19</sup>	Deletes the QC Control with no Control charts associated.

#### 4.7.3.3.2 Control Lots

In the Quality Control panel, the Control Lots panel displays information on the selected Test/Instrument and Control. Each Control Lot is composed of the following items.

Item	Description
Control Lot ID	Identifier of the Quality Control Lot.
Close	The following icon allows to close an online Control chart (Period) or close a Pre-Period (if the Pre-Period Management is enabled).  
Comment	Optional comment.
N. Results	Number of QC results received for the current Control chart.
Calc Mean	Mean calculated on the received QC results flagged as Accepted
Calc SD	Standard deviation calculated on the received QC results flagged as Accepted

19. Displayed only if the selected Control has no Control charts associated.

The panel is composed of the following buttons.

Button	Description
Add	Adds a new Control Lot.
Edit	Allows to change the configuration of the selected Control Lot.
QC results	Allows to refresh the QC Results panel based on the selected Control and Control Lot .

#### 4.7.3.3.3 QC Results

In the Quality Control panel, the QC Results panel displays information on the selected Test/Instrument, Control and Control Lot. The panel also shows the QC results received from the Instrument. Each QC Results is composed of the following items.

Item	Description
Data result	Date and time of the result received from the Analyzer or manually inserted by the User. Date format depends on the User settings.
Result	Result value received from the Instrument or manually inserted by the User. It can be a quantitative result (numeric value) or a qualitative results (alphanumeric value). Result is displayed in the same format that has been received from the Instrument.
Status	Icon that represent the status of the QC result after the configured rules evaluation. Refer to <a href="#">Table 50 QC result status icons, page 130</a> .
Accepted	Checkbox that identifies the acceptance of the QC results. It can be unchecked in order to not accept the current result. If a result received from the Instrument is not numeric, the checkbox is automatically unchecked.
Reagent	Reagent value possibly sent by the Instrument along with the related result.
Control serial number	Serial number of the Control Lot possibly sent by the Instrument along with the related result.
Reagent serial number	Serial number of the reagent possibly sent by the Instrument along with the related result.
Expires	Expiration date of the reagent possibly sent by the Instrument along with the related result.

Item	Description
Comment	Free text comment possibly sent by the Instrument along with the related result.
User	Nemo if the QC results is received from an Analyzer, otherwise the User that adds the QC results manually.
Rules applied	Reports the list of rules applied, if the QC result is evaluated by Westgard rules. Otherwise, Margins if the QC result is evaluated by Margins rules.

**Table 50:** QC result status icons

Icon	Description
	QC result is considered as valid after evaluation.
	QC result is considered as failed after evaluation. Non-numeric results are always considered as failed (and never evaluated).
	QC result is considered as warning after evaluation.

The panel is composed of the following buttons.

Button	Description
Search	Performs the search of QC results based on the filters set..
Refresh	Allow to refresh the QC results list, applying the configured filters.
Add	Adds a new QC result to the Control chart. It is displayed only in case DMS has no received from instruments any results for a specific Control Lot.
Save	Allows to save changes on the QC results. If User modify the acceptance status of a QC results or the related comment, it is mandatory to insert a comment.
Clear Filter	Clears all the configured filters.

#### 4.7.3.3.4 QC Graph

In the lowest part of the Quality Control panel, the graph related to all results of the selected Quality Control is displayed.

By default, QC Graph is displayed with theoretic statistic values (mean and Standard deviation) and all accepted QC results are connected together by a light blue line and they are plotted as follow:

- Valid and Warning QC results are marked as blue bullets
- Failed QC results are marked as red triangular bullet

Values are displayed by default only for failed QC results. Values for Valid and warning QC results can be displayed by activating the related option ([View settings / Show Values](#)). In the plot area, graph is divided into horizontal sections according to statistical values.



On the Y-axis all values identified by the horizontal lines are displayed, while on the X-axis the date of the QC results (in the format dd-mm) are reported. In case values higher than 4SD are received (and flagged as [Accepted](#)), these values will be normalized to Mean  $\pm$  4SD.

On the right side of the QC results, a legend reports all information related to plot area, specifying the Control ID and the Coefficient of Variation (CV).

If the User manually removes the [Accepted](#) flag from a QC result in the related table, this point will not be plotted in the QC Graph.

If a QC result is not numeric, DMS automatically removes the [Accepted](#) flag and the point is not plotted into the graph. In case User manually accepts this result, its value is plotted and connected to the other points of the graph.

The [QC Graph](#) panel is composed of the following buttons.

Button	Description
<p>View settings</p>	<p>Allows to change the graph visualization:</p> <ul style="list-style-type: none"> <li>• <b>View only valid</b>: displays only Valid and Warning Quality Control results on the QC Graph</li> <li>• <b>View Calculated Values</b>: displays all points plotted with calculated statistical values. Calculated statistical values change at every received Quality Control result.</li> <li>• <b>Show Values</b>: displays values for the Valid and Warning Quality Control results if <b>View only valid</b> is checked, otherwise, also the failed result values are displayed.</li> </ul> <p>By default, all options are unchecked and can be combined together.</p>
<p>QC Display</p>	<p>Opens a popup to navigate all QC results available on the system.</p>
	<p>Slider to modify the number of result points displayed on the QC Graph. By default, the maximum number of displayed points is equal to the number of all Valid, Warning and Failed Quality Control results in status Accepted of the selected Control graph. DMS is able to display the last 60 QC results at most in the QC graph.</p> <p>Moving the slider to the left, the number of QC result points displayed in the graph is reduced, removing the oldest ones.</p>

The **QC Display** button allows to displays the graph in a full screen pop-up:

- In the upper part, the User can select the status of the results to be displayed in the graph.
- In the central part, Levey-Jennings chart of the QC results is displayed.
- In the right part, the list of tests, grouped by result status, is displayed:
  - Rejected if the Validation rules did not accept the test results;
  - Warned if the Validation rules notified a warning about the results;
  - Validated if the results were accepted;
  - Without Results if the test has no controls with results in the "today" date, meaning that today Quality Controls must still be performed.
- In the left part, the list of all the controls, for the selected test, related to any Analyzer of the same class. More than one control can be displayed contemporaneously by checking the related option.
- In the lower part, results of the tests and selected controls are displayed. It includes a slide bar to select the date range of results. By default, the date

range covers the last 30 days (up to “today”). Result value is highlighted in red/yellow based on the QC result status.

#### 4.7.3.4 West area

This area reports the list of all tests configured for Quality Controls with the information of the related Instrument and the icon representing the QC status.

In case an instrument is configured with at least one submodule, the list of tests displayed refers to submodules only; the main module is not shown.

In case a Test/Module related to the same Specialty Code is configured, only one row is displayed

Tests list is sorted by default in the following order:

- tests that have the last accepted online Rejected QC for at least one Control ID performed in the active QC Period (for Analyzers which have QC Lifetime (hours) set or equal to “0” and QC expiration date equal to “000-00-00 00:00:00”, the QC Period is related to the last 3 days)
- tests that have the last accepted online Warning QC for at least one Control ID performed in the active QC Period (for Analyzers which have QC Lifetime (hours) set or equal to “0” and QC expiration date equal to “000-00-00 00:00:00”, the QC Period is related to the last 3 days), no other Control IDs with last QC result in Rejected status
- tests that have the last accepted online Valid QC for all Control IDs performed in the active QC Period (for Analyzers which have QC Lifetime (hours) set or equal to “0” and QC expiration date equal to “000-00-00 00:00:00”, the QC Period is related to the last 3 days)
- tests that have no QCs in the active QC Period (for Analyzers which have QC Lifetime (hours) set different from “0”, the QC Period is related to the last 3 days)
- tests that have no QCs in QC Period, but only historicized QC
- all tests that have no performed QCs

If a test on instrument has not accepted QC results only, the related record is not displayed in tests list.

The area is composed of the following items.

Item	Description
Test Name	Test code
Instrument	Instrument configured for the QC test
QC Status	<p>QC status for the specific couple Test/Instrument. In particular, the icon displayed is related to:</p> <ul style="list-style-type: none"> <li>the worst status among the available ones, in case of more Control IDs for the current record</li> <li>the status of the last QC result, in case of multiple Control Lots for the same Control ID</li> </ul> <p>Refer to <a href="#">Table 51 QC status icons for test/instrument, page 135</a>.</p> <p>Clicking on the icon related to an instrument that does not have submodules, DMS opens the Quality Control screen with the tests list filtered by instrument equal to the selected one. Clicking on the icon related to an instrument that has submodules, a pop-up opens to allow user to choose one or more submodules to filter the tests list. Multiple selection is allowed using the keyboard key CTRL and clicking on the desired rows.</p>

Tests list is not automatically refreshed, but it is possible to click on refresh icon in the grid bottom bar.

Clicking on the column header related to the item of interest, it is possible set the following filters.

Item	Filter	Description
Test Name	Free text filter	Allows to extract all records containing the string reported in the filter
Instrument		
QC Status	Period Warned	Allows to extract online Quality Control results performed in the current period, with the worst status as warning
	Period Rejected	Allows to extract online Quality Control results performed in the current period, with the worst status as failed
	Period Validated	Allows to extract online Quality Control results performed in the current period, all in valid status

Item	Filter	Description
	Historical Results	Allows to extract Quality Control results manually moved in the historical area and that don't have online results (they can have been performed in the current period or not).

The area is composed of the following buttons:

Button	Description
Refresh	Allows to refresh the test list.
All Data	Allows to reset all the applied filters.

**Table 51:** QC status icons for test/instrument

Icon	Description
	All Control IDs related to the current test on instrument have last QC results evaluated as Valid.
	There is at least one Control ID related to the current test on instrument with last QC result evaluated as Failed.
	There is at least one Control ID related to the current test on instrument with last QC result evaluated as Warning. No Control ID with last QC result evaluated as Failed.
	No Quality Control has been run in the current period for the related test on instrument. It is possible that this test on instrument has QC results produced in a previous day or used for the pre-period or moved in the historical area.
	Test disabled on the Instrument.

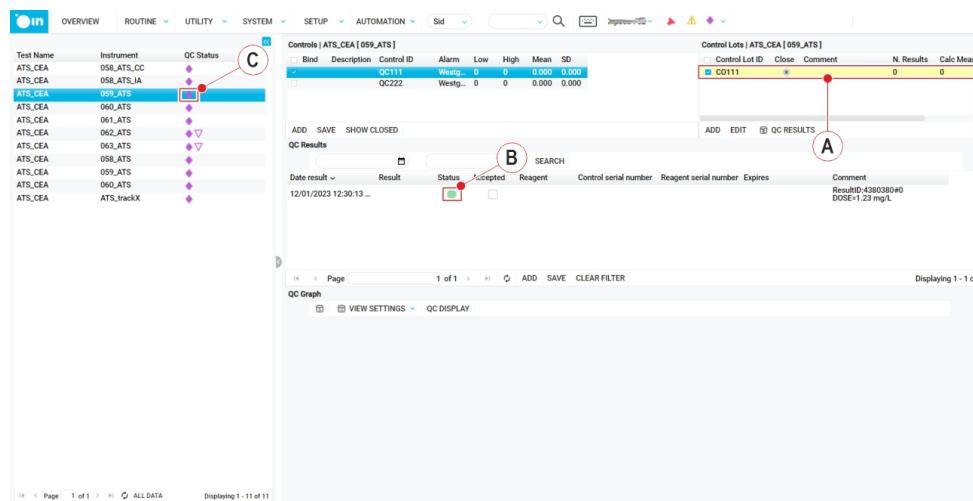
#### 4.7.3.5 Pre-Period Management

If enabled, this feature introduces some functionality:

- All new Control charts opened in the Pre-Period after the closure of the Control chart (Period) and all new Control charts (Period) created after new QC Result receiving (for a new Control Lot and only if received by instrument) are considered as Control chart in Pre-Period
- All QC Control charts in Pre-Period are highlighted in yellow ([Figure 26 – A](#)).

- All QC results related to a Control chart in Pre-Period are considered as neutral (no evaluation rules – Westgard rules – are applied, no disable action is considered if Disable test on QC instrument option is enabled and patient results are never rejected due to QC results in Pre-Period chart, even if Reject Result by QC instrument option is enabled)
- Since no evaluation rules are applied, all QC results linked to a Control chart in Pre-Period are always considered as valid (Figure 26 – B) and they are not taken into consideration to calculate the test's status of the West area (Figure 26 – C).

**Figure 26:**



If QC results are externally evaluated by a configured ratifier, Pre-Period shall not be used.

## 4.7.4 Export configuration changelog

The Export configuration changelog screen allows to export a report with the changes done for the following configurations:

- Users settings
- Enable/Disable actions on tests and instruments
- Instruments configuration
- Tests configuration
- Normal values rules defined for a test
- DMS configuration tables
- General Settings
- Site Editor configuration
- Automated QC
- Batch tests
- Decision making rules
- GEM rules
- Automation tests configuration

The report is in English language only.

The report does not trace any change done at the operating system or database by FSE through the Command Line Interface (CLI).

In case a User is removed from DMS, the report will indicate the User ID (key of Users table) instead of the name for all the changes performed by that User.

It is possible to choose a report either in PDF format or CSV format by the field Save as.

### 4.7.4.1 PDF report

The Configuration Changelog report in PDF format is composed of an header, a body and a footer.