those clotting curves with high noise level in the absorbance along the curve. If this is the case, CND will be reported as a result (see Section 9.2.2.5).

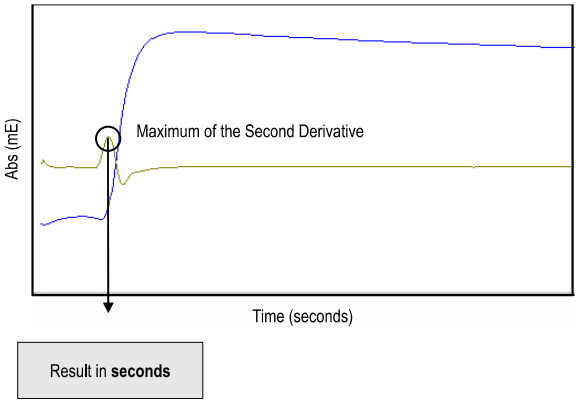


Figure 9.21. Graphic Description of the "Maximum Acceleration for Extrinsic Pathway" Algorithm

Derived Fibrinogen

This algorithm estimates the fibrinogen concentration in the sample from the PT primary curve by calculating the absorbance increase (**mE**) between the beginning and the end of clot formation.

Point 1 is the point, on the primary curve, where the first derivative is maximum.

Point 2 and **Point 3** are the closest points under and over Point 1 where the first derivative has a value that is the 20% and 10% of its maximum, respectively.

The absorbance increase between **Point 2** and **Point 3** gives the estimation of fibrinogen concentration in **mE**.

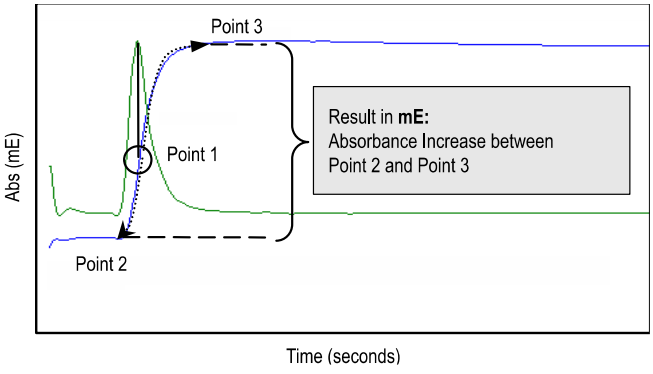


Figure 9.22. Graphic Description of the "Derived Fibrinogen" Algorithm

Fibrinogen Clauss

This algorithm estimates the clotting time (in **seconds**) of the sample by calculating the 50% of the absorbance increase (**mE**) between the beginning and the end of clot formation.

Point 1 is the point, on the primary curve, where the first derivative is maximum.

Point 2 and **Point 3** are the closest points under and over **Point 1** where the first derivative has a value that is the 20% of its maximum.

The half of the difference between the **Point 2** and **Point 3** returns the clotting time result (in **seconds**).

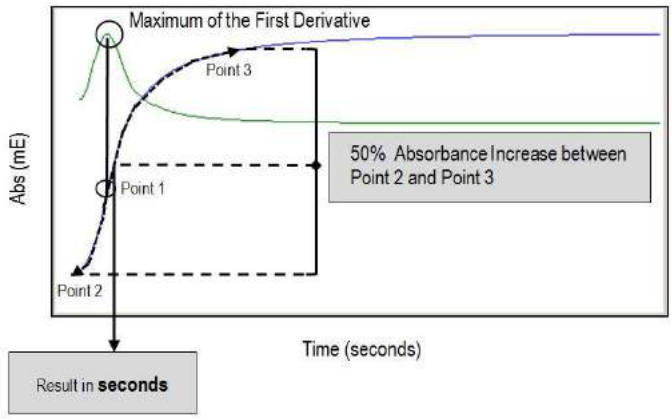


Figure 9.23. Graphic Description of the "Fibrinogen Clauss" Algorithm

Time to Absorbance Increment

The clotting time (in **seconds**) corresponds to the time in which the absorbance has increased 40 mE from the initial absorbance (A_0 + 40 mE).

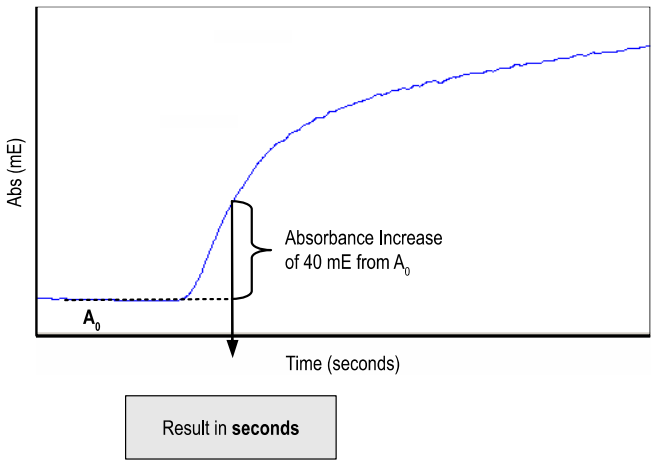


Figure 9.24. Graphic Description of the "Time to Absorbance Increment" Algorithm

9.2.2.3 Algorithms for Chromogenic Tests

The algorithms used in chromogenic tests calculate the rate (slope) of colour formation (mE/min) or the absolute absorbance increase (mE) due to the enzymatic activity (hydrolysis of a chromogenic substrate).

Two Slopes (30-90)

It measures the absorbance increase (due to colour formation) during 1 minute and the result is reported in **mE/min** (slope of the reaction curve).

It is called "Two Slopes (30-90)" because it calculates the slope of 2 stretches (30-60 and 60-90) and it checks the linearity between them.

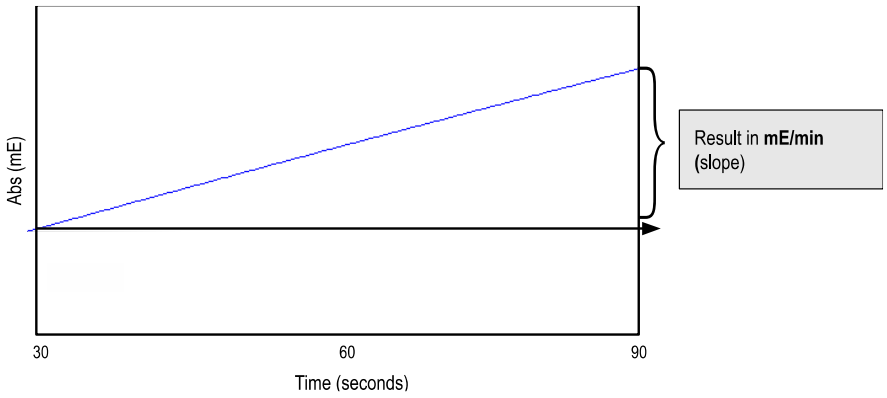


Figure 9.25. Graphic Description of the "Two Slopes (30-90)" Algorithm

One Slope (5-180)

It is called "One Slope (5-180)" because it calculates the slope of the regression curve in one stretch (5-180) and checks the linearity.

The absorbance increase obtained after the Reading Time (180 seconds) is reported in **mE**.

In case that the slope gives a negative value, zero will be reported as a result.

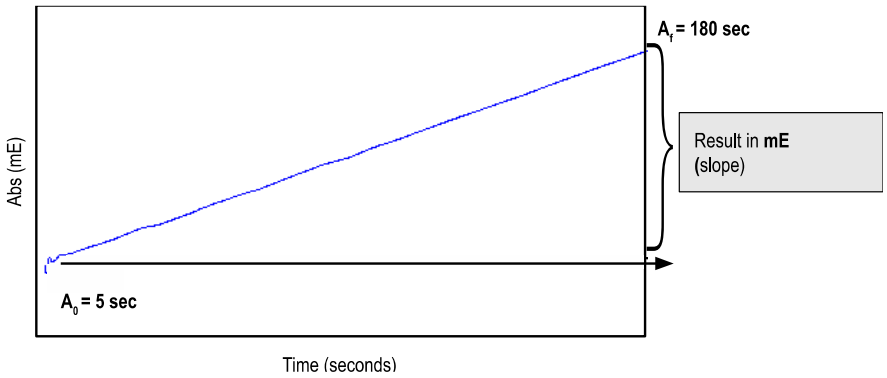


Figure 9.26. Graphic Description of the "One Slope (5-180)" Algorithm

One Slope (5-180) for Anti-Xa

It is called "One Slope (5-180) for Anti-Xa" because it calculates the slope of the regression curve in one stretch (5-180) and checks the linearity. The difference between this algorithm and the original "**One Slope (5-180)"** is the allowed error when checking the linearity, which is higher in this case.

The absorbance increase obtained after the Reading Time (180 seconds) is reported in **mE**.

In case that the slope gives a negative value, zero will be reported as a result.

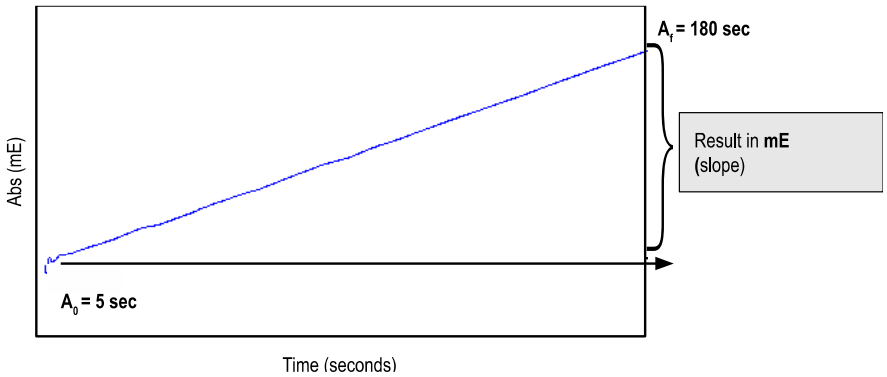


Figure 9.27. Graphic Description of the "One Slope (5-180) for Anti-Xa" Algorithm

One Slope (30-300) for FVIII

It is called "One Slope (30-300) for FVIII" because it calculates the slope of the regression curve in one stretch (30-300) and checks the linearity. It is the same algorithm than the original "**One Slope (5-180)**" but with different Reading Times.

The absorbance increase obtained after the Reading Time (300 seconds) is reported in **mE**.

In case that the slope gives a negative value, zero will be reported as a result.

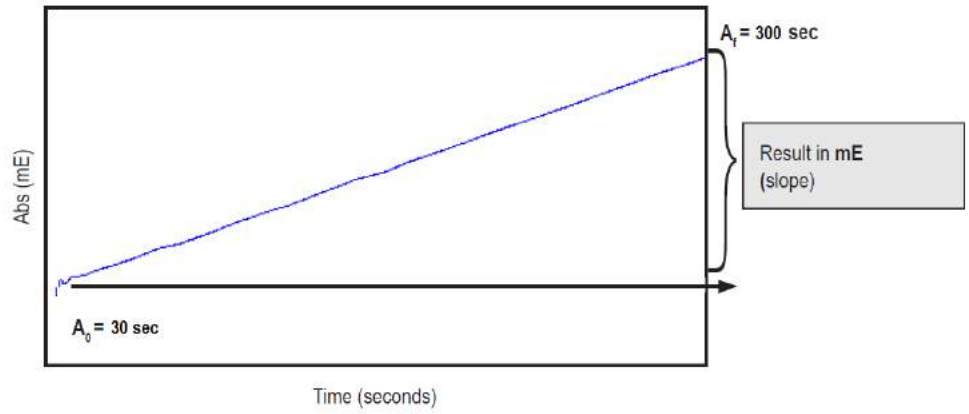


Figure 9.28. Graphic Description of the "One Slope (30-300) for FVIII" Algorithm

9.2.2.4 Algorithms for Immunoturbidimetric Tests

The algorithms used in immunoturbidimetric tests calculate differences of absorbance (mE) between two points due to the increase in light scattering (turbidity) produced by the agglutination of latex particles.

Absorbance Increase

It measures the increase of absorbance (*e.g.* as a result of light scattering) from the beginning (A_0) to the end of the Reading Time (A_f) and the result is reported in **mE**.

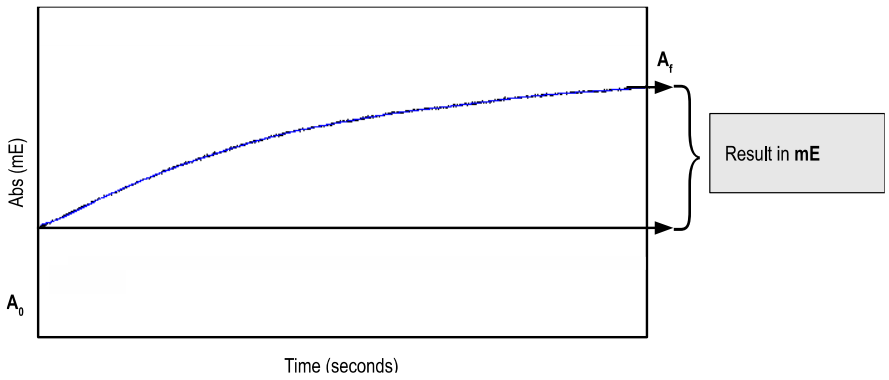


Figure 9.29. Graphic Description of the "Absorbance Increase" Algorithm

Polynomial Absorbance Increase

It performs a filtering of the primary curve by means of a third order polynomial regression. Once the polynomial equation is obtained, it measures the absorbance increase from the beginning (A_0) to the end of the Reading Time (A_f) and the result is reported in **mE**.

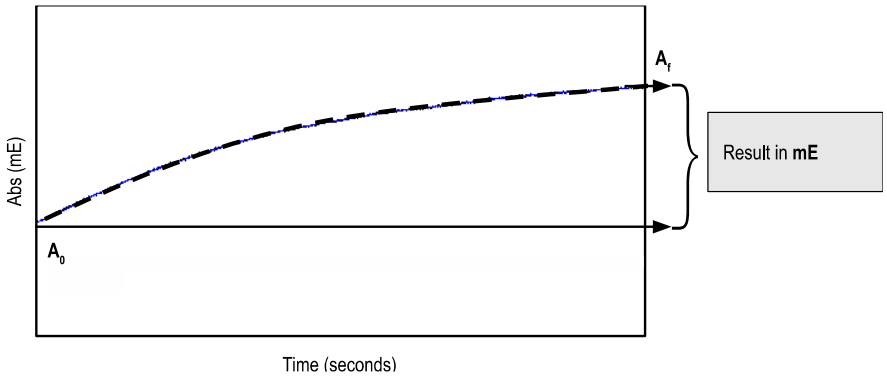


Figure 9.30. ***Graphic Description of the "Polynomial Absorbance Increase" Algorithm***

Polynomial VWFag

This algorithm has been specifically designed to be used in the GRIFOLS VWF:Ag test. It performs a filtering of the primary curve by means of a third order polynomial regression. Once the polynomial equation is obtained, it measures the absorbance increase from 60 seconds (A_0) to 180 seconds (A_f) and the result is reported in **mE**. It also includes an extra check to detect prozone curves.

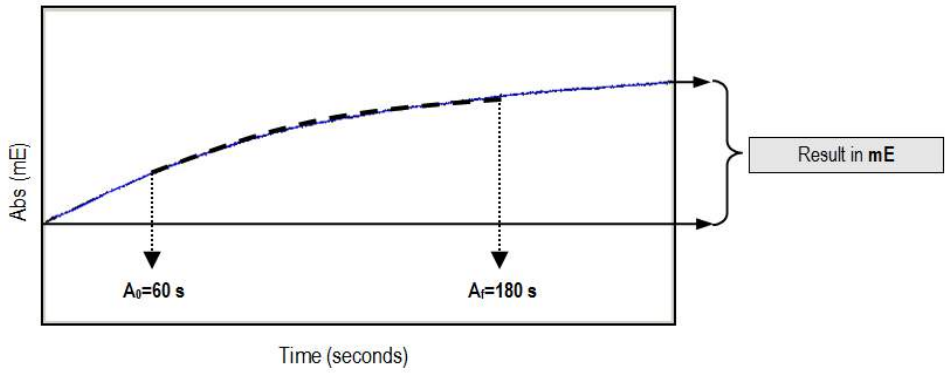


Figure 9.31. Graphic Description of the "Polynomial VWFag" Algorithm

NOTE: Although the algorithm calculates the absorbance increment from 60 to 180 seconds, it needs a programmed Reading Time of 360 seconds to be able to perform the internal calculations. Otherwise, the algorithm will not work properly.

DDimer NG

This algorithm has been specifically designed to be used in the GRIFOLS DDimer test. It performs a filtering of the primary curve and calculates the increase of absorbance (*e.g.* as a result of light scattering) from the beginning (A_0) to the absorbance level at 130 seconds (A_f), and the result is reported in **mE**. It also includes an extra check to detect prozone curves.

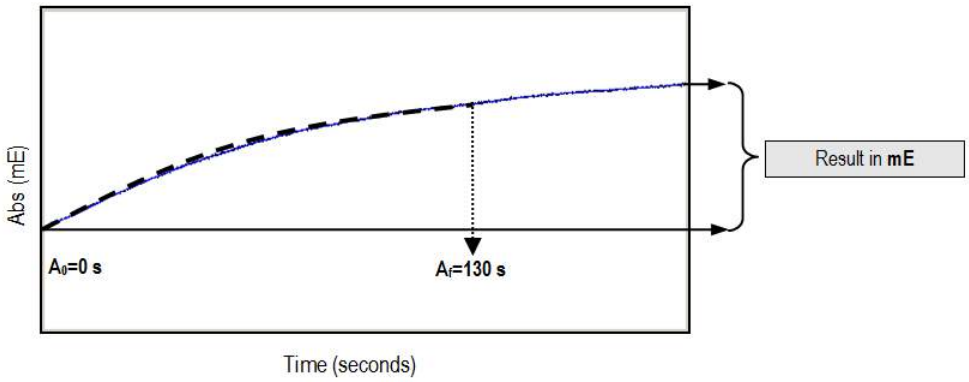


Figure 9.32. Graphic Description of the "Green DDimer" Algorithm

NOTE: Although the algorithm calculates the absorbance increment from 0 to 130 seconds, it needs a programmed Minimum Reading Time of 20 seconds and a Reading Time of 200 seconds to be able to perform the internal calculations. Otherwise, the algorithm will not work properly.

9.2.2.5 Warnings of the Algorithms

Once the algorithm has been applied to provide a result (with all the calculations and checkings), sometimes the result is given with additional information and, sometimes, it is not possible to provide a result.

- When there is result with additional information, this is indicated by means of a blue dot . The Operator should check this information because it may give important information regarding the sample characteristics, Test Programming, etc.

Figure 9.33. Warning for Algorithms in the Sample Result

- When there is no result, CND, IND, LIN or OUT can appear in the Results Box together with a blue dot , which indicates that there is additional information that the Operator should check:
  - **CND:** Clot Not Detected (in clotting tests). The algorithm applied has not been able to detect a clot in the primary curve.
  - **LIN:** Lack of Linearity (in chromogenic tests). The algorithm applied has failed while checking the linearity of the primary curve.

- **OUT:** An absorbance value of the primary curve is out of the reader's working range.
- **IND:** Indeterminate. The algorithm applied has not been able to obtain a result due to an incidence.

A detailed list with all the warnings of the algorithms for the tests performed in the analyzer is described in Section 21.1.3.3.

9.2.3 Editing a Test

An existing test can be edited by selecting the test from the list displayed on the left of the **Tests** window and pressing the **Edit** button. This gives access to the same screens as described above, but with the current parameters of the selected test.

The critical parameters of a protected test (like the tests validated by GRIFOLS) cannot be edited. However, the program leaves some fields free to access so that the tests can be customised as required by the laboratory: **User Label**, **Export Label**, **Reading Time**, **Alternative Time**, **Ranges of Normality** and **Duplicates** .

NOTE: When editing a validated test, the Reading Time and the number of replicates must be higher or equal to the originally programmed values.

NOTE: When a test is in use (it means, when it has samples orders in the **Worksheet**), the settings of its Test Programming cannot be edited.

9.2.4 Deleting a Test

To delete a test, select it from the list in the **Tests** window and press  .

When the test is deleted, all the Calibration Curves and the Controls associated with the test are automatically eliminated, once confirmed by the Operator.

NOTE: If a test is in use (it means, if it has samples orders, with or without results, in the **Worksheet**), it cannot be deleted.

9.2.5 Copying a Test

The **Copy Test** () option allows the Operator to make a copy of any of the tests on the menu, whether protected or not. To use it, select the Test and press  . A new ID for the test is later added and all the parameters can be edited and modified.

DANGER: The tests provided by Diagnostic Grifols, S.A. have been validated so that the critical parameters cannot be modified. Copying a test validated by GRIFOLS and modifying it, may lead to incorrect results.

For tests not previously validated by GRIFOLS, the Supervisor shall be in charge of individually validating each test with the appropriate products in the **QNext** before using it for analytical purposes.

9.2.6 Reseting Counter

The Q**Next** has a counter for the determinations performed for each test. The determinations include any test performed including Calibrations, Standards, Controls and Samples. To reset the counter for one test:

- Select the test whose counter is to be reset from the list in the **Tests** window.
- Press the **Reset Counter** () button, located below the **Tests** list in the **Tests** window.

9.3 Profiles Programming

A **Profile** is a group of existing tests to which a common name is given, thus allowing them to be entered as a block in the **Worksheet**.

NOTE: Profiles are merely tools for querying and viewing results. The running of the tests in the Q**Next** is unrelated to the order of the tests in the profile.

To create profiles, press the **Profiles**  option on the **Other Options** () menu in the Q**Manager** window. The **Profiles Management** window appears, which allows the Operator to:

- View the programmed **Profiles**.
- Program **New Profiles**.
- **Edit** existing **Profiles**.
- **Delete Profiles**.
- Program a **Default Profile**.

- Program an **STAT Profile**.
- Program an **Obligatory Profile**.

9.3.1 Programming a New Profile

To program a **New Profile**, press  in the **Profiles** window. The **New Profile** window appears, and a field for the **Name** and **Description** of the profile, a list – on the left-hand side – of all the **Tests available** in the analyzer and – on the right-hand side – the list of **Profile Tests**.

NOTE: The following symbols can not be introduced in the Profile **Name:** *, |, :, ?, <, >, /, “.

To program the profile, please proceed as described below:

- Select the tests from the field of **Available Tests** to be included in the profile.
- Press  to add them to the field of **Profile Tests**. If the Operator would like to include all the tests from the **Available Tests** field, press  directly.
- However, to **Delete** a **Test** from the Profile, the test needs to be selected and the  button pressed. The test will appear in the **Available Test** field. To delete all the tests in the profile, press  .

9.3.2 Editing a Profile

An existing profile can be edited by selecting it from the list displayed on the left of the **Profiles** window and pressing the  button. This accesses the same window as in the previous case, but with the current settings of the **Profile**. The various **Profile Programming** fields can be edited, except for the **Name**.

9.3.3 Deleting a Profile

To delete a profile, select it from the list in the **Profiles** window and press **Delete** button.

9.3.4 Programming a Default Profile

The QNext allows setting a **Default Profile** that will be applied to all the samples (including the Unknown Samples) that enter the analyzer and that do not have any test ordered in the **Worksheet**, neither manually nor via LIS.

The Default Profile will not be applied if an Obligatory Profile is activated (see Section 9.3.6) or if a STAT Profile is activated for prioritized samples (see Section 9.3.5).

In the **Default Profile** field, it is possible to choose which of the already programmed profiles will be applied to the samples.

9.3.5 Programming an STAT Profile

The Q**Next** allows setting an **STAT Profile** that will be applied to all the samples that enter the analyzer as prioritized. The tests programmed in this profile will be added to the tests ordered manually or via LIS in the **Worksheet**.

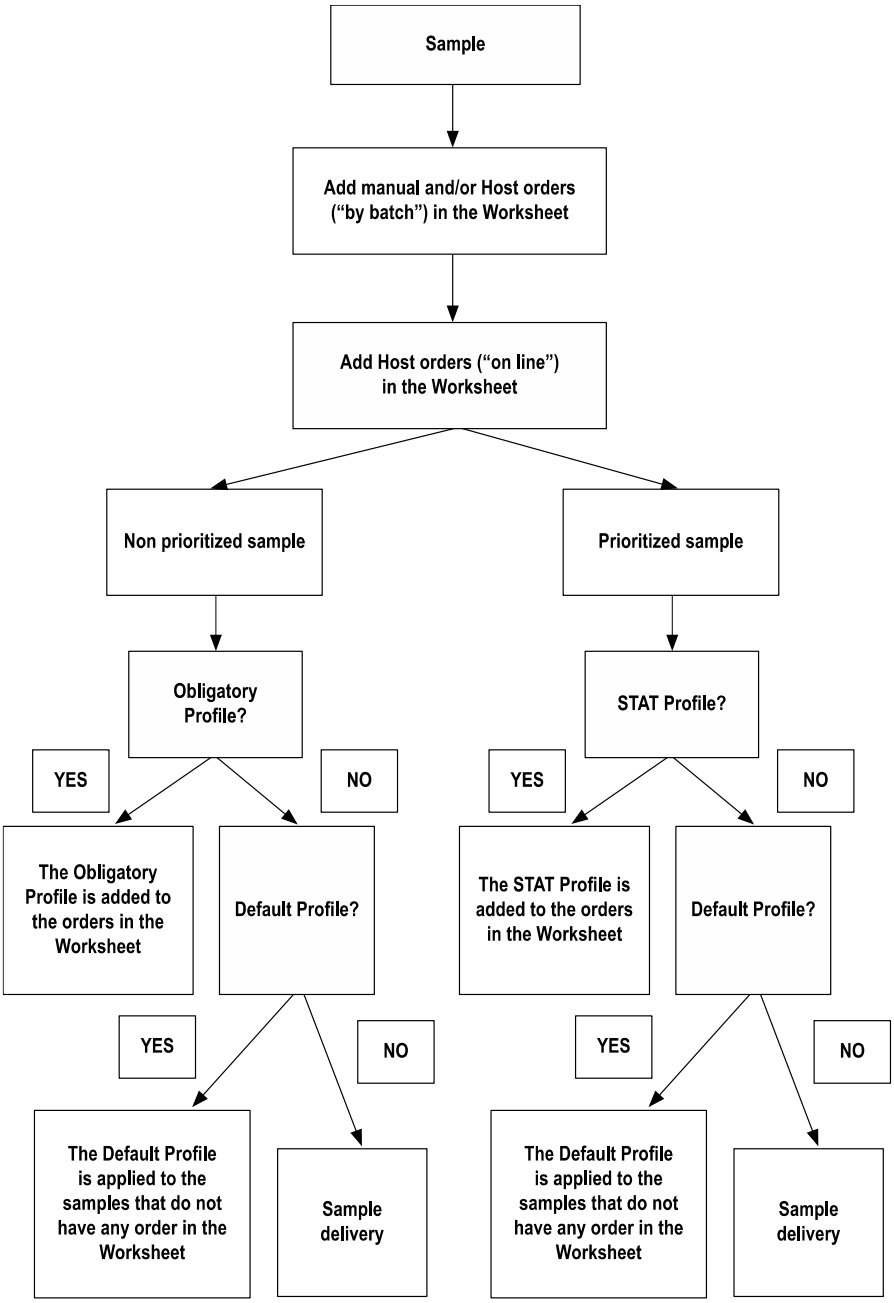
In the **STAT Profile** field, it is possible to choose which of the already programmed profiles will be applied to the prioritized samples (see Section 9.3).

9.3.6 Programming an Obligatory Profile

The Q**Next** allows setting an **Obligatory Profile** that will be applied to all the non prioritized samples. The tests programmed in this profile will be added to the tests ordered manually or via LIS in the **Worksheet**.

In the **Obligatory Profile** field, it is possible to choose which of the already programmed profiles will be applied to the samples (see Section 9.3).

A flowchart where it is possible to see the orders that will be performed on a given sample that is introduced in the instrument is shown next:



9.4 Reflex Testing Programming

A **Reflex Testing** is the automatic programming, in the **Worksheet**, of a test order which is conditional to the results of a test previously executed. If the analyzer configuration has the **Recirculate Samples** option enabled (see Section 7.3.2), the **Reflex Testing** is performed automatically because the sample in question has orders underway and the analyzer is keeping it in the Recirculation Area until all the orders have been completed (including Reflex Testing). Otherwise, the sample will need to be inserted into the Samples Entry Area again.

To create a **Reflex Testing**, press  on the **Other Options** menu () in the Q**Manager** window. This displays the **Reflex Test Management** window which allows the Operator to:

- View the programmed **Reflex Testing**.
- Program a **New Reflex Testing**.
- **Edit** existing **Reflex Testing**.
- **Delete Reflex Testing**.

9.4.1 Programming a New Reflex Testing

To program a **New Reflex Testing**, please proceed as described below:

Press  in the **Reflex Test Management** window. The **New Reflex Test** window displays a field for the **Name** and **Description** of the Reflex Testing and a table of information with the **Tests**, the **Conditions** for Reflex Testing and the **Tests** involved in the Reflex Testing.

A **Reflex Testing** can include more than one fettered step. In this window, it is possible to view the different steps involved in a Reflex Testing.

- Then, press the **New Step** button. The program displays the **New Reflex Testing Step** window (Figure 9.34) to enter the Reflex Testing step and its conditions.

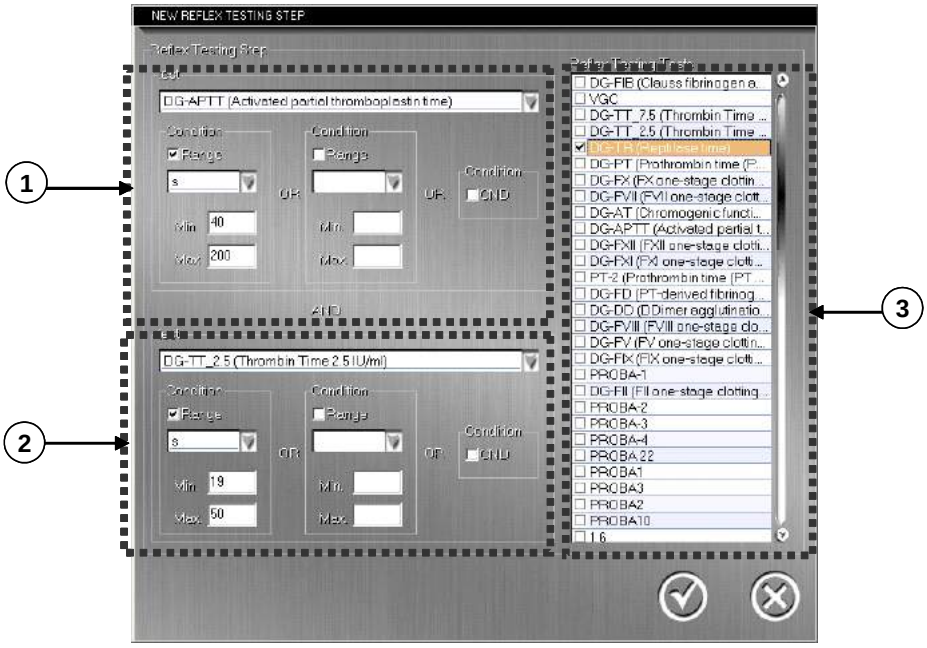


Figure 9.34. New Reflex Testing Step Window

This is for entering the information on:

(1) Information on **Test 1:** The drop-down menu allows the Operator to select:

- The **Base Test** from among the tests available in the analyzer (see Section 9.2.1).
- **Conditions** which will lead to the automatic programming of the tests involved in Reflex Testing. It is possible to enter two conditions using the logical operator **OR**. The **Range** option is for selecting the units, on the drop-down menu, and for entering the values which define the condition in the **Max.** and **Min.** fields for each condition entered.

(2) Information on **Test 2:** Through the logical operator **AND**, the program allows **conditions** for a second test to be added to the conditions of the first test.

(3) **Reflex Testing Tests:** List with the possible tests for Reflex Testing if the conditions established for **Test 1** and for **Test 2**, if any, are fulfilled.

- When the **Accept** button is pressed the program allows the Reflex Testing and all its information to be saved and to be reflected in the Table in the **New Reflex Testing** window.

It is possible to add a second Reflex Testing step to an existing one by selecting the desired Reflex Testing, pressing the button and selecting the **New Step** option. The program again displays the window indicated in Figure 9.34 where, on the drop-down menus for tests, the tests

that appear are the tests programmed as **Reflex Testing Tests** in the first programmed Reflex Testing step, since it is the only test available for applying new conditions.

- When the **Accept** button is pressed in the **New Reflex Testing** window, the program updates the **Name** of the Reflex Testing in the list which appears in the **Reflex Tests Management** window.

NOTE: When there is a Reflex Testing programmed, the Operator should add the products needed in the Products Tray or the orders will be automatically cancelled.

9.4.2 Editing a Reflex Testing

An existing Reflex Testing can be edited by selecting it from the list on the left of the **Reflex Tests Management** window and pressing  . This leads to the same screen as the **New Reflex Testing** window, but with the current Reflex Testing parameters. The various **Reflex Testing Programming** fields can be edited, including the **Name** of the Reflex Testing. It is also possible to **Edit** or **Delete** a single **Step** if the Reflex Testing being edited consists of more than one step.

9.4.3 Deleting a Reflex Testing

To delete a Reflex Testing, select it from the list in the **Reflex Tests Management** window and press  .

9.5 Products Layouts Programming

The **Products Layout** () option on the **Other Options** () menu in the Q**Manager** window allows the configurations of the Products Trays to be viewed and pre-defined based on the work routine that is performed. Using Product Layouts, the Operator only needs to select the appropriate Layout, allocate the product lots being used and place the products in the positions indicated, as described in Section 15.4.

The **Products Layout Management** window allows the Operator to:

- View the existing **Product Layouts**.
- Programming a **New Product Layout**.
- **Edit** existing **Products Layouts**.
- **Delete** existing **Products Layouts**.
- **Copy Products Layouts**.

9.5.1 Programming a New Product Layout

To program **New Products Layouts**, please proceed as described below:

- Press the **Products Layout** button on the **Other Options** ( ) menu in the Q**Manager** window. The program displays the **Products Layout Management** window with the list of all the Layouts programmed so far in the analyzer.
- To program a new Layout, press the **New Layout** ( ) button. This opens the **Edit Products Layout** window which allows the Operator to:

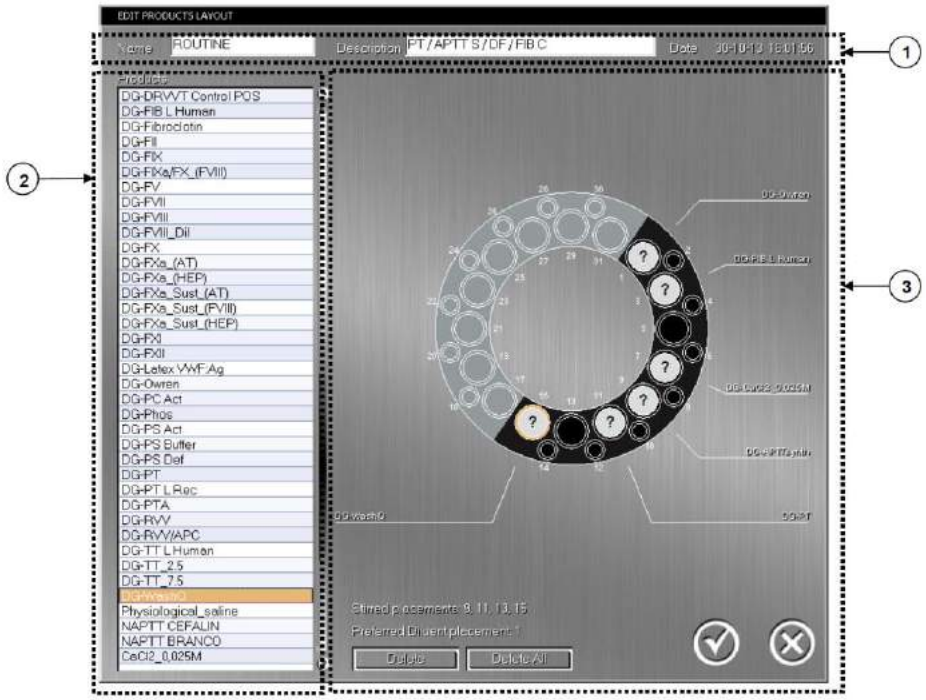


Figure 9.35. Edit Products Layout Window

(1) **Layout Identification:** Information for identifying and describing the Layout. The following parameters must be entered here:

- Layout **Name** (a name (SR - date - time) automatically appears in this field by default, but this can be modified).
- Layout **Description.**

The date and time at which the Layout was programmed also appear.

(2) List of **Products** Programmed in the analyzer (see Section 9.1.1).

(3) Layout **Configuration**. To set the Layout, proceed as follows:

- Select, from the list of **Products** programmed in the analyzer, one of the products for the Layout.
- Then select the desired position on the outline of the Products Trays. The program will automatically display the position with the product and a question mark "?" referring to the product lot. Proceed in this way until the entire Layout has been configured. Because the lots may vary with each use, they must be entered in the Q**Executor** when loading the analyzer, as indicated in Section 15.4.
- If the Operator would like to delete any of the products from the Layout configuration, select the product and then press **Delete**. All the products in the Layout can be deleted by pressing the **Delete All** button.

9.5.2 Editing a Products Layout

Editing an existing **Product Layout** is done by selecting the Layout from the list displayed on the left of the **Products Layout Management** window and pressing the **Edit** button. The program will display the same screen as above but with the current products on the selected **Layout**.

The action buttons () and () allow the changes made to be saved or cancelled, respectively.

To modify the settings, proceed as described in Section 9.5.1.

9.5.3 Deleting a Products Layout

To delete a Products Layout, select it from the list in the **Products Layout Management** window and press the **Delete**  button.

9.5.4 Copying a Products Layout

The **Copy Products Layouts** option () allows making a copy of any of the Layouts on the menu if this has been previously selected. After allocating a new ID, the Operator can edit and modify all the components to obtain a new Layout.

9.6 Quality Control

The **Quality Control** () option provides access to the **Quality Control (QC) Management** menu: Obtainment of charts, programming automatic QC orders, configuration of QC multirules (Westgard Rules) and establishing a QC Policy. For more information, please see Section 11.

9.7 Q Analyzers

This option allows managing and visualizing the different analyzers managed by a same Q**Manager**. It also informs about the analyzers that are connected and/or visible.

Figure 9.36. Q Analyzers Management

- **Name:** Analyzer identification programmed in the **Setup** window (Figure 7.6, no. 6).
- **Connected:** Informs if the analyzer is connected to this Q**Manager**.
- **Serial Number:** Informs about the Serial Number of the analyzer.
- **Q ID:** Correlative number that the Q**Manager** automatically assigns to the different instruments that are connected or have been connected to it. This identification number will be the one used in the **Worksheet** to indicate the analyzer where the CAL/QC/STD orders will be processed (Figures 10.1, 10.2, 10.5 and 10.6).
- **Visible:** This option is customizable by the Operator, pressing the **Edit** button, and it allows selecting if each of the available instruments will appear or not on the menus of the Q**Manager** where the analyzer can be selected. Since the instruments that at some point have been part of the system cannot be deleted because results executed in them may exist, there is the possibility of making them not visible.

9.8 Test Calibrations

The **Calibrations** () option provides access to functions relating to the Management, Viewing, Editing and Deletion of Calibration Curves. For more information, please see Section 10.3.

9.9 Reports Programming

The Q**Manager** has a module for creating and customising reports. This option allows the Operator to select which fields of information available in the analyzer's **Database** will be included in the report. The report is automatically configured based on the number of information fields requested.

If the number of fields selected exceeds the maximum capacity for vertical orientation, the program will display a message indicating the need to select horizontal orientation to display all the fields on the same page.

These customised reports are configured in advance in the **Reports** option, accessible from the **Other Options** ( ) menu in the Q**Manager** window. The program displays the **Reports** window with a list of all the reports programmed in the analyzer.

The window also allows the Operator to:

- Program New Reports.
- Edit existing Reports.
- Delete Reports.

9.9.1 Programming a New Report

To program a New Report, proceed as described below:

- Press the **New Report** ( ) button. The program offers the **New Report** window as shown in Figure 9.37.

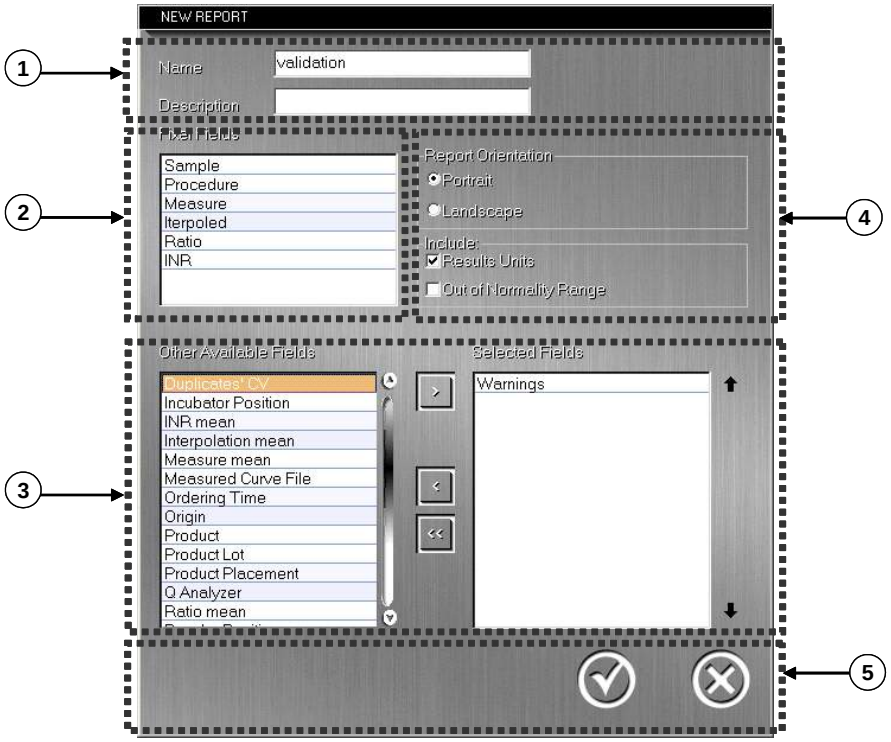


Figure 9.37. New Report Window

Once in the **New Report** window, enter all the following information:

(1) **Report Description:** Information which allows the report to be identified and described. Enter the **Name** of the report and a **Description**.

(2) **Fixed fields:** Information which will appear by default in the customised reports.

(3) **Other available fields:** Information on all the fields available in the analyzer and which can be selected by the Operator for inclusion in the report configuration. For this, select the required field and press . The selected field will automatically appear in the list of **Selected Fields**. To remove a specific field, select it from the **Selected Fields** list and press . The button removes all the fields.

NOTE: To change the order in which the fields are viewed, select the corresponding field and, using the (⇧⇩) arrows, located next to the **Selected Fields** list, move the field up or down to the desired level.

(4) **Page configuration:** The program allows the Operator to select:

- Report orientation: Portrait or Landscape.
- Print options: Inclusion of units in the results and/or tag results outside of the margins.

(5) Finally, the action buttons  and  allow the Operator to save or cancel the changes.

9.9.2 Edit Report

Existing reports are edited by selecting the test from the list displayed on the left of the **Reports** window and by pressing the **Edit** () button. The same window as described above will be opened, but with the settings of the selected report.

9.9.3 Delete Report

To delete a report, select it from the list in the **Reports** window and press the **Delete** button.

9.10 Users

The **Users** () option allows different levels of Operators to be recorded and identified, so that they can work with the Q**Next**. If the analyzer is configured with the **Enable Passwords** option on, the various Operators must be programmed before being able to work with the analyzer.

To this end, the program manages a group of passwords which give access to different programming levels.

There are 3 different access levels:

1. **Technical Service:** Provides access to **Technical Service** on the **Other Options** menu in the Q**Executor** window. Access to this menu is always password-protected, whatever the status of **Enable Passwords**.
2. **Supervisor:** Predefined user with access to the entire program, with the exception of the **Technical Service** menu.
3. **Operator:** The Supervisor can create different Operators and define the parts of the program to which they will have access. This can be customised for each Operator.

Figure 9.38 displays the **Users** window, accessed by entering the Supervisor's password and pressing the **Users** option of the **Other Options** () menu..

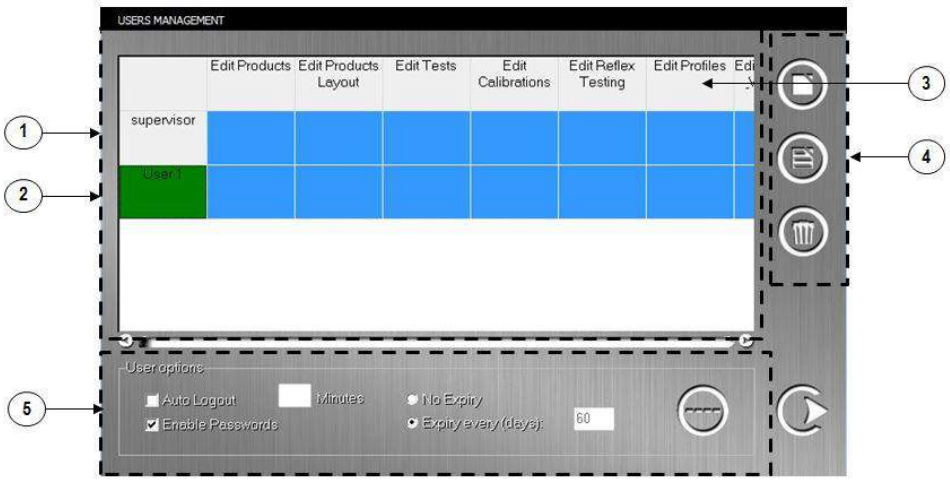


Figure 9.38. Users Management Window

(1) Name of the Supervisor and accesses granted.

(2) Name of the Operator and accesses granted.

(3) Accesses to the various program options.

(4) Action buttons.

(5) Passwords Management Configuration.

9.10.1 Users Registration

The action buttons (Figure 9.38, no. 4) **New User** (), **Edit User** () and **Delete User** () allow the list of desired Operators to be established.

To register a new Operator, press and enter the name used to work with the analyzer under **User** and the full name under **Name**. Then, **Accept**, and the system will provide a one-time 4-digit password to the new Operator registered that shall be used during the first login.

The Supervisor user cannot be deleted.

9.10.2 Users Access Configuration

Access to the various options of the program is configurable and can be customised for each Operator.

The Supervisor shall select, for each Operator, the program options displayed at the top of the table (Figure 9.38, no. 3) to which he wishes to grant him access, selecting it in the corresponding intersecting box.

9.10.3 Passwords Management Configuration

The configuration options (Figure 9.38, no. 5) allow:

- **Auto Logout** and **Minutes:** The program will disconnect the Operator when no actions are performed within the minutes programmed.
- **Enable Passwords:** The program allows the option of disabling the use of **Passwords** and granting access to all program options (except the **Technical Service** menu).

⚠ **CAUTION:** The manufacturer does not recommend disabling the **Enable Passwords** option, since the system is then unable to trace who has performed the actions and makes parts of the program designed to be maintained and controlled by Supervisor accessible to all.

- **Password Expiration** and **period** for which they are valid.

⚠ **CAUTION:** The QNext is configured by the manufacturer with the **Enable Passwords** option on, with 60 days of expiration, and with the **Auto Logout** every 5 minutes enabled. Disabling any of these options mean that the equipment is working under non-manufacturer recommended conditions.

- **Reset Password:** The  button allows the password associated to a specific Operator to be reset.

  To use it, select the specific **Operator** and press the  button. This Operator will be provided with a new one-time 4-digit password that will be required when connecting to the analyzer again.

Operator passwords do not appear in this window, since they are confidential. When a specific Operator connects to the analyzer by pressing the **Log In** button, the program opens an identification window where the **Username** and **Password** must be entered.

If this is the first time that an Operator is connecting to the program, introduce the name of the **Operator** and the one-time 4-digit password provided when registering the Operator, and **Accept**.

A message indicating that this is the first login of the Operator is displayed. Then, a window where the Operator password must be introduced and reconfirmed appears. The password is stored and associated to this Operator until the date indicated in the configuration options.

If a wrong **Username** or **password** is introduced 5 consecutive times when attempting to login, the Operator will be blocked for 15 minutes. After these 15 minutes, the Operator can retry the login process again.

9.11 QManager Setup

The Q**Manager Setup** option ( ) allows customizing different options and configurations of the Q software.

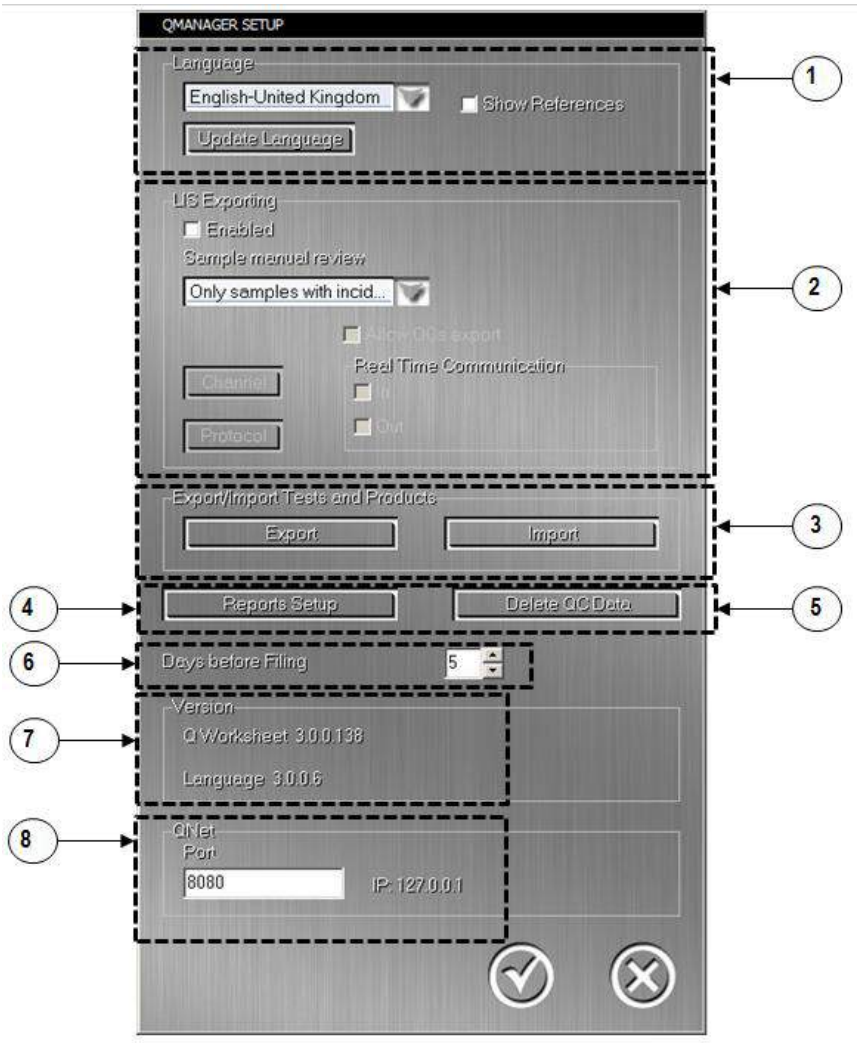


Figure 9.39. QManager Setup Window

(1) Language selection and updating.

(2) LIS Exporting.

(3) Importation/Exportation of Tests and Products.

(4) Reports configuration.

(5) Delete QC data.

(6) Temporary Database configuration.

(7) Information on versions.

(8) Communications Port Configuration.

9.11.1 Language Selection and Updating

It allows changing the Q software language.

In the Q Analyzers, the different software languages are defined in a language file called "**Lang.db**". The Q software language file version can be updated using an **USB data storage device**. For more information, please, see Section 7.3.1.

CAUTION: To protect the data of the software, the **USB data storage device** used to update the language file version, should be previously scanned to ensure that the device is Virus Free.

NOTE: The language file version installed in the instrument can be found both, in the **QManager** and **QExecutor Setup** windows, in the **Version** sections (see Figures 7.6 and 9.39, respectively).

9.11.2 LIS Exporting

By enabling the **LIS Exporting** option, it is possible to configure the communication with the Laboratory Information System (LIS).

The **Sample Manual Review** option allows establishing the **Sample Review Policy** that will be applied to all sample results before exporting them to the LIS. There are 3 available options:

- **None**: All sample results will be exported to the LIS without the Operator reviewing them.
- **Only sample with incidences**: Only sample results with an incidence (blue dot) will have to be reviewed by the Operator before exporting them to the LIS.
- **All samples**: All sample results will have to be reviewed by the Operator before exporting them to the LIS.

WARNING: The selection of "**None**" **Sample Review Policy** is not a recommended practice.

There is also the possibility of exporting the QC results to the LIS by enabling the **Allow QCs Export** option. For the QC results, there is no selectable QC Review Policy. By default, all QC results will have to be reviewed before exporting them to the LIS.

NOTE: Cancelled QCs cannot be exported to the LIS.

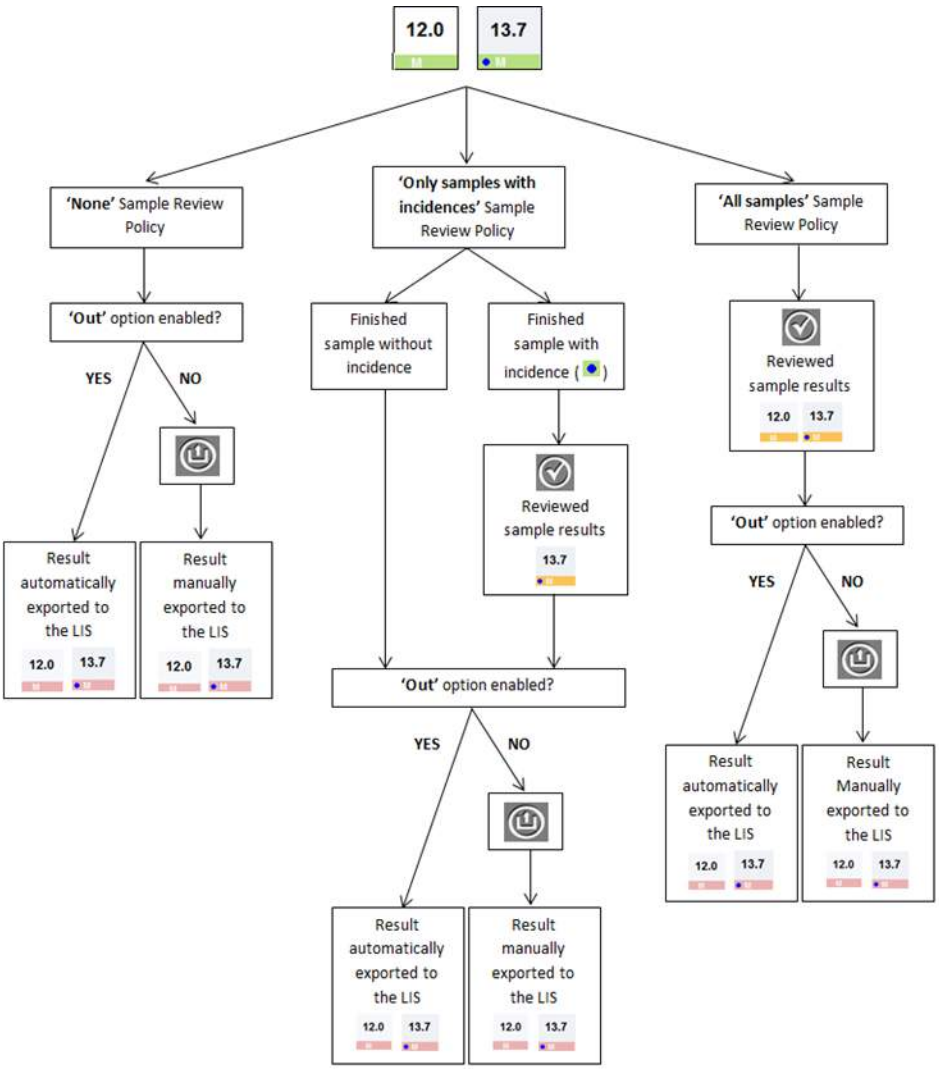
The **Real Time Communication** option allows the samples orders import and the samples and QCs results export to the LIS to be automatically performed, without the need of the Operator pressing the **Import Orders** or the **Export Results** buttons from the main **QManager** window:

- By enabling the **In** option, all new sample orders will be automatically imported to the **Worksheet** in real time.
- By enabling the **Out** option, all reviewed QCs and samples results will be automatically exported to the LIS, after applying the selected **Samples Review Policy.**

NOTE: Canceled samples results or recalculated samples results can not be automatically exported to the LIS, regardless of the **Out** option being enabled. The Operator will have to manually do it by pressing the **Export Results** button from the **QManager** window.

NOTE: When exporting samples results cancelled or with incidences, the additional information regarding the cause of the incidence or cancellation will also be exported to the LIS.

The following diagram shows a flowchart of the samples results export options:



When pressing the **Protocol** button, it is possible to access a window that allows setting the sending of the **Patient ID** field to the LIS when this is empty. In this way, the compatibility with the different LIS connections is guaranteed. There are 3 available options:

- Send the **Patient ID** field **empty**.
- Use the sample identification (**Sample ID**).
- Use a **fixed identification** that can be defined (for example, an asterisk).

The **Channel** button is only used by the Technical Service personnel to configure the communication system (Serial Port, TCP/IP or file systems) for the LIS connectivity.

Contact your authorised Technical Service to request support when setting the communication with the LIS is required.

9.11.3 Importation/Exportation of Tests and Products

It allows importing and exporting tests, products and the lots associated to the selected products, if any.

When pressing **Export**, a window for selecting the Tests and Products to be exported to a ".ieq" file is displayed. It is also possible to include the lots associated to the selected products, if any.

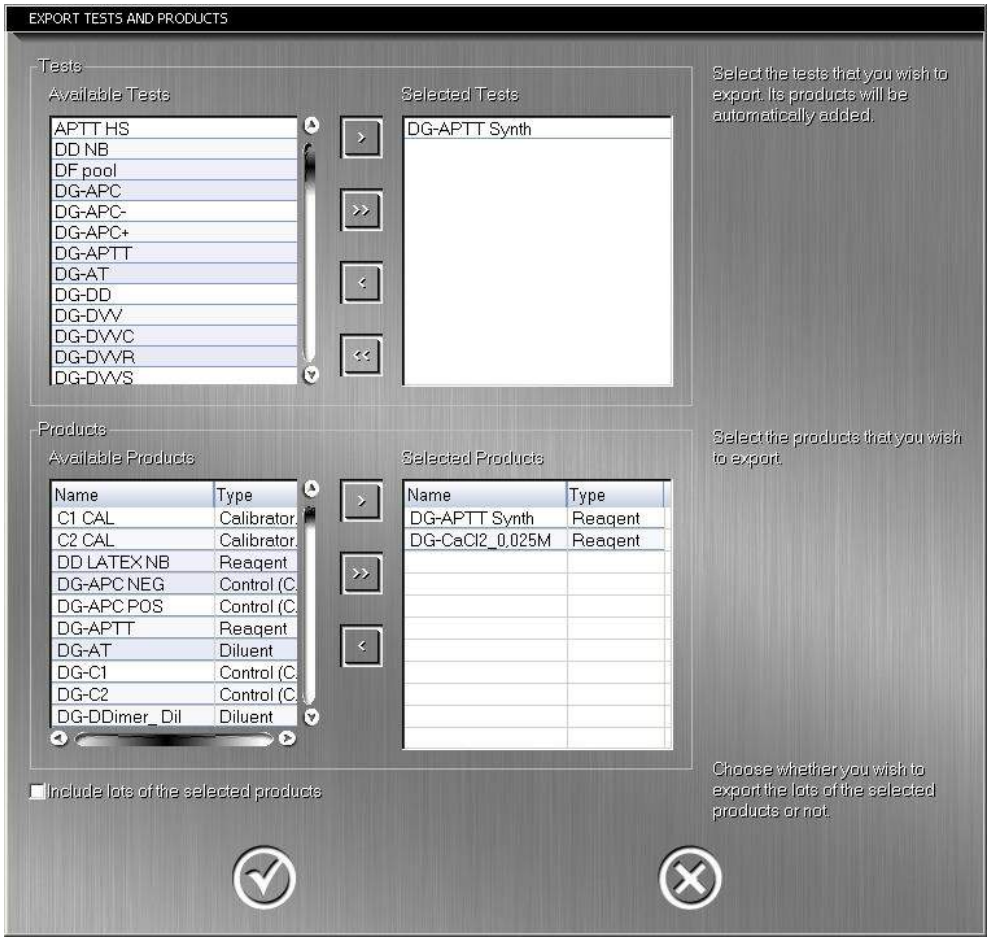


Figure 9.40. Export Tests and Products Window

When pressing **Import**, a window for browsing the ".ieq" file to be imported is displayed.

Then, a window where it is possible to select the Tests and Products to be imported from this ".ieq" file is displayed. A symbol appears before the name of tests and products included in this file:

[=]: If the validation date of the test or product to be imported is the same than the one existing in the instrument.

[+]: When the test or product to be imported is new (it does not exist in the instrument).

[!+] or **[!-]:** If the test or product to be imported has a later or earlier validation date than the one existing in the instrument, respectively.

It is also possible to include the lots associated to the selected products, if any.

Instructions for Importing the "QValidated Tests&Products.ieq"

When a new validated tests and products file for Q Analyzers is released, it is recommended to update the instrument with the last version of this file: "Q**ValidatedTests&Products_x.y.ieq**". To import it, the Operator should proceed as follows:

- Go to the **Setup** option on the **Other Options** menu  of the Q**Manager** and press **Import** (Figure 9.39, no. 3).
- Browse the file "Q**ValidatedTests&Products_x.y.ieq**" (*e.g.* in a **USB data storage device**) and press **Accept** (Figure 9.41).

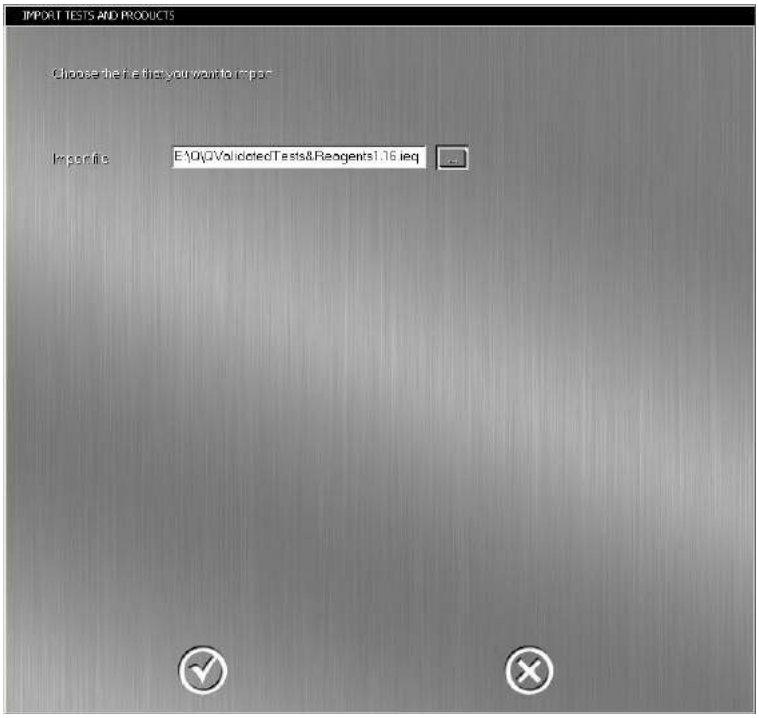


Figure 9.41. Importing New Tests and Products. Step 1

- Press the  button to select all the available tests and products (Figure 9.42). **DO NOT** choose the option “Include lots of the selected products”.

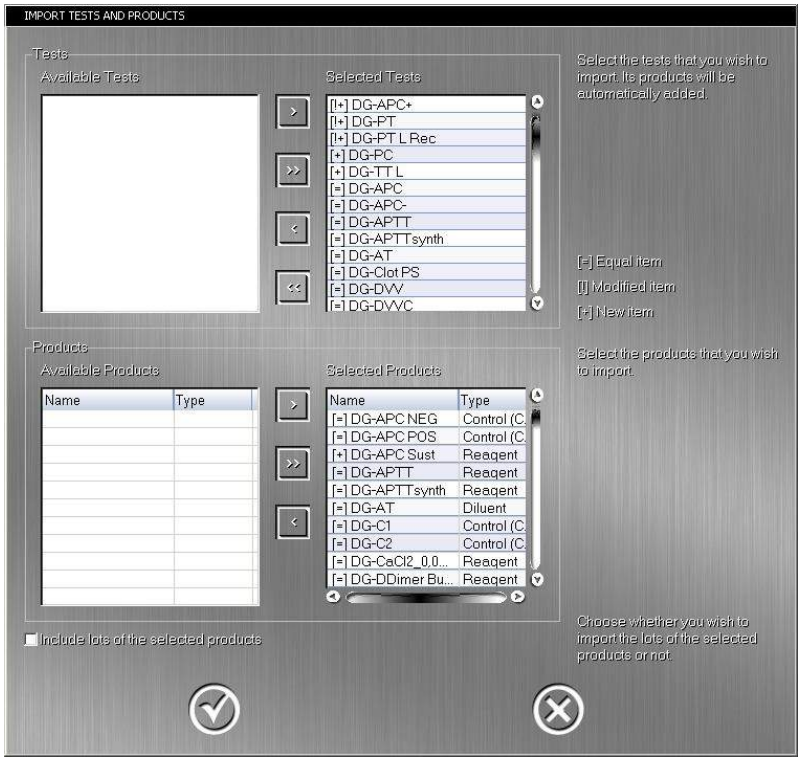


Figure 9.42. Importing New Tests and Products. Step 2

- Press **Accept** and a window informing about the correct importation of all the tests and products will be displayed (Figure 9.43).

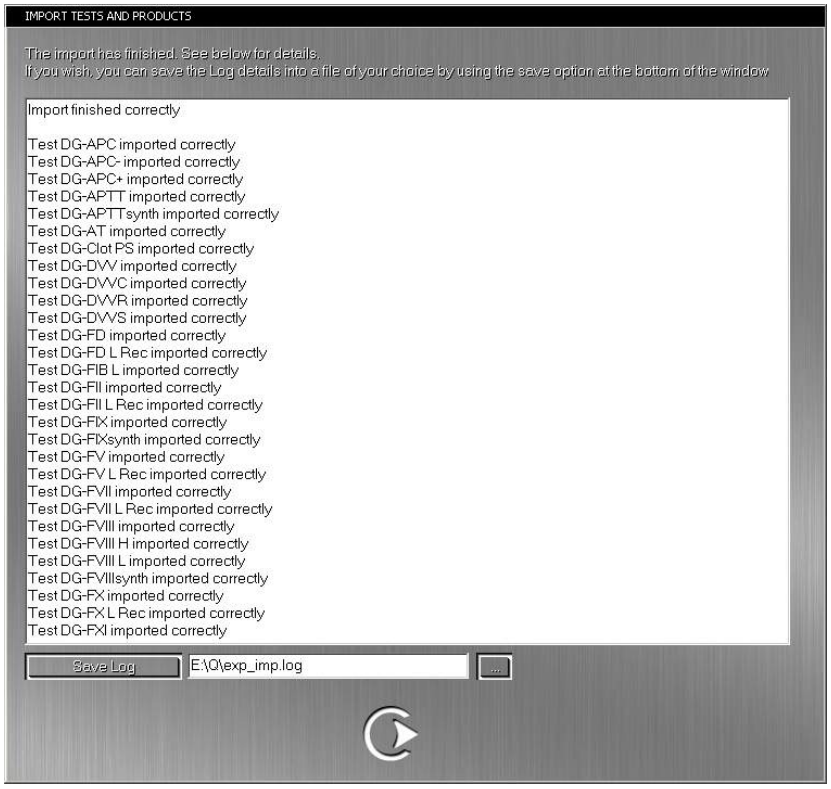


Figure 9.43. Importing New Tests and Products. Step 3

- Exit this window. The new validated tests and products will be available in the corresponding **Tests** and **Products Programming** menus.

Instructions for Importing the ".ieq" file with the Values Table of the different Lots of Controls and Calibrators

When a new batch of GRIFOLS Calibrator (**DG-Ref**) or Control (**DG-C1** or **DG-C2**) is released, a ".ieq" file containing the values table will be distributed by the authorized service representative in your country: "**DG-Ref XXXXX.ieq**", "**DG-C1 XXXXX.ieq**" or "**DG-C2 XXXXX.ieq**". This allows automatic introduction of Calibrators and controls tables. To import this kind of files, the Operator should proceed as follows:

- Go to the **Setup** option on the **Other Options** menu  of the Q**Manager** and press **Import** (Figure 9.39, no. 3).
- Browse the file "**DG-Ref XXXXX.ieq**", "**DG-C1 XXXXX.ieq**" or "**DG-C2 XXXXX.ieq**" (*e.g.* in an **USB data storage device**) and press **Accept** (Figure 9.44).

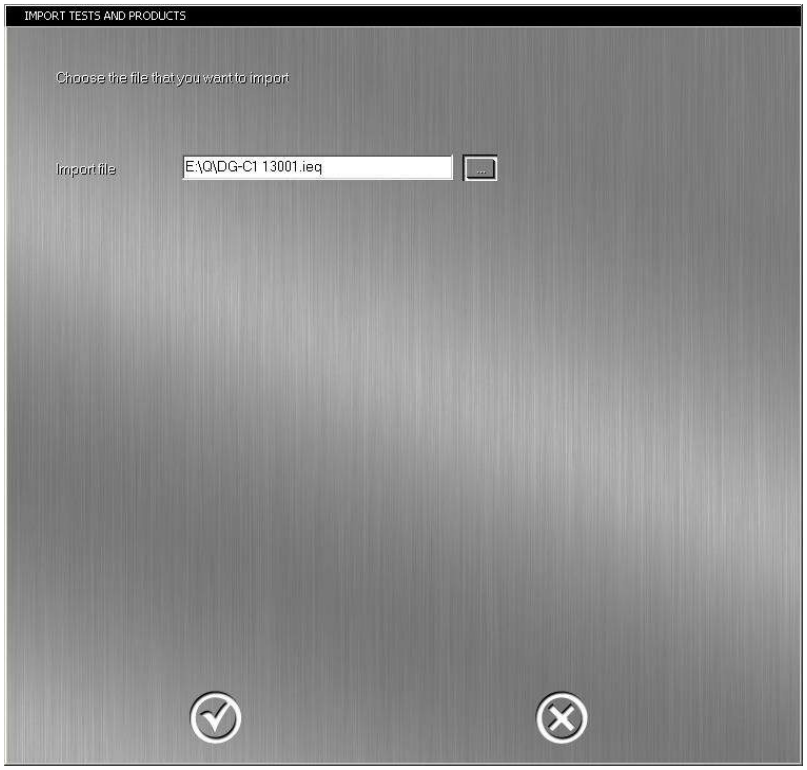


Figure 9.44. Importing the Values Table of a Product Lot. Step 1

- Select the product **DG-Ref**, **DG-C1** or **DG-C2**, press the  button and activate the option "**Include lots of the selected products**".

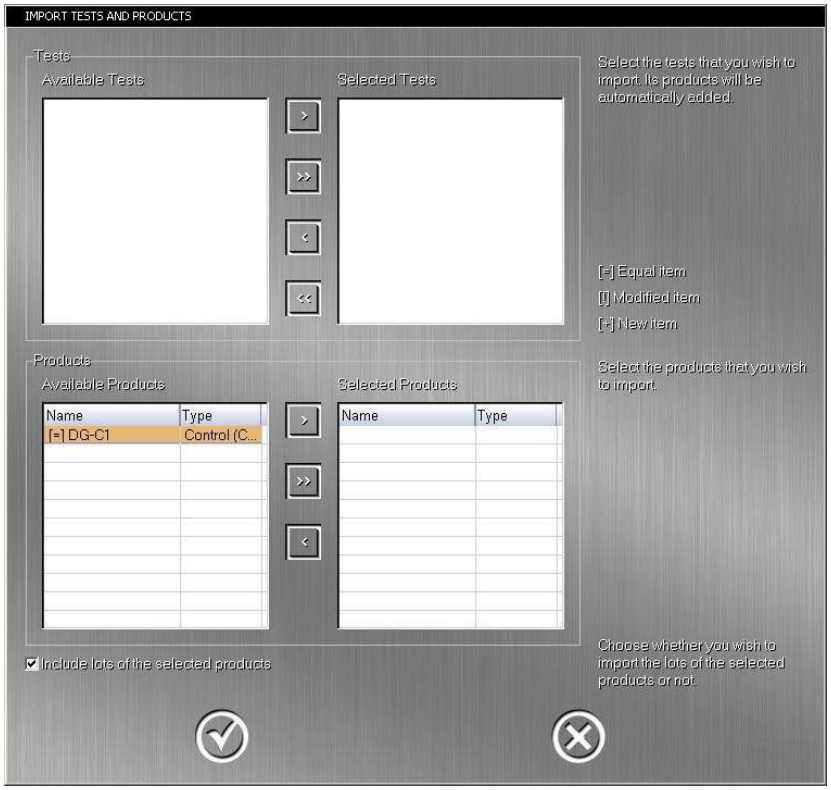


Figure 9.45. Importing the Values Table of a Product Lot. Step 2

- Press **Accept** and a window informing about the correct importation of the product will be displayed (Figure 9.46).

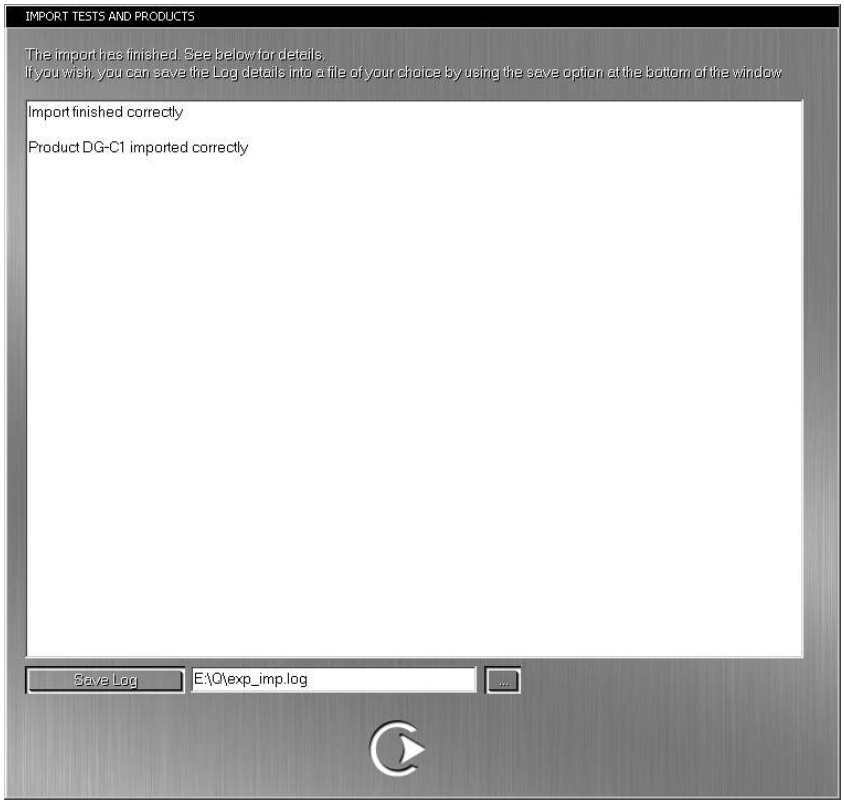


Figure 9.46. Importing the Values Table of a Product Lot. Step 3

- Exit this window. The new product lot with the values table will be available in the programming window of the product in question, ready to be used.

9.11.4 Report Configuration

The **Report Setup** button offers the possibility of customising reports by including the name of the **Center**.

9.11.5 Delete QC Data

The **Delete QC Data** option allows new data for **Quality Control** to be compiled again. For more information, please see Section 11.9.

9.11.6 Temporary Database Configuration

The option **Days Before Filing** allows the number of days in the **Temporary Database** to be configured (prior to sending data to the **Historical Database**). During this period, it will be possible to recover in the **Worksheet** the primary data and the primary curve associated with a sample that has been filed.

- If 0: The data go directly to the **Historical Database** when the samples in the **Worksheet** are filed.
- If 1 to 7: Period of days during which the results of the samples which have been filed and exported from the **Worksheet** can be recovered.

9.11.7 Information on Versions

The program indicates the version number of the **QManager** software and the software language file.

9.11.8 Communications Port Configuration

Option for setting up the Communications Port of the Q**Manager** with the Q**Executor** for the establishment of nets of Q Analyzers (Q**Net**). The default value is 8080.

Contact your authorised local Technical Service Desk to request support when establishment of nets needs to be performed.

10 Calibration Curve and Standard

To transform the time and absorbance values (**primary unit**) into units of concentration, activity, ratio or INR (**secondary unit**), the Q**Next** has three different procedures:

- Conversion to activity or concentration by interpolation/extrapolation of the primary unit in a **Calibration Curve**.
- Conversion to ratio by means of a **Standard** value (representation of the normality), either population or commercial.
- Conversion to INR (International Normalized Ratio) by means of a **Standard** value (population or commercial freeze-dried plasma) and the **ISI** (International Sensitivity Index) from the current lot of the PT (Prothrombin Time) reagent used.

INR = (PT Patient / PT Standard)^{ISI}.

10.1 Calculation with Calibration Curves

The first method for calculating results in secondary unit (**concentration** or **activity**) consists in performing a **Calibration Curve** by performing several dilutions of a single Calibrator or using several Independent Calibrators that have different levels. A **Calibrator** is a sample with a known value for a test.

NOTE: There is no need to interrupt the analyzer's work routine to calibrate a test. The Q**Next** can calibrate a test at the same time as it carries out the programmed routine.

10.1.1 Programming a Calibration Curve

To program a Calibration Curve, the Operator must first program the Calibrator or Calibrators as **Products** (see Section 9.1.1.3), as well as all the other products (reagents, diluents and cleaning agents) required to perform the Calibration Curve.

WARNING: For a same test, it is not allowed to program a second Calibration Curve while the first one is still in the **Worksheet**.

10.1.1.1 Programming Automatic Dilutions for the Calibration Curve

To program a Calibration Curve performed with several dilution points of a single Calibrator in the **Worksheet**, proceed as follows:

- Keep the finger pressing on the Test Box of the test to be calibrated. The program displays a drop-down menu with various options.

- Select the **Calibrator (CAL)** option.

WARNING: It is not allowed to program Calibration Curves for different tests that share the Calibrator with the same Calibrator lot if the tests use different diluents in the same instrument.

- The **Calibrator (CAL) Order** window appears. Select the following information in the window:
  - Q **Analyzer**.
  - **Calibrator** to be used.
  - Commercial **Presentation** of the Calibrator.
  - **Lot** (previously programmed, see Section 9.1.1.3).
  - **Diluent** used to perform the dilutions (programmed in **Products**, see Section 9.1.1.1).
  - The assigned **Value** of the Calibrator for the selected test (previously programmed, see Section 9.1.1.3) automatically appears.
  - **Calibration Points:** Dilutions of the Calibrator that will be performed to generate the Calibration Curve. A minimum of 3 and a maximum of 10 dilution points have to be entered.

    If a Calibration Curve for this Calibrator and this test has been previously processed in the analyzer, the program suggests the dilution points used then. The Operator can confirm or change them.

NOTE: For the tests validated by GRIFOLS, the information about the **diluent** and the recommended **calibration points** is provided in the **Test Characteristics** tab.

WARNING: The dilution programmed in the Test will also be applied to the Calibration Curve (Figures 9.6, no. 2).

NOTE: The drop-down menus which appear in the Calibration Points section allow the Operator to select some of the most usual dilutions. However, the Operator can enter any dilution.

NOTE: Dilutions have to be entered using the X/Y format, *i.e.* X Calibrator volume in a total volume of Y (Diluent + Calibrator).

NOTE: The dilutions performed to plot a Calibration Curve are always processed per duplicate, regardless of how the test is programmed.

- Press **Accept** to confirm the order of the Calibration Curve. The orders for the different dilution points are automatically loaded in the **Worksheet** (Figure 10.1).

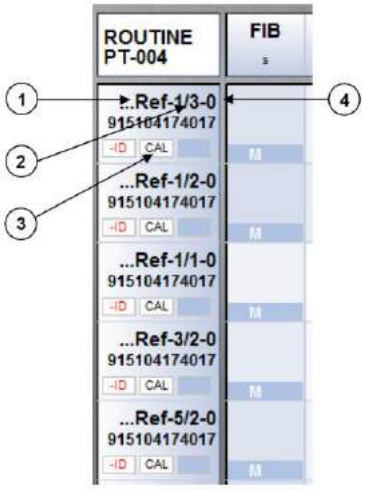


Figure 10.1. Calibration Points Order in the Worksheet

(1) User label for the product used as Calibrator (see Section 9.1.1.3).

(2) Dilution factor.

(3) CAL**:** Internal program code to identify a Calibrator.

(4) Q ID**:** Analyzer's identification number where the Calibration Curve is going to be processed.

10.1.1.2 Programming a Calibration Curve with Independent Calibrators

To program a Calibration Curve performed with several Independent Calibrators that have different levels in the **Worksheet**, proceed as follows:

- Keep the finger pressing on the Test Box of the test to be calibrated. The program displays a drop-down menu with various options.
- Select the **Independent Calibrators** option.
- The **Calibrator (CAL) Order** window appears. Select the following information in the window:
  - Q **Analyzer**.
  - **Calibrators** to be used, one by one. A minimum of 3 Independent Calibrators have to be programmed.

- Commercial **Presentation** of the selected Calibrator.
- Calibrator **Lot** (previously programmed, see Section 9.1.1.3).
- The assigned **Value** of each Calibrator for the selected test (previously programmed, see Section 9.1.1.3) automatically appears.

NOTE: For the tests validated by GRIFOLS, the information about the recommended **Independent Calibrators** is provided in the **Test Characteristics** tab.

NOTE: The Independent Calibrators used to plot a Calibration Curve are always processed per duplicate, regardless of how the test is programmed.

- Press **Accept** to confirm the order of the Calibration Curve. The orders of the different Independent Calibrators are automatically loaded in the **Worksheet** (Figure 10.2).

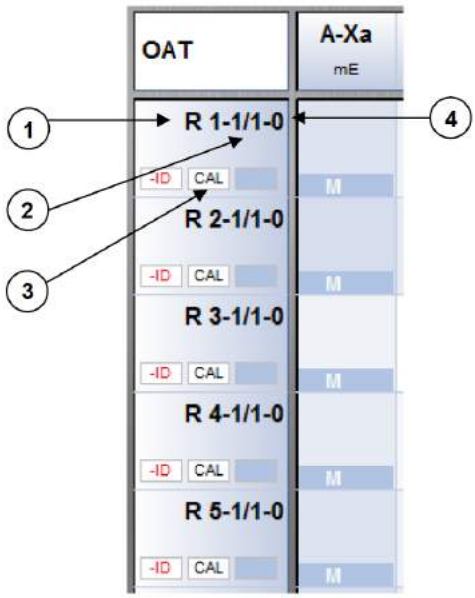


Figure 10.2. Independent Calibrators Order in the Worksheet

(1) User label for the product used as Calibrator (see Section 9.1.1.3).

(2) Dilution factor: It is always 1/1, which means it is going to perform the dilution programmed in the test, if any.

(3) CAL**:** Internal program code to identify a Calibrator.

(4) Q ID**:** Analyzer's identification number where the Calibration Curve is going to be processed.

10.1.2 Execution of a Calibration Curve

To perform a Calibration Curve, the Operator should proceed as follows:

- Press the **Open Upper Door** button.
- If performing a Calibration Curve by multiple dilutions of a single Calibrator, place the **diluent** in any position of the **Products Tray** (proceed as described in Section 15.4).
- To enter **Calibrators** (single or independent), there are two possibilities:
  - In their **original vials** placing them in the **Products Trays** so that they can be automatically identified (see Section 15.4).
  - Transfering them to a **tube** or **microtube** which is placed in a Q**sample holder** and manually identify it (see Section 15.6). If the Calibrator volume is < 1.5 mL the use of a microtube is recommended, since the dead volume is lower.
- Gently close the Upper Door, pressing down from the top until hearing the click of the clousure.
- If the configuration is correct, press **Accept**.
- Press  to start analysis.

NOTE: The Q**Next** will automatically perform the dilutions and pre-dilutions required to carry out the calibration points programmed in the **Calibrator Order** window. To do so, the analyzer may use more than one Q**cell** cuvette per dilution, to perform intermediate dilutions.

10.1.3 Revision of the Results of a Calibration Curve

Once the analyzer has processed all the points on the Calibration Curve, touching any Results Box associated with the curve on the **Worksheet** will cause the **Validate Calibration Curve** window to appear.

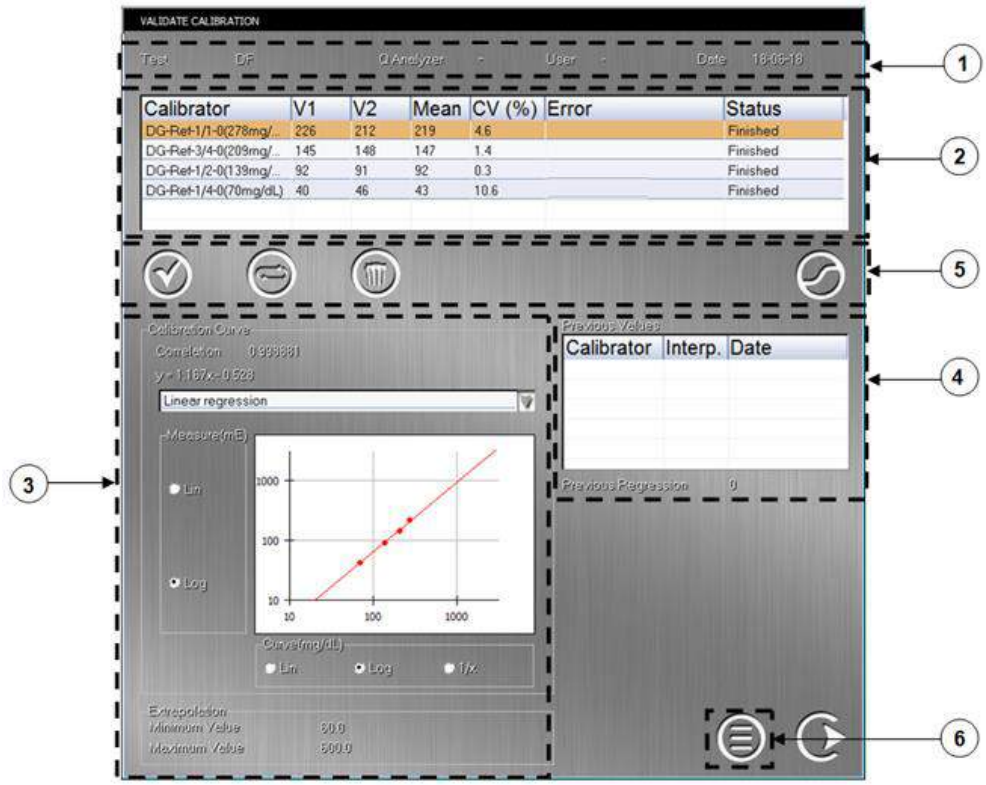


Figure 10.3. Validate Calibration Curve Window

(1) Header: Includes Name of the Test, Analyzer, Operator and Date.

(2) Calibration Curve Values Table.

(3) Calibration Curve Area.

(4) Values Table of previous Calibration Curve.

(5) Action Buttons Area.

(6) Printing of the Calibration Curve Report.

10.1.3.1 Header

This is the part of the **Validate Calibration Curve** window which identifies the Calibration Curve. It contains the following information:

- **Name of the Test** with which the Calibration Curve is associated.

- Q **Analyzer**.
- **Operator** who has validated the calibration.
- **Date** of the calibration.

10.1.3.2 Calibration Curve Values Table

Table with the calibration values obtained for each calibration point. This table contains the following information:

- **Calibrator:** Calibrator or Calibrators and dilutions ID's.
- **V1, V2:** Values of each of the replicates.
- **Mean:** Arithmetical Mean of values.
- **CV (%):** Coefficient of Variation.
- **Error:** Reports the errors associated with the obtainment of a result:
  - **CND:** Clot Not Detected (in clotting tests). The algorithm applied has not been able to detect a clot in the primary curve (see Section 9.2.2.5).
  - **LIN:** Lack of Linearity (in chromogenic tests). The algorithm applied has failed while checking the linearity of the primary curve (see Section 9.2.2.5).
  - **OUT:** At least, one absorbance value of the primary curve is out of the reader's working range (see Section 9.2.2.5).
  - **IND:** Indeterminate result. It is impossible to calculate the result due to lack of data (Calibration Curve, Standard, ISI, etc.) or because the results of a repetition have not been reviewed or because the algorithm applied has not been able to obtain a result due to some incidence (see Section 9.2.2.5).
  - **CV:** The Coefficient of Variation of duplicates (CVd) has exceeded the CV allowed in the Test Programming (Figure 9.6, no. 7 and Figure 9.11, no. 5).
  - **X:** Cancelled test.
- **Status:** Status of the petition for the different calibration points in the Calibration Curve.

10.1.3.3 Calibration Curve Area

Area of the **Validate Calibration Curve** window where the primary data values (time, absorbance or slope) obtained for the different calibration points are plotted on the y-axis and the secondary data values (concentration or activity) on the x-axis.

The default representation of the Calibration Curve is Lin-Lin and on a point-to-point basis, but it is possible to change both, the transformation of the axes and the method of adjustment of the Calibration Curve:

- **Transformation of the axes.** Different mathematical transformations can be applied to the measured results and the calibration points target values to aid in making the Calibration Curve more linear.
  - **Lin:** Linear adjustment.

- **Log:** Logarithmic adjustment.
- **1/x:** Reciprocal representation (available only for the x-axis).

- **Adjustment method.** There is a pull-down menu with 4 adjustment methods available:
  - **Point to point.**

    Linear regression: An adjustment to a regression line is performed. The correlation coefficient (R) and the mathematical equation obtained (y = ax + b) are shown. A minimum of three calibration points are necessary for the system to be able to apply this adjustment method.

    Polynomial 2nd order and **polynomial 3rd order:** These math models are available to improve curve fit. The correlation coefficient (R) and the mathematical equation obtained are shown for both polynomial regression methods ($y = ax^2 + bx + c$ for **2nd order**, and $y = ax^3 + bx^2 + cx + d$ for **3rd order**). A minimum of three calibration points for the **Polynomial 2nd order** and four for the **Polynomial 3rd order** are necessary for the system to be able to apply this adjustment method.
  - **Two Stretch Polynomial 2nd Order.** This adjustment method is available to improve curve fit. In this math model, the curve is adjusted to two polynomial second order equations, following these criteria:
    - If the number of Calibration Points (n) is even, the polynomial adjustment is applied to n/2+1 points for each stretch.
    - If the number of Calibration Points (n) is odd, the polynomial adjustment is applied to n/2+1.5 points for the high stretch and n/2+0.5 points for the low stretch.

    The correlation coefficient (R) and the mathematical equations obtained are shown for both polynomial regressions, with the format: $y = ax^2 + bx + c$. A minimum of four calibration points are necessary for the system to be able to apply this adjustment method.

NOTE: When **Polynomial 2nd** or **3rd order** adjustments are used, in case there is more than one result in secondary unit for a single primary unit value that falls within the measuring range (that is, between the Minimum and Maximum Extrapolation Values programmed), the message "The Calibration Curve interpolation is not valid" will appear when trying to validate the Calibration Curve. This ensures that no wrong result is given.

In this case, the Operator should try to change the adjustment or the transformation of the axes.

NOTE: For the tests validated by GRIFOLS, the appropriate transformation of the axes and the adjustment method are provided in the **Test Characteristics** tab.

10.1.3.4 Values Table of the Previous Calibration Curve

Table of values of the different calibration points obtained in the previously validated Calibration Curve.

10.1.3.5 Action Buttons Area

The window contains some action buttons which allow performing actions on each of the results of the calibration points. The operation of these buttons is described below:

Validate: Allows the validation of each of the points of the Calibration Curve. To validate the entire Calibration Curve, each of the duplicate results of each calibration point must be validated one by one. The full validation of the Calibration Curve is completed by accepting the confirmation window that is shown after pressing the **Exit** button.

Once validated, the program saves the Mean of the values accepted for the different calibration points on the **Calibration Curve** and the results remain in the **Worksheet** until they are filed by the Operator. From this point on, the program will use this Calibration Curve to obtain the results in secondary unit of all samples processed and the results in the **Worksheet** pending revision and, that depend on this curve will be automatically recalculated.

Cancelled: Allows the result selected on the Values Table of the Calibration Points to be cancelled. The cancelled calibration point will not be used to adjust the Calibration Curve.

To validate a Calibration Curve, a minimum of three points is required for point-to-point, linear regression and 2nd order polynomial adjustments and four points for 3rd order polynomial.

Repeat: The button allows the Operator to order a repetition of the selected calibration point. The status of the corresponding box in the **Worksheet** returns to Pending (blue) until the selected calibration point is reprocessed. The action of repeating implies the loss of the values previously obtained.

View: This button gives access to the **Results** window of the calibration point selected. The window allows the Operator to review and view the results and the primary reading curve individually (Figures 13.1, 13.2 and 13.3).

Once the Calibration Curve has been validated and its results have been removed from the **Worksheet**, these are automatically saved in the **Historical Database** and the primary reading chart cannot be recovered anymore.

Exit: This button exits the **Validate Calibration Curve** window, and it is the last step to complete the Validation of a Calibration Curve.

NOTE: If the minimum number of calibration points has been validated, when the **Exit** button is pressed, the program displays a dialogue box which asks for confirmation to validate the Calibration Curve.

If orders of repetition of calibration points are still pending, or if the minimum number of validated calibration points is not available, the program does not display the dialogue box until it has more results.

10.1.3.6 Printing of the Calibration Curve Report

In the **Validate Calibration Curve** window there is a **Print Report** button that allows visualizing and printing a default report of the Calibration Curve.

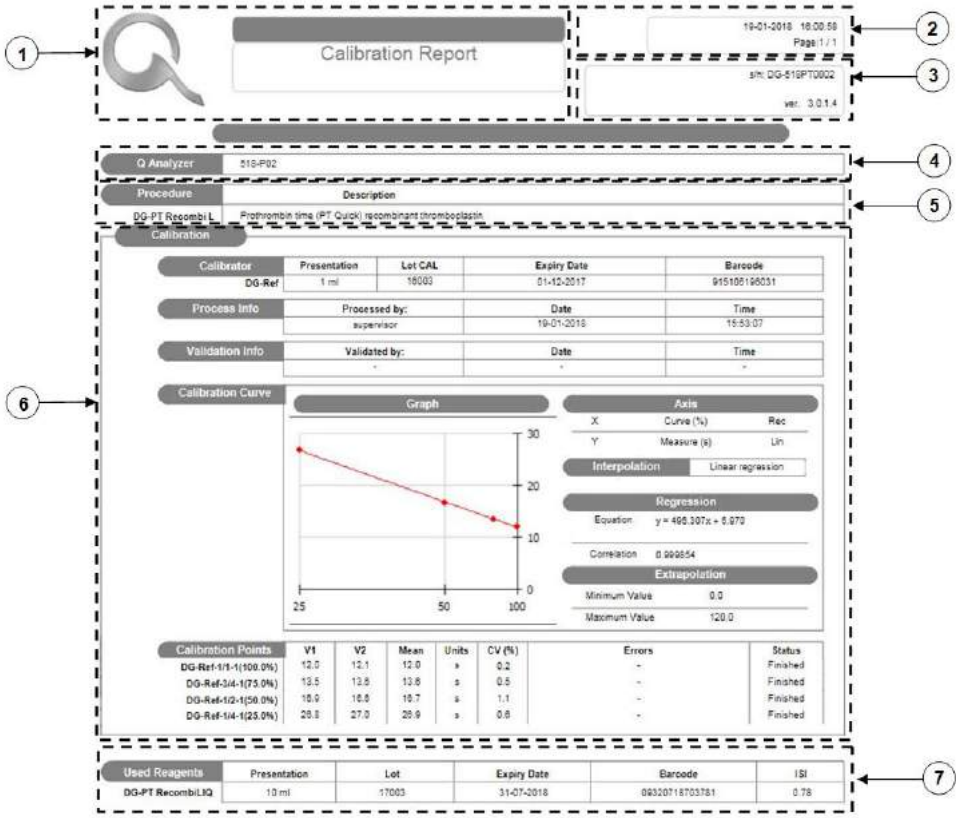


Figure 10.4. Calibration Curve Report

A report with the following information is created:

(1) **Report Title** and **Name of the centre**.

(2) **Printing Date** and **Time** and **Page Number/Total number of pages**.

(3) **Serial Number** and **QManager's Software Version** of the analyzer in which the Calibration Curve has been performed.

(4) Name of the Q **Analyzer** in which the calibration has been run.

(5) **Test** for which the Calibration Curve has been performed.

(6) Information about the **Calibration Curve:**

- Information about the **Calibrator:** Presentation, lot, expiry date and barcode.
- Information on the Calibration Curve **process:** Operator, date and time.
- Information about the Calibration Curve **validation**: Person who has validated the curve, date and time.
- **Calibration Curve:** Graph, axis transformation, adjustment method, mathematical equation and correlation coefficient and minimum and maximum extrapolation values.
- **Calibration points:** Results, errors and status of the calibration points at the moment of printing the report.

(7) **Products used** to run the Calibration Curve.

A **Calibration Curve Report** can be printed regardless of whether it has been validated or not. The only difference is that when the calibration curve has not yet been validated, in the **Calibration Points** section of the report, the value for both replicates and the CVs are shown, whereas once validated only the mean is shown.

10.2 Calculation with Standard (STD)

The second method for calculating results in secondary unit (**ratio**) consists in analysing a **Standard** (population or commercial freeze-dried). A **Standard** is a type of sample used to normalize samples results calculating a **ratio** between the time value obtained for the samples and the time value obtained for the Standard.

NOTE: There is no need of interrupting the analyzer's work routine to run a Standard. The Q**Next** allows Standards to be analysed at the same time than the routine work.

10.2.1 Programming a Standard (STD) on the Worksheet

To process a Standard as a Commercial Product, the Operator must have previously programmed the Standard as a **Product** (see Section 9.1.1.1) as well as all the other products (reagents, diluents and cleaning agents) required to run the test. If processing a Population Standard, there is no need of previously programming it.

Programming the Standard (STD) in the **Worksheet** is performed as described below:

- Keep the finger pressing on the Test Box of the test for which a Standard (STD) is going to be run. The program displays a drop-down menu with different options.
- Select the **Standard (STD)** option.
- The **Enter Standard** window is displayed. Select the following information in this window:
  - Q **Analyzer.**
  - **Standard** used, select either: Population or Commercial Product.
  - If using a **Population Standard**, indicate the **Number** of determinations required to obtain the value of the Standard (STD).
  - However, if using a **Commercial Product**, select the **Standard** ID, the **Lot** and the **Presentation** from the drop-down menus.
- Press **Accept** to confirm the Standard (STD) programming in the **Worksheet**. The orders for analysing the Standard will be automatically updated on the **Worksheet** (Figures 10.5 and 10.6).

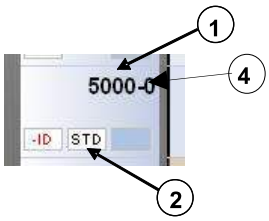


Figure 10.5. Commercial Standard on the Worksheet

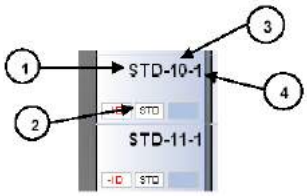


Figure 10.6. Poblational Standard on the Worksheet

(1) User label for the product used as Standard (see Section 9.1.1.1).

(2) STD: Code that the program uses to identify the Standard.

(3) Number of Population Standard orders.

(4) Q_ID: Identification number of the analyzer where the Standard is going to be processed.

NOTE: Standards are always processed per duplicate, regardless of the Test Programming.

WARNING: It is always possible to enter new Standards except for a same test and a same instrument while the results of previous Standards are in the **Worksheet**.

10.2.2 Analysing a Standard (STD)

There are several possibilities to enter Standards:

- In its **original vial** (if it is a **Commercial Standard**) placing it in the **Products Trays** so that it can be automatically identified.
- In the **primary tubes** (if it is a **Population Standard**), which have to be manually identified and placed with no barcode in Q**sample holders**.
- Transfering them to a **tube** or **microtube**, which is manually identified and placed in a Q**sample holder**. If the Standard volume is < 1.5 mL the use of a microtube is recommended, since there is less dead volume.

If the Standard is going to be placed with its **original vial**, the Operator should proceed as follows (see Section 15.4):

- Press the **Open Upper Door** button.
- Place the Standard in a **Products Tray**.
- Gently close the **Upper Door**, pressing down from the top until hearing the click of the clousure.
- If the configuration is correct, press **Accept**.
- Press  to start analysis.

If the Standard is going to be placed in a Q**sample holder** (primary tube or microtube) and be manually identified, the Operator should proceed as follows (see Section 15.6):

- Place the Standard in a Q**sample holder**.
- Press  and select **Standard (STD)**.
- The program indicates the Operator to place the Q**sample holder** in the External Identification Area to be identified (Figure 4.1, no. 7).
- Select the Standard ID from the list displayed and **Accept**.
- Place the Q**sample holder** with the Standard in the Samples Entry Area.
- Press  to start the **Samples Desk** and to start analysis.

10.2.3 Revision of the Results of a Standard

Once the analyzer has processed the Standard per duplicate, touching any of the Results Boxes associated with the Standard (STD) on the **Worksheet** will display the **Validate Standard** window:

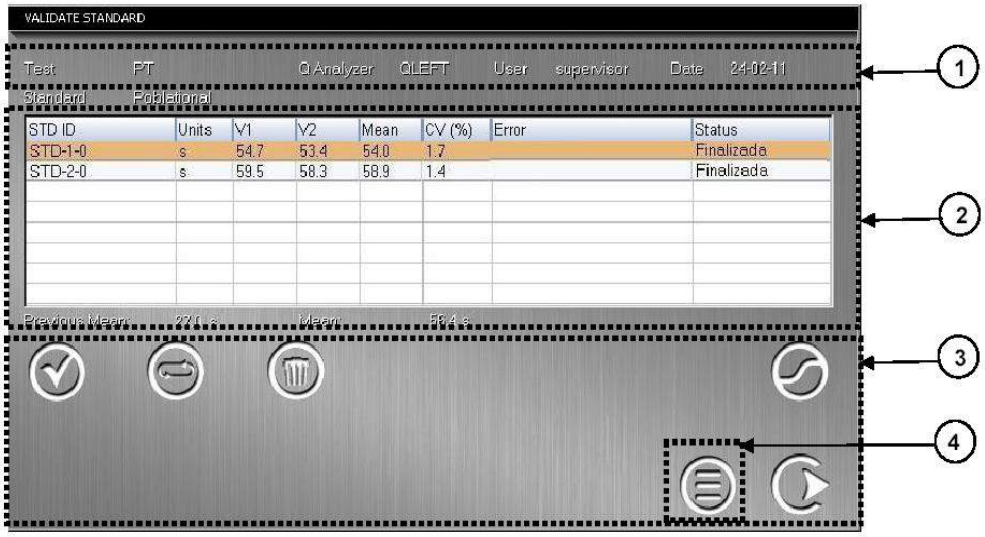


Figure 10.7. Validate Standard Window

(1) Header: Includes the names of the Test, Analyzer, Operator, Date run and Standard type.

(2) Standard Values Table.

(3) Action Buttons Area.

(4) Printing of the Standard Report.

10.2.3.1 Header

This is the part of the **Validate Standard** window which identifies the Standard. For this, it contains information on:

- **Name of the test** with which the Standard is associated.
- Q **Analyzer** that has processed the Standard.
- **Operator** who has validated the Standard.
- **Date** when the Standard was run.
- Standard **type**.

10.2.3.2 Standard Values Table

Table with the values obtained for each analysis of the Standard (Figure 10.7, no. 2). For the unit of measurement selected in the **Worksheet**, the program displays:

- **Standard:** Standard ID and order number.

- **V1, V2:** Values of each of the replicates of the duplicate.
- **Mean:** Geometrical mean of values.
- **Error:** Notifies the errors associated with the obtainment of a result:
  - **CND:** Clot Not Detected (in clotting tests). The algorithm applied has not been able to detect a clot in the primary curve (see Section 9.2.2.5).
  - **LIN:** Lack of Linearity (in chromogenic tests). The algorithm applied has failed while checking the linearity of the primary curve (see Section 9.2.2.5).
  - **OUT:** At least one absorbance value of the primary curve is out of the reader's working range (see Section 9.2.2.5).
  - **IND:** Indeterminate result. It is impossible to calculate the result due to lack of data (Calibration Curve, Standard, ISI, etc.) or because the results of a repetition have not been reviewed or because the algorithm applied has not been able to obtain a result due to some incidences (see Section 9.2.2.5).
  - **CV:** The Coefficient of Variation of duplicates (CVd) has exceeded the CV allowed in the Test Programming (Figure 9.6, no. 7 and Figure 9.11, no. 5).
  - **X:** Cancelled test.
- **Status:** Status of the different orders.

The program also informs about the value of the **previous mean** and the value of the **current mean** of the Standard.

10.2.3.3 Action Buttons Area

To manage the results of the Standard, the window has action buttons which allow the Operator to act on each of the results. The purpose of these buttons is described below:

Validate: Selecting each of the lines for a duplicate analysis, this button allows the Mean of this determination to be validated. To validate the Mean of the Population Standard, each of the duplicate results for this Standard should be validated individually. The full validation of the standard is completed by accepting the confirmation window that is shown after pressing the **Exit** button.

Once validated, the program saves the value of the **current mean** obtained on the basis of the accepted values and the results remain in the **Worksheet** until they are filed by the Operator.

From the moment the Standard has been validated, the program uses the value of the Mean to obtain the analytical results and will automatically recalculate the results in the **Worksheet** which are pending revision.

Cancel: Allows the result selected in the Standard Values Table to be cancelled. The cancelled value will not be used to obtain the value of the Standard.

Repeat: This button allows the selected Standard order to be repeated. The status of the corresponding box in the **Worksheet** turns to Pending (blue) while it waits to be rerun. Repeating it implies the loss of the values previously obtained.

View: The button accesses the **Results** window of the order for the selected Standard. The window allows the Operator to review and view individually the results and the primary reading chart (Figures 13.1, 13.2 and 13.3)**.**

Once the Standard results have been validated and removed from the **Worksheet**, they are automatically filed in the **Historical Database** and the primary reading chart cannot be recovered anymore.

Exit: This button exits the **Validate Standard** window, saving the changes and decisions taken (validate, reject and/or repeat).

NOTE: By pressing the **Exit** button, the program displays a dialogue box asking the Operator to confirm if the value of the Standard wants to be saved as a valid value.

If there are still petitions associated with the Standard pending analysis, the program does not display the dialogue box and waits until more results are available.

10.2.3.4 Printing of the Standard Report

In the **Validate Standard** window there is a **Print Report** button that allows visualizing and printing a default report of the Standard.

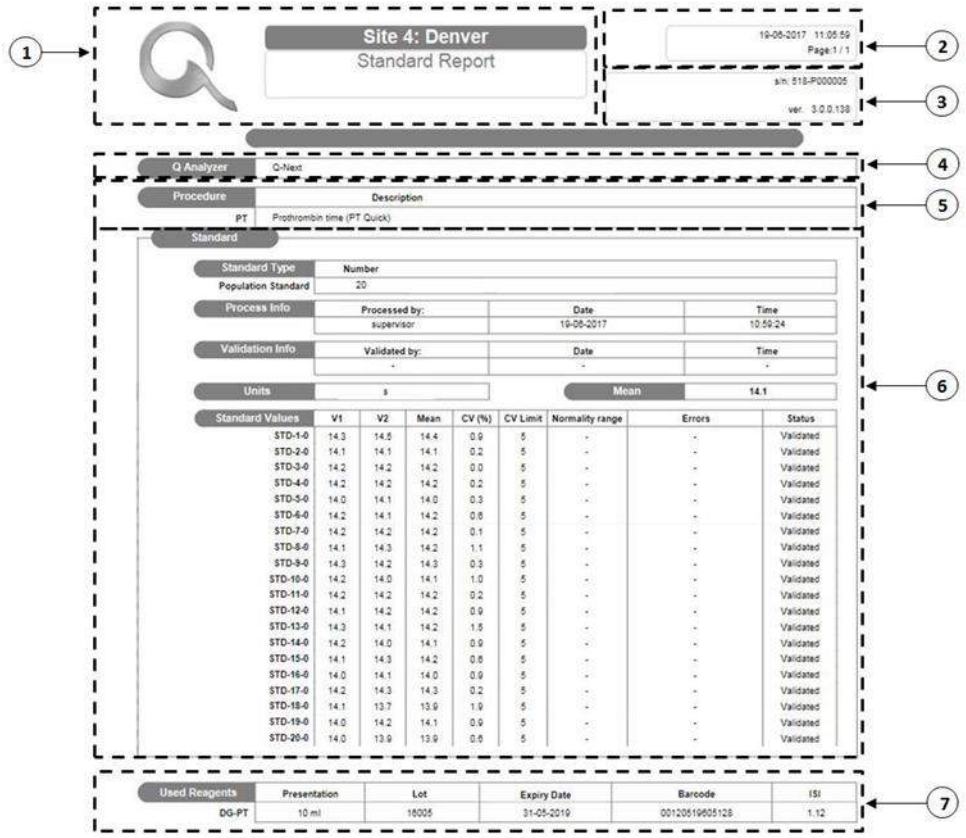


Figure 10.8. Standard Report

A report with the following information is created:

(1) **Report Title** and **Name of the centre**.

(2) **Printing Date** and **Page Number/Total number of pages**.

(3) **Serial Number** and Q**Manager's Software Version** of the analyzer in which the Standard has been run.

(4) Name of the Q **Analyzer** in which the Standard has been run.

(5) Test for which the Standard has been run.

(6) Information about the **Standard:**

- Information about the **Standard Type.**
- Information on the Standard **process:** Operator, date and time.

- Information about the Standard **validation**: Person who has validated the standard, date and time.
- Standard **Mean**.
- **Values Table** for each individual determination.

(7) **Products used** to run the Standard.

A **Standard Report** can be printed regardless of whether it has been validated or not. The only format difference is that in a **Validated Standard Report** the Values Table for each individual determination is not shown.

10.3 Management Calibrations of Tests or Standards

Once the Calibration Curves or the value of the Standards have been validated, the data is stored in a **Database**. The Q**Next** manages the Calibration Curves or the Standards in such a way that they depend simultaneously on: The test, the analyzer and the products lots used.

To access the **Database** with the results of the Calibration Curves or the Standards, select the **Calibrations** option from the  menu of the Q**Manager** window.

The program displays the **Calibrations Management** window, which allows the Operator to select the **Test** whose Calibration Curves and/or Standards will be shown.

The bottom list displays all the **Calibrations and/or Standards** available for the selected test. The curves are identified by the **Lot** number of all the products used in the test, the **Operator** and the **Date** of calibration.

NOTE: If both a Calibration Curve and a Standard are processed for a single test, the results of both are stored in the Calibration Curve file.

10.3.1 Editing/Viewing a Calibration or Standard

If a specific Calibration Curve or Standard is selected and the **Edit** () button on the right of the window is pressed, the program displays the **Edit Calibration** window with all the information on the Calibration Curve and the Standard.

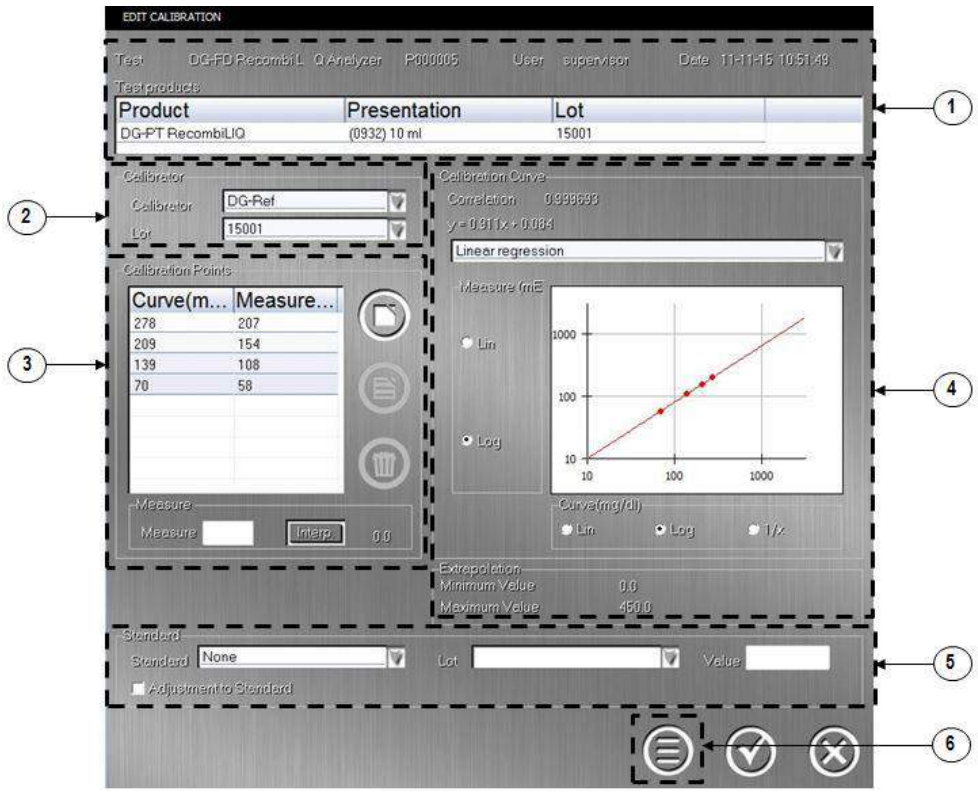


Figure 10.9. Edit Calibrations Window

(1) Information on the **Test:** Includes Names of the **Test, Analyzer**, **Operator**, **Date** and **Products** used in the test.

(2) Information on the **Calibrator:** Includes Name of the **Calibrator** and **Lot**.

(3) Values Table with the **Calibration Points** (secondary unit and primary unit values) and a field for calculating concentrations or activities by interpolation of a primary unit value in the Calibration Curve.

(4) **Calibration Curve** Area: Includes the chart, the transformation of the axes and the method of adjustment with its corresponding equation (if applicable). The **Maximum and Minimum Extrapolation Values** defined in the Test Programming are also shown here (see Figures 9.6, no. 7 and Figure 9.11, no. 5).

(5) **Standard** Information Area**:** Includes the name of the **Standard**, **Lot**, the **Value** of the Standard obtained with the analysis and an **Adjustment Standard** option, which allows automatically adjusting the secondary unit values of all Calibration Points to the Standard value (the Standard value will be considered as the 100% of activity).

(6) **Printing** of the Calibration Curve and Standard Report.

In the **Edit Calibration** window there is a **Print Report** button that allows visualizing and printing a report of the Calibration Curve and the Standard run for the selected test.

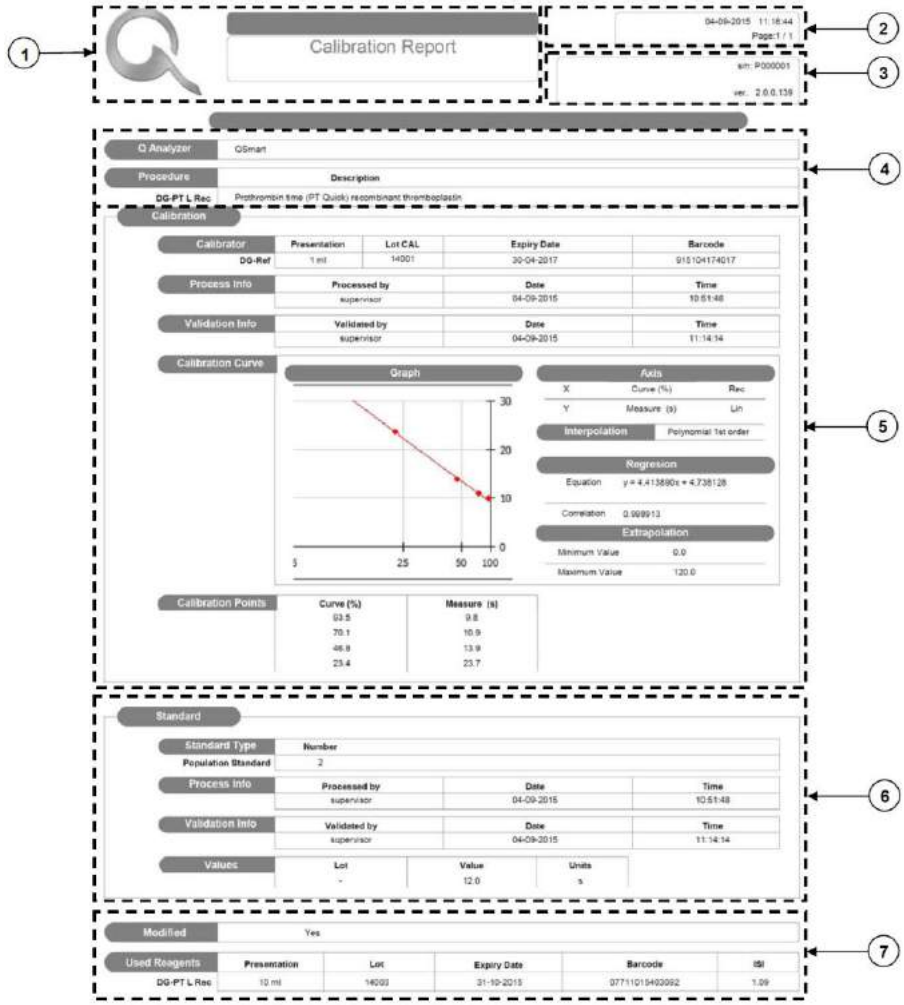


Figure 10.10. Calibration Curve and Standard Report

A report with the following information is created:

(1) **Report Title** and **Name of the centre**.

(2) **Printing Date** and **Page Number/Total number of pages**.

(3) **Serial Number** and Q**Manager's Software Version** of the analyzer in which the Calibration Curve and Standard have been run.

(4) Name of the Q **Analyzer** in which the Calibration Curve and/or Standard has been run for the selected **Test**.

(5) Information about the **Calibration Curve:**
- Information about the **Calibrator.**
- Information on the Calibration Curve **process:** Operator, date and time.
- Information about the Calibration Curve **validation**.
- Information of the **Calibration Curve:** Graph, axes, adjustment method and extrapolation.
- **Calibration points**.

(6) Information about the **Standard:**
- Information about the **Standard.**
- Information on the Standard **process:** Operator, date and time.
- Information about the Standard **validation**.
- Standard **Mean Value**.

(7) Information about the **modification** status and the **products** used.

The values of the Calibration Curve and the Standard can be edited and modified. The action buttons  and  allow the changes made to be saved or cancelled, respectively.

The modified Calibration Curve or Standard is displayed with an asterisk (*) in the list that appears in the **Calibrations Management** window. To maintain traceability of the change made, the program will also tag the secondary analytical results obtained from the interpolation in this curve as manually modified in the results reports.

⚠ **CAUTION:** If the Operator presses **Accept** in the **Edit Calibration** window even if no modifications have been done, the instrument will consider that it has been manually edited and tag it with an asterisk (*).

⚠ **CAUTION:** When a Calibration Curve is modified and accepted as valid, the analyzer automatically recalculates the results in the **Worksheet** associated with this test which are pending revision.

The determinations in process for this test will be directly calculated using this new, validated curve.

To recalculate results of this test which have been reviewed and/or exported, please see Section 10.3.3.

NOTE: In the case of tests (*e.g.* APTT, PT) requiring Standard management to calculate ratios without needing a Calibration Curve, it is also possible to edit or manually enter the value of the Standard without having to enter a Calibration Curve.

10.3.2 Manual Entry of a Calibration Curve

To enter the parameters of a Calibration Curve or a Standard manually, please proceed as described below:

- Select the option **Calibrations** of the menu  from the Q**Manager** window.
- Select the **Test** on the drop-down menu.
- Choose the Q **Analyzer**.
- Press the  button. The **Calibration: Test Products Lots** window appears, with the ID's of all the lots programmed in the **Products** window (see Section 9.1.1).
- Select the **Presentation** and the **Lot** in the respective drop-down menus in the window and press **Accept**. The program displays a window similar to the one in Figure 10.9.
- Enter the parameters and values required as given in the product's Instructions for Use.
- Press **Accept** to save the calibration or value of the Standard. These will be reflected in the **Calibrations** window tagged with a manual modification symbol (*).

10.3.3 Recalculate Results

The **Recalculate Results** () button allows the Operator to recalculate, based on the last Calibration Curve and/or Standard, all the results that are in the **Worksheet** that have already been Reviewed and/or Exported to the LIS. This will cause their status changing to finished. The results in the **Worksheet** that have not yet been reviewed are automatically recalculated.

The secondary analytical results obtained on the basis of a recalculation process due to a manual edition of a Calibration Curve are tagged by the program as having been manually modified (*) in the **Results Report** of a group of samples to maintain the traceability of the change made.

The **Recalculate Results** option can also be selected from the drop-down menu that appears when the finger is kept on the box corresponding to the name of the test or on the corresponding boxes with Results.

CAUTION: The **Recalculate Results** option replaces the results calculated with the previous Calibration Curve and these cannot be recovered.

11 Quality Control

Fundamental principle of QNext **Quality Control** program is to compare the performance of a given test with its expected behaviour under stable conditions.

A **Control (QC)** is a type of sample with an assigned range for one or several tests to be used as **Quality Control** of these tests.

As tools to determine wheter a test is in or out of control, QNext offers two methods that can be used simultaneously:

- **Westgard Rules Method:** It refers to the use of a combination of control rules for the interpretation of Controls (QC) results (see Section 11.3).
- **Control Range Method:** Static **Quality Control** method based on comparing each Control (QC) result with the range supplied by the manufacturer or with the range established by each laboratory through consecutive Control determinations (see Section 11.4).

Moreover, QNext offers the following visualization tools (see Section 11.8):

- **Levey-Jennings Charts:** Graphical method for showing Control results against time or number of sequential runs.
- **Control Statistics:** Histogram of frequencies and a table with the most representative parameters of each Control.

Additionally, QNext allows defining a **Quality Control Policy** that has the following consequences:

- Blocking the execution of a test that is out of control, or even the entire analyzer.
- Interacting with a determined group of samples to allow their revision if the test is under control or cancel them if the test is out of control (see Section 11.2).

11.1 Record of Controls (QC)

Before using a Control (QC) in the QNext, this has to be programmed. To program Controls proceed as described in Section 9.1.1.2.

11.2 Defining a Quality Control Policy

The **Quality Control Policy** of QNext allows blocking the execution of a test in an instrument if a **Control** (QC) result for this test and instrument does not fulfill the established criteria and, consequently, determines that the test is out of control. The performance of this test in this instrument will be unblocked when a Control (QC) that fulfils the established criteria is processed and, consequently, determines that the test is again under control.

This blockage will only occur when **Quality Control Policy** is different from **None**.

Additionally, the **Quality Control Policy** allows the interaction with a determined group of samples to allow their revision if the test is under control or cancel them if the test is out of control. This interaction can be programmed at four different levels:

- **Retrospective:** It allows running samples for a test but it does not allow reviewing and exporting their results until a Control (QC) result that determines that this test is under control is obtained and validated.

  If the Control does not fulfill the established criteria and consequently determines that the test is out of control, its validation would cancel all the samples processed before it until the previous correct Control result.

- **Prospective:** It does not allow running samples and reviewing and exporting their results for a test until a Control (QC) result that determines that the test is under control is obtained and validated.

- **Both:** It does not allow running samples for a test until a Control (QC) result that determines that the test is under control is obtained and validated. Moreover, it will not allow reviewing and exporting their results until a new Control (QC) that determines that the test is under control is obtained and validated.

  If the Control does not fulfill the established criteria and, consequently, determines that the test is out of control, its validation would cancel all the samples processed before it until the previous correct Control result.

- **None:** Any Control (QC) is involved in the revision or cancellation of samples results.

WARNING: The selection of "**None**" **Quality Control Policy** will be under Operator responsibility because it can provoke wrong sample results due to the non compliance of a Control result.

The revision of a sample can only be made if all its results can be reviewed.

To access to the options described above, select **Quality Control Policy** in the menu that appears after selecting **Quality Control (QC)** option from the menu of the Q**Manager**. A window with the four described **Quality Policy** options appears. Choose the desired option according to the **Quality Control Policy** of the laboratory.

If a **Quality Control Policy** has been programmed, when a Control (QC) that has been finished for a test and instrument does not fulfill with the established criteria and, therefore, determines that the test is out of control (indicated as rejected Control), the execution of this test in this instrument is automatically blocked until a Control (QC) that fulfills the established criteria is obtained for this test in this instrument, and therefore determines that the test is under control (indicated as accepted Control).

If the option **Stop** Q**System when QC fails** is activated, when a Control (QC) result that does not fulfill the established criteria (Westgard Rules and/or Control Range) is validated, the analyzer will stop the performance of any new order regardless of the test. In this situation, the system will remain blocked until a correct Control (QC) is validated.

NOTE: The **Quality Control Policy** cannot be modified while there are still Controls pending validation.

11.3 Westgard Rules

Westgard Rules (known also as QC Multi-Rules) refer to the use of a combination of statistical control rules for the interpretation of Control data. Westgard Rules make use of a 1_{2s} rule as a warning to trigger the inspection by two rules that are sensitive to random errors (1_{3s} and R_{4s}) and three other rules that are sensitive to systematic errors (2_{2s}, 4_{1s} and 10_{X}). The objectives are: Reducing the false rejections that occur if 2s limits are used to reject a Control, improving error detection when 3s limits are used with Controls that have exceeded the warning rule and providing guidance for problem-solving by relating the violated control rule to the type of error that would be expected.

To apply the Westgard Rules, an estimated Mean value and a Standard Deviation for each Control level is required. The option **Controls to Start Rules Check** defines the minimum number of Control measurements required to estimate the Mean and the Standard Deviation. At least 20 measurements (default value) should be made on separate days to estimate the Mean and the Standard Deviation correctly.

The Mean and the Standard Deviation are dynamic parameters. This means that every time a new result is obtained, the Mean and the Standard Deviation are recalculated including this last measurement. While this has the advantage that the Mean and the Standard Deviation are always updated with the last 20 measurements (by default), the ability to detect systematic deviations that increase or decrease slowly along a relevant period of time could be slightly impaired. Although in practice this is not a limitation for coagulation applications, the use of additional rules specific to detect systematic errors as for example 10_{X} or 4_{1s} can be used to enhance the detection of these kind of events.

To program the Westgard Rules, access the **Quality Control** option on the  menu of the Q**Manager** window and select the **Westgard Rules** option. The program displays the **Westgard Rules** window shown in Figure 11.1 for programming the statistical rules which will be applied to the Controls results.

NOTE: The Westgard Rules cannot be modified while there are still Controls pending validation.

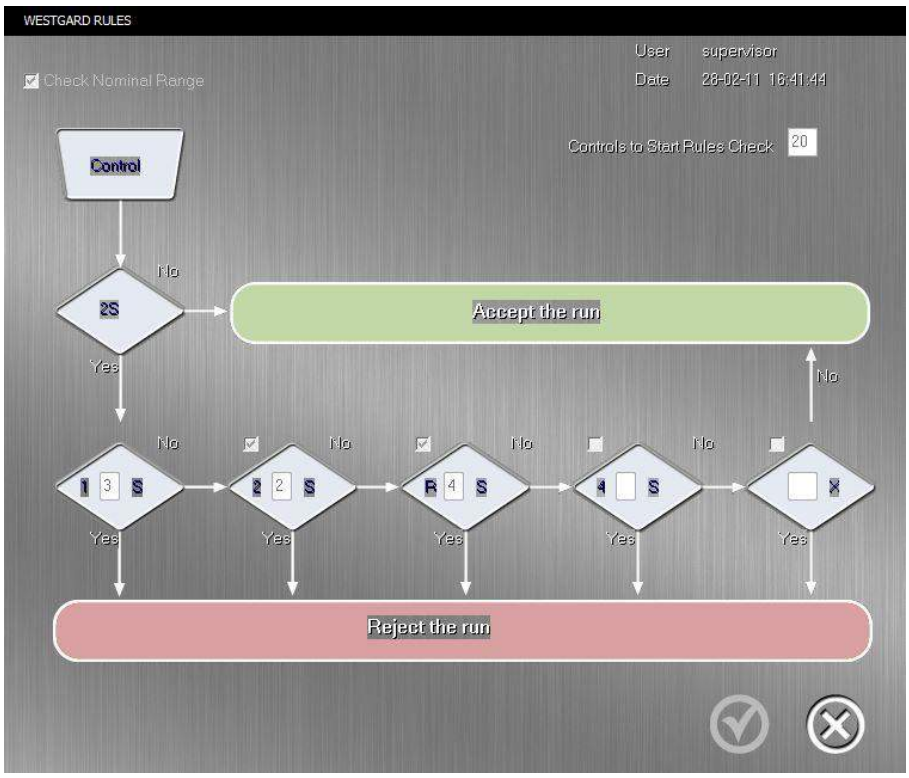


Figure 11.1. Westgard Rules Programming Window

As Figure 11.1 shows, the program allows enabling six different control rules:

- **Rule 1_{2s}:** Refers to the control rule where the Control limits are set as the Mean ± 2s (s: Standard Deviation). This is the warning rule that triggers the inspection by the other rules.
- **Rule 1_{as}:** Refers to the control rule that rejects a run when a single Control measurement exceeds the Mean value in more than "a" times the Standard Deviation "s". Usually "a" should be set to 3. This rule is used to detect random errors.
- **Rule 2_{as}:** Refers to the control rule that rejects a run when two consecutive Control measurements exceed the Mean value in more than "a" times the Standard Deviation "s" in the same direction relative to the Mean. A common value for "a" is 2. This rule is used to detect systematic errors.
- **Rule R_{as}:** Refers to the control rule where a run is rejected when two consecutive Control measurements exceed the Mean value in more than "a/2" times the Standard Deviation (s) in the opposite direction relative to the Mean. A common value for "a" is 4. This rule is used to detect random errors.

Although the following rules are not commonly used in coagulation applications, the Operator has the possibility to enable them.

- **Rule 4_{as}:** Refers to the control rule where a run is rejected when four consecutive Control values are on the same side relative to the Mean and exceed its value in more than "a" times the Standard Deviation. If this rule is used, a common value for "a" is 1. This rule is used to detect systematic errors.
- **Rule ax:** Refers to the control rule where a run is rejected when "a" consecutive measurements fall on the same side relative to the Mean. If this rule is used, common values for "a" are 8, 10 or 12. This rule detects systematic errors.

The last four rules can be enabled separately. It is suggested that at least two decision rules should be enabled, one to detect systematic errors and another to detect random errors. The most typical configuration enables the following rules: **1_{3s} / 2_{2s} / R_{4s} / 4_{1s} / 10x**, which were recommended for clinical chemistry applications in the early 1980s. For coagulation applications recent studies recommend either a single rule like **1_{3s}**, or the rule **1_{3s} / 2_{2s} / R_{4s}**. The latter is the default configuration in Q**Next**.

The Q**Next** applies the control rules to all the measurement units. For example, for PT (Prothrombin Time) test, it is not possible to apply the control rules only to the "seconds" unit and not to the "ratio" or "INR" units.

While no Control **Database** is available with this minimum number of values, the program will use the Control Range Method (see Section 11.4) as the method for decision.

Also, at the top of the **Westgard Rules** window, the system will display the **Operator** and the **Date** on which the last modification of the Westgard Rules was made.

11.4 Control Range Method

The Control Range Method is a system of static **Quality Control** which consists of checking that the value obtained for a specific Control is within the ranges defined by the Control manufacturer or established by each laboratory through consecutive Control determinations, and entered in the Q**Next** program via the **Values Table** of the **Control** record (see Section 9.1.1.2).

The option **Check Nominal Range**, placed on the header of the **Westgard Rules** window, is enabled in the default configuration of Q**Next**.

⚠ **CAUTION:** Each laboratory should define the most appropriate **Quality Control** protocol in each case.

11.5 Ordering a Control (QC)

Controls can be entered in Q**Next** so that they are processed in two different ways:

- Manually, through the **Worksheet**.

- Automatically, through **QC Planning**.

11.5.1 Manual Control (QC) Scheduling

To manually schedule a Control (QC) in the **Worksheet**, please proceed as follows:

- Keep the finger on the box with a sample ID. The program displays a drop-down menu with different options. Select the **Control (QC)** option. A **Control (QC**) **Order** window appears. Here, select the following information:
  - Q **Analyzer** in which the Control is going to be processed.
  - **Control** used, to be selected among the Controls recorded in the analyzer.
  - Control **Lot** to be analyzed.

  When **Accept** button is pressed, a Control (QC) order will automatically be placed in the **Worksheet** (Figure 11.2) for all tests for which the selected Control lot has ranges defined in its **Values Table**.
- Alternatively, keeping the finger pressing on a Test Box will cause the program to display another drop-down menu for selecting the **Control (QC)** option. In the **Control (QC**) **Order** window, select the Q **Analyzer**, the **Control** and the **Lot** as described in the previous point. The program will only show the Control lots that have values entered for this test.

  When **Accept** button is pressed, a Control (QC) order will automatically be placed in the **Worksheet** (Figure 11.2) for this test.

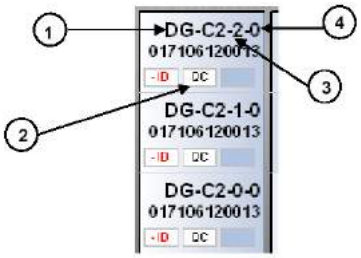


Figure 11.2. Window Displaying Control Order on the Worksheet

(1) User Label for the product used as Control (see Section 9.1.1.2).

(2) Program code to identify the Control (QC).

(3) Control (QC) order number.

(4) Analyzer's identification number where the Control (QC) is going to be processed.

It is possible, at a later stage, to add new tests to the Control (QC) order, providing that the test to be added is defined in the **Values Table** of the Control lot used. To do this, press the corresponding box in the **Worksheet** so that the Control order for that test will be pending.

NOTE: Controls can be run per single or duplicate, depending on the Test Programming.

11.5.2 Automatic Scheduling of a Control (QC)

Q**Next** allows programming Control testing in such a way that they are automatically processed with a determined frequence. The Control (QC) order will automatically appear in the **Worksheet** for each selected test, with the programmed frequence and for the instrument where it has been programmed.

NOTE: If the **QC Policy** is different from **None**, there cannot be two unvalidated Control results for the same Control, Test and Instrument in the **Worksheet**. Therefore, the second Control order will not be automatically placed until the previous one is validated or rejected.

To do so, select **QC Planning** in the **Quality Control** menu. The **QC Planning** window allows setting up different testing frequences for each Control. Proceed as follows:

- Press **New** () in the **QC Planning** window. The program displays the window **New QC Frequency** with the possibility of selecting:
  - The Q **Analyzer** in which the Control is going to be processed.
  - **Control (QC):** List with the available Controls (see Section 9.1.1.2). Select the Control for which a testing frequency wants to be defined. The program allows choosing only among the Controls (QC) that have lots available in the analyzer (see Section 9.1.1.2).
  - **Frequency** with which the Control wants to be run. It is possible to choose between the following options: **Every new Lot of Test Products** and/or **Periodically** (here you can choose between **Number of Tests** or **Number of Minutes**).
  - **Test:** Select the tests for which this Control wants to be processed with the previously programmed frequency. The program allows choosing only among the tests for which the Control (QC) has values entered (see Section 9.1.1.2).
- Press **Accept** and the program will automatically display the programmed frequency in the list of the **QC Planning** window. An informative window will remind the Operator of the need of introducing the Control in the Products Tray so that the programmed Control can be automatically processed.

If, when the analyzer requires the Control, this is not available in the Products Tray, it will cancel the order with the corresponding warning.

- The buttons  and  allow Editing and Deleting the already existing QC Planifications.

11.6 Analysing a Control (QC)

- If the Control is going to be loaded with its original vial in the **Products Tray** so that they can be automatically identified, the Operator should proceed as follows (see Section 15.4):
  - Press the Open Upper Door button.
  - Place the Control in a Products Tray.
  - Gently close the Upper Door, pressing down from the top until hearing the click of the clousure.
  - If the configuration is correct, press Accept.
  - Press  to start analysis.
- If the Control is going to be transferred to a microtube so that the dead volume is lower and this is going to be manually identified and placed in a Q**sample holder**, the Operator should proceed as follows (see Section 15.6):
  - Place the microtube with the Control vial content in a Q**sample holder**.
  - Press  and **Control (QC)**.
  - The program indicates the Operator to place the Q**sample holder** in the External Identification to be identified (Figure 4.1, no. 7).
  - Select the Control ID from the list displayed and **Accept**.
  - Place the Q**sample holder** with the Control tube in the Samples Entry Area.
  - Press  to start the **Samples Desk** and to start analysis.

11.7 Validating the Control

Once the Control has been finished, the result will appear in the corresponding box on the **Worksheet**. The result of a Control is accepted or rejected, on the basis of the **Westgard Rules** (see Section 11.3) or the **Control Range Method** (see Section 11.4).

For more information about the validation of a Control result, see Section 13.3.

When the box corresponding to the result of a Control is pressed, the **Validate QC Result** window opens up.

Figure 11.3. Validate QC Result Window

(1) Results ID Area.

(2) Results Area.

(3) Action Buttons Area.

(4) Levey-Jennings Chart Area.

(5) Button for printing the Control Report.

11.7.1 Result ID Area

The top part of the **Validate QC Result** window (Figure 11.3, no. 1), displays a header with the most relevant data for identifying the result of the Control:

- Control ID.
- Test Name.
- Analyzer ID.
- Operator who is validating the Control.
- Date/Time of the run.
- Status of the order.

11.7.2 Results Area

It contains information on the result itself (**V1**, **V2**, **Mean**, **CV (%), CV Limit, Nominal Range**) and the **post-results Errors** (Westgard Rules, Control Range, CV, etc.).

11.7.3 Action Buttons

The window contains the following action buttons:

Validate: When a Control (QC) is validated, the program allows reviewing the results of the affected tests in accordance with the QC Policy selected in Section 11.2.

When a Control (QC) that has any error (related with Westgard Rules and/or the Control Range) is validated and the option **Stop QSystem when QC fails** is activated, the system will remain blocked until a correct Control (QC) is validated.

When the Operator wishes to remove a Control from the **Worksheet**, the **File Results** button must be pressed and it will be automatically saved in the **QC Database**.

Later, viewing of validated Control results and its evolution will be available under the **QC Graph** option in the **QC Management** window that appears after selecting **Quality Control** option on the **Other Options** () menu of the QManager (see Section 11.8.4).

NOTE: When the result of a Control is validated, the parameters are saved in the **QC Database**.

The calculations of the dynamic Mean and Standard Deviation are performed using the information of this **Database**.

Omit: The result of the Control (QC) will not be taken into account in any of the statistical calculations (dynamic Means and Standard Deviations), Levey-Jennings Mean and application of the Westgard Rules is not fulfilled. However, the Control will still be displayed in the charts.

When a Control is omitted, the program allows the Operator to enter the reason for the omission to facilitate traceability.

Repeat: It orders the repetition of the Control order for this test. The corresponding box in the **Worksheet** turns the status to Pending (blue) while waiting for the Control to be run again and the previous result is deleted.

Chart: The program displays the evolution of the absorbance depending on the time for each result (V1 and V2). An **Incidents Area** also appears with information related with the test execution and with the obtention of results.

11.7.4 Levey-Jennings Chart Area

This area has a Levey-Jennings Chart for the last 50 Control results. It allows the visualization of the Control results with the different units and it also enables to select the information to be shown in the chart for the later printing.

11.7.5 Printing of the Control Report

In the **Validate Control** window, there is a **Print Report** button  that enables the visualization and printing of a default Control (QC) Report for each test.

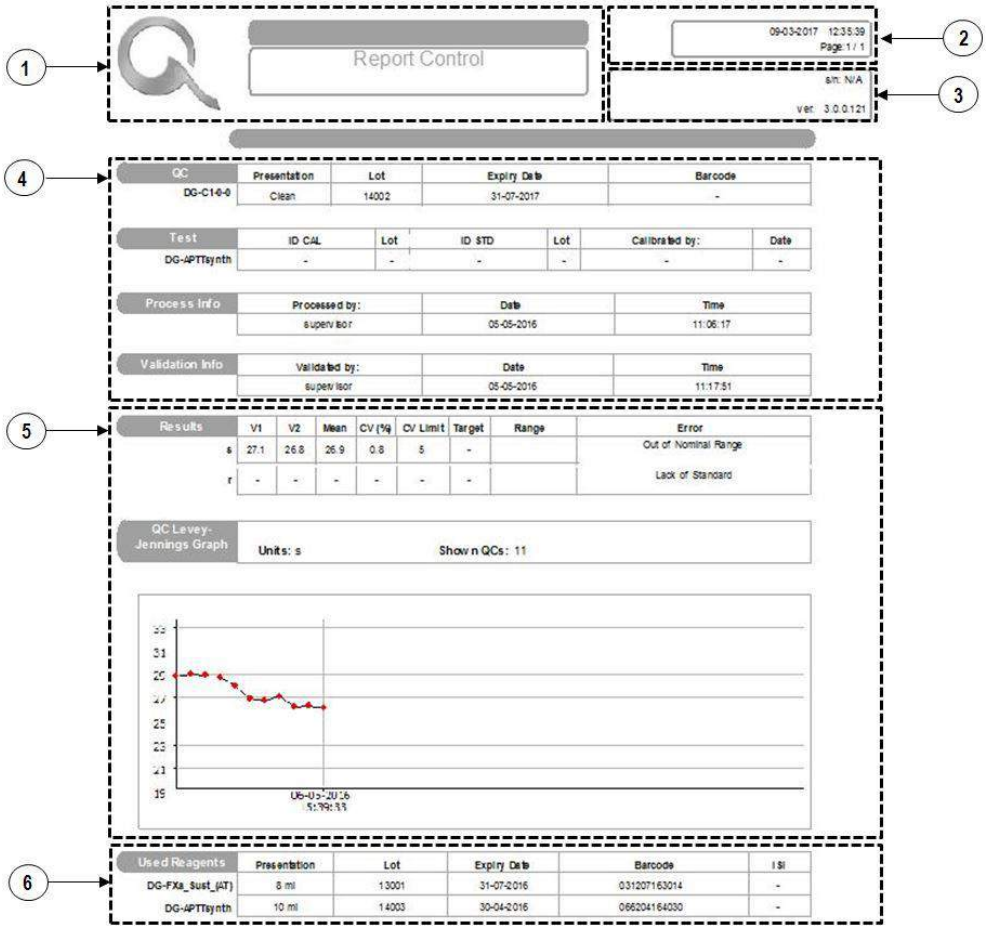


Figure 11.4. Control Report

A report with the following information is created:

(1) **Report Title** and **Name of the centre**.

(2) **Printing Date** and **Page Number/Total number of pages**.

(3) **Serial Number** of the analyzer in which the control has been processed, and **QManager's Software Version**.

(4) Information about the **Control order** that has been run:

- Information about the **Control**.
- Information about the **test** applied to the Control.
- Information about the **process:** Operator, date and time.

- Information about the **validation** of the Control order.

(5) Information about the **results** of the Control order:

- **Results** obtained in the selected unit.
- Information about the **number of Controls** obtained in the Levey-Jennings Chart.
- **Levey-Jennings Chart** of the **Control** results.

(6) **Products Used** to run the Control order.

11.8 Levey-Jennings Charts

To facilitate the analysis of the values obtained for a specific Control over time, the **QC** module of the program creates charts to analyse drift, cycles and other patterns that may indicate quality problems.

The Levey-Jennings Chart is built as a graphic representation of the validated results of a given Control processed for a given test in a given instrument on x and y axes that contain the Mean and the Standard Deviation on the y-axis. The analyses are presented sequentially along the x-axis.

To view the QC Reports, select **QC Graph** in the **QC Management** window that appears after selecting **Quality Control** option on the **Other Options** () menu of the Q**Manager**. The program displays the window shown in Figure 11.5.

The window gives access to two viewing tools:

- Levey-Jennings Graph.
- Control statistics.

However, first of all it is necessary to define the study conditions: The Analyzer, the Control (QC) ID and the period of time to be studied must be selected from the **Database**.

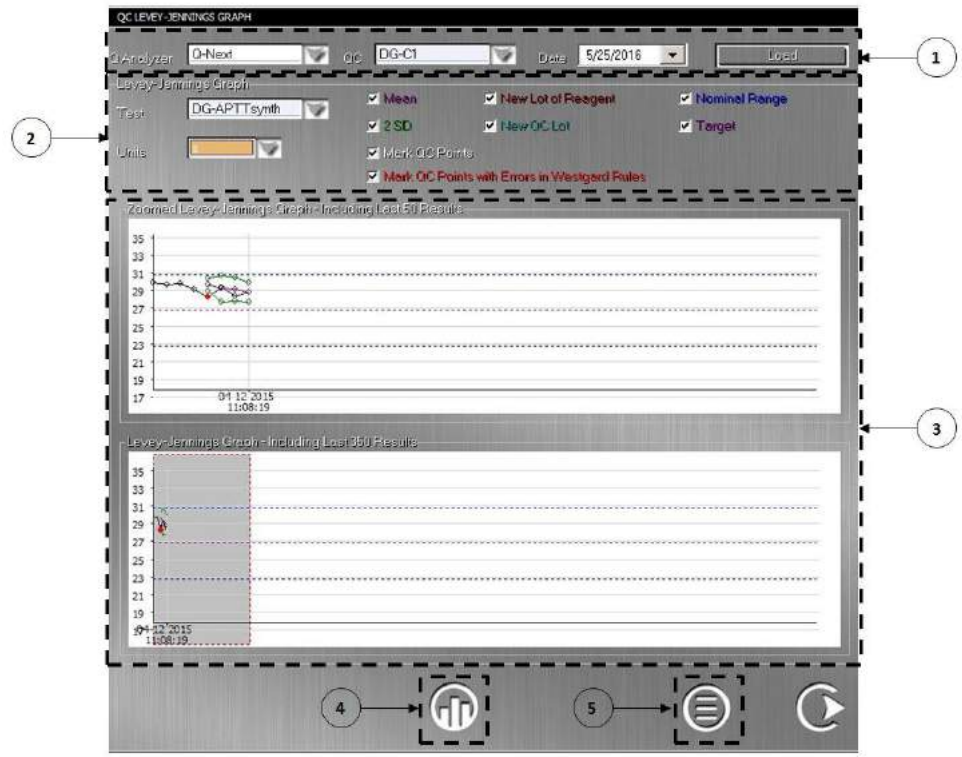


Figure 11.5. Levey-Jennings Charts Window

(1) Selection of the range for study.

(2) Levey-Jennings Chart Settings Area.

(3) Levey-Jennings Charts.

(4) Access button to Control statistics.

(5) Printing of the Quality Control Historic Report.

11.8.1 Selecting a Range for Study

In the area for selecting a range for study (Figure 11.5, no. 1) select:

- Q **Analyzer:** Allows selecting the analyzer in which the Control that wants to be checked has been processed.
- **QC:** Drop-down menu with Control names. Select the Control (QC) to be studied.
- **Date:** Allows selecting the interval of data to be searched for the selected Control (QC) (up to the entered date).

After selecting the range press “Load” to obtain the data from the **Historical Database**.

11.8.2 Settings Area of the Levey-Jennings Chart

The drop-down menus in the Chart Configuration Area (Figure 11.5, no. 2) allow the Operator to select the **Test** and the **Units** (of concentration, activity or time) that want to be studied.

The program also provides the option of Enabling/Disabling various options for representing the chart, such as displaying:

- The dynamic Mean.
- The dynamic Standard Deviation.
- The different analyses of the Control as points.
- Changes of Products lot.
- Changes of Control (QC) lot.
- Control (QC) with errors in the Westgard Rules.
- Nominal Range.
- Target (assigned value).

11.8.3 Levey-Jennings Charts

The program then displays two Levey-Jennings Chart Areas for the selected configuration. The top chart contains information on the last 50 Control (QC) analyses for this test.

The lower chart extends the representation to 350 runs.

When a point on the Levey-Jennings Chart is selected, the program presents the **QC Information** window, with the following information:

- Product and Control (QC) lots involved.
- The results of the **Control** (QC) and the result of applying the Westgard Rules and the Control Range.

This window also allows the Operator to **Omit** a Control so that this is ignored at the Levey-Jennings Chart level. Despite this omission does not involve a recalculation of the Control results already validated, it does affect the new samples orders or those pending revision, since this Control will be omitted when the QC Policy is applied.

11.8.4 Control Statistics

When the button for accessing the **Control Statistics** () is pressed, the program recovers the statistical data for this Control for a specific period of time, up to a maximum of 350 values.

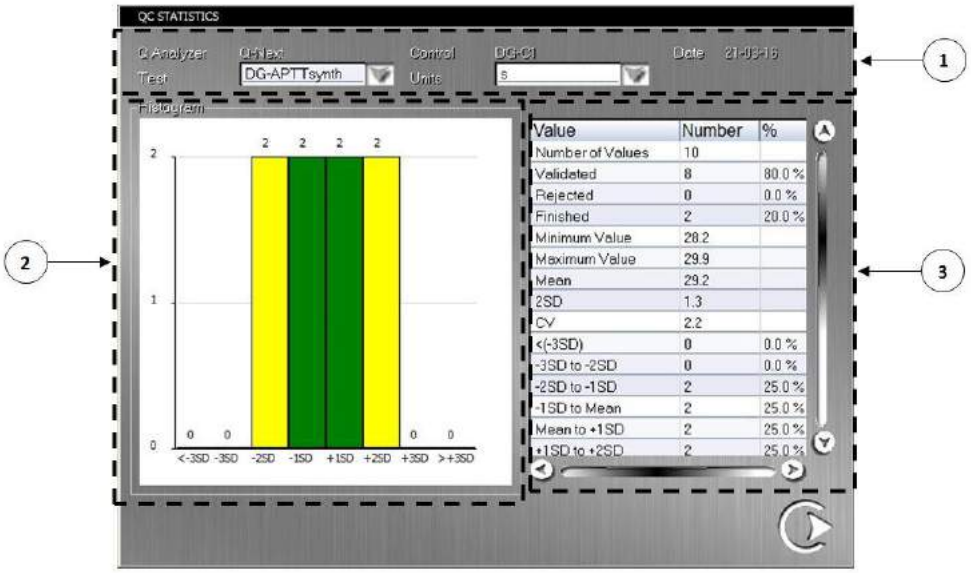


Figure 11.6. Control Statistics Window

(1) Area for identifying the Control and selecting the Test and the Units to be statistically analysed.

(2) Chart Area.

(3) Statistical table of results.

Figure 11.6 shows the **Control Statistics** window which includes a histogram (Figure 11.6, no. 2) showing the number of Controls classified according to whether the distance between the result and the Mean is +/- 1, 2, 3 Standard Deviations (SD).

It also includes a table (Figure 11.6, no. 3) with extended statistical information, such as:

- No. of values in each range.
- No. of results and % of the Control (QC) classified by status (validated, rejected and finished).
- Minimum Value.
- Maximum Value.
- The Mean.
- The Standard Deviation (SD).
- The Coefficient of Variation (CV).

11.8.5 Printing of the Quality Control Historic Report

In the **QC Levey-Jennings Graphs** window, there is a **Print Report** button that allows visualizing and printing a default report with the information of the **Quality Control** historic data.

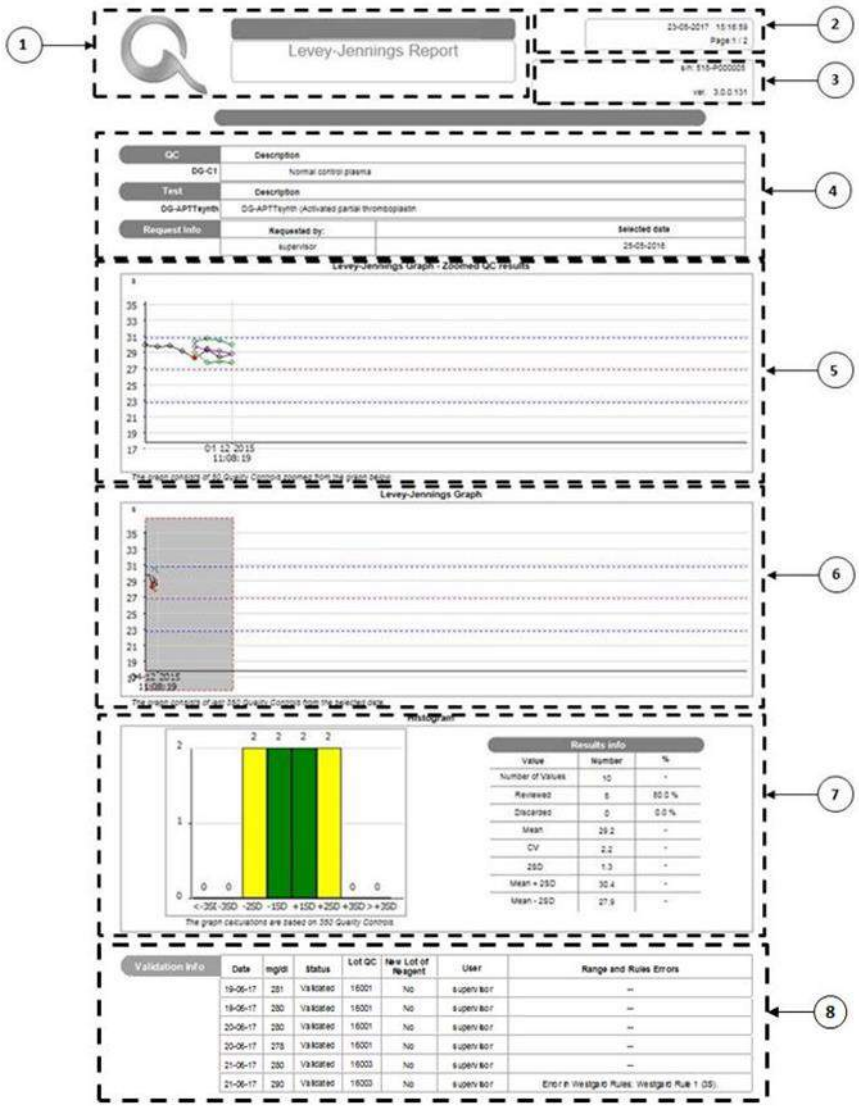


Figure 11.7. Quality Control Historic Report

A report with the following information is created:

(1) **Report Title** and **Name of the centre**.

(2) **Printing Date** and **Page Number/Total number of pages**.

(3) **Serial Number** of the analyzer in which the Control has been processed, and Q**Manager's Software Version**.

(4) Information selected to create the report:

- Selected **Control**.
- **Test** for which the values of the Control are selected.
- Information about the **Operator** and the **Date** in which the report is requested.

(5) Graphic with the enlargement of **50 Control values:** It shows the 50 values contained in the zoom.

(6) Graphic with **all the Control values:** It shows the last 350 Control values from the selected date.

(7) **Histogram** with the statistic information of all the Control values: Number of values in the graphic 6, number of checked and/or discarded values, mean, CV and SD from the values and range of normality of the Control (Mean +2SD, Mean -2SD).

(8) List of validated and rejected QC results.

11.9 Deleting QC Data

This option will be used when deleting all the existing QC data is required, for example because the instrument is changed or transferred and the historical data obtained until the moment is no longer necessary.

The **Delete QC Data** option, which appears in the **Setup** option of the **Other Options** ( ) menu of the Q**Manager** (Figure 9.39, no. 5) allows to begin again the collection of data to which the statistical rules will be applied. It is necessary to restart the analyzer to complete the deletion process.

CAUTION: When the **Delete QC Data** option is used, all the **Quality Control** data obtained until the date will be lost.

12 Analysing Samples

The whole process of analysing a sample comprises two steps: The assignment of a test/s order/s to the sample, and the identification and placement of the sample inside the Q**Next** in order to run its order/s.

The Operator will perform different actions depending on the samples identification (automatic or manual) and the way of placing orders (see Section 15.6).

12.1 Analysing Samples with Positive Identification

12.1.1 Ordering Samples with Positive Identification

For those samples with **Positive Identification** (BC labelled), Q**Next** provides several options to assign them orders:

Positive Samples Identification and Connection to the Host

The Q**Next** must be connected to a Host or Laboratory Information System (LIS). There are two ways of working:

- **By batch:** The analyzer will communicate with the LIS and acquire the entire workload pending analysis when the Operator asks for this.
  - Press the **Setup** button on the **Other Options** menu in the Q**Manager** window and check that the **LIS Exporting** option is enabled.
  - Press **Import Orders** button: The program will acquire the entire workload pending analysis and upload the samples identifications and tests orders in the **Worksheet**.
- **By sample:** The analyzer communicates with the LIS in real time to acquire the pending workload sample by sample as they are being identified.
  - Press the **Setup** button on the **Other Options** menu in the Q**Manager** window and check that the **LIS Exporting** and **Real-time Communication** options are enabled.
  - The **Worksheet** will be automatically updated with the samples identifications and tests orders as the analyzer identifies the samples.

Positive Samples Identification and Default Profile

When sample identification is positive through barcode reading and the order of tests is automatic because the analyzer has a **Default Profile** programmed (see Section 9.3.4), the **Worksheet** will be updated as the analyzer automatically identifies the sample.

12.1.2 Analysing Samples with Positive Identification

To run samples with positive identification, the Operator should proceed as follows:

- Place the sample tubes in the Q**sample holders**.
- Place the Q**sample holders** with the samples in the Samples Entry Area.

- Press  to activate the Samples Desk and start analysis.

12.2 Analysing Samples with Manual Identification

12.2.1 Ordering Samples with Manual Identification

For those samples with **Manual Identification** (not BC labelled), Q**Next** provides the following options to assign them orders:

Manual Samples Identification and Default Profile

When samples identification is manual and the order of tests is automatic because the analyzer has a **Default Profile** programmed (see Section 9.3.4), the orders in the **Worksheet** will be created once the Operator finishes loading the samples with manual identification as described in Section 15.6.2.3.

Manual Samples Identification and Manual Tests Orders

Proceed as described below:

- Press the **New Sample** button in the Q**Manager** window. The program displays a dialogue box where the Operator must enter the **Sample ID**. Optionally, the Operator can also enter the **Patient** and **Ward** ID's.
- Enter the tests orders for the samples. To do so, the following options can be used:
  - To order a single test to a sample, touch the empty Results Box where the test intersects with the ID of the corresponding sample.
  - To order a test to all the samples, use the **Order Tests** option from the drop-down menu that the program displays when the box for that test is pressed (see Section 8.3.1).
  - To order all the tests to a sample, use the **Order Tests** option from the drop-down menu that the program displays when the Sample Box is pressed (see Section 8.3.2).
  - To place several correlative orders (several tests to a sample, one test to several samples or several tests to several samples), touch and drag the corresponding empty Results Boxes and then keep the finger pressed on the selection for a few seconds. This makes the program to display a drop-down menu with the following options: **Order Tests**, **Clear Orders**, **Uncancel Orders**, **Recalculate Results** and **Repeat Tests**.

12.2.2 Analysing Samples with Manual Identification

To run samples with manual identification, the Operator should proceed as follows:

- Place the sample tubes in the Q**sample holders**.
- Press the **Insert** Q**sample holder** button () and select the **Sample** option.

- The program will indicate the Operator to place the Q**sample holder** on the External Identification Area (Figure 4.1, no. 7) so that the Q**sample holder** ID is read. Then, when the sample ID is introduced, an association is made between the Q**sample holder** ID and the sample ID.
- If working with a Default Profile, introduce the Sample ID per duplicate in this moment in the **Introduce Sample** window (Figure 15.2, no. 1). If the order has been manually placed in the Q**Manager** window, select the corresponding sample ID from the list of **Samples** (Figure 15.2, no. 3).

  The configuration of the analyzer with regards to the **Cap Piercing** option can be modified in this window for this sample if so desired (Figure 15.2, no. 2).
- Place the Q**sample holders** with the samples in the Samples Entry Area.
- Press  to activate the Samples Desk and start analysis.

13 Results

DANGER: The results obtained by the Q**Next** should first be reviewed by the Supervisor and then interpreted and validated by medical staff.

The revision of a result in the Q**Next** does not make it clinically valid, because it must be interpreted together with the patient's medical history and other laboratory tests.

Once a petition has concluded, the Results Box (Figure 8.5) displays the final result of the test: The Mean value of the duplicates, if any, for the measurement unit chosen and the Mean value of the corrected results for a test with parallelism (see Section 8.3.3).

For a detailed analysis of the results, press on the corresponding Results Box. In this case, the program will open the **Results** window (see Figures 13.1, 13.2, 13.3 and 13.5 for some examples of **Results** windows depending on the kind of Test).

13.1 Results of a Test

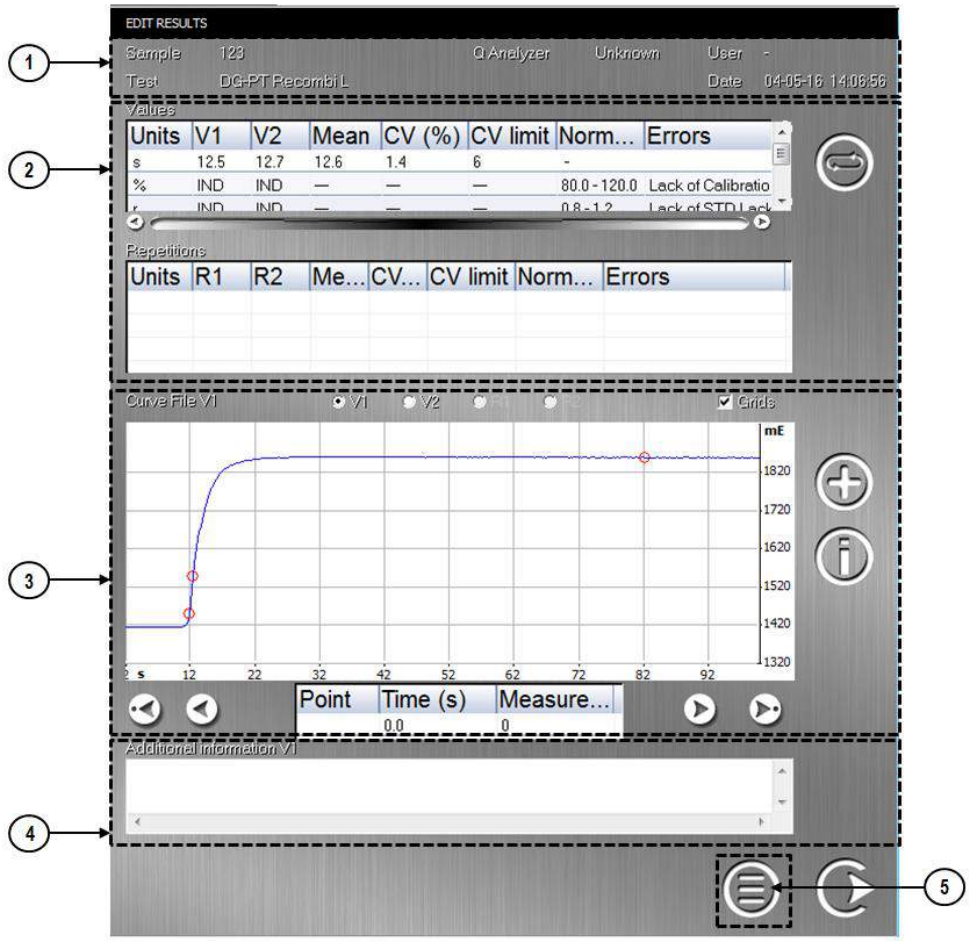


Figure 13.1. Results Window for Coagulation Tests

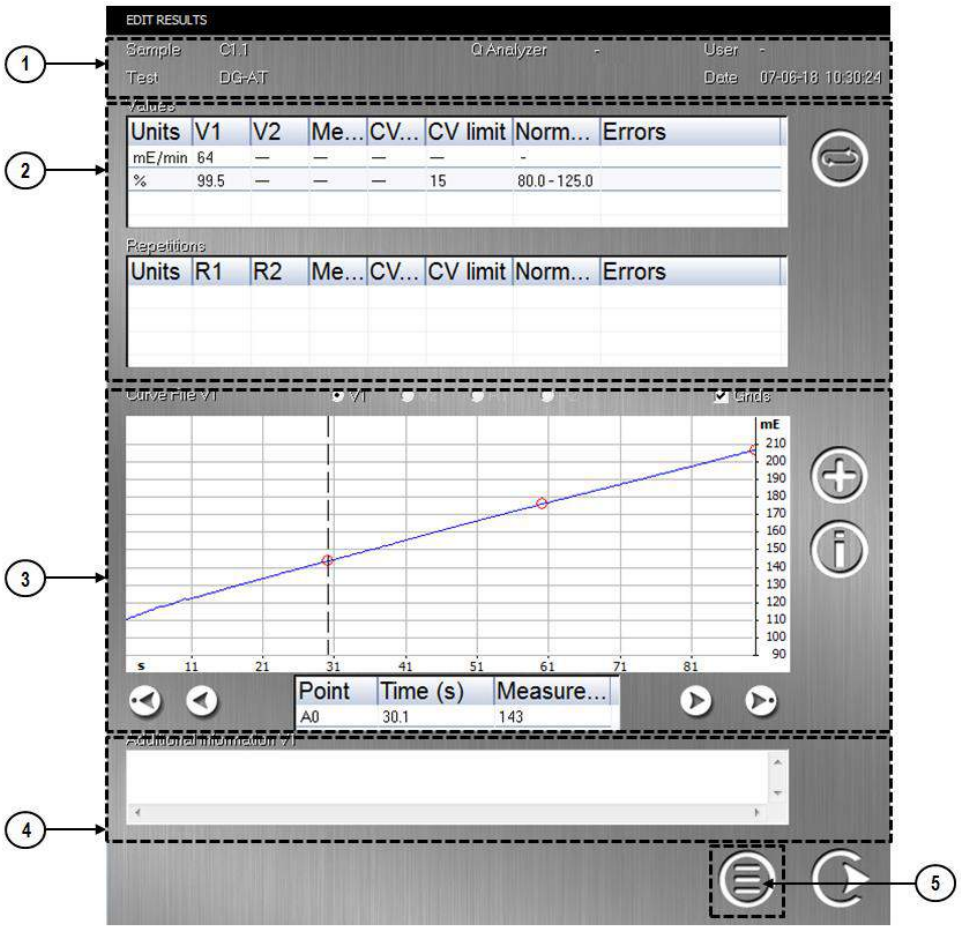


Figure 13.2. Results Window for Chromogenic Tests

NOTE: No chromogenic GRIFOLS hemostasis assay is currently available on the US market.

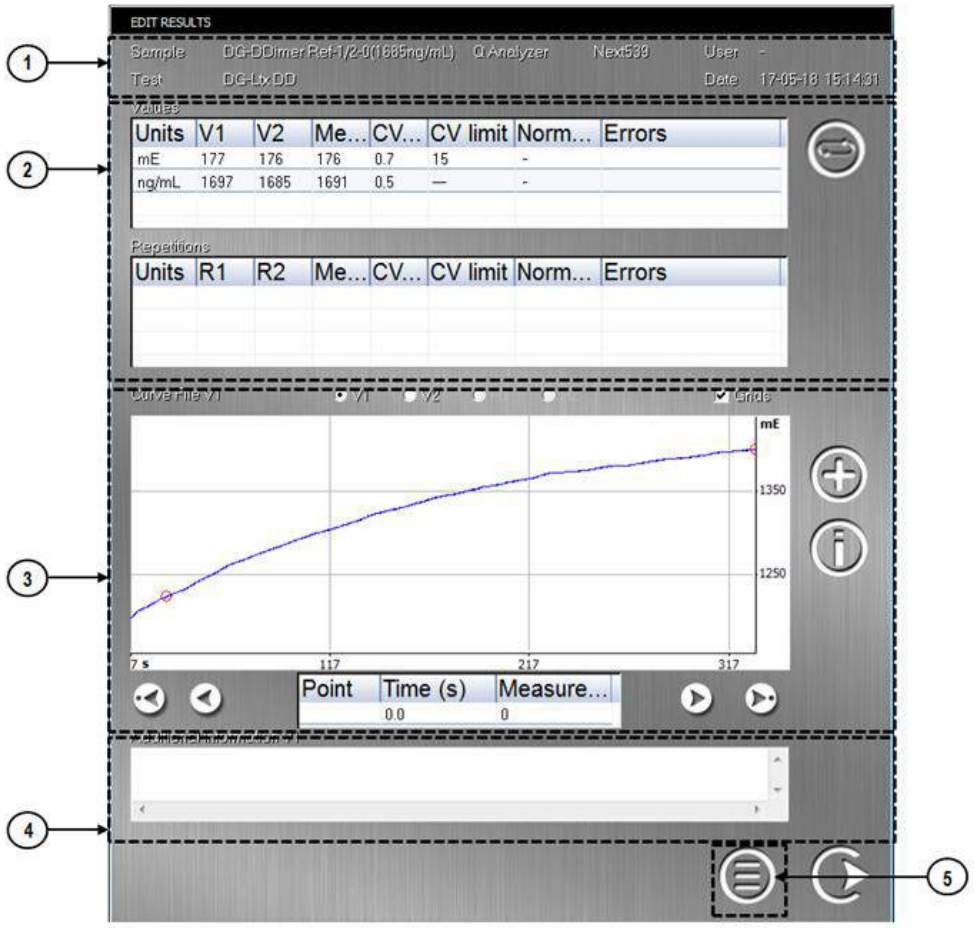


Figure 13.3. Results Window for Immunoturbidimetric Tests

NOTE: No immunoturbidimetric GRIFOLS hemostasis assay is currently available on the US market.

(1) Result ID Area.

(2) Results Area.

(3) Primary Reading Curve Area.

(4) Incidents Area.

(5) Button for printing the Results Report of a Sample.

13.1.1 Result's Identification Area

The top part of the **Results** window (Figures 13.1, 13.2 and 13.3, no. 1), displays a header with the most relevant data for identifying the result:

- Sample ID.
- Test name.
- Analyzer ID.
- Operator.
- Date and Time.

13.1.2 Results Area

The Results Area (Figures 13.1, 13.2 and 13.3, no. 2) comprises two tables. The top table contains information on the result (simple or duplicate) and the bottom one includes the same information for a manual repetition of the test. In both and for each unit of measurement defined during Test Programming (Figure 9.6, no. 6; Figure 9.11, no. 4 and Figure 9.13, no. 3), the table displays:

- **V1, V2:** Individual values for each of the replicates.
- **Mean:** Arithmetical Mean of the values.
- **CV (%):** Coefficient of Variation.
- The CV permitted in the test (**CV limit**), which is defined when the test is programmed.
- The **Normality Range**, which is defined when the test is programmed.
- **Errors:** Reports the errors associated with the obtainment of a result:
  - **CND:** Clot Not Detected. Possible result in clotting tests.
  - **LIN:** This indicates a linearity error in the measurement of a chromogenic test.
  - **OUT:** Indicates that, at least, one absorbance value is outside the working range of the reader.
  - **IND:** Indeterminate result. It is impossible to calculate due to a lack of data (Calibration Curve, Standard, ISI, etc.) or because the results of a repetition have not been reviewed.
  - **CV:** This indicates that Coefficient of Variation of duplicates has exceeded the Coefficient of Variation allowed in the Test Programming (Figure 9.6, no. 7 and Figure 9.11, no. 5).
  - **X:** Cancelled test.

This area also has the following action buttons:

Repeat: It orders the repetition of the test order per duplicate. The status of the corresponding box on the **Worksheet** returns to Pending (blue).

Accept Repetition: This button only appears when there is a repetition and it is located on the right-hand side of the **Repetitions Results** table. The button allows the Operator to confirm the results obtained from the repetition of the test and to cancel the results previously obtained.

Cancel Repetition: This button only appears when there is a repetition and it is located on the right-hand side of the **Repetitions Results** table. The button rejects the results obtained from the repetition of the test and keeps the previous results in the **Worksheet**.

13.1.3 Primary Reading Curve Area

The Reading Curve Area (Figures 13.1, 13.2 and 13.3, no. 3) shows the evolution of absorbance based on the time for each result (V1 and V2) and on the repetitions (R1 and R2), if any. The **Grids** option allows showing or hiding the division lines of the graphic.

At the bottom, the window displays a table giving the time and absorbance values for the most representative points according to the calculation algorithm used during Test Programming (see Section 9.2.1.1).

NOTE: Dragging the finger across an area of the chart increases the size of that area (zoom).

The area also contains the following action buttons:

Recover: It recovers the viewing adjustments of the original curve after zooming in.

Technical information: It opens a window with information on the result to aid traceability; name of the text file of the reading curve, date and time at which the sample was aspirated and the petition processed, position occupied by the Q**cell** in the incubator, Reading Time, wavelength, Calibration Curve, associated policy on quality and the number of the reader which has performed the reading. The products lots involved in the analysis are also displayed.

The **Scroll** buttons ( , ), located at the bottom, move the cursor through the most signification points of the chart, depending on the selected reading algorithm and the test (maximum speed, end points of the two slopes, etc.), moving through them. The ( , ) buttons allow the Operator to scroll over the entire chart.

The numerical value of the points displayed on the chart is updated in the table beneath the Reading Chart Area.

13.1.4 Incidents Area

The **Incidents Area** (Figures 13.1, 13.2 and 13.3, no. 4) displays information about all incidents and warnings arisen during the performance of the test or the interpretation of the primary reading curve (over-incubation, anomalous behaviour in the primary reading curve, etc.) that could have affected the result.

When there is additional information in this area, this is indicated to the Operator by means of a blue dot in the Results Box (Figure 8.5, no. 2).

The **Exit** button closes the **Results** window.

13.1.5 Printing of the Results Report of a Sample

In the **Results** window for Coagulative/Chromogenic/Immunoturbidimetric Tests there is a **Print Report** button that allows visualizing and printing a report of the Results of a Sample.

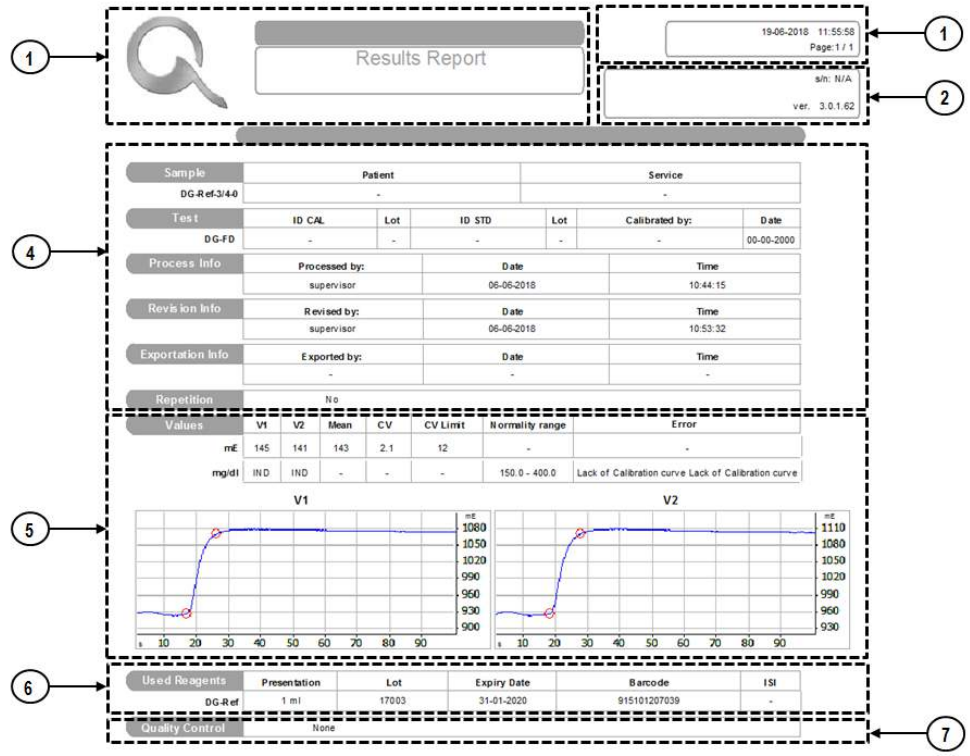


Figure 13.4. Report of the Results of a Sample

A report with the following information is created:

(1) **Title of the Report** and **Name of the centre**.

(2) **Printing Date** and **Time** and **Page Number/Total number of pages**.

(3) **Serial Number** of the analyzer in which the sample has been processed, and Q**Manager's Software Version**.

(4) Information about the **sample's order:**

- Information about the **sample.**
- Information about the **test** applied to the sample.
- Information about the **Operator** and the **date** in which the order has been made.
- Information about the **revision** of the sample's order.
- Information about the **exportation** of the sample's order.
- Informations about the **repetition** of the sample's order.

(5) Information about the **results** of the sample's order:
   - Obtained **Results** with all the units.
   - **Reading graph** obtained for each duplicate.

(6) **Products used** to run the sample's order.

(7) **Quality Control Policy** applied to the sample's order.

The report can be printed, by pressing the **Print** button (), in paper if a printer is installed or in **.xps** format.

13.2 Results of a Test with Parallelism

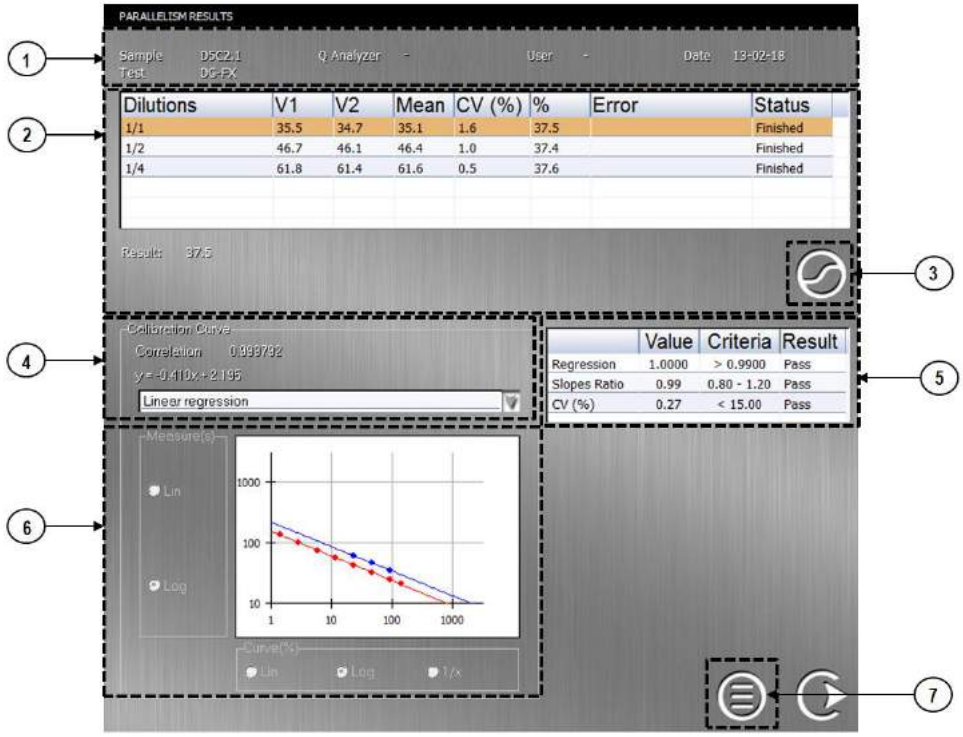


Figure 13.5. Results Window for a Test with Parallelism

NOTE: There is no GRIFOLS hemostasis assay, currently available on the US market, validated with the **Parallelism** option enabled.

(1) Results ID Area.

(2) Results Area.

(3) Button for viewing the Results window of each Dilution Point.

(4) Calibration Curve Area.

(5) Parallelism Results Acceptance Criteria.

(6) Parallelism Graph.

(7) Button for printing the Parallelism Sample's Results Report.

13.2.1 Results Identification Area

The top part of the **Parallelism Results** window (Figure 13.5, no. 1), displays a header with the most relevant data for identifying the sample's result:

- Sample ID.
- Test name.
- Analyzer ID.
- Operator.
- Date and Time.

13.2.2 Results Area

The Results Area (Figure 13.5, no. 2) comprises a **table** that contains information on the results and below it, there is the **final result** (Mean of all dilution points in secondary unit, each corrected by the corresponding dilution factor).

For each **Dilution Point** defined during Test Programming, the **table** displays:

- **V1, V2:** Individual values for each of the replicates.
- **Mean:** Arithmetical Mean of the primary unit values.
- **CV (%):** Coefficient of Variation.
- **%:** Mean of the replicates in secondary unit and corrected by their dilution factor.
- **Error:** Reports the errors associated with the obtainment of a result:
  - **CND:** Clot Not Detected. Possible result in clotting tests.
  - **LIN:** This indicates a linearity error in the measurement of a chromogenic test.
  - **OUT:** Indicates that the absorbance value is outside the working range of the reader.
  - **IND:** Indeterminate result. It is impossible to calculate due to a lack of data (Calibration Curve, Standard or ISI) or because there is an anomalous behaviour in the primary reading curve.
  - **CV:** This indicates that Coefficient of Variation of duplicates has exceeded the Coefficient of Variation allowed in the Test Programming (Figure 9.6, no. 7 and Figure 9.11, no. 5).
  - **PAR:** Some parallelism acceptance criterion (regression coefficient and/or slopes ratio) of a test with parallelism has failed (Figure 9.9, no. 3).
  - **X:** Cancelled test.
- **Status:** Status of the petition for the different dilution points.

13.2.3 Button for Viewing the Results Window of Each Dilution Point

Button for viewing the **Results** window of the **Sample's Dilution Point** selected. The window allows the Operator to review and view the results and the primary reading curves individually (Figure 13.1).

13.2.4 Calibration Curve Area

This area shows the mathematical information of the Calibration Curve that has been used to calculate the parallelism results of the sample: The **regression line equation** and the **correlation coefficient (R)**.

13.2.5 Parallelism Results Acceptance Criteria

In this area there is a table with the **Parallelism Acceptance Criteria** that have been programmed (**Regression**, **Slopes Ratio** and/or **CV (%)**) to check the reliability of the final averaged sample result (Figure 9.9, no. 3), the **values** of the sample curve for each defined criterion and if it has passed or failed according to the limits programmed for each criterion.

13.2.6 Parallelism Graph

Area of the **Parallelism Results** window where the **Calibration Curve** and the **Sample Curve** are plotted on the same graph.

For each dilution point, the average of the duplicates in primary unit (y axis) is plotted *versus* the value in secondary unit without correcting for the dilution factor (x axis). The transformation of the axes is the same than the one chosen when validating the Calibration Curve, and both curves are displayed with linear regression.

13.2.7 Printing the Results Report of a Sample with Parallelism

In the **Parallelism Results** window there is a **Print Report** button that allows visualizing and printing a report of the Results of a sample that has been tested with a test with Parallelism.

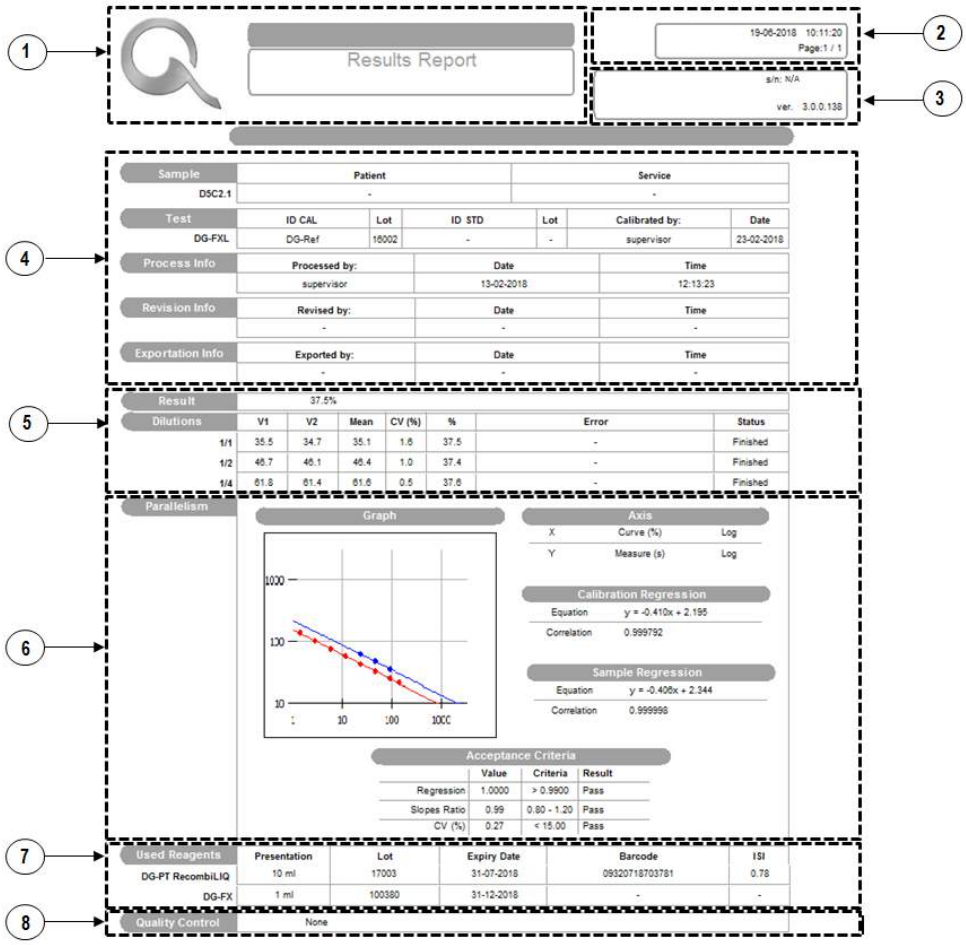


Figure 13.6. Parallelism Results Report

NOTE: There is no GRIFOLS hemostasis assay, currently available on the US market, validated with the **Parallelism** option enabled.

A report with the following information is created:

(1) **Title of the Report** and **Name of the centre**.

(2) **Printing Date** and **Time** and **Page Number/Total number of pages.**

(3) **Serial Number** of the analyzer in which the sample has been processed, and Q**Manager's Software Version**.

(4) Information about the **sample's order:**

- Information about the **sample.**
- Information about the **test** applied to the sample.
- Information about the **Operator** and the **date** in which the order has been made.
- Information about the **revision** of the sample's order.
- Information about the **exportation** of the sample's order.

(5) Information about the **results:**

- Final **Result** (Mean of all dilution points in secondary unit, each corrected by the corresponding dilution factor).
- **Sample's Dilution Points:** Results, errors and status of the dilution points at the moment of printing the report.

(6) Information about the **Parallelism:**

- **Graph:** Calibration Curve and Sample Curve plotted on the same graph.
- **Axis:** Information on the transformation of the axis.
- **Calibration Regression:** Regression line equation and correlation coefficient.
- **Sample Regression:** Regression line equation and correlation coefficient.
- **Acceptance Criteria:** Table with the limits, values and results for the Parallelism Acceptance Criteria programmed (regression, slopes ratio and CV (%)).

(7) **Products used** to run the sample's order.

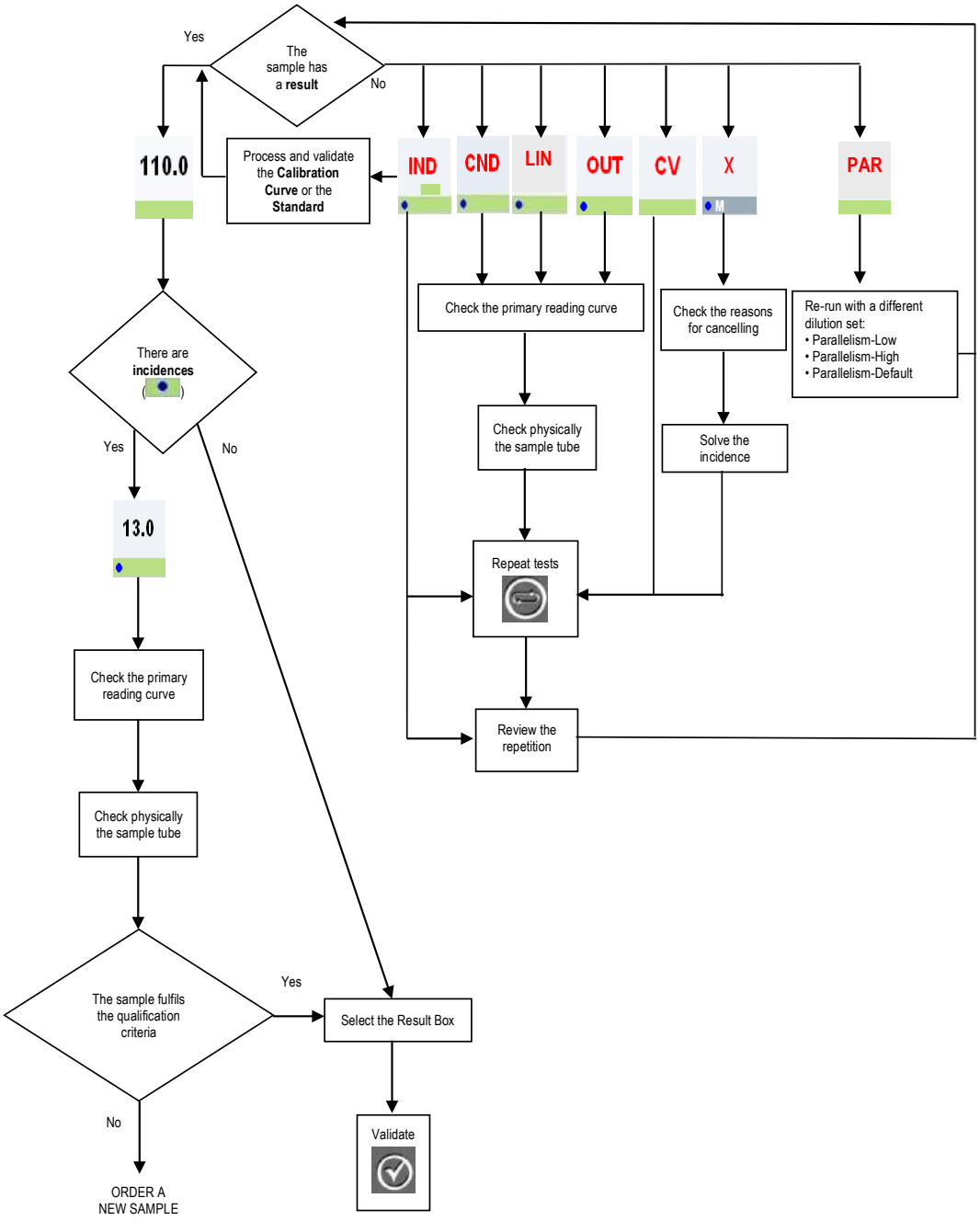
(8) **Quality Control Policy** applied to the sample's order.

The report can be printed, by pressing the **Print** button (), in paper if a printer is installed or in **.xps** format.

13.3 Results Revision

13.3.1 Results Revision Criteria

The flowchart below gives an outline of the possible steps to be followed to review the results. It is only given as an example and it can be modified in accordance with the laboratory's **Quality Control Policy**. For further information see Section 8.3.3.


Yes
The sample has a result
No
110.0
Process and validate the Calibration Curve or the Standard
IND
CND
LIN
OUT
CV
X
PAR
Check the primary reading curve
Check the reasons for cancelling
Re-run with a different dilution set:
• Parallelism-Low
• Parallelism-High
• Parallelism-Default
There are incidences
Yes
No
Check physically the sample tube
Solve the incidence
13.0
Repeat tests
Check the primary reading curve
Review the repetition
Check physically the sample tube
The sample fulfils the qualification criteria
Yes
Select the Result Box
No
Validate
ORDER A NEW SAMPLE

13.3.2 Results Revision

The results can be reviewed by following these options:

- **Revision of the results of a sample:** To review the results of the various orders for a sample, the following options are available:
  - Select the box which corresponds to the sample to be reviewed (the program will automatically highlight the selected box, turning it orange) and press the **Review** button located at the top of the screen to indicate that all the completed results of the sample have been reviewed, regardless of the test to which they belong. If this sample has orders, repetitions or Reflex Testing pending or underway, the program will display a message indicating that not all the results for this sample can be reviewed.
  - Keep pressing the finger on the corresponding Sample Box to access a drop-down menu with the **Review** option. Selecting it will cause the program to consider that all the completed results for the sample have been reviewed, regardless of the test to which they belong.
- **Revision of the results of a series of samples:** The following options can be used to review the results of a series of samples, regardless of the sample and the test to which they belong:
  - Keeping the finger pressed on the screen, drag to select the desired Sample Boxes. The program will highlight the selected samples in orange and, by pressing the **Review** button at the top of the screen, it will consider that the results of all completed orders relating to this selection have been reviewed.
  - Press the  button to select and therefore, highlight in orange, all the samples present on the **Worksheet**. Then, press **Review** and the program will consider that all the results of all the completed orders for this selection have been reviewed.
  - Press the  button. The program will allow the discrete selection of the Sample Boxes that the Operator wants to validate. Then, press **Review** and the program will consider that all the results of all the completed samples in the selection have been reviewed.

14 Printing Reports

14.1 Printing Out a List of Cumulative Results

Results for the samples can be printed using the **Print Reports** ( ) button in the top of the main Q**Manager** window. This option allows the results that are in the **Worksheet** or that have been filed to the **Historical Database** to be visualized and/or printed.

After pressing on the button, the program will display the **Print Report** window. This window contains some fields that the Operator must select before printing the report;

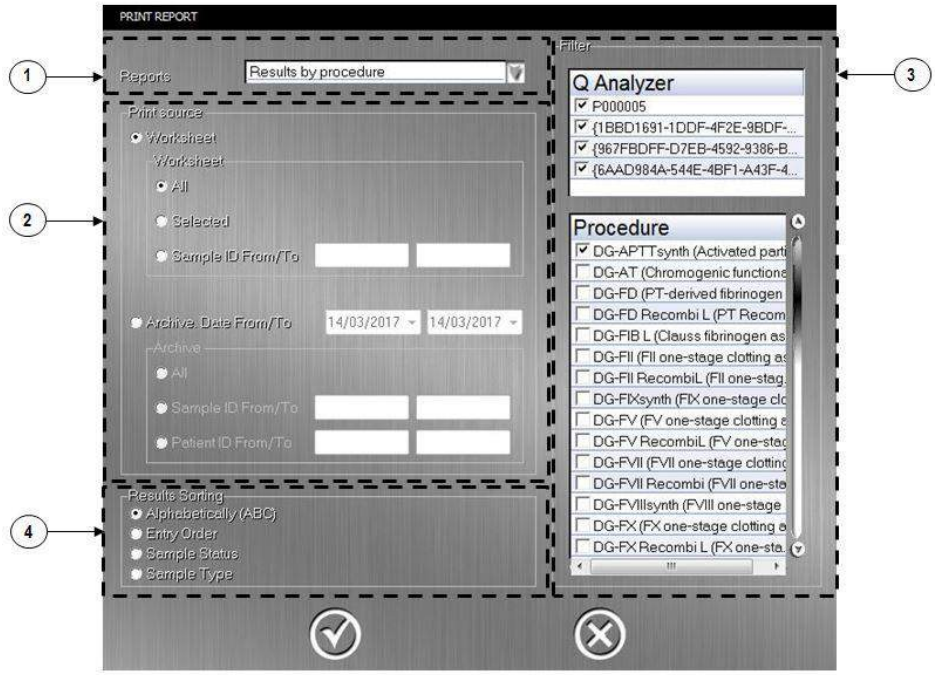


Figure 14.1. Print Report Window

(1) **Select the Type of Report**. The program allows the type of report to be selected. There are two types of report:

- **Standard Reports:** These are typical reports that appear predefined on the Q**Next** program.
  - **Results by Sample** (Figure 14.2). The report will display the value obtained for all the tests and units. If there are replicates, the report will only reflect the Mean value.

- **Results by Sample with Duplicates** (Figure 14.3). The report will reflect the value of the duplicates and the Mean for each test in all the units.
- **Results by Procedure/Test** (Figure 14.4). The report will contain the results for each test, with all their units. If there are replicates, the report will only reflect the Mean value.
- **Results by Procedure/Test with Duplicates** (Figure 14.5). The report reflects the value of the duplicates and their Mean for each test and in all units.

- **Customised Reports:** Reports configured in advance by the Operator using the **Reports** option (see Section 9.9).

The last type of report used appears selected by default in the window every time that the Operator wishes to print a new report.

(2) **Select the Source and Range of Results to be printed.** The program allows the Operator to select the source and range of results to be shown in the report. The selection can include results from:

- The **Worksheet:** This option must be selected when the results to be printed are still in the **Worksheet** and have not yet been filed. Among these, the program allows the Operator to print:
  - **All** the results in the Worksheet.
  - Only the results that have been previously **selected** in the Worksheet.
  - A range of results selected using sample ID (**Sample ID From/To**).
- The **Historical Database:** This option must be selected when the results to be printed have been previously filed by the Operator. The program displays the **Date From/To** field to select the time interval. Within this range, the report could contain:
  - **All the results**.
  - A range of results within the alphanumeric interval selected in the Sample ID field (**Sample ID From/To**).
  - A range of results within the alphanumeric interval selected in the Patient ID field (**Patient ID From/To**).

NOTE: The date of the selection is the date on which the Operator has filed the results, not the date when the orders were executed.

---

(3) **Select the Q Analyzer and Test.** The program allows the Operator to filter the printout by Q **Analyzer** and by **Tests**, and to display only the results of the selected tests. By default, the program displays all the tests executed in the analyzer as disabled.

NOTE: Every time that the Operator selects a test from the filter list for inclusion in a report, the program checks whether there is sufficient space in the page to list this test with all its units.

Otherwise, the program displays a warning indicating that this test cannot be added to the report and allows page orientation to be changed.

(4) **Results Sorting**. The Operator can sort the results that appear in the report according to these 4 options:

- **Alphabetically (ABC)**. This option appears selected by default.
- **By order of entry** (chronological).
- **Sample status** (pending, processing).
- **Sample Type:** Samples, Controls (QC), Standards (STD), etc.

NOTE: Paper orientation is selected automatically based on the number of tests, samples and replicates included in the report.

Once the different fields of the **Print Report** window have been selected, press **Accept** and the program will display a preview window. Press **Print** ( ) to obtain the report in paper if you have a printer installed or in **.xps** format.

14.2 Report Format

Figures 14.2, 14.3, 14.4 and 14.5 display an example of the reports supplied by the Q**Next**.

The reports include the following information:

(1) **Title of the Report** and **Name of the centre** (configured as described in Section 9.11.4).

(2) **Printing Date** and **Page Number/Total number of pages**.

(3) **Serial Number** of the analyzer in which the samples have been processed, and Q**Manager's Software Version**.

(4) **Results Area**. To assess the result well, apart from the corresponding numerical values, the following observations are included:

- (*): Manual Sample Identification.
- (A): Manual Product Identification.
- (B): Manual modification of the Calibration Curve.

- (P): Use of expired products.
- (Q): Results reviewed without enabling **Quality Control Policy.**
- (D): Test run per duplicate.
- (C): CV Error.
- (R): Result from a Repetition.
- (I): There are Incidents relating to the Result.
- (!): Result outside the Clinical range of the test.
- (#): Non-validated test.
- Status of the order at the time of printing: Cancelled (CN), Pending (PE), Processing (PR), Finished (FI), Reviewed (RV) and Exported (EX).

(5) **Footer** with the legend of the icons or abbreviations used in the **Results Boxes**.

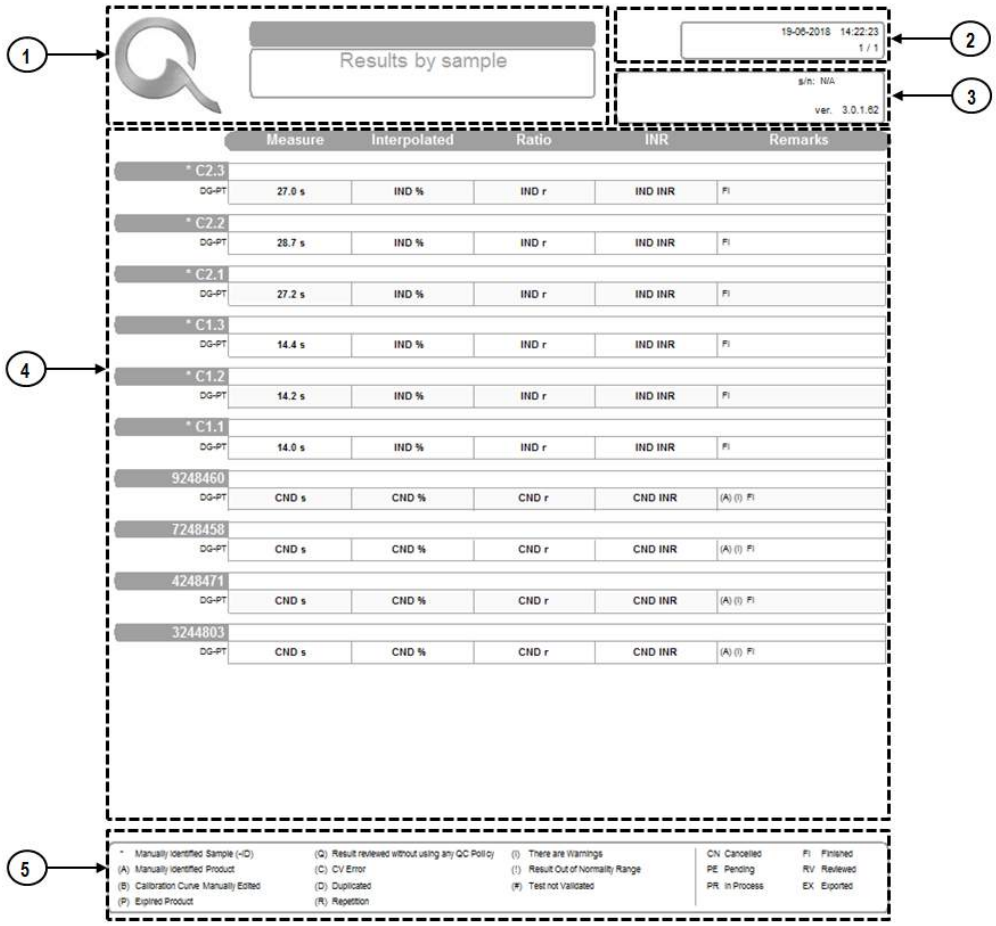


Figure 14.2. Report of Results By Sample

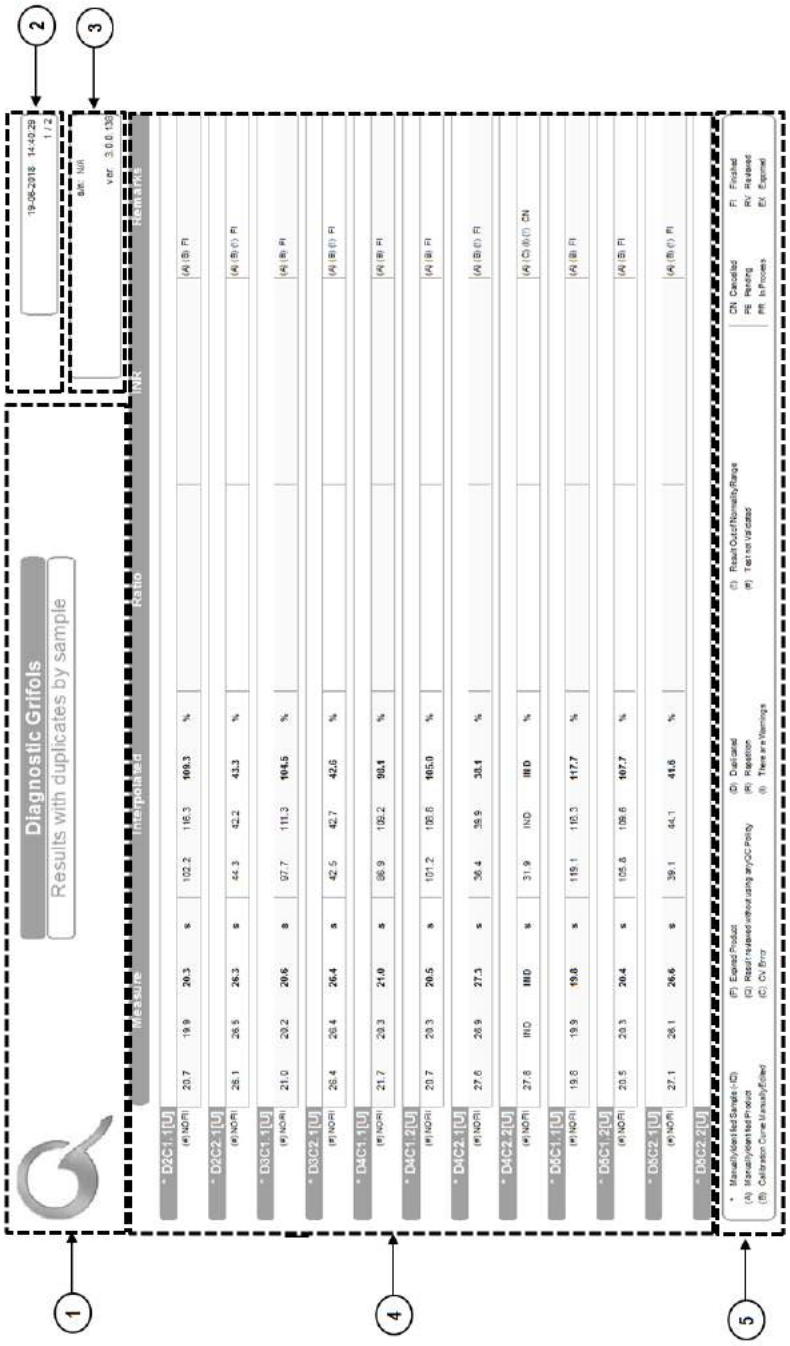


Figure 14.3. Report of Results with Duplicates By Sample

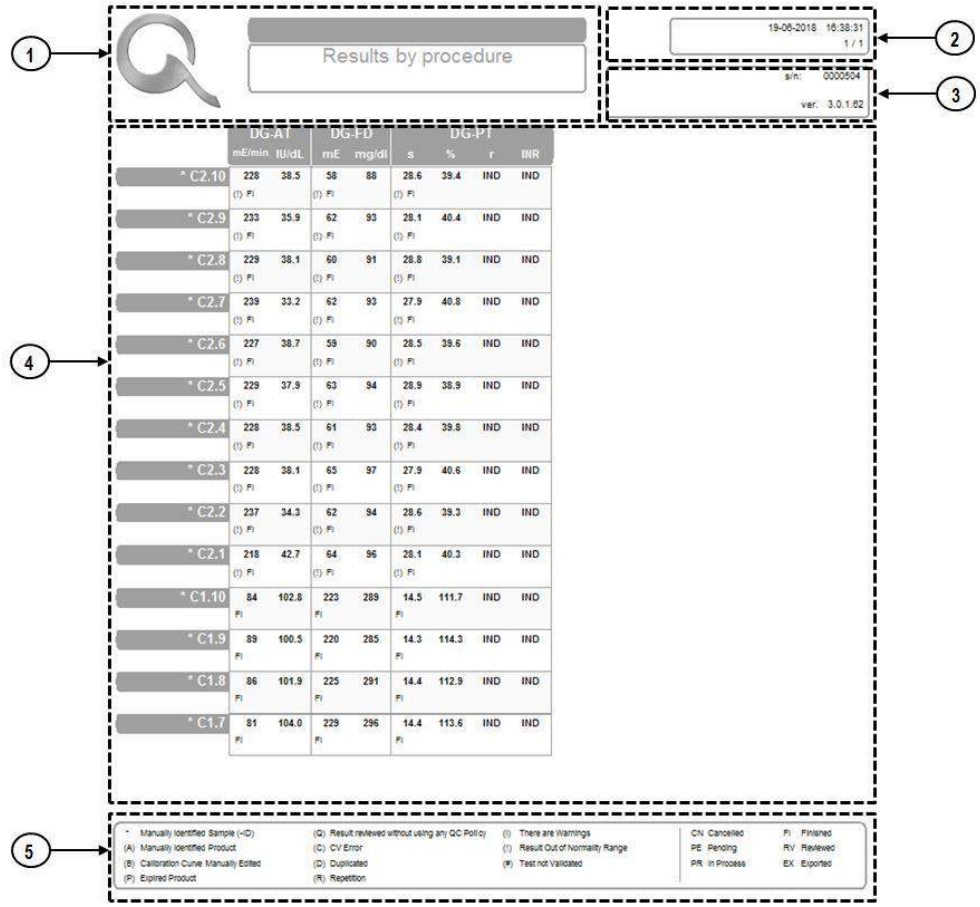


Figure 14.4. Report of Results By Procedure

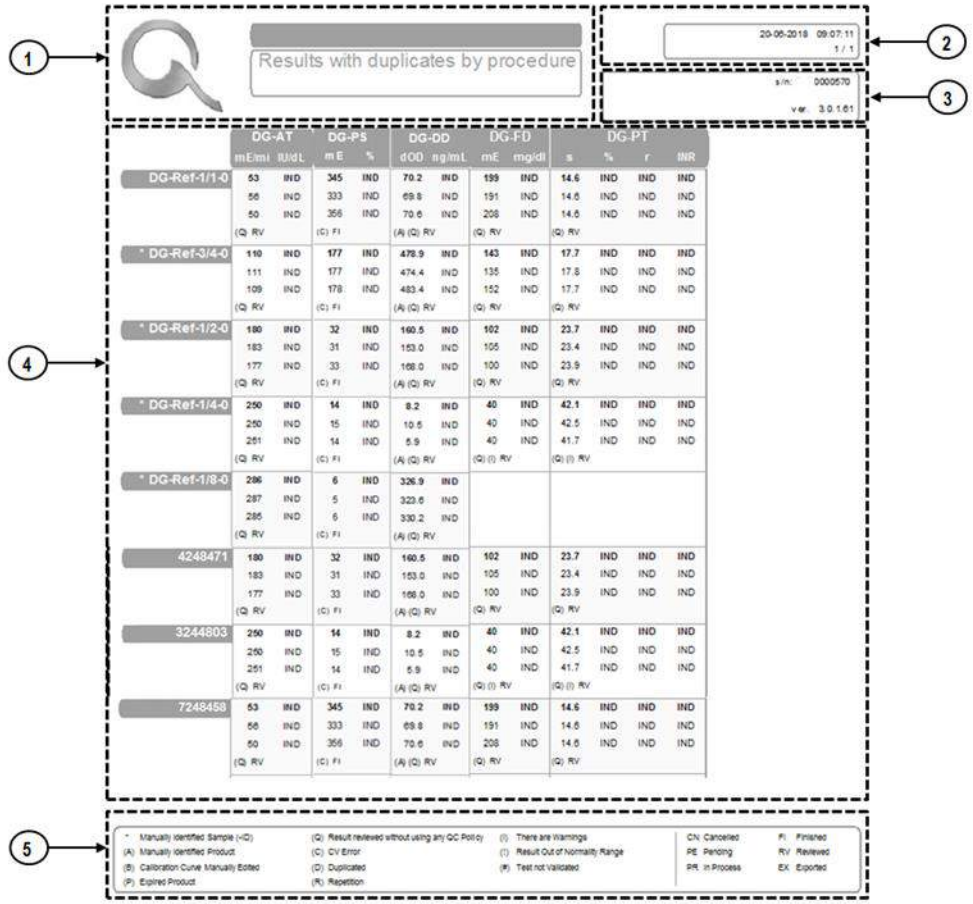
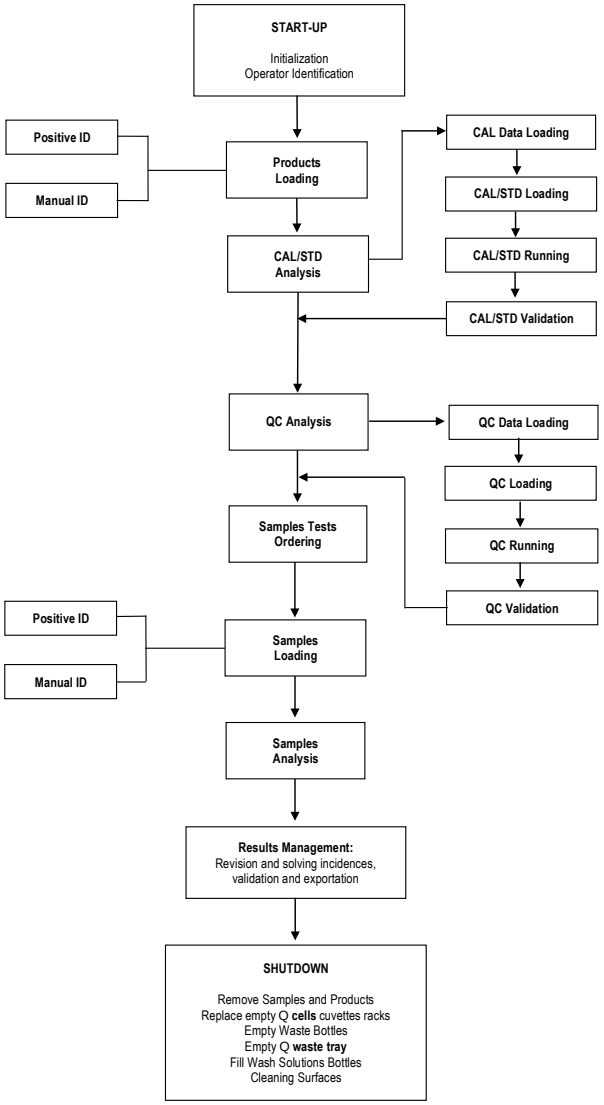


Figure 14.5. Report of Results with Duplicates By Procedure

15 Quick Start Guide

CAUTION: Do not use the equipment if it is not working properly or has been damaged.

The following diagram shows the workflow of the daily routine operations:



15.1 Start-Up

To start-up the equipment, connect the Q**Next** to the main electricity supply.

Turn on the Main Switch of the analyzer, located at the back and on the left-hand side (Figure 4.1, no. 1).

If the analyzer is turned-off, gently press the **Start** button on the screen (Figure 4.1, no. 2).

At this point, the analyzer program will start and the equipment will perform automatic checks of the various modules in the analyzer (checking fluid circuits, temperatures, pressure/vacuum levels, etc.) that the Operator can follow in the **Start-up** window. The entire process takes about 15 minutes.

NOTE: If the equipment does not respond and the green pilot light of the **Start** button on the analyzer screen does not light up, it is possible that the Main Switch of the power source is not on. Check that the equipment is plugged in and turn the Main Switch to **I**.

If start-up concludes correctly, the Q**Executor** window will display the respective temperature, pressure and vacuum indicators in green or temporarily in orange and all the buttons that can be accessed.

If start-up has not concluded correctly:

- Some of the temperature, pressure and/or vacuum indicators will be displayed in red.
- An alert window opens up.
- The **Start-up** window indicates that a module has been unable to complete the start-up process.

CAUTION: If the fluidic module is not properly initialized, neither is the reader module. When re-initialization is performed, both modules are checked.

- The **Emergency Stop** ( ) button is not accessible and the **ON** ( ) button appears in its place.

CAUTION: If the analyzer has not started properly, re-start using the button in the Q**Executor** window. If the problem persists, contact the Technical Service.

15.2 Operator Identification

Since the program manages a group of passwords (see configuration in Section 9.10) giving access to different levels of programming, each new Operator wishing to use the Q**Next** should be identified and log off when the work with the analyzer is finished.

To do so, press the **Login** button. The program displays a **Connection** window for entering the **User name** and the **Password**. From then on, all the action buttons are operative, although this Operator will only be able to access the options enabled for his/her specific user level. To configure privileges, please see Section 9.10.

To **Logout**, press the  button again. The Operator must confirm that he/she wants to interrupt the connection with the analyzer.

NOTE: To complete the Operator Identification process and be able to work with the analyzer, the Operator must be identified in both system programs, the **QManager** and the **QExecutor.**

15.3 Operator Checks

Before beginning to work with the analyzer, the following checks should be performed:

- **Status of the Wash and Waste Solutions Desk**. To do so, check in the Q**Executor** window that the workload programmed in the analyzer can be run since:
  - There is a sufficient volume of diluted **System Solution A** and **System Solution B** in the bottles.
  - There is enough free volume in the Waste Bottles.
  - The level of discarded cuvettes in the Q**waste tray** does not exceed the maximum number permitted and will allow the cuvettes from the workload to be discarded.
- **Status of the** Q**cells cuvettes Desk:** Check that the analyzer contains at least one Q**cells** rack with cuvettes in one of the two load positions.
- **Status of the Samples Desk:** Check that there are no samples in the desk.
- The **Upper** and **Lower Doors** of the analyzer are closed.

NOTE: For maximum autonomy, it is recommended that the session starts with:

- Full bottles of **System Solutions A** and **B**.
- Empty Waste Bottles.
- Empty Q**waste tray**.

- Full Q**cells** cuvettes racks.

If Operator intervention is necessary in any of these processes, proceed as described in Section 15.8.

15.4 Products Loading

NOTE: All those products that are not part of the tests validated in Q**Next** must be programmed first. To program **Products**, **Presentations**, **Lots**, see Section 9.1.

NOTE: The analyzer allows **Products Layouts** to be configured to facilitate identification of products without barcodes. To configure the **Products Layouts**, see Section 9.5.

CAUTION: To obtain reliable and high-quality results, follow the product manufacturer's recommendations for use, handling, maintenance and stability thoroughly.

CAUTION: Before inserting products in the Q**Next**, remove container caps.

To insert the products in the Q**Next**, please proceed as follows:

- Press the **Open Upper Door** button to access the Products Trays.
- To load the products, it is recommended to physically remove the trays. The Black Tray (positions 1-15) can be removed by pulling the knobs gently. To remove the Grey Tray (positions 16-30) which is located at the back, press **Move Trays** button.
- If the products have barcodes, they can be placed randomly in the trays, facing the barcode towards the groove of the tray, where it can be read and the product automatically identified.

WARNING: If the product requires magnetic stirring, place the Q**stirrer** in the corresponding product vial and load the vial in one of the four stirring positions (positions 9, 11, 13 and 15) of the Black Tray. If the product is loaded in any of the non-stirred positions, the system will advise the Operator that the stirrer should be removed.

NOTE: If all the product containers used in the Q**Next** have barcodes, the system provides positive identification.

- If the products have no barcodes, press the **Trays Content** button and select one of the available Trays in the **Trays Content** window:
  - **Last One:** This refers to the last **Trays configuration** used in the analyzer and stores the information on the product lots used.
  - **Empty Trays:** Layout with empty Products Trays.
  - A screen will appear with the graph of the Products Desk.
  - **Pre-customised Layout:** Products Tray previously configured in the analyzer in accordance with the Operator's definition (to configure new **Products Layouts**, please see Section 9.5).

  A screen will appear with the graph of the Products Desk.
- If the products have no barcodes, the Operator can also proceed with manual identification:
  - Introduce the Product **Lot** manually. To do so, first press on the position in which the product vial is going to be placed (represented by a "**?**" symbol if a pre-customised layout has been chosen (Figure 15.1, no. 1). And then, select the **Product**, the commercial **Presentation** and the specific **Lot** (Figure 15.1, no. 2) with which you are going to work.
  - Press **Assign Product Position** (Figure 15.1, no. 3).
  - Once the product has been assigned, the program displays its position as **Unknown Volume** ( ).
  - Load the product in the position indicated in the **Trays Content** window**.**
  - Repeat the process for all the required products. To facilitate the loading process, the software automatically suggests the next empty position in the Products Tray.

⚠ **CAUTION:** The program will display alerts when the positions selected on the Product Layout do not comply with the specifications for the selected product or contradict analyzer configuration, *i.e.*:

( )**:** Diluent not placed in position no. 1.

( )**:** Stirred product placed in a non-stirred position. This product will not be stirred.

( )**:** This reagent needs a cleaning agent, which is not present.

( )**:** Product lot that has expired (when the option **Check Products Expiry Date** is disabled).

( )**:** Product vial that has exceeded its on board stability (when the option **Check**

Products On Board Stability is disabled).

( ): Product lot that cannot be automatically registered.

( ): Product that has been cancelled because the product lot has expired (when the option **Check Products Expiry Date** is enabled).

( ): Product that has been cancelled because the product vial has exceeded its on board stability (when the option **Check Products On Board Stability** is enabled).

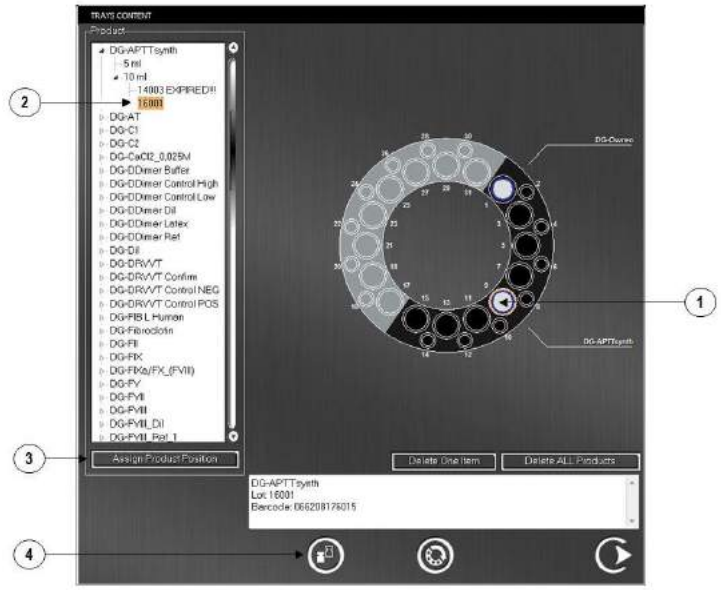


Figure 15.1. Products Loading Window

NOTE: If a **Pre-customised Layout** has been chosen, the **Trays Content** window only displays a template of product container location. However, the Operator can change and customise this Layout.

Vials of the same product and lot and different lots can also be loaded in free positions in the tray, providing that they are correctly identified.

These modifications are considered temporary and are not saved in the corresponding **Products Layout** configuration.

- Insert the trays in the analyzer. If there is one tray present in the back, simply place the other tray in the empty space. Otherwise, insert one of the trays in the analyzer and gently turn it clockwise until the system hooks it and positions it automatically. Then place the other tray in the empty space.

⚠ **CAUTION:** The Products Desk should always work with one Black Tray and one Grey Tray. Do not insert two trays of the same colour into the analyzer.

- Press **Accept** in the **Trays Content** window to confirm the Layout.
- Gently close the Upper Door, pressing down from the top until hearing the click of the clousure.
- The program performs a brief initialization and, if **Automatic Identification** is enabled (see Section 7.3.2), it requests confirmation for the displayed **Trays Content**.
- If the configuration is correct, press **Accept**.
- If the configuration is not the one required, press  to open the Upper Door and modify the products positioning.
- Proceed in the same way, but selecting **Last one** in the **Trays Content** window, this will allow the Operator to modify the previous Layout.

NOTE: If using products with and without barcodes, proceed as described for manual identification and load the products which can be automatically identified in free positions.

When the Upper Door is closed, the analyzer automatically identifies the products with barcodes and adds them to the corresponding positions on the Layout.

If a product with positive ID is placed in a position configured for a product with manual ID, automatic identification will prevail.

⚠ **CAUTION:** If during the automatic products identification the label at the back of the Products Desk is read, the position is considered to be empty, regardless of a previous manual identification.

⚠ **CAUTION:** If during the automatic products identification the analyzer cannot read any barcode in a position (neither the product's label nor the label at the back of the Products Desk) and there is a product with manual ID in that position, manual identification will prevail.

Therefore, the Operator must ensure that the product's barcode is correctly faced in the Products Tray groove.

CAUTION: Manual identification of products is a risky practice that should be avoided. Repeated checks of manually identified products are strongly recomended.

CAUTION: To avoid condensation in the Products Desk, do not leave the Upper Door of Q**Next** opened for long periods of time when the instrument is turned on. It is recommended to have the products already prepared and open the Upper Door the minimum possible time, just to load and unload products.

15.5 Calibrators, Standards or Controls Loading

The system offers the possibility of loading Calibrators, Standards and/or Controls at the same time as sample analysis.

There is the possibility of entering Calibrators, Standards and Controls in their original vials directly in the analyzer using the Products Trays so that they can be automatically identified (see Section 15.4).

For entering Calibrators, Standards and Controls in microtubes with manual identification, these must be placed in Q**sample holders** and the Operator should proceed as follows:

- Enter the order in the **Worksheet** as described in Sections 10.1.1, 10.2.1 and 11.5.
- Place the tube in a Q**sample holder**.
- Press  and select the required option: **Calibrator (CAL)**, **Standard (STD)** or **Control (QC)**.
- The program indicates the Operator to place the Q**sample holder** in the External Identification Area to be identified (Figure 4.1, no. 7).
- Select the corresponding Calibrator, Standard or Control ID from the list displayed and press **Accept.**
- Press  to start the **Samples Desk** and start the analysis.
- Place the Q**sample holder** with the sample tube in the Samples Entry Area.

For more information on how to process **Calibrators (CAL),** please see Section 10.1.1; to process a **Standard (STD)** see Section 10.2.2; and to process a **Control (QC),** please see Section 11.5.

15.6 Sample Loading

15.6.1 Qualification of Samples

The quality of the sample directly affects the quality of the results obtained and, therefore, the reliability of the diagnosis. Since there are numerous variables which can affect the results of the analysis: Type of anticoagulant, conservation of the sample, type of tube, transport, etc., having a detailed procedure which includes each step from extraction of the sample to the obtaining of the results is absolutely necessary to ensure correct diagnosis.

⚠	**CAUTION:** The use of samples which are excessively hemolysed, icteric, lipemic, turbid or with blood or fibrin clots may lead to wrong results. Do not use this kind of samples in the analyzer.
⚠	**CAUTION:** To obtain reliable and high-quality results, do not leave samples inside the instrument for long periods of time as it may not be suitable for its required stability.
⚠	**WARNING:** The points described below are merely general aspects to be taken into account when qualifying samples. Each laboratory should, however, have its own protocol.

Before inserting a sample in the Q**Next**, please bear in mind the following points:

- CLSI: H21-A5 (*Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays; Approved Guideline - Fifth Edition 2008*) recommendations should be followed for processing samples.
- Do not use samples that have not been properly stored.
- A tube with an incorrect level of plasma should be rejected as an incorrect extraction.
- Frozen samples should be rapidly thawed at 37 ºC, gently swirled for correct homogenization and tested immediately.

15.6.2 Sample Loading

⚠	**CAUTION:** Before placing a sample tube in a Q**sample holder** for processing with the analyzer, please check its Instructions for Use (see Section 4.3.2).

The Operator should place the sample tubes in their respective Q**sample holders**. From then on, the procedure will depend on the configuration of the analyzer regarding sample tubes identification and tests ordering. This can be simplified as follows:

- **Positive samples ID and connection to the Host:** Automatic identification of samples tubes by barcode reading and automatic tests orders through the Laboratory Information System (LIS).
- **Positive samples ID and programmed Profile:** Automatic identification of sample tubes by barcode reading and automatic tests orders trough a programmed profile.
- **Manual samples ID and programmed Profile:** Manual identification of sample tubes and automatic assignment of orders through a programmed profile.

- **Manual samples ID and Manual Tests ordering:** Manual identification of sample tubes and manual tests orders through the **Worksheet** (see Section 12.2.1).

15.6.2.1 Positive Samples Identification and Connection to the Host

⚠ **CAUTION:** To configure the connection between the Q**Next** and the Laboratory Information System (LIS), contact authorised Technical Service.

If the analyzer is connected to the host, the Operator can work in one of the following two ways:

- **By batch:** The analyzer communicates with the host and acquires the entire workload pending analysis when the Operator asks for this. To do so, proceed as described below:
  - Press **Import Orders** button in the Q**Manager:** The program will acquire the entire workload pending analysis and upload the samples identifications and tests orders in the **Worksheet**. For more information, please refer to Section 12.1.1.
  - Place the samples with barcodes in Q**sample holders**.
  - Place the Q**sample holders** with the samples in the Samples Entry Area.
  - Press  to activate the Samples Desk and start analysis.

  As the analyzer identifies the samples, it will indicate, in the Information Area in the Q**Executor** window, which samples have been managed by the Recirculation Area and will update the **Worksheet**.
- **By sample:** The analyzer communicates with the host in real time to acquire the pending workload sample by sample as they are being identified. To do this, proceed as follows:
  - Place the samples with barcodes in Q**sample holders**.
  - Place the Q**sample holders** with the samples in the Samples Entry Area.
  - Press  to activate the Samples Desk and start analysis.

  The program will automatically perform the orders for the samples in accordance with the information received from the host. The results will be updated in the respective boxes in the **Worksheet**. For more information, please see Section 12.1.1.

15.6.2.2 Positive Samples Identification and Programmed Profile

To work in this way, the instrument must have a **Profile** programmed (see Section 9.3). The Q**Next** will apply the profile or profiles programmed to the samples following the operation procedure described in Section 9.3. For this to occur, please proceed as follows:

- Place the samples with barcodes in Q**sample holders**.
- Place the Q**sample holders** with the samples in the Samples Entry Area.

- Press  to activate the Samples Desk and start analysis.

The program will automatically execute the tests in the programmed **Default Profile** to the samples which enter into the analyzer and are identified via barcode.

NOTE: The analyzer will classify a sample as **Unknown** when:

- The analyzer cannot read the barcode of the sample.
- There is no barcode.
- There is no manual identification.

The sample should later be identified as described in Section 15.7.3.1.

15.6.2.3 Manual Samples Identification and Programmed Profile

To work in this way, the Q**Next** must have a **Default Profile** programmed (see Section 9.3.4). In this case, the Operator should proceed as follows:

- Place the sample tubes in the Q**sample holders**.
- Press the **Insert** Q**sample holder** button () and select the **Sample** option.
- The program indicates the Operator to place the Q**sample holder** on the External Identification Area (Figure 4.1, no. 7) so that the Q**sample holder** ID is read. Then, when the sample ID is introduced, an association is made between the Q**sample holder** ID and the sample ID.
- Introduce the samples ID in this moment in the **Introduce Sample** window. The system forces double identification, to prevent sample ID errors (Figure 15.2, no. 1).

The configuration of the analyzer with regards to the cap piercing option can be modified in this window for this sample if so desired (Figure 15.2, no. 2).

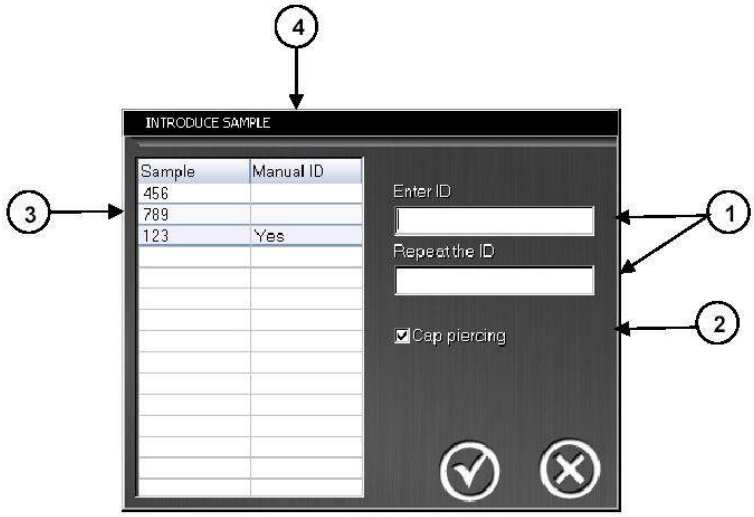


Figure 15.2. Introduce Sample Window

CAUTION: The use of capped sample tubes with the option sample tube cap piercing disabled can lead to errors in the results.

- Place the Q**sample holders** with the samples in the Samples Entry Area.
- Press  to activate the Samples Desk and start analysis.

NOTE: To minimise the risk of confusion with manual sample ID, place the sample tube in the Q**sample holder** before the holder is identified and keep the tube in the Q**sample holder** until it is returned to the Samples Delivery Area.

15.6.2.4 Manual Identification of Samples and Manual Tests Orders

In this case, the Operator should proceed as follows:

- Manually identify the sample tubes and select the corresponding tests orders in the **Worksheet** in the Q**Manager** window, as described in Section 12.2.
- Place the sample tubes in the Q**sample holders**.

- Press the **Insert** Q**sample holder** () button and select the **Sample** option.
- The program indicates the Operator to place the Q**sample holder** on the External Identification Area (Figure 4.1, no. 7) so that the Q**sample holder** ID is read. The radiofrequency reader will read the internal ID of the Q**sample holder** and will allocate it to the manual ID of the sample tube which is then performed. Then, when the sample ID is introduced, an association is made between the Q**sample holder** ID and the sample ID.
- Select the sample ID from the list of Samples located on the left of the **Introduce Sample** window (Figure 15.2, no. 3). The samples that had been manually introduced before will be indicated (Figure 15.2, no. 4).

  The configuration of the analyzer with regards to the cap piercing option can be modified in this window for this sample if so desired (Figure 15.2, no. 2).
- Place the Q**sample holders** with the samples in the Samples Entry Area.
- Press  to activate the Samples Desk and start analysis.

NOTE: If a Q**sample holder** ID coincides with one used previously and which already had an allocated sample ID, the program will allow the Operator to reallocate the new sample to this Q**sample holder** or to cancel allocation.

The program will automatically run the petitions programmed for the samples in the Worksheet and will update the results in the corresponding Results Boxes of the **Worksheet**.

CAUTION: Manual identification of samples is a risky practice that should be avoided. Repeated checks of manually identified samples are strongly recomended.

15.6.3 STAT Samples Loading

The analyzer's Samples Desk has been designed to allow the prioritization of STAT samples simply by placing them in front of all the samples that are in the Samples Entry Area.

However, the software also offers two options to introduce STAT samples as prioritized so that these are pipetted before all the other samples in the Samples Recirculation Area:

(1) For Samples with **Automatic Identification:**

- Press the **STAT Samples** button. The non-STAT samples located in the Samples Entry Area waiting to access the Recirculation Area are automatically moved backwards to clear the Samples Entry Area and the Recirculation Area is stopped so that no new samples are pipetted.

- Place the Q**sample holder** with the STAT sample on the **External Identification Area** (Figure 4.1, no. 7) so that the Q**sample holder** ID is read.
- Then, the analyzer asks the Operator if the STAT sample needs to be manually identified. Press the **Cancel** button and place the Q**sample holder** in the Samples Entry Area, in the position indicated by a red intermittent arrow (nearest link to the pipetting position).
- Finally, press **Accept**. The Samples Desk is automatically enabled.
- To introduce more STAT samples, repeat the process.

(2) For Samples with **Manual Identification:**

- Press the **STAT Samples** button. The non-STAT samples located in the Samples Entry Area waiting to access the Recirculation Area are automatically moved backwards to clear the Samples Entry Area.
- Place the Q**sample holder** with the STAT sample on the **External Identification Area** (Figure 4.1, no. 7) so that the Q**sample holder** ID is read.
- Then, the analyzer asks the Operator if the STAT sample needs to be manually identified. Press **Accept**.
- If the sample/s has been previously indicated as STAT in the **Worksheet** (see Section 8.3.2) and tests have been assigned to it (see Section 12.2.1), the STAT sample will appear in the list shown on the left-hand area of the **Introduce STAT Sample** window (Figure 15.3, no. 1). Select the sample and press **Accept**.

  The configuration of the analyzer with regards to the cap piercing option can be modified in this window only for this sample if so desired (Figure 15.3, no. 2).

Figure 15.3. Introduce Stat Sample Window

- If the sample has not been previously programmed as STAT in the **Worksheet**, introduce the sample ID in this moment. The system forces double identification to prevent sample ID errors (Figure 15.3, no. 3). Then press **Accept** .
- Place the Q**sample holder** with the STAT sample in the Samples Entry Area, in the position indicated by a red intermittent arrow (nearest link to the pipetting position).
- Finally, press **Accept** . The Samples Desk is automatically enabled.
- To introduce more STAT samples, repeat the process.

NOTE: If the Operator wants to apply the same test profile to all the samples considered urgent, the analyzer offers the possibility of programming a special tests profile: **STAT Profile**. To do so, the Operator must enable this option in the **Profiles** window (see Section 9.3.5).

15.6.4 Ordering a Test with Parallelism

When a test with Parallelism is ordered to a sample, the **Default** Dilutions Set is applied by default if no action is performed.

To change the Parallelism Dilutions Set to be applied to a sample, the Operator should proceed as follows:

- Order the test to the sample in the **Worksheet** (see Sections 12.1.1 and 12.2.1).

Figure 15.4. Ordering a Test with Parallelism - Default Dilutions Set

- Once ordered, press steadily the highlighted box that indicates that the Test has been ordered to the sample, until a drop-down menu is displayed.
- Select the desired Dilutions Set in the displayed menu: **Parallelism – Low** or **Parallelism – High** (see Figure 15.5).

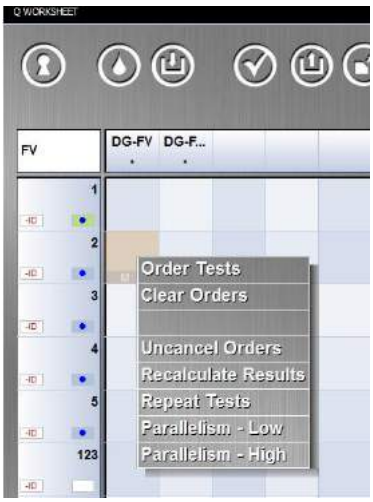


Figure 15.5. Ordering Different Parallelism Dilutions Sets to a Sample

15.7 Executing the Analysis

15.7.1 Running Samples

Once all products have been loaded in the analyzer and, if necessary, Samples, Calibrators, Controls and/or Standards manually identified, proceed as described below:

- Place the Q**sample holders** with the sample tubes in the Samples Entry Area.
- Press the **Start** button ( ) to activate the transport system that carries the Q**sample holders** into the Recirculation Area.

The links of the recirculation chain pick the Q**sample holders** and carry them first to the Q**sample holders** internal identification position and then, to the barcode identification and sample aspiration position. At this point, the Samples Recirculation Chain will spin the holder around until the barcode is read.

NOTE: If the tubes are identified with barcodes, the system provides positive sample ID.

NOTE: Since the system allows for continuous, random and concurrent loading of Samples, Calibrators, Controls and Standards, the Operator can load them in no particular order, as described in Sections 15.5 and 15.6.

While there are samples pending analysis in the Samples Entry Area, the Recirculation Area will remain active. However, bear in mind that:

- When the analyzer detects 20 empty, consecutive links in the Recirculation Area, it automatically stops the samples entry and the **Pause** button () returns to **Start** button status (). If the Operator wishes to continue working with the analyzer press  to re-start the Samples Entry.
- If the analyzer detects 15 links in the Recirculation Area with **Unknown Samples** (unable to read the barcode or with no manual ID), it automatically stops the Recirculation Area and it informs that the reason is that the number of **Unknown Samples** has achieved its maximum limit and that to continue working they must be identified. Identify them as described in Section 15.7.3.1 and once done, press  to re-start the Samples Entry.

⚠ **CAUTION:** Do not touch, remove or change the position of the samples and/or their Q**sample holders** until the analyzer releases them automatically from the Recirculation Area.

15.7.2 Samples Analysis

As the Samples (and also Calibrators, Controls or Standards if entered through the Samples Entry Area) pass through the identification and aspiration position, apart from identifying the sample, the Samples Arm perforates the cap (if this option is enabled, see Section 7.3.2) and performs all the plasma aspirations required to run all the orders allocated to this sample. At this point, the orders are considered to be "In process".

If the analyzer is configured in such a way that the **Recirculate Samples** option is enabled (see Section 7.3.2), the sample remains in the Recirculation Area until all the samples results are obtained. Once the analyzer has completed all the requests ordered to a sample, this is automatically released to the Samples Delivery Area.

The Operator can see the status of the samples and their orders in the Q**Manager** window (see Section 8.3).

The system also allows real-time monitoring of the orders in process and an estimation of the time to obtain all results for a sample through the Q**Executor** window (see Section 6.2).

15.7.3 Unknown Sample Resolution

When a sample has not been manually identified or the Barcode Reader has not been able to read the label (because it is illegible, not present, the format is unknown, the label is badly positioned, etc.), the sample is tagged by the system as an **Unknown Sample**.

The Q**Executor** window notifies the presence of **Unknown Samples** through a graphic representation in the Recirculation Area. The samples labelled as **Unknown** appear with a question mark "**?**". When this area is touched, the system notifies the number of **Unknown Samples** in the **Information Area**.

If the analyzer has a **Default Profile** set (see Section 9.3.4), it automatically performs the tests in this profile to the **Unknown Samples**. If there is no Default Profile set, no test is performed. Then, it will be necessary to identify the **Unknown Samples** manually.

NOTE: All the Unknown Samples with or without results are automatically removed from the **Worksheet** when the instrument is turned off, unless they are previously resolved.

15.7.3.1 Unknown Sample Identification

A sample catalogued as **Unknown** is never released automatically from the Recirculation Area. For the analyzer to release the **Unknown Samples** and manually identify them, the Operator should proceed as follows:

- Stop the Samples Entry by pressing the button or wait until it stops automatically because there are no more samples in the Samples Entry Area.
- Press the button. The analyzer moves the Recirculation Area until the first link with an **Unknown Sample** is in a position it from the Recirculation Area.
- Accept the message to release the sample.
- A dialogue box opens telling the Operator to identify the Q**sample holder** in the external Identification Area and then the sample itself. The system automatically changes the **Unknown Sample** label to the samples ID introduced.

CAUTION: For maximum safety when identifying an **Unknown Sample**, do not remove the sample tube from the Q**sample holder** until identification of the Q**sample holder** and the sample has been completed.

If, after identifying the sample, the system detects that there are pending tests, the program asks for the sample to be re-introduced in the Samples Entry Area.

- If there is more than one Unknown Sample, the system allows releasing and identifying the **Unknown Samples** consecutively and individually. Proceed as described above until all the **Unknown Samples** have been identified.

15.8 Reloading Consumables

15.8.1 Replace/Insert Product

The Operator can add or replace any product (Reagent, Diluent, Calibrator, Control or commercial Standard) without stopping or re-starting the work under way in the analyzer. To do so, please proceed as follows:

- Press the **Open Upper Door** button to access the Products Trays. Because the instrument may be working in this area, it may not allow immediate access, in which case a warning message will appear informing the Operator the need of waiting until the current process has concluded. The door will automatically open when it is possible.
- Press the **Trays Content** button and select the **Last One** configuration in the **Trays Content** window.
- If the product is in the Grey Tray at the back, press the **Move Trays** button to move the Grey Tray and place it so that it is accessible to the Operator.

WARNING: The Products Desk may condense water if the Upper Door is open for long periods of time. Keep the door open only as long as strictly necessary to complete these operations.

- To **Replace a Product:**
  - Physically replace the vial in the corresponding position in the tray by another vial of the same product.
  - Select the position of the replaced product on the screen and press **Reset Product** button (), see Figure 15.1, no. 4.

CAUTION: Refilling of products is a risky practice that should be avoided**.**

WARNING: The Q**Executor** window always displays the same graph for the Trays Content. The Operator must ensure that the product is placed in the correct position, checking that the number of the tray position indicated on the screen is the same as the number of the position in the tray.

- To **Insert a Product:**
  - Insert the vial in an empty position. In case of a product with manual identification, proceed as described in Section 15.4.
- Press **Accept** in the **Trays Content** window.
- Gently close the Upper Door pressing it down until hearing the click of the closure. At this point, if Automatic Products Identification is enabled (see Section 7.3.2), the system will perform a products identification round and request confirmation for the trays.

- If there was no operation in course, press the **Start** button () to continue running the orders. If the instrument was performing some test, the samples entrance is activated automatically without needing the Operator intervention.

NOTE: The Upper Door can be opened at any time. However, opening it blocks any analyzer operation immediately. The steps described above should be done continuously, with no pauses, in order not to affect current processes too much.

If opening the door causes over-incubation of the tests being performed, the analyzer will notify this incident in the result of the order.

15.8.2 QCells Reloading

When new Q**cells** cuvettes need to be reloaded, proceed as described below:

- Take out the empty rack by gently pulling it from one end.
- Place a new rack in the empty loading position of the Q**cells** Desk, with the label facing outwards. For more details, please see Section 4.3.1.1.

CAUTION: Empty Q**cells** racks should be discarded in accordance with current local legislation.

CAUTION: Taking the Q**cells** cuvettes rack out while it is in use may block the system or damage the equipment. Never take a rack out unless you are sure that it is empty or the analyzer is on standby.

15.8.3 Refilling Wash Solutions

When the Wash Solutions need to be refilled, please proceed as follows:

- Press the **Open Lower Door** button.
- Disconnect the tubes from the indicated bottle.
- Remove the bottle from the analyzer.
- Fill it.
- Insert the bottle back into its initial position, connect the tubes and close the Lower Door.

CAUTION: When the Wash Solutions Bottles are inserted into the analyzer, ensure that each Bottle (A and B) is placed in its corresponding position.

CAUTION: If any Wash Solution Bottle is disconnected and connected again without changing significantly its volume (less than 1 L), a Priming of the Fluid Circuit after closing the Lower Door is strongly recommended (see Section 7.2.1).

CAUTION: When the Wash Solutions Bottles are inserted into the analyzer, ensure that the connection tubes to the bottles are not pinched or bended over as this could cause the analyzer malfunction.

CAUTION: While the analyzer is working, the bottles are subjected to pressure. For the system to work properly, ensure that the caps of the bottles are tightly fitted and that the tubes are properly connected.

NOTE: After closing the Lower Door, if the volume of any Wash Solution Bottle has changed in more than 1 L, the system will perform a **fluidics initialization**, which takes about 5 minutes.

15.8.4 Emptying the Waste Solutions

When the Waste Solutions need to be emptied, please proceed as follows:

- Open the **Lower Door** of the analyzer.
- Disconnect the tubes from the bottle and remove the bottle from the instrument.
- Empty the Bottle in accordance with legal requirements.
- Return the Bottle to its initial position, connect the tubes and close the Lower Door.

DANGER: Waste Bottles may contain hazardous liquids. Handle them as if they were potentially infectious substances.

WARNING: The contents of the Waste Bottles should be eliminated in accordance with current local legislation.

CAUTION: When the Waste Bottles are inserted into the analyzer, ensure that the connection tubes to the bottles are not pinched or bended as this could cause the analyzer malfunction.

NOTE: After closing the Lower Door, if the volume of any Waste Bottle has Changed in more than 1 L, the system will perform a **fluidics initialization**, which takes about 5 minutes.

Alternatively, the analyzer offers the possibility of emptying the Waste Bottles automatically. For more information, please see Section 7.2.5.

15.8.5 Replacement of the QWaste Tray

When the Q**waste tray** needs to be replaced, please proceed as follows:

- Select the **Reset** Q**cells** option on the  menu of the Q**Executor** window.
- Accepting the confirmation message displayed by the analyzer will cause the Lower Door to open automatically and the counter of discarded Q**cells** cuvettes to reset.
- Remove the Q**waste tray** from the instrument and eliminate it in accordance with legal requirements.
- Insert a new Q**waste tray** and close the Lower Door.

	**DANGER:** The Q**waste tray** may contain Q**cells** cuvettes with hazardous liquids. Handle it as if it was a potentially-infectious substance.
	**DANGER:** The Q**waste tray** with the Q**cells** cuvettes used by the analyzer should be disposed of in accordance with current local legislation.

15.9 Results Management

15.9.1 Results Viewing

Once the test has finished, the information about the results appears in the **Worksheet** window.

There are three possible status for a finished result:

- The test has **correctly finished**. The colour code is green.
- The test has **correctly finished** but there is **additional information** to be checked by the Operator. The colour code is green with a blue dot.
- The test has been **cancelled**. The colour code is dark-grey with a **red cross** and a blue dot, which means there is **additional information** that describes the reason for cancellation to be checked by the Operator.

For more detailed information, please check Section 8.3.2.

15.9.2 Results Revision and Exportation

Before revising the results, the Operator should perform the following checkings:

- Check all information available about:
  - Ranges of Normality.

- CV of the duplicates (if programmed).
- Incidences during testing or related to algorithms checkings.

- Review the results and export them to the LIS (see Section 8.1).

To review Calibrators, Standards and Controls results see the corresponding procedure described in Sections 10.1.3, 10.2.3 and 11.7, respectively.

15.9.3 Results Printing

Once the results have been reviewed and exported, the Operator has the possibility of printing them.

To do so, proceed as follows:

- Select the samples for which the Operator wants to print a Report.
- Press the **Print Report** button in the Q**Manager** window. For more detailed information, please refer to Section 14.

15.9.4 Results Filing

Once Operator's intervention with the results is finished, the Operator can file them.

To do so, proceed as follows:

- Select the samples to be filed.
- Press the **File Results** button in the Q**Manager** window. For more detailed information, please refer to Section 8.1.

⚠ **CAUTION:** For an optimum performance of the analyzer, it is recommended to file the samples when there is a maximum of 200 samples in the Q**Manager**.

15.10 Unloading and Shutdown of the Analyzer

Once the workload is complete, at the end of the working session, proceed as follows:

- Remove the products from the analyzer:
  - Press the **Open Upper Door** button.
  - Remove the Black Tray and empty it.
  - To remove the Grey Tray, press  to put it in an accessible position and empty it.

⚠ **CAUTION:** To remove the trays, first remove the tray placed in the frontal position. To remove the second tray, press always the **Move Trays** button. Do not force the trays to move them manually.

- Discard or keep the products, according to the Instructions for Use.
- Load the empty trays in the analyzer (see Section 15.4).
- Close the Upper Door.
- Accept the confirmation message.

- Press the **Open Lower Door** button.
- Remove and empty the Waste Solutions, as described in Section 15.8.4.
- Fill the Wash Solutions Bottles with diluted **System Solution A** and **System Solution B**, respectively.
- Remove the Q**waste tray** and empty it, as described in Section 15.8.5.
- Replace the empty Q**cells** cuvettes racks as described in Section 15.8.2.
- Close the Lower Door.
- Remove the samples from the Samples Desk.
- Turn off the analyzer using the **Start/Stop** button.

⚠ **CAUTION:** The samples and products used in the analyzer should be eliminated in accordance with current local legislation.

⚠ **CAUTION:** The instrument performs a Final Wash of the fluid circuit automatically when turning it off through the **Start/Stop** button to prevent the formation of precipitates which might disrupt normal liquid dispensing. Make sure that the analyzer completes it successfully.

16 Maintenance

16.1 Maintenance Schedule

Maintenance is a series of operations performed at regular intervals to ensure that the Q**Next** remains operational and reliable.

There are different kinds of maintenance operations. Some are very simple and can be carried out by the Operator. Others, however, must be performed by a Qualified Personnel.

Among the operations that an Operator can perform are cleaning and decontaminating the equipment.

As a general rule, and provided that the equipment is working properly, the Maintenance Schedule to be followed is the indicated below:

Table 16.1. Maintenance Schedule

PERIOD	ACTION	PERFORMED BY
When the Operator wants to verify the correct operation of certain instrument modules.	Verify the instrument's temperature, the samples and reagents dispensation and the readers as indicated in Sections 16.5.1, 16.5.2 and 16.5.3, respectively.	Supervisor
When drops of samples or other substances fall into any part of the analyzer.	Clean incubator carrousel, reader block, Products Trays and the Samples Entry Area, as indicated in Section 16.4.1.	Operator
Daily	• Check for liquid leaking (see Section 16.2.1). • Check for condensation (see Section 16.2.2)	Supervisor/Operator
Weekly	• Clean the Probes, the guideway of the Products Probe and the Probes' Washing Stations of possible rests of saline solution (see Section 16.3.1).	Supervisor/Operator
Monthly	• Decontamination (see Section	Supervisor/Operator

PERIOD	ACTION	PERFORMED BY
	16.4.2). • Cleaning surfaces (see Section 16.4.1)	
Every 12 months	• Preventive Maintenance: Revision of the general state of the Q**Next.**	Qualified Personnel

The maintenance operations scheduled each month or more and performed by the Operator or a Qualified Personnel should be recorded in the "SERVICING LOG" at the back of these Instructions for Use.

Technical Service can be provided by your supplier or other authorised services by Diagnostic Grifols, S.A.

	**DANGER:** During cleaning and/or decontamination, the Operator should wear protective gear (gloves, lab coat, laboratory goggles, etc.).
	**WARNING:** Before cleaning and decontamination, remove all samples, products and Q**cells** from inside the equipment.
	**WARNING:** Take care to ensure that cleaning/decontamination solutions do not enter the openings of the equipment.
	**WARNING:** Do not dismantle the equipment under any circumstances. If liquid had leaked inside the analyzer unplug it from the power. In this case, cleaning should be performed by a Supervisor. Call the authorised Technical Service closest to you.
	**CAUTION:** Due to the fragile nature of the removable parts (bottles, bottle caps, Q**waste tray**), special care should be taken when cleaning and/or decontaminating these parts.
	**CAUTION:** Before using any means of cleaning or decontamination other than those recommended by the manufacturer, the Supervisor should check with the manufacturer that the methods proposed will not damage the equipment.

16.2 Daily Maintenance

16.2.1 Checking for Leaks

Check that there are no liquids in the following area which should not be there:

- The Incubation Area.
- The Products Trays.
- The Products Desk.
- The Samples Desk.
- The Reading Area.
- The Probe Washers (samples and products).
- The surface on which the analyzer stands.

Carefully clean any liquids or drops with a damp cloth, as described in Section 16.4.1 and notify authorised Technical Service if it occurs again.

16.2.2 Checking for condensation

The Products Desk may condense water along the working day, depending on the local temperatures and the environmental humidity. Check that there is no water in the Products Trays and in the bottom of the Products Desk.

When condensation is detected, it is very important to remove the Black and Grey Trays and carefully dry both trays and the whole Products Desk with a thin cloth. Pay special attention to the rail that guides the Trays and clean it with a cloth and with the aid of a point, if necessary.

16.3 Weekly Maintenance

16.3.1 Cleaning the Probes and the Probes' Washing Stations

At least weekly, the Operator should check if there are rests of saline solution in the Probes and the Probes' Washing Stations. If so, proceed as follows:

- Open the Upper Door.
- Clean carefully the tip of the Samples and Products Probes, the guideway of the Products Probe and the Probes' Washing Stations of possible rests of saline solution with a cloth moistened with water.
- Close the Upper Door.

16.4 Monthly Maintenance

16.4.1 Cleaning Surfaces

16.4.1.1 Cleaning the Outside

The Q**Next** has been manufactured with top-quality materials. However, biological samples, saline solutions, acid or alkaline solvents must be removed from both inside and outside the equipment before they can damage it.

The outside of the equipment (casing and Upper Door of the analyzer) should be cleaned periodically with a damp cloth and mild detergent.

CAUTION: The Upper Door of the analyzer should be cleaned with soft, non-abrasive products to prevent scratching of the blue dome when cleaning.

CAUTION: In case of accidental spillage of sample in the Samples Desk, clean the desk itself and the Q**sample holders** involved, as described in Section 16.4.1.4.

16.4.1.2 Cleaning the Screen

Clean the screen regularly with a cloth which does not leave fluff, moistened with a solution of 50% vol. isopropylic alcohol.

WARNING: Do not spray the screen directly with cleansers since they may filter inside, causing damage and danger of electric shock to the Operator.

WARNING: It is important to avoid cleaning the touch screen with caustic chemical agents.

DANGER: Isopropylic alcohol is highly flammable and irritating.

NOTE: The presence of dirt on the screen can cause the screen pointer malfunction. Clean it carefully before contacting the Technical Service.

16.4.1.3 Cleaning the Products Desk

The Products Trays can be removed for cleaning. To do so, please proceed as follows:

- In the Q**Executor** window, press the **Open Upper Door** button. The analyzer will open the Upper Door, providing access to the Products Desk and will place the Products Arm on the left side, making easy the removal of the trays.
- Take out the Black Tray (positions 1-15) by pulling it gently by the knobs.

- To remove the Grey Tray (positions 16-30) which is located at the bottom, press the **Move Trays** button, the analyzer will move the Products Desk so that the Grey Tray is accessible to the Operator.
- Take out the Grey Tray by pulling it gently by the knobs.
- Clean both trays with a cloth moistened with water and detergent.
- Clean the entire surface of the empty Products Desk in the same way, including the rail that guides the trays with the aid of a point, and dry it.

CAUTION: In case of accidental spillage of a potentially-contaminating liquid or small spots of residue and incrustations, a towelette soaked in 0.5% vol. solution of sodium hypoclorite can be used to disinfect and clean the Products Trays and Desk.

16.4.1.4 Cleaning the Samples Entry Area

Both, the Samples Entry and Delivery Areas should be cleaned with a cloth moistened with water and a mild detergent, including the base of the Q**sample holders**.

NOTE: The presence of dirt in the base of the Q**sample holders** can cause them scrolling problems through the Samples Entry and Delivery Areas.

CAUTION: In case of accidental spillage of a potentially-contaminating liquid or small spots of residue and incrustations, a towelette soaked in 0.5% vol.solution of sodium hypoclorite can be used to disinfect and clean the Samples Entry Area and the Q**sample holders**.

16.4.1.5 Cleaning the Incubation and Reading Areas

The covers protecting the Reading Area should also be cleaned with a damp cloth.

Also, with the help of some single-use swabs moistened with water and detergent, clean all accessible surfaces of the incubation positions.

CAUTION: Take care that cleaning/decontaminating solution does not enter the openings of the covers, since it could damage the reader.

16.4.1.6 Cleaning the Waste and Wash Solutions Desk

The Wash and Waste Solution Bottles should be removed from the equipment for emptying and cleaning:

- In the Q**Executor** window, press the  button. The Lower Door of the analyzer will open, giving access to the Wash and Waste Solutions Desk.
- Disconnect the connectors from the bottles.
- Remove the bottles from the analyzer and empty the liquid into special containers, in accordance with current regulations in your country.
- Rinse the inside of the bottles with plenty of purified water. To decontaminate the bottles, proceed as described in Section 16.4.2.3.
- Clean the outside of the bottles with soap and water.

16.4.2 Decontaminating the Equipment

To avoid the risk of infection, it is important to decontaminate the instrument before running certain operations.

Decontamination is also important for the correct maintenance of the fluidic circuit. This correct maintenance allows working in optimum conditions that assure the quality of the results.

The equipment should be decontaminated once a month or in any of the following cases:

- After spills, leaks, etc. of potentially-contaminating liquids.
- When preparing the equipment for transport or storage.
- Before Technical Service intervention.
- When disposing of the equipment.

The fluid circuit and all surfaces in contact with potentially-contaminating liquids should be decontaminated.

16.4.2.1 Information on Contaminating Liquids

To avoid any risks during the disinfection process, follow the procedures established in the laboratory, in accordance with local laws on accident prevention.

DANGER: Any part of the equipment which might be in contact with samples of blood, serum or any other biological liquid should be treated as potentially-contaminated.

Special care should be taken when handling the following parts of the equipment:

- Samples and Products Probes.

- Waste Bottles.
- Waste Bottles connections.
- Q**waste tray**.
- Used Q**cells** cuvettes.
- Products Trays, particularly if they are carrying vials and/or tubes with products.
- Q**sample holders**, particularly if they are carrying tubes with samples.

NOTE: The following procedures do not ensure that the equipment is totally free of contamination, but they do reduce the risk.

16.4.2.2 Information on Decontaminating Liquids

To decontaminate the Q**Next**, the following solutions will be required:

- 4000 mL of a 0.5% vol. solution of sodium hypochlorite.
- 4000 mL of purified water.

When handling these liquids, please observe the following recommendations:

- The corresponding Instructions for Use.
- Laboratory safety regulations.
- Current local legislation on accident prevention.

DANGER: The sodium hypochlorite solution is corrosive and can irritate the skin and the eyes. It is toxic if inhaled, absorbed or ingested.

WARNING: Before using any cleaning or decontaminating product other than those recommended by the manufacturer, the Supervisor should check with the manufacturer that the proposed methods will not damage the equipment.

16.4.2.3 Decontaminating the Fluid Circuit

The equipment should be decontaminated every month or whenever it needs to be transported, stored or disposed of from its place of work and before Technical Service intervention.

The Q**Next** fluid circuit Decontamination process is performed automatically in two steps, as described below:

- Prepare 4 L of 0.5% (v/v) sodium hypoclorite solution (Decontaminating solution).
- Access the Q**Executor** window.

- Open the Lower Door of the analyzer.
- Remove the 4 bottles and empty them into special containers according to the current legislation in your country.
- Fill each of the Wash Solutions Bottles A and B with 1500 mL of 0.5% (v/v) sodium hypoclorite solution and each of the Waste Bottles W1 and W2 with 500 mL of 0.5% (v/v) sodium hypoclorite solution.
- Close the Lower Door.
- If initialization starts, press **Cancel**.
- Select **Other Options** (), **User Maintenance**, **Decontamination**. Press **Accept** and wait for the process to finish (approximately 15 minutes).
- The system performs an automatic priming of the entire fluid system.
- Once it is finished, it asks the Operator to remove the decontaminant solution from the Wash Solutions Bottles and to perform the second part of the Decontamination process, the **Rinse**.
- Press **Accept** and open the Lower Door of the analyzer.
- Empty the 2 Wash Solutions Bottles and Rinse them several times with purified water to eliminate any remaining solution of sodium hypoclorite.
- Then, fill each of the Wash Solutions Bottles A and B with 1500 mL of purified water and each of the Waste Bottles W1 and W2 with 500 mL of purified water.
- Once the 4 bottles are in its position in the analyzer, close the Lower Door.
- Select **Other Options** (), **User Maintenance**, **Rinse** and press **Accept**. The instrument will perform an automatic Rinse of the entire fluid system with purified water.
- Once it has finished, press **Accept** again and open the Lower Door to empty the 4 bottles and fill the 2 Wash Solutions Bottles A and B with their respective solutions (see Section 15.8.3).
- Press  to initialize the system.

NOTE: The bottles and their caps can also be placed in an autoclave. To prevent the bottles becoming misshapen, uncap them before putting them in the autoclave.

16.5 Verification of the Instrument's Correct Operation

16.5.1 Temperature Verification

This procedure is aimed at verifying the correct temperature regulation of the following modules: Incubator, products entrance and reader of the Q**Next**. To perform this procedure, contact with your local service representative.

16.5.2 Dispensation Verification

This procedure is aimed at verifying the precision and veracity in the dispensation of the Samples and Products Arms. To perform this procedure, contact with your local service representative.

16.5.3 Reader Verification

This procedure is aimed at verifying the readers' precision, reproducibility and linearity. To perform this procedure, contact with your local service representative.

16.6 QDiagnostic

The Q**Next** software has an option called **Diagnostic** that allows the Operator or Qualified Personnel to run a self-test of the instrument. This option can help to diagnose a problem in the instrument or simply check the proper functioning of the instrument as a regular maintenance activity.

When the Q**Diagnostic** is finished, it automatically generates a report in **.pdf** format with the results of all the tests run.

To perform a Diagnostic of Q**Next**, proceed as follows:

- Turn on the Q**Next**.
- When the black screen with the big Q logo appears (Figure 16.1), double-click on the center of the screen.

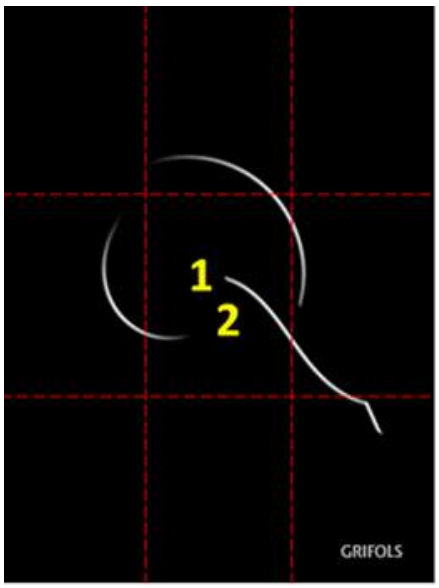


Figure 16.1. Black Window with Big Q Logo

- Once the "**Service Menu**" is available (Figure 16.2), click on **Diagnostic** option in the **Main** tab.

Figure 16.2. Service Menu Window

NOTE: It takes a while for the buttons in the **Service Menu** window to be enabled.

- The **Diagnostic** window is displayed:

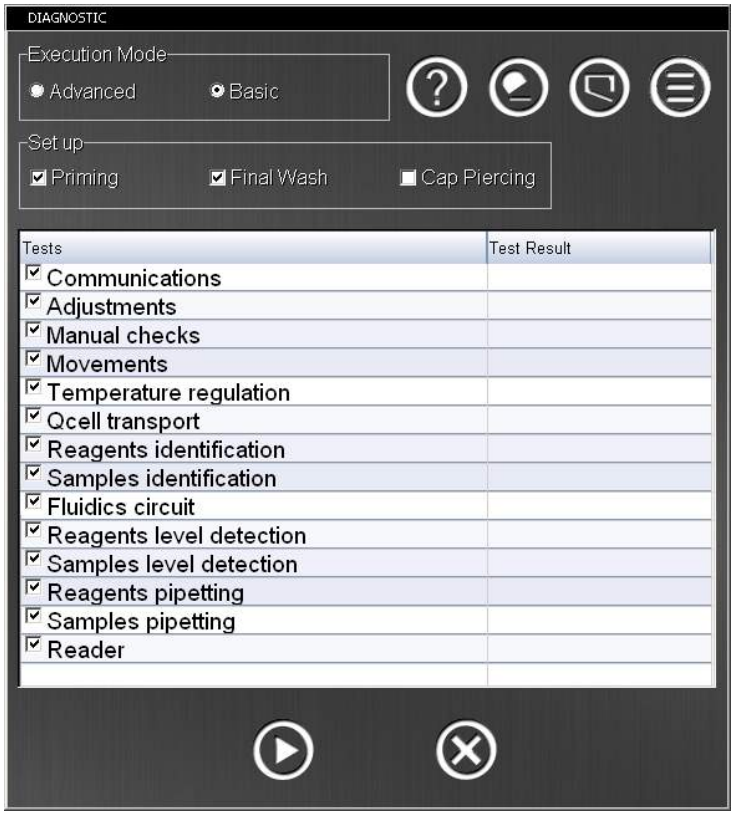


Figure 16.3. Diagnostic Window

The **Diagnostic** window already has the options to perform the whole Operator Diagnostic procedure (**Basic** Mode) selected by default.

Select the **Cap Piercing** option if the laboratory is working with this option activated.

In the **Tests** list, the Diagnostic tests can be selected/deselected independently by clicking on their checkbox. **Communications** and **Adjustments** tests are always selected by default and cannot be deselected.

- Press the button. When pressing this button, a window details the materials required and the actions to be performed by the Operator before beginning the Diagnostic procedure so that the instrument is able to execute the selected tests (Figure 16.4).

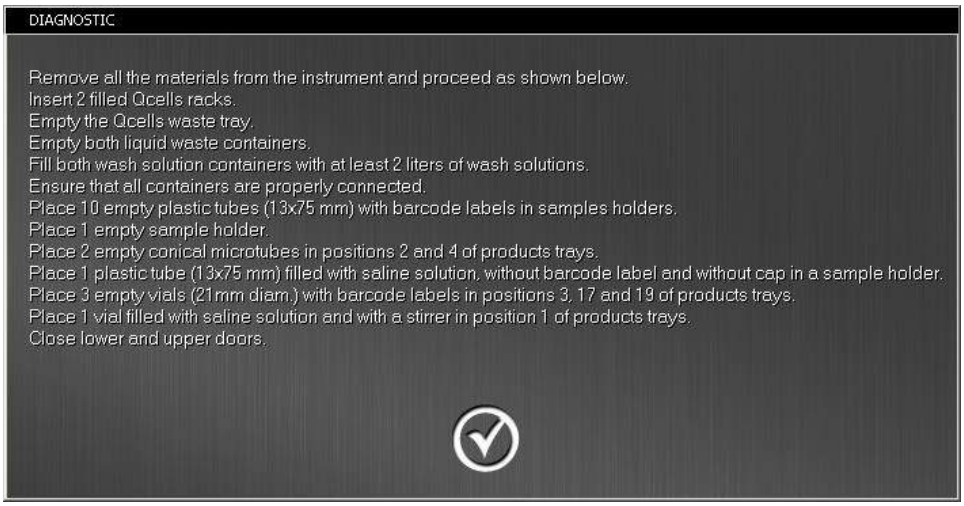


Figure 16.4. Required Materials and Actions Window

- Once all the actions required to execute the selected tests have been performed (Figure 16.4), press the button and then **Accept**.

CAUTION: For the proper operation of the Q**Diagnostic** procedure, it is very important to place the required material in the indicated positions and perform all necessary actions, otherwise, its execution could fail.

- Once the Diagnostic starts, the **Progress** window (Figure 16.5) details the list of tests selected and their status:
  - Test in execution: “PROCESSING”.
  - Test waiting to be executed: “PENDING”.
  - Test execution interrupted: “CANCELLED”.
  - Test executed successfully: “PASS”.
  - Test executed with errors: “FAIL”.

Figure 16.5. *Q**Diagnostic Progress Window***

On the top of the window, the total remaining time is detailed; and at the bottom, a progress bar for the test in process is shown.

If the **Cancel** button is pressed, all the processing and pending tests are cancelled.

When the failed execution of one test affects to other tests then these tests are automatically cancelled.

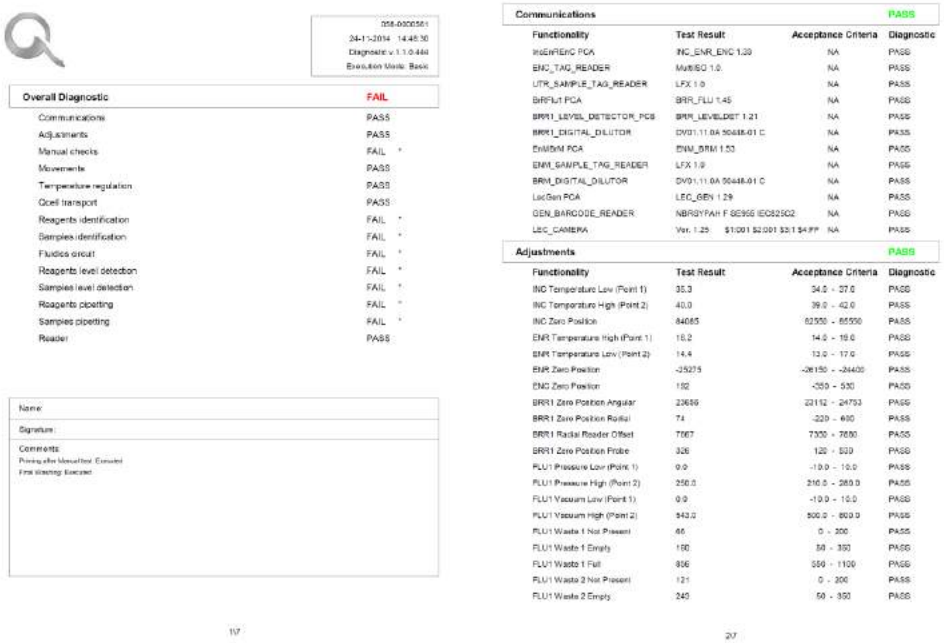
- The **Communications** and **Adjustments** tests are automatically performed by the instrument but the **Manual checks** test requires Operator intervention. To do so, follow the software instructions.
- Once the **Manual checks** test has been completed, the instrument performs the rest of selected tests automatically.
- The instrument automatically generates a report in **.pdf** format with the results of all the Diagnostic tests that have been initiated, regardless of they are finished or cancelled. These reports are automatically saved with the following format: "Diagnostic (date){time}.pdf" in the Q folder.

- To view or save a Q**Diagnostic** test report into an external USB data storage device, press **Print Report** button (Figure 16.3). After clicking on it, there are two options available:
  - **Create:** It opens the last generated report, which can be saved in the USB in **.pdf** format.
  - **Open:** To browse a previously generated report.

The first page of the report contains the following information (Figure 16.6, a):

- Instrument Serial Number.
- Date and time.
- Diagnostic program version.
- Execution mode: Basic or Advanced.
- Overall Diagnostic result: PASS or FAIL.
- Individual Diagnostic Tests with result: PASS, FAIL, Cancelled or Not Executed.
- Section for comments, name and signature.

Next pages detail each test results (Figure 16.6, b).



(a) (b)

Figure 16.6. Diagnostic Report

- Once the Q Diagnostic procedure has been finished and the corresponding diagnostic report/s duly saved, press the **Cancel** button. Then the Operator has two possibilities:
  - Initialize the instrument: To do so, press , "**Resume Application**" in the **Main** tab of the , "**Service Menu**" (Figure 16.2).
  - Shutdown the analyzer: To do so, press the **Start/Stop** button of the screen.

16.7 Complete Backup

The Q**Next** software has an option called **Backup** that allows the Operator or Qualified Personnel to do a backup of the complete Q folder with the software files and results.

To do a backup of Q**Next**, proceed as follows:

- Turn on the Q**Next**.
- When the black screen with the big Q logo appears (Figure 16.1), double-click on the center of the screen.
- Once the **Service Menu** is available (Figure 16.2), select the **Backup** tab.
- Connect an external USB data storage device.
- Select the unit of the USB data storage device (different from the "E:\" unit) (Figure 16.7, no. 1).

NOTE: The detection of the USB data storage device could take a while.

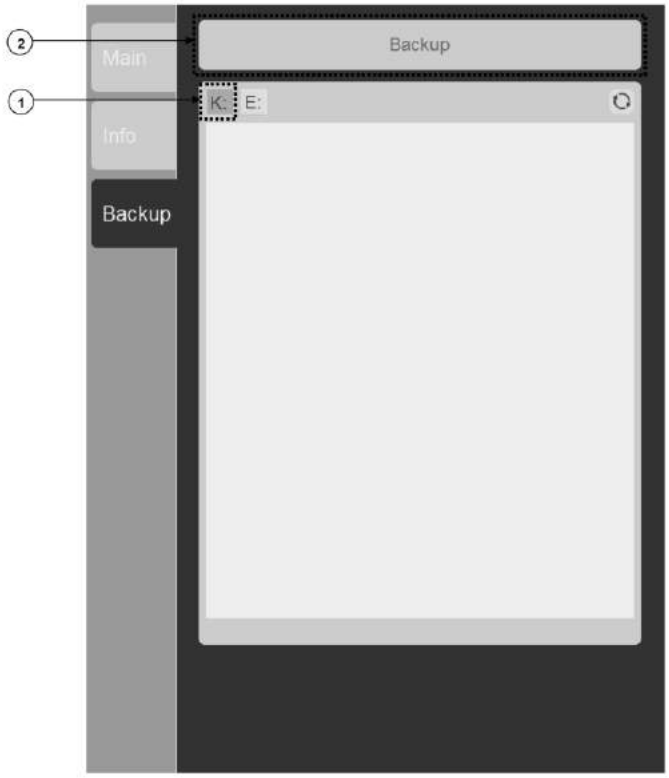


Figure 16.7. Backup Tab

- Click on the **Backup** button at the top of the window (Figure 16.7, no. 2). A confirmation window opens with the following options (Figure 16.8):
  - Enable/disable the **inclusion of logs** in the backup file.
  - Editable field for the **description** of the backup file.

Figure 16.8. Backup Window

- If **Include logs** option is enabled, introduce the date from which the logs want to be included in the backup (Figure 16.9):

Figure 16.9. Include Logs Window

- Press **OK** and the backup process will be initiated.
- When the backup has been finished, a backup folder is automatically saved in the selected unit. The backup folder is named with the following format: BAK_yyyy-mm-dd_hh_mm_ss.
- Then, the Operator has two possibilities:
  - Initialize the instrument: To do so, press "**Resume Application**" in the **Main** tab of the "**Service Menu**" (Figure 16.2).
  - Turn down the analyzer: To do so, press the **Start/Stop** button of the screen.

16.8 Technical Service Maintenance

The Q**Next** should be checked every year by a Qualified Personnel trained by the manufacturer.

CAUTION: Before the Qualified Personnel starts to work, remove the Q**sample holders** with the samples tubes from the Samples Entry Area and the products from the Products Trays and run the **Decontamination** process.

WARNING: After the Technical Service intervention, the Operator should verify the correct functioning of the analyzer by performing a *Performance Qualification* (PQ) test.

Maintenance includes, among other things:

- Replacement of the Q**cells** cuvettes disposal funnel.
- Mechanical revision (adjustments, gears, lubrication, sensors, etc.).

- Revision of fluid system (tubes, valves, diluter syringes, connectors, etc.).
- Revision of the state of washers and Probes.
- Optical element revision (LEDs, photometer check).
- Revision of the IT system (disk check, making backup copies).

17 Transport and Storage

WARNING: The equipment must be decontaminated prior to transport and/or storage.

If the Q**Next** needs to be stored for a long period, it should be packaged as if it was going to be transported.

The environmental conditions for storage and transport should be as specified in Section 3.1.

The spatial requirements for storing the equipment are as follows:

- Size: 95 cm height x 80 cm depth x 120 cm width.
- Approximate weight: 182 kg.

WARNING: Only use the original packaging for transporting the equipment.

18 Cybersecurity

Diagnostic Grifols, S.A. has implemented technical safeguards (*i.e.,* security features) in the **QNext** to achieve a good cyber hygiene and to reduce cybersecurity risks events to an acceptable residual risk level. With the aim to facilitate healthcare providers' efforts in maintaining effective security programs and meeting any relevant regulatory requirements and/or standards a Manufacturer Disclosure Statement for Medical Device Security (MDS2) can be provided upon request.

This document supplies healthcare providers with important information to assist them in assessing the vulnerability and risks associated with protecting private data transmitted or maintained by the **QNext**.

19 Disposal of the Equipment

To dispose of the Q**Next**, all possible remains of samples and products should be eliminated and all surfaces thoroughly cleaned and decontaminated. Once decontaminated, it should be sent to an authorised electronic waste processing site.

	**DANGER:** This instrument should only be dismantled by a Qualified Personnel.
	**CAUTION:** Once the instrument has reached the end of its useful life, bear in mind that all current local legislation must be complied during disposal.

Within the EU, the Q**Next** is considered waste and is subject to the stipulations of European Directive **2012/19/EU** on Waste Electric and Electronic Equipment (WEEE).

To dispose of the equipment, contact your local service representative directly.

20 Warranty

The terms and conditions of the warranty are provided in a separate document. For more information, please contact your local service representative.

The following parts are not covered by the warranty:

- External connections to the equipment.
- Fluid pipes and their connectors.
- Syringes.
- Wash and Waste Solution Bottles.
- Probes.
- Qwaste tray.
- Qcells cuvettes disposal desk funnel.
- Qsample holders.
- Products Trays and other accessories.
- Parts subject to wear and tear due to use (misuse) such as the surface of the Samples Entry, touch screen, etc.

The warranty does not cover:

- Damage caused by switching on and operating the equipment in environments which contravene these Instructions for Use.
- Damage caused by accidents, negligence or failure to comply with these Instructions for Use.
- Damage caused in cases of *force majeure* (atmospheric, geological phenomena, etc.).
- Damage caused by mishandling, including mishandling by technical staff not authorised by GRIFOLS.
- Plastic or rubber parts, and enamel or paint which have deteriorated because of hits or use, unless caused by actual manufacturing defect.
- Breakdowns or defects due to transport.

The replacement of the equipment is at the discretion of the Local Service Representative.

⚠ **CAUTION:** Repairs should be performed only by staff specifically authorised by GRIFOLS.

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21 Troubleshooting

Certain alerts and incidents may arise during normal use of the **QNext** which the Operator can solve without the help of specialised Technical Service.

Incidents are classified in different types:

- Incidences during testing:
  - Red window.
  - Information warning: With three level of priority, High, Medium and Low.
  - Warning in sample result.

    Incidences during sample testing.

    Incidences that cause test cancelling.

    Incidences related with the primary curve.
- Incidences post-result.

21.1 Incidences During Testing

Any alert or incident occurred during testing will be informed to the Operator.

21.1.1 Red Window (High Level Incidents)

The incident requires immediate Operator intervention; a red window will appear with different options for the Operator to choose.

Mechanical Incidents

Table 21.1. Red Window (Mechanical High Level Incidents)

ERROR	MESSAGE	DESCRIPTION	TROUBLESHOOTING
010001304 020001304 030001304 040001304 040002304 040003304 060001304 060003304 070016304	**Movement Error** in *Device X*	A problem has been detected when trying to move the *Device X*.	- Press **Retry** - If the error appears again, press **Abort**. **Open** the **Upper Door** and check if there is anything blocking the movement of the *Device X*. - Retry the **Initialization** and if the problem persists, contact your **Technical Service**.
010001305	**Current Limit** in	A possible mechanical blockage has been found	

020001305 030001305 040001305 040002305 040003305 060001305 060003305 070016305	*Device X*	while moving the *Device X*.	
010001305	**Current Limit** in Incubator Servo	A possible mechanical blockage has been found while moving the Incubator, probably due to a wrongly positioned **Qcell** cuvette.	- Press **Retry**. - If the error appears again, press **Abort**. **Open** the **Upper Door**, look for the Q**cell** cuvette that is blocking the incubator movement or that is blocked between the Q**cell** rack and the incubator, and try to move it, to unblock the movement. If none blocked cuvette is found between the Q**cell** rack and the incubator, try to take out and introduce again both **Qcells** cuvettes racks. - Retry the **Initialization** and, if the problem persists, contact your **Technical Service.**
030001305	**Current Limit** in Cuvettes Entry Servo	A possible mechanical blockage has been found while dispensing cuvettes.	
201600006 201600008 201600009	One of the Trays is **not detected** (Grey or Black)	One of the Products Trays has not been found.	- Press **Open Door** and place the Tray if it is not present. - If **both Trays are present**, but the analyzer cannot detect one of them, clean both Trays and the rails that guide the Trays in the Products Desks with a damp cloth. - If the error appears again, press **Abort**. Retry the **Initialization** and if the problem persists, contact your **Technical Service**.

201600005 201600007	**Wrong Tray** detected. Expected: Black/Grey Tray	A wrong Products Tray has been detected.	- Press **Open Door** and place the correct tray. - If this is not possible, the Operator should press **Abort** and once the correct tray has been placed retry the **Initialization**. - If the problem persists, contact your **Technical Service**.
090030303 090031303	**Cannot Open** Upper/Lower Door	The Upper/Lower Door cannot be opened.	- Press **Retry**. - If the error appears again, press **Abort** and **manually open** the corresponding door (Section 4.1.5). - Retry the **Initialization** and if the problem persists, contact your **Technical Service**.
090030302 090031302	Upper/Lower Door **Opened Unexpectedly**	The Upper/Lower Door has been unexpectedly opened.	- **Close** the Upper/Lower Door. - Press **Abort**. - Retry the **Initialization** and if the problem persists, contact your **Technical Service**.

Electronical Incidents

Table 21.2. Red Window (Electronical High Level Incidents)

ERROR	MESSAGE	DESCRIPTION	TROUBLESHOOTING
230100001	Connection with **Q Manager** could not be established	A communication failure between **QExecutor** and **QManager** windows during the results sending to the **QManager** has been detected.	- Press **Abort** and retry the **Initialization**. - If the problem appears again, **restart** the analyzer.

ERROR	MESSAGE	DESCRIPTION	TROUBLESHOOTING
			- If the problem persists, contact your **Technical Service**.
010000105 040000105 090000105 080000105 060000105	*Device X* **not communicate**	A **communication failure** with the *Device X* has been detected.	
010000103 040000103 090000103 080000103 060000103 030003103 100001103 070019103 040006103 040007103 060007103 090040103 090040304 030003301 090073301	**Timeout** in *Device X*	The *Device X* has **exceeded the maximum time allowed** to perform the action that is pending.	
030002301	**Timeout Error** in *Cuvettes Entry Cuvette Pusher*	The **Qcell** *cuvette pusher* **has exceeded the maximum time allowed** to introduce a **Qcell** cuvette into the Incubator.	- Press **Retry.** - If the error appears again, press **Abort**. **Open the Upper Door,** check if there is a Q**cell** cuvette blocked between the Q**cell** rack and the incubator. If this is the case, **try to move it** to unblock it. If none blocked cuvette is found, try to take out and introduce again both **Qcells** cuvettes racks. - Retry the **Initialization**. If the problem persists contact your **Technical Service**.

Fluidic Incidents

Table 21.3. Red Window (Fluidic High Level Incidents)

ERROR	MESSAGE	DESCRIPTION	TROUBLESHOOTING
200800035	The initial **pressure checking** has failed	The fluidic circuit is **not** able to **achieve** the desirable levels of **pressure/vacuum.**	- Press **Abort** and check **bottles connections** and that the **bottles are correctly closed**. - Retry the **Initialization** and, if the problem still appears, **restart** the analyzer. - If the problem persists, contact the **Technical Service**.
200800036 200800037	The initial **vacuum checking** of the waste *container X* has failed		
050002302	**Vacuum failure** in fluidics vacuum regulator		
050001301	**Pressure Failure** in Fluidics Pressure Regulator		
201306017 201206018 201206019 200806017	The **stabilization** of the Fluidics Pressure Regulator has failed	The system is **not** able to **stabilize** the **pressure/vacuum.**	
201307017	The **stabilization** of the Fluidics Vacuum Regulator has failed		
050001305	**Out of margins** in Fluidics Pressure Regulator	The levels of **pressure/vacuum** are **over the acceptance limits.**	
050002305	**Out of margins** in Fluidics Vacuum Regulator		

Pipetting Incidents

Table 21.4. Red Window (Pipetting High Level Incidents)

ERROR	MESSAGE	DESCRIPTION	TROUBLESHOOTING
200506011 200504011 200606011 200604011	*Samples/Reagents Robot X* **CPD sensor** values **over the** accepted limits	The Correct Pipetting Detector (**CPD**) values of the *Samples/Products Robot X* are **over/out of the margins.**	- Press **Abort** and retry the **Test/Initialization** again before doing any troubleshooting action. - If the problem appears again, perform up to 3 cycles of **Final Wash** followed by a **Priming** of the Fluidic Circuit (see Section 7.2), and retry the analysis. - If the problem persists, perform a **Decontamination + Rinse** of the Fluidic Circuit, and retry the analysis. - If the error keeps appearing, contact the **Technical Service**.
200506009 200504009 200506010 200504010 200606009 200604009 200606010 200604010	*Samples/Reagents Robot X* **CPD sensor** values **out of** acceptable **margins**		
040004301 060008301	**CPD is not stable** in *Samples/Reagents Robot X* Correct Pipetting Detector	The Correct Pipetting Detector (**CPD**) values of the *Samples/Products Robot X* are **not stable** after finishing a pipetting step. It could be caused by a partial clot in the probe.	
200700013	**Probe obstruction** detected in *Samples/Reagents Robot X*	An **overpressure** has been detected while pipetting the sample. This can be due to the presence of a real **clot** in the sample, accumulation of **saline residues** in the Fluidic Circuit or a	

040004302 060008302	**Clot detected** in *Samples/Reagents Robot X* Correct Pipetting Detector	**clamped tube.**	
200106001 200104001	**Air detected** during liquid aspiration in *Samples/Reagents Robot X*	The Correct Pipetting Detection (**CPD**) system has detected that the Probe has **aspirated air** when pipetting. It can be due to a wrong level detection.	- Press **Abort** and check the **absence of bubbles/clots** in the vial/tube. Once this factor has been excluded, repeat the analysis. - If the problem appears again, perform up to 3 cycles of **Final Wash** followed by a **Priming** of the Fluidic Circuit (see Section 7.2), and retry the analysis. - If the problem persists, perform a **Decontamination + Rinse** of the Fluidic Circuit, and retry the analysis. - If the error keeps appearing, contact the **Technical Service**.
200106003 200104003	**Partial aspiration** detected in *Samples/Reagents Robot X*	The Correct Pipetting Detection system (**CPD**) has detected that the Probe has **aspirated air** and **liquid** when pipetting. It can be due to a wrong level detection.	
040005303 060006303	**Imprecise Level** in *Samples/Reagents Robot X* Level Detector	The system has found differences between the values obtained when performing the **double level detection** in samples/products. It can be due to **wrong Probe adjustment** in the sample/product tube/vial or the presence of **bubbles.**	- Press **Abort** and check the absence of **bubbles** in the tube/vial. Once this factor has been excluded, **repeat the analysis**. - If the problem appears again, place the tube/vial **in another position** of the Tray or **Qsample holder.** - If the problem persists, contact the **Technical Service.**

040007321 060007321	**Dilutor not empty** in *Samples/Reagents Robot X* Digital Pump/Dilutor	There is a failure in the Samples and Products dilutor.	- Press **Retry**. - If the error appears again, press **Abort** and retry the **Initialization**. - If the problem persists, contact your **Technical Service.**
040004303 060008303	**Overpressure** in *Samples/Reagents Robot X* Correct Pipetting Detector	An overpressure or a clot has been detected in the Probe.	- Press **Open Door** and the Upper Door will be automatically opened. - **Check** if there is **dirt** accumulated in the Probe and, if so, clean it. **Close the door** and the instrument will continue the tests in process. - If the error appears again, press **Abort** and perform up to 3 cycles of **Final Wash** followed by a **Priming** of the Fluidic Circuit (see Section 7.2) to try to clean the pipetting system. Retry the **Initialization** and continue working. - If the problem persists, perform a **Decontamination + Rinse** of the Fluidic Circuit, and retry the analysis. - If the error keeps appearing, contact your **Technical Service**.

Other High Level Incidents

Table 21.5. Red Window (Other High Level Incidents)

ERROR	MESSAGE	DESCRIPTION	TROUBLESHOOTING
200400004 200400005	**Solution A/B bottle is empty**. Fill the solution A/B bottle to continue	The Wash Solution Bottle A/B is empty.	- Press **Open Door** and the Lower Door will be automatically opened. - **Fill the bottle** with the corresponding Wash Solution, **empty the Waste bottles** or **place the** corresponding **bottle** into its position; depending on the error message shown. - **Close the door** and the instrument will continue the tests in process. - If the Operator cannot perform the actions described, press **Abort** and retry the **Initialization** once the troubleshooting has been done.
200500002	Available **Waste bottles are full**. Empty the waste bottles to continue	The available Waste Bottles are full.	
200400006 200400007	Solution A/B Bottle is **not present**	The Wash Solution Bottle A/B is not present.	
200900003 200900043 200900045	Waste Bottle 1/2 is **not present**	The Waste Bottle 1/2 is not present.	
220200012 230200004	**Insufficient level** of product X	There is not enough level of product X to run the pending Tests.	The Operator has 3 options: - Press **Open Door** to automatically open the Upper Door and replace the vial as described in Section 15.8.1 or introduce a new one in another tray position to continue working. - Press **Cancel** to cancel the test in process. - Press **Abort** to cancel all the tests in process and pending.
230200005	Reagent X in position Y is **empty**	There is no product X in the Products Tray position Y.	

200200003	The **Qcells** are detected as reversed.	Reversed **Qcells** cuvettes have been detected.	- Press **Retry** to continue with the process. - If the error appears again, press **Abort** and all tests in process will be cancelled. - Take the **Qcells** cuvettes rack out and visually check the remaining **Qcells** cuvettes orientation, if possible. If reversed **Qcells** cuvettes are detected, change the rack and notify it to Technical Service. If none reversed **Qcells** cuvettes are detected inside the racks, introduce the racks again in their position. - Retry the **Initialization** and if the problem persists, contact your Technical Service.
210100001	There are not enough **Qcells** in racks	There are not enough **Qcells** cuvettes to finish the test/s in process.	The Operator has 3 options: - Replace the empty **Qcells** racks by new ones to continue working. - Press **Cancel**: The test/s in process will be cancelled. - Press **Abort**: All tests in process will be cancelled.

21.1.2 Information Warning

Information about the incidents occurred during testing will be notified in the Q**Manager**, in the **System Alerts Area** (Figure 8.1, no. 5).

These warnings are classified with different priority: High, Medium and Low. The level of priority is related to the urgency required to solve the problem.

21.1.2.1 High

Table 21.6. High Priority Information Warnings

ERROR CODE	MESSAGE	DESCRIPTION
210100002	Q**waste tray** is full	The Q**waste tray** has reached its maximum capacity (400 cuvettes). Empty the Q**waste tray** to allow the analyzer to continue with the processes (see Section 15.8.5).
220200003	Cuvettes racks empty	There are no more cuvettes. Place new cuvettes racks to maintain analyzer's autonomy. Proceed as described in Section 15.8.2.
220100001	Insufficient light level	The light level in the readers is not enough to work properly. Retry the **Initialization** and if the problem persists please contact you Technical Service.
200400004/5 200500004/5 200600004/5 200900004/5 201000004/5 201200004/5	Wash Bottle A/B is empty	Wash Solution Bottle A/B is empty and the analyzer has stopped working. The Operator should refill the corresponding bottle with Wash Solution to restart the process.
200400002 200500002 200600002 200900002 201000002 201200002	Waste Bottles are full	Both Waste Bottles are full and the analyzer has stopped working. The Operator should empty the bottles to restart the process.

ERROR CODE	MESSAGE	DESCRIPTION
230200005	Product X in position X is empty	The product indicated is empty and the analyzer cannot continue working. The Operator should add a new vial to be able to finish the tests in process/pending (see Section 15.8.1).
230200006 220200015	Product X in position X is expired	The product indicated is expired and the analyzer cannot continue working because it cannot use this reagent. The Operator should add a new non-expired vial to be able to finish the tests in process/pending (see Section 15.8.1).
230200007 220200014	Product X in position X is beyond its on-board stability	The product indicated has exceeded its on-board stability and the analyzer cannot continue working because it cannot use this reagent. The Operator should add a new vial to be able to finish the tests in process/pending (see Section 15.8.1).

21.1.2.2 Medium

Table 21.7. Medium Priority Information Warnings

ERROR CODE	MESSAGE	DESCRIPTION
230100001	LIS Communication error	Communications with the LIS are interrupted or it is not possible to import/export data. Check the LIS configuration and if the problem persists contact your Technical Service.
220200004	Q**waste tray** is reaching full capacity.	Check the level of the Q**waste tray** in the Information Area of the Q**Executor** window (Figure 6.1, no. 3) to see if it has reached the

ERROR CODE	MESSAGE	DESCRIPTION
		safety level (350 cuvettes). Replace the Q**waste tray** by a new one to ensure that the analyzer keeps its autonomy. To do so, proceed as described in Section 15.8.5.
220200013 220200012	Product X in position X is under the warning volume	The instrument is warning the Operator that this product is about to finish. The Operator should prepare a new vial and add it when ready so that the analyzer does not stop working because it does not have enough product (see Section 15.8.1).

21.1.2.3 Low

Table 21.8. Low Priority Information Warnings

ERROR CODE	MESSAGE	DESCRIPTION
220200003	Cuvettes racks empty	One of the two Q**cells** racks is empty. Replace with a new one to maintain analyzer's autonomy. Proceed as described in Section 15.8.2.
220200008	Waste (1 or 2) is full	Waste Bottle 1 or 2 is full. Empty it to maintain analyzer's autonomy. Proceed as described in Section 15.8.4.
220200007	Low level in Solution A/B Bottle	Check the available volume of Wash Solutions in the Information Area of the Q**Executor** window (Figure 6.1, no. 3) to see whether the Wash Solution volume indicated by the program is low (below minimum safety level). Refill the corresponding Bottle with the Wash Solution, as described in Section 15.8.3.

21.1.3 Warning in Sample Result

21.1.3.1 Incidences during Sample Testing

Information related with any incident occurred during the realization of a test will be notified in the Incidents Area of the corresponding **Results** window (Figures 13.1, 13.2 and 13.3, no. 4).

Table 21.9. Warnings in Samples Results

MESSAGE	DESCRIPTION
Over-incubated Test	Incubation longer than the margin permitted in the Test Programming plus 120 seconds has occurred. The Operator needs to review the results to be sure that these have not been affected by the incident.
Probe Temperature Out of margin	The Probe was working out of the working range while dispensing some sample or product for this test. The Operator needs to review the results to be sure that these have not been affected by the incident.
Products Desk Temperature Out of margin	The Products Desk was working out of the working range while aspirating some product for this test. The Operator needs to review the results to be sure that this has not been affected for the incident.
Reader Temperature Out of margin	The Reader was working out of the working range while reading the test. The Operator needs to review the results to be sure that this has not been affected for the incident.
Incubator Temperature Out of margin	The Incubator was working out of the working range while incubating the test. The Operator needs to review the results to be sure that this has not been affected for the incident.
Sample with possible interfering substance. Check sample	The test has been programmed with 405 + 620 nm and the result has been obtained at 620 nm.

MESSAGE	DESCRIPTION
conditions	The Operator needs to review the sample because it may contain some interfering substance.

21.1.3.2 Incidences that Cause Test Cancelling

Any alert or incident that has occurred during the test and due to the impossibility to solve the problem finishes with the test cancelling.

Table 21.10. Incidences that Cause Test Cancelling

MESSAGE	DESCRIPTION
Insufficient level in: Sample	The level detected in the sample is too low and the analyzer cancels the requests. Check that the level in the sample tube is enough and that it has no bubbles. Otherwise, transfer the volume of the sample to a microtube, if so desired, uncancel the petition (see Sections 8.3.2 and 8.3.3) and process the sample again.
Not level in: Sample Not level found in sample	Not level has been detected in the sample and the analyzer cancels the requests. Check the level in the sample tube and that it has no bubbles. Otherwise, transfer, if so desired, the volume of the sample to a microtube, uncancel the petition (see Sections 8.3.2 and 8.3.3) and process the sample again.
Pipetting Operations: Correct. Pipetting Detector air aspiration	Conditions were not appropriate during sample/product aspiration and the requests have been cancelled. Visually inspect the sample/products and check that there are no clots, bubbles, etc. Once these factors have been excluded, repeat the analysis.
Fluidic Operations: Probe obstruction detected	An obstruction has been found during sample/product aspiration and the requests have been cancelled.

MESSAGE	DESCRIPTION
	Visually inspect the sample/products and check that there are no clots. Once these factors have been excluded, repeat the analysis.
Reagent ID in position X is under the warning level	The level detected in the product is under the warning level programmed in the corresponding Products Programming. Check the product level and add a new vial in the same position pressing the **Reset Product** () button or place it in a new product position (see Section 15.8.1).
Product (reagent ID) in position X is **empty**	There is insufficient volume of product or the vial cannot be found. Check that the program displays the product as cancelled on the graphic representation of the Products Tray in the Q**Executor** window (Figure 6.1, no. 2). If so, add a new vial in the same position pressing the **Reset Product** () button or place it in a new product position (see Section 15.8.1).
Product (reagent ID) **not present**	The product requested for the test has not been identified or found. Check that the product is not identified on the graphic representation of the Products Tray in the Q**Executor** window (Figure 6.1, no. 2). Then check that: • The product is physically in the Products Tray. • The product has a barcode label that is in good condition and correctly placed as shown in Figure 4.19. If none of these is the cause for the incident, identify the product manually (see Section 15.4) to continue working, and if the problem persists, contact your **Technical Service**.
Product (reagent ID) in position X is **expired** The product appears as **Cancelled** in the Q**Executor**	The product has been cancelled because it has expired (see Section 6.2.4.2). Check that the program displays the cancelled product on the graphic representation of the Products Tray in the Q**Executor** window (Figure 6.1, no. 2). Load a new, non-

MESSAGE	DESCRIPTION
window.	expired lot in the same position or in a new product position (see Section 15.8.1).
Product (reagent ID) in position X has **exceeded its on board stability** (on board stability) The product appears as **Cancelled** in the Q**Executor** window.	The product has been cancelled because the reagent vial has exceeded its on board stability (see Section 6.2.4.2). Check that the program displays the cancelled product on the graphic representation of the Products Desk in the Q**Executor** window (Figure 6.1, no. 2). Load a new product vial in the same position, pressing the **Reset Product** () button, or place it in a new product position (see Section 15.8.1).

21.1.3.3 Incidences in the Primary Curve

Any alert or incident related with the checking that is performed after having applied the algorithm to the primary curve will also be notified in the Incidents Area of the corresponding **Results** window. For more information, see Section 9.2.2.5.

Warnings Common to All Algorithms

Table 21.11. Warnings Common to All Algorithms

WARNING	DESCRIPTION
Reaction absorbance with high values. Check sample conditions	A result has been obtained, but the warning indicates that some absorbance value of the primary curve is higher than 2.0 OD but lower than 3.0 OD. The Operator should check the sample because the high absorbance values could be indicative of the presence in the sample of some substance that produces optical interference such as lipids, bilirrubin or hemoglobin.
OUT: Reaction absorbance out of reader working range. Check sample conditions	There is no available result for the sample because some absorbance value of the primary curve is higher than 3.0 OD. The Operator should check the sample because the high absorbance values could be indicative of the presence in the sample of some substance that produces optical interference such as lipids, bilirrubin or hemoglobin.

IND: Abnormal increase of absorbance at the beginning of the Reading Time	There is no available result for the sample because an abnormal increase of absorbance has been detected at the beginning of the Reading Time. The Operator should repeat the test because this situation normally is due to an irregular entrance of the Q**cell** cuvette in the reader.

Warnings of the Algorithms for Clotting Tests

Table 21.12. Warnings of the Algorithms for Clotting Tests

WARNING	DESCRIPTION
Weak reaction absorbance increase	A result for the sample is obtained, but the warning indicates that the absorbance increase detected because of the clot formation is low. The Operator could suspect that this weak reaction could be indicative of low fibrinogen levels in the sample for example or other.
Unstable Final Absorbance: Reading Time too short or clot not stable	A result for the sample is obtained, but the warning indicates that the absorbance does not remain stable at the end of the Reading Time. The Operator could repeat the test increasing the Reading Time, and if the problem persists, it could be due to a non-stable clot.
CND: Short clotting time	There is no available result for the sample because the clotting time result is very close to the beginning of the Reading Time. This warning indicates that it is difficult to give a clotting time accurately in this part of the curve. The Operator could repeat the test changing the sample dilution of the test.
CND: Clotting time too long	There is no available result for the sample because the clotting time is detected above the 80% of the Reading Time. The Operator could repeat the test increasing the Reading Time.
CND: Reaction absorbance increase too weak	There is no available result for the sample because the absorbance increase detected because of the clot formation is very low. The Operator could suspect that this weak reaction could be indicative of low fibrinogen levels in the sample for example or other.

CND: Artifacts detected in the curve	There is no available result for the sample because an abnormal absorbance increase, not due to clot formation, has been detected during the Reading Time. The Operator should repeat the test.
IND: Unexpected curve shape	There is no available result for the sample because the shape of the curve is not the expected one, and the algorithm is not able to apply the mathematical calculations. The Operator should repeat the test.
Specific Warning for the Algorithms "Maximum Rate for PT", "Maximum Acceleration for PT", "Derived Fibrinogen" and "Fibrinogen Clauss"	
CND: Reaction absorbance increase too weak	There is no available result for the sample because once the maximum rate point has been detected (**Point 1**); the checking to ensure that after clot formation there is absorbance stabilization has failed. This stabilization is only detected when the algorithm is able to calculate "**Point 3**" (see Figures 9.16, 9.19, 9.22 and 9.23). The Operator could suspect that specific properties of the sample have caused unexpected optical interferences.
Specific Warning for the Algorithm ''Time to Absorbance increment''	
OUT: Reaction absorbance out of reader working range. Check sample conditions	There is no available result for the sample because the absorbance value of the primary curve at the clotting point (A_0 + 40 mE, see Figure 9.24) is higher than 3.0 OD. The Operator should check the sample because the high absorbance values could be indicative of the presence in the sample of some substance that produces optical interference such as lipids, bilirrubin or hemoglobin.
Specific Warning for the Algorithm "Maximum Acceleration for TT an TR"	
CND: Abnormal absorbance increase	There is no available result for the sample because an abnormal absorbance increase, not due to clot formation, has been detected at the beginning of the Reading Time (see Figure 9.20). The Operator should repeat the test.

Warnings of the Algorithms for Chromogenic Tests

Table 21.13. Warnings of the Algorithms for Chromogenic Tests

WARNING	DESCRIPTION
Specific Warning for the Algorithm "Two Slopes (30-90)"	
Poor Linearity	A result for the sample is obtained, but the Coefficient of Variation (CV) calculated between both slopes (30-60 and 60-90) is 25%-50%. The Operator could suspect that the analyte concentration in the reaction mixture is too high or that the substrate concentration is not enough.
LIN: Poor Linearity	There is no available result for the sample because the CV calculated between both slopes is > 50%. The Operator could suspect that the analyte concentration in the reaction mixture is too high or that the substrate concentration is not enough.
Specific Warning for the Algorithms "One Slope (5-180)" and "One Slope (5-180) for Anti-Xa"	
LIN: Poor Linearity	There is no available result for the sample because the difference between the primary curve and the calculated regression line is too high (>23 mE for "**One Slope (5-180)**" and >30 mE for "**One Slope (5-180) for Anti-Xa**"). The Operator could suspect that the analyte concentration in the reaction mixture is too high or that the substrate concentration is not enough.

Warnings of the Algorithms for Immunoturbidimetric Tests

Table 21.14. Warnings of the Algorithms for Immunoturbidimetric Tests

WARNING	DESCRIPTION
Specific Warning for the Algorithms ''DDimer NG'' and ''Polynomial VWFag''	
IND: Prozone	There is no available result for the sample because the quantity of antigen contained in the sample is so high that prozone has been detected in the primary curve. The Operator should repeat the test. If the problem persists, manually dilute the sample and run it again, taking into account the dilution factor.

Specific Warning for the Algorithms ''Polynomial Absorbance Increase'' and ''Polynomial VWFag''	
IND: Unexpected curve shape	There is no available result for the sample because the shape of the curve is not well adjusted to a third order polynomial regression, which indicates that the curve shape is unexpected. The Operator should repeat the test.

21.2 Incidences Post-Result

The result has been obtained but there is some incidence related with the checkings and calculations that are performed once the primary unit result has been obtained.

Table 21.15. Incidences Post-Result

MESSAGE	DESCRIPTION
CV Error (CV appears in the sample Results Box)	The CV established in the Test Programming has been exceeded. Repeat the analysis and/or run Controls (QC).
Result outside established clinical range (The **Outside Margin** ( ) symbol appears in the sample Results Box)	A result has been obtained which is outside the normality range established in the Test Programming. Review the primary curve; check the patient's clinical file and concordance with other results before considering that the results have been reviewed. In case of doubt, repeat the analysis.
Repetition of the request is pending revision (IND appears in the sample Results Box)	Repeated request pending revision. Perform the revision of the results as described in Section 13.3.
Lack of Calibration Curve (IND appears in the Results Box for all the samples)	The test in question has no associated Calibration Curve for the Product lot in use. Proceed to calibrate the test as described in Section 10.1.

MESSAGE	DESCRIPTION
Lack of STD (IND appears in the Results Box for all the samples)	The test in question has no associated Standard value for the Product lot in use. Proceed to run the Standard (STD) as described in Section 10.2.
PAR appears in the sample Results Box	Some parallelism acceptance criteria (regression coefficient and/or slopes ratio) of a test with parallelism has failed.
CND: Sample with possible interfering substance. Re-run the sample by a Clauss Fibrinogen test	CND is shown as a result of a Derived Fibrinogen test, when the sample has been read at 620 nm (probably due to possible interfering substances), because it is not correct to provide a result at this wavelength for Derived Fibrinogen test (programmed either at 620 nm or at 405 + 620 nm). This test is based on an estimation of the fibrinogen concentration from the absorbance increase that occurs due to clot formation and the absorbance increase depends on the wavelength. The analyzer will provide a result for a PT test, but not for a DF test. Re-run the sample using a Clauss Fibrinogen test.
Error in Westgard Rules (QC appears in the **Results** window for the Control (QC))	The configuration of the Westgard Rules has been breached and therefore the instrument indicates that there may be a random and/or systematic error to be evaluated. • Analyze the statistical data provided by the analyzer. • Review the conditions of the reagents and the Control (QC) and replace them if necessary. • Repeat the analysis. If the problem persists, contact your Technical Service.
Out of nominal range	A Control (QC) value which is outside the Manufacturer's Range has been obtained (Figure 9.2, no. 2). • Analyze the statistical data provided by the analyzer. • Review the conditions of the reagents and the Control (QC), and replace them if necessary.

MESSAGE	DESCRIPTION
(QC appears in the Control (QC) Results Box)	• Repeat the analysis. If the problem persists, contact your Technical Service.
QC pending validation (The Control (QC) Results Box appears green, indicating that the order has been Completed)	The Control (QC) is still pending revision and if the option **Review Before Exporting Results** is enabled (see Section 9.11.2), the results of the tests affected by this Control cannot be reviewed. Review the results of the Control (QC), as described in Section 11.7.

Servicing Performed

Model: **Serial Number:** **Date Installed:**

DATE	ACTIONS	QUALIFIED PERSONNEL / OPERATOR	QUALIFIED PERSONNEL / SUPERVISOR

DATE	ACTIONS	QUALIFIED PERSONNEL / OPERATOR	QUALIFIED PERSONNEL / SUPERVISOR

Decontamination Certificate

The following Decontamination Certificate must be filled in every time that the instrument is decontaminated. This Decontamination Certificate must be given to your Technical Service before any intervention takes place.

DECONTAMINATION CERTIFICATE	
Serial Number	
Centre	
Decontamination was successfully completed according to the procedure described in Section 16.4.2.	☐ PASS ☐ FAIL Comments:
Date	
Name and position	
Signature	
E-mail address	

Specific information for Australia:

SPONSOR

Grifols Australia Pty Ltd
Unit 5/80 Fairbank Road
Clayton South, VIC 3169
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Telephone: +61 3 9535 9333

Changes Included in QNext v3.0.1

- First version of the **QNext** User's Manual for the USA market.