

navify® Lab Operations

Configuration guide for **Blood donation testing labs**

User Guide

Publication version 1.2

Software version 3.12



Publication information

Publication version	Software version	Revision date	Change description
0.9	3.01.09 and higher	April 2020	Draft version for testing
1.0	3.01.09 and higher	May 2020	First version
1.1	3.01.09 to 3.02 (excluding 3.02.02 and 3.02.03)	December 2020	Updated cover page to specify software versions
1.2	3.12 and higher	January 2026	Updated to software version 3.12.00 Updated document format, added publication information, preface, glossary, and index. Changed name to navify ® Lab Operations. What is new in publication version 1.2 (15)

☰ Revision history of User Guide

Edition notice

This publication is intended for Roche service representatives in order to reconfigure the **navify**® Lab Operations software for the appropriate use in blood bank laboratories. The reconfiguration eliminates any possibility to modify results by the software, which is a prerequisite for its use in a blood bank environment. The minimum software version required for the use in a blood bank lab is 3.03.05.

We have made every effort to make sure that all the information contained in this publication is correct at the time of publishing. However, the manufacturer of this product may need to update the publication information as output of product surveillance activities. A new version of this publication is then created.

Where to find information

The **User Assistance** contains all information about the product, including:

- Safety
- Routine operation
- Configuration information

The **User Guide** focuses on routine operation. The content is organized in line with the normal operation workflow.

General attention

To avoid incorrect results, make sure that you are familiar with the instructions and safety information.

- ▶ Pay particular attention to all safety notices.
- ▶ Always follow the instructions in this publication.
- ▶ Do not use the software in a way that is not described in this publication.
- ▶ Store all publications in a place that is safe and easy to access.

Training

Do not perform operation tasks or maintenance actions unless you have received training from Roche Diagnostics.

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Electronic user documentation can be downloaded using the eLabDoc e-service on **navify**[®] Portal

navifyportal.roche.com

For more information, contact your local affiliate or Roche Service representative.

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Glossary

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Intended use

navify® Lab Operations software is intended to be used for:

- the configuration and connectivity management of instruments and software systems
- the management of data regarding
 - Samples
 - Technical validation including automatic release
 - Quality control (both qualitative and quantitative)
 - Test results and their entry (offline workplaces)
- the management and storing of information, such as
 - Samples Archiving Storage information
 - Rule engine for technical validation
 - Notifications from any part of the system
 - Reagent and Calibrator management
 - Turn Around Time management
 - Production statistics

In addition to the above intended use, the **navify**® Lab Operations software is intended for:

- the management of data regarding
 - Order Data
 - Patient Data for Clinical Labs
For Blood/Plasma Donor Screening Labs this functionality can be used to manage blood donor sample data
 - Medical Validation support for Clinical Labs
For Blood/Plasma Donor Screening Labs this functionality can be used to support two step validation processes/schemes
 - Result Consolidation and Reporting
 - Billing support
- the management and storing of information, such as
 - General statistics (Data Warehouse)
 - Software systems that are connected to **navify**® Lab Operations for which **navify**® Lab Operations provides user access to
- Microbiology workflows and data for (Microbiology module):
 - Human samples

navify® Lab Operations is intended for Clinical Laboratories.

navify® Lab Operations is intended for Blood/Plasma Donor Screening Laboratories (Excluding U.S.).

Use environment and intended users

navify® Lab Operations is intended for Clinical Laboratories.

navify® Lab Operations is intended for Blood/Plasma Donor Screening Laboratories (Excluding U.S.).

You can find different user profiles using the **navify**® Lab Operations software.

Lab Technician

Lab technicians utilize the solution to perform technical validation on patient and QC results, manually edit orders (add or remove tests, edit patient-demographic data), enter patient and QC results that have been obtained from offline workplaces, print patient and QC reports, archive samples, retrieve samples from the archive, etc. Access level depends on specific user rights.

Lab Physician/Director

Lab Physicians/Directors utilize the solution to check technically validated results, search for samples or test results on patient results, and add comments to the results or order. Access level depends on specific user rights.

Lab IT Administrator

Lab IT Administrators maintain users and authorization, and maintain tests and senders. Access level will depend on specific user rights.

GP/Hospital doctor/Hospital nurse/ Community nurse

These users are not employees of the laboratory; thus their access is restricted to the Lab Link module only. They enter orders manually within the Lab Link module, release printouts of barcode labels for the tubes for positive patient/sample identification, release printouts of reports for the patient for blood drawing, and view and print the patient result report of their patients.

Phlebotomist

These users are employees of the laboratory, but their access is restricted to the Lab Link module only. Phlebotomists confirm in the software that the samples have been taken according to the order.

IT Manager

- Network and security configurations
- WLAN device configuration security type EAP
- EAP Settings management (EAP settings and EAP settings assignment)


Roche Service representative (global and local)

Roche Service representatives configure the system and data (test, test groups, senders, instruments, reports, interfaces, etc.) according to specific requirements of the customers with regards to connected hosts, instruments, and sample workflow. Access level depends on specific user rights.

Symbols and abbreviations

Product names

Except where the context clearly indicates otherwise, the following product names and descriptors are used.

Product name	Descriptor
navify [®] Lab Operations	software
navify [®] Lab Operations general lab	module
navify [®] Lab Operations emergency lab	module
navify [®] Lab Operations lab flow	module
navify [®] Lab Operations lab link	module
navify [®] Lab Operations microbiology	module
navify [®] Lab Operations total quality management	module
System Simulation Tool	tool
navify [®] Quality Control	application
navify [®] Instrument Maintenance	application
cobas [®] p 312 pre-analytical system	pre-analytical instrument system
cobas [®] p 512 pre-analytical system	pre-analytical instrument system
 Product names	

Product name	Descriptor
cobas [®] p 612 pre-analytical system	pre-analytical instrument system
cobas [®] 8100 automated workflow series	pre-analytical instrument workflow series
Roche PVT pre-analytical systems	pre-analytical instrument systems
MODULAR PRE-ANALYTICS EVO	pre-analytical instrument
cobas [®] prime pre-analytical system	pre-analytical instrument system
cobas [®] e 801 module	analytical module
cobas [®] c 311 analyzer	analytical instrument
cobas [®] pro integrated solutions	analytical instrument solutions
cobas [®] pure integrated solutions	analytical instrument solutions
cobas [®] 6000 analyzer series	analytical instrument
cobas [®] 6500 urine analyzer series	analytical instrument series
cobas [®] 8000 modular analyzer series	analytical instrument series
cobas [®] 6800/8800 systems	analytical instrument
LIAISON [®] XL LAS Analyzer	analytical instrument
cobas [®] p 501 post-analytical unit	post-analytical instrument unit
cobas [®] p 701 post-analytical unit	post-analytical instrument unit
CCM Address Extension Unit	transport system module extension
cobas [®] connection modules (CCM)	transport system module extension
LIAISON [®] XL Connection Module	transport system module extension
add-on buffer unit	instrument buffer

Product names

Product names

Except where the context clearly indicates otherwise, the following product names and descriptors are used.

Product name	Descriptor
navify [®] Lab Operations	software













Product names





Symbols used in the publication

Product name	Descriptor
navify [®] Lab Operations general lab	module
navify [®] Lab Operations emergency lab	module
navify [®] Lab Operations lab flow	module
navify [®] Lab Operations lab link	module
navify [®] Lab Operations microbiology	module
navify [®] Lab Operations total quality management	module
☰ Product names	




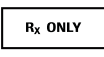

Symbol	Explanation
•	List item
▶☰	Related topics containing further information
💡	Tip. Extra information on correct use or useful hints.
▶	Start of a task
ⓘ	Extra information within a task
➔	Result of an action within a task.
📅	Frequency of a task.
🕒	Duration of a task.
🧰	Materials that are required for a task.
☑️	Prerequisites of a task.
▶☰	Topic. Used in cross-references to topics.
▶	Task. Used in cross-references to tasks.
📷	Figure. Used in figure titles and cross-references to figures.
☰	Table. Used in table titles and cross-references to tables.
√ _{xy}	Equation. Used in cross-references to equations.
☰ Symbols used in the publication	


Symbols used on product

Symbol	Explanation
	Code example. Used in code titles and cross-references to codes.
	Context search. Used on the context search tab.
	Search. Used on the search tab.
	Table of contents. Used on the table of contents tab.
	Hardware explorer. Used on the hardware explorer tab.
	History. Used on the history tab to show previously viewed topics.
	Favorites. Used on the favorites tab and on the content panel.
	Enlarge. Button used on images.
	Settings. Button used to open the settings dialog.
	Contact. Used in the User Assistance. Functionality currently unavailable.
	Tip. Extra information on correct use or useful hints.
[]	Square bracket. Used in the items name as defined by your software administrator.
	Symbols used in the publication

Symbol	Explanation
	Global Trade Item Number
	Date of manufacture
	Manufacturer
	Consult instructions for use on this website: navifyportal.roche.com

 Symbols used on product


Symbol	Explanation
	Consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	Catalog number
	Unique identifier of an instrument used in the Global Unique Device Identification Database
	For USA only: Caution: Federal law restricts this device to sale by or on the order of a physician.
	For USA only: in vitro diagnostic. Software intended for use in the diagnosis of disease or other conditions, and for use in the collection, preparation, and examination of human samples.

 Symbols used on product

Abbreviations

The following abbreviations are used.

Abbreviation	Definition
ANSI	American National Standards Institute
EN	European standard
n/a	not applicable
QC	Quality Control
SD	Standard deviation
UPS	Uninterruptible Power Supply

 Abbreviations

What is new in publication version 1.2

Configuration tasks

- Changed not permitted parameters to recommendations in General parameters, QC, Rejection rules, and Actions.
- Updated **Formula res. mod.** definition.
- Updated work condition procedure
- Minor editorial changes
- [About general parameters \(23\)](#)
- [About QC \(27\)](#)

- [About restrictions for rules \(31\)](#)
- [About restrictions for actions \(33\)](#)
- [Configuring the work conditions \(43\)](#)

Safety classifications

The safety precautions and important user notes are classified according to the ANSI Z535.6 standard. Familiarize yourself with the following meanings and icons.

These symbols and signal words are used for specific hazards:

WARNING!

Warning...

- ▶ ...indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION!

Caution...

- ▶ ...indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE!

Notice...

- ▶ ...indicates a hazardous situation that, if not avoided, may result in damage to the system.

Important information that is not safety relevant is displayed as the following icon:



Tip...

...indicates additional information on correct use or useful tips.

Data privacy information

Roche Diagnostics provides a guide that explains the EU GDPR provisions to help your laboratory or medical organization comply with its requirements while using **navify**® Lab Operations. In order to get the latest available version of the guide please contact your Roche Service representative.

General tasks

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About reconfiguration

To make sure that the software does not allow any result modification, certain restrictions apply and you must perform certain configuration changes as explained in detail in the following sections.



After completing the blood bank reconfiguration, make sure that you disable all administrator users to prevent any unauthorized configuration changes. Do not disable ROCHE users.

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General parameters

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About general parameters

The general parameters allow you to enable or disable software features and define values for certain software functions.

To prevent the modification of results, you must configure the general parameters in [Administration > General > General parameters](#).

Update the general parameters according to the following table:

Parameter	Required value	Description
Value replacing results which exceed the maximum length allowed by the system	No action required	This parameter defines a value that replaces the received value when it exceeds the maximum number of allowed characters (11). The cobas ® 6800/8800 systems driver performs an alphanumeric result modification to make sure that a result value never exceeds the maximum length when sent to navify ® Lab Operations.
Force direct result entry as long as the order is modified on the order entry screen.	No	If you configure the value No , you can save an order without entering a test result.
Default value to be assigned to tests for which no result is received	Do not define a value and leave the field empty.	When an instrument sends an empty result for a patient test, QC, or calibration, the software automatically assigns the value configured for this parameter.
Number of decimals in the application	6	Do not limit the number of decimals and configure the maximum number that is supported (6).
Add comment when editing validated tests	No	If you configure the value No , a comment is not required when you edit validated results and want to save them.
Use technical validation criteria only for medical validation.	No	If you configure the value No , the 2-step validation procedure is enabled (technical and medical validation). However, the user is only allowed to perform the technical validation (user right Validate medically is not recommended).

☰ General parameters configuration

Configuring general parameters

Refer to the General parameters configuration table and do the steps that follow.

► To configure general parameters

- 1 Choose **Administration > General > General parameters**.
- 2 Double-click the parameter you want to configure.
→ The lower configuration area is enabled and the data related to the selected parameter is loaded.
- 3 In the **Value** field, do any of the following:
 - If the field has a drop-down list, choose the value you want to assign to the parameter.
 - If the field does not have a drop-down list, enter the value you want to assign to the parameter.
- 4 Choose the **Confirm** button.

QC

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About QC

It is recommended not to use the QC rules alarms for validation activities and automated rules.

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Rule engine

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About restrictions for rules

The use of rejection rules is not recommended.

To prevent the modification of results, the following restrictions apply to the rule engine:

- Do not create a rejection rule in **Administration > Rule engine > Rules**.
- Make sure that all rejection rules are disabled or deleted in a blood bank lab.

Disabling or deleting a rejection rule

You can disable or delete rejection rules.

► To disable or delete a rejection rule

- 1 Choose **Administration > Rule engine > Rules**.
- 2 In the **> Rules** table, choose a rejection rule that is enabled.
 - ❗ The **Status** column shows whether a rule is enabled or disabled.
- 3 Do any of the following:
 - To disable the rule, choose the **Disable** button.
 - To delete the rule, choose the **Delete** button.
 - The rule status is changed in the **Status** column or the rule is removed from the table.

About restrictions for actions

When adding an action to a rule in **Administration > Rule engine > Rules**, the following restrictions apply.

The following actions are not recommended:

- **Add comment**
- **Add result**
- **Add result alarm**
- **Remove comment**
- **Manual dilution**



-
- When creating a rule in **Administration > Rule engine > Rules**, avoid adding any of the not recommended actions.
 - Make sure none of the not recommended actions are enabled in a rule used in a blood bank lab.
 - When configuring the **Assign instrument** action, make sure that it is not used for blood bank tests.
-

Removing actions

You can remove actions from the main screen or the graphical view tab.

► To remove an action from the main screen

- 1 Choose **Administration > Rule engine > Rules**. Then, double-click the rule to edit.
- 2 In the **3. Conditions and actions** area, choose the **Edit** button.
- 3 In the **List of conditions and actions** area, select the check box of the action you want to delete.
- 4 Choose the **Delete** button.
- 5 To save the changes, choose the **Exit edit mode** button.

► To remove an action from the Graphical view tab

- 1 Choose **Administration > Rule engine > Rules**.
- 2 In the table, double-click the desired rule.
- 3 Choose the **Graphical view** tab.
- 4 Double-click the item you want to edit.
 - In the **3. Conditions and actions** area, the settings are loaded in edit mode.
- 5 In the **List of conditions and actions** area, select the check box of the action you want to delete.
- 6 Choose the **Delete** button.
- 7 To save the changes, choose the **Exit edit mode** button.

User rights

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About blood bank user rights

You must prevent the modification of results at the user level.

The following user rights are not permitted for users assigned to a blood bank location:

- **Delete order tests**
- **Enter results**
- **Validate medically**
- **Work with administration screens**



User rights are defined in the profile.

- Make sure that no blood bank user is assigned to a profile that grants any of the prohibited rights.
 - It is recommended that the technical validation (TECH_VAL) profile is assigned to blood bank users as this profile grants the permitted rights for blood bank labs by default.
-

Disabling user rights from a profile

You must disable the prohibited user rights from the profiles assigned to the blood bank location.

► To disable user rights from a profile

- 1 Choose **Administration > Users > Profiles**.
- 2 From the table, select the profile.
 - In the lower area, the users assigned to the selected profile are displayed.
- 3 Choose the **Rights** button.
- 4 From the list, choose the right to disable.
 - ❗ The **Assigned** column shows whether a right is enabled or disabled by default.
- 5 Choose the **Change access** button to disable the right.
 - ❗ When creating a user in **Administration > Users > Users**, make sure that you do not assign a profile that grants any of the prohibited rights.

Drivers

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Disabling result modification by drivers

For drivers used in a blood bank lab, configuring any result modification of blood bank tests is not permitted.

In **Administration > ICA > Instrument definition**, do not add the following options from the **Tests** drop-down menu.

- **Alphanum. res. mod.:** replacement of alphanumeric test result with a configured value.
- **Range res. mod.:** replacement of test result within an interval with a configured value related to another interval.
- **Formula res. mod.:** replacement of a test result with a result based on a configured formula in a formula-type test.



Make sure that none of these result modification options are configured for drivers used in a blood bank lab.

► To disable result modification by drivers

- 1 Choose **Administration > ICA > Instrument definition**. Then, choose a driver.
- 2 From the **Tests** drop-down list, choose the **Alphanum. res. mod.** option.
 - If this option is configured, choose the **Delete** button, and then the **Yes** button.
- 3 From the **Tests** drop-down list, choose the **Range res. mod.** option.
 - If this option is configured, choose the **Delete** button, and then the **Yes** button.
- 4 From the **Tests** drop-down list, choose the **Formula res. mod.** option.
 - If this option is configured, choose the **Delete** button, and then the **Yes** button.

Configuring the test volume

The software must send the required test volume for a blood bank test to a **cobas**® 6800/8800 system.

The configuration option **Volume** is now available in **Administration > ICA > Instrument definition > Test mapping** for the instrument driver. This option allows you to enter the test volume. To enable it, you must install the latest driver.



With this option, the workaround by adding the action **Instrument dilution** in the rule engine for sending the test volume to the analyzer is no longer needed.

► To configure the test volume

- 1 Choose **Administration > ICA > Instrument definition**. Then, choose a driver that supports the volume mapping.
- 2 From the **Tests** drop-down list, choose the **Tests** option.
- 3 On the **Settings** tab in the lower area of the screen, enter the test volume in μL in the **Volume** field.

Configuring the work conditions

The **Work conditions** configuration screen allows you to configure the communication between ICA and pre-analytical instruments, post-analytical instruments, and analyzers.

When configuring work conditions in **Administration > ICA > Instrument definition**, the following restrictions apply:

- The **Register comments in the database** option is not permitted and must be disabled.
- The **Overwrite test result** option must be configured as explained below.

► To configure work conditions for a blood bank lab

- 1 Choose **Administration > ICA > Instrument definition**. Then, choose the driver.
- 2 From the **Tests** drop-down list, choose the **Work conditions** option and do the following:
 - In the **Overwrite test result** area, choose the **Yes** option from the drop-down list. Make sure that the check box **Add results from tests other than cobas e flow tests as repetition** is selected.
 - In the **Specific conditions** area, clear the **Register comments in the database** check box.

Configuring the CS (communication server) settings

To prevent a result modification at the driver level, do the following:

- Make sure that the CS setting **RESULT_WHEN_VALUE_EMPTY** is not configured (for example **cobas**® 8800 instrument, **cobas**® 6800 instrument, or **cobas**® **pro** integrated solutions).
- Make sure that the latest driver is installed.
- Make sure that the CS setting **RESULTS_WITH_LIMITED_CHARS** is configured as explained below.

► To configure the CS settings

- 1 Choose **Administration > ICA > Instrument definition**. Then, choose a driver.
- 2 From the **Tests** drop-down list, choose the **CS settings** option.
- 3 Do the following:
 - Make sure that no value is entered in the **RESULT_WHEN_VALUE_EMPTY** field. Otherwise, delete the value and choose the **Confirm** button.
 - From the **RESULTS_WITH_LIMITED_CHARS** drop-down list, choose the **Short mapping** option.

Test administration

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About test administration

When you register a test in the software, you can enter test details and configure how the test is processed. When registering a blood bank test, the following configurations are not permitted in **Administration > Tests > Tests**.

Prohibited fields on Detail tab

- **Formula:** do not enter a formula used by the software to determine the result based on other test results or variables.
- **Factor:** do not enter a numerical value to convert results from the **Primary unit** to the **Secondary unit**.



Make sure that the **Formula** and **Factor** fields are empty for all blood bank tests. Otherwise, delete the entered values.

Prohibited check boxes on Result tab

- **Direct result:** Make sure that this check box is cleared. Manual entry of a result is not required when the test is added to an order.
- **Automatic result:** Make sure that this check box is cleared. A fixed result cannot be automatically assigned to the test.

Disabling reference ranges

Configuring reference ranges for blood bank tests is not permitted. Make sure that blood bank tests have no reference ranges assigned.

► To disable reference ranges from a blood bank test

- 1 Choose **Administration > Tests > Tests**.
- 2 In the table, choose the test from which you want to disable the reference ranges, and choose the **Test reference ranges** option from the drop-down list.
- 3 On the dialog box, choose the **Yes** option.
→ A new version of the test is created.
- 4 In the **Test references** screen, choose the test and choose the **Disable** button.

Disabling numeric delta checks

Enabling delta check to compare a current test result with previous results is not permitted. Make sure that delta checks are disabled for blood bank tests.

► To disable delta checks from a blood bank test

- 1 Choose **Administration > Tests > Tests**.
- 2 In the table, choose the test from which you want to disable the delta check option, and choose the **Test DeltaCheck** option from the drop-down list.
- 3 On the dialog box, choose the **Yes** option.
→ A new version of the test is created.
- 4 In the **Test DeltaCheck** screen, select the test, choose the **Disable** button, and then the **Yes** button.

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Result status

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About the result status feature

If you configure a condition related to a test and apply it to the result status, only the following result statuses can be enabled in **Administration > Validation > Result status**:

- **The result could not be automatically validated. It is out of the tolerance range**
- **Automatic validation is hold by a rule**
- **An instrument alarm is blocking the automatic validation**
- **Empty result received**
- **Alarm received from the instrument**
- **Unknown alarm received from the instrument**
- **QC maintenance error message received from the instrument**
- Error message triggered by a rule violation
- **Warning message triggered by a rule violation**
- **The result sent by the instrument is flagged as 'previous result'. The test repetition was triggered due to the received alarm**
- **The associated QC result was received in pass-through mode**
- **The result contains letters**
- **Automatic rerun**
- **Test repetition requested**
- **Automatically technically validated**
- **The result corresponds to a repeated test**
- **Closed result**
- **Result received from an instrument with a calibration error**
- **Result received from an instrument with a calibration warning**
- **The associated QC status is pending to be calculated**



Make sure that no other result statuses are enabled.

Disabling result statuses

You must disable all not permitted result statuses.

► To disable result statuses

- 1 Choose **Administration > Validation > Result status**.
- 2 In the table, choose the result statuses you want to disable.
- 3 Choose the **Disable** button.

Alarm mapping

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About alarm mapping

Make sure that alarms received from **cobas**® 6800/8800 systems are mapped in the software before alarms from other instruments are received. Otherwise, the software can incorrectly interpret an alarm received from **cobas**® 6800/8800 systems as an alarm value from another instrument.

Make sure that every instrument alarm is properly mapped to the correct **navify**® Lab Operations alarm in [Administration > Validation > Alarm types](#) and [Administration > ICA > Instrument definition > Alarm types](#)

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Sending targets

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Sending targets following technical validation

When assigning targets for a blood bank lab, you must configure targets to be sent to the host following technical result validation.

► To send targets following technical validation

- 1 Choose **Administration > Reports > Target assignment**.
 - 2 Double-click the desired target assignment and choose the **Host** tab.
 - 3 From the **Trigger value** group box, choose the following option:
 - **Technical validation**: target sent to the host once the order has been technically validated.
- ❗ When technically validated, the order is sent to the host at the time configured in the **Schedule send** group box.

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HCA

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About the host connectivity agent (HCA)

When configuring messages in the HCA for blood bank labs, it is not permitted to define a code to execute for the following fields of a result message:

- **InstrumentMeasureUnit**
- **PrimaryUnit**
- **TextComment**
- **ValueResult**



Make sure that no code to execute is defined for these fields in any of the outgoing result messages.

Deleting a code to execute

You must delete the code to execute in all the outgoing results messages.

► To delete a code to execute

- 1 Choose **Administration > HCA > Host message configuration** and choose the desired host.
- 2 To configure an outgoing message, select the desired message (Direction: Send). Then, choose the **Send** button.
- 3 Double-click the desired field, delete the entered code from the **Code to execute** field.
- 4 Choose the **Confirm** button.

Blood bank configuration check

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Performing an automated blood bank configuration check

After completing the blood bank reconfiguration, you must perform an automated check. This check verifies that the **navify**® Lab Operations software is configured as specified in this guide.

▶ To perform an automated blood bank configuration check

- 1 Choose **Monitoring > Configuration traces > Blood bank configuration check**. Then, choose the **Check** button.
 - Potential deviations from the blood bank configuration are displayed.
- 2 For each deviation, enter a comment to be displayed in the **Deviation comments** column of the report.
 - ❗ Only the user who performed the check is able to comment possible deviations.
- 3 The Roche Service representative must print a report and send it to the Local Safety Office.
- 4 After each subsequent configuration change, perform a new configuration check and send a new report to the Local Safety Office.

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Requirements

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Requirements for combined blood bank and clinical labs

For installations in combined blood bank and clinical labs, make sure that the following requirements are implemented:

- Different test IDs are created for blood bank and clinical lab tests.
- Unique orders are created for blood donors that cannot be combined with clinical lab orders.
- Different hosts are defined for blood bank and clinical labs. If blood bank tests are sent following technical validation (medical validation is not permitted) and clinical tests are sent after medical validation, the following 2 hosts must be configured:
 - Host for managing blood bank tests: configured to send the results when technically validated.
 - Host for managing clinical tests: configured to send the results when medically validated.
- Different handling of blood bank and clinical tests is controlled at the test level. For example, you can enable result modification for clinical tests but not for blood bank tests.

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Glossary

administrator

User role that has the rights to manage users, configure and monitor the system, and monitor the solution.

authorization

Access rights granted to a person, program, device, or computer process or act of granting those rights to access certain information.

caution

Safety alert symbol indicating a hazardous situation which, if not avoided, could result in minor or reversible injury.

EAP

Protocol that supports multiple authentication methods.

medical validation

Result validation of a technically released test result based on its plausibility and in comparison with a diagnosis.

power supply

Electrical device that is used to convert electric current from a source to the correct voltage, current, and frequency to power the load.

safety precautions

Measures that are taken to avoid potential hazards.

technical validation

Validation of a patient result based on technical information such as valid QC results or calibration, as well as verifying and either confirming that measurements have been carried out according to the rules of laboratory best practices or taking the necessary actions if they have not.

test

Measuring procedure that requires laboratory equipment and reagents in a specific clinical context and for a specific clinical purpose, in a specific population.

uninterruptible power supply

Device with a battery that allows limited continued operation of an instrument or other device during a power outage.

user rights

Tasks that a user is permitted to perform on a computer system or domain.

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Published by

Roche Diagnostics, S.L.
E-08174 Sant Cugat del Vallès
Spain

www.roche.com