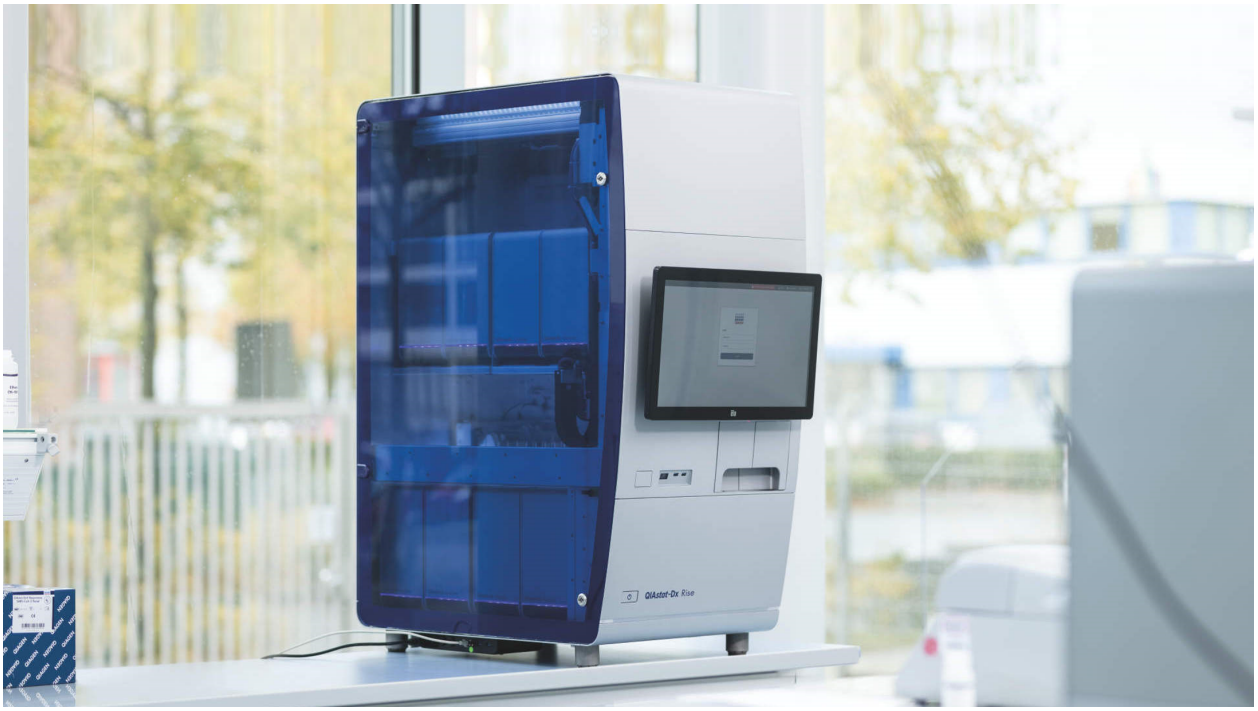
May 2024

QIAstat-Dx® Rise Quick-Start Guide

For use with software version 2.4



Version 1

IVD For In Vitro Diagnostic Use

CE

REF 9003163

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Sample to Insight

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1. Introduction

The QIAstat-Dx Rise system is intended as an in-vitro diagnostic device for use with QIAstat-Dx assays and provides full automation from sample preparation to real- time PCR detection for molecular applications. The system is designed for professional use only and it is not a device for self-testing or near-patient testing.

The QIAstat-Dx Rise can only be used in combination with at least two QIAstat-Dx Analytical Modules (AM) processing QIAstat- Dx assay cartridges according to the instructions contained in the QIAstat-Dx RiseUser Manual and in the QIAstat-Dx assay instructions for use.

1.1. Further information

- Safety Data Sheets (SDSs): **www.qiagen.com/safety**
- Technical assistance: support.qiagen.com
- QIAstat-Dx Rise™ User Manual - For use with software version 2.4

1.2. Notes Before Starting

This Quick-Start Guide is intended to provide an overview of the workflow and is not a substitute for the QIAstat-Dx Rise User Manual. Therefore, it is essential that the QIAstat-Dx Rise User Manual is read and understood thoroughly before starting a test.

- The safety information in the user manual should be given particular attention.
- Improper use of the QIAstat-Dx Rise may cause personal injuries or damage to the instrument.
- The QIAstat-Dx Rise must only be operated by qualified personnel who have been appropriately trained.
- When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles.

Before starting a test, make sure the sure the instructions for use of the assays to be run are available.

2. Starting the QIAstat-Dx Rise

1. Turn on the QIAstat-Dx Rise by pressing the power switch on the side of the instrument. Press the ON/OFF button on the front of the QIAstat-Dx Rise.

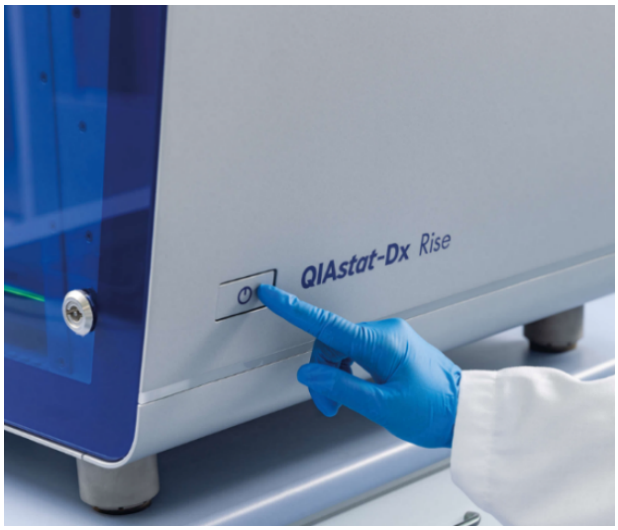

Figure 1. On/Off button on the QIAstat-Dx Rise.

2. Login with the credentials you have already generated.

2.1. Loading a Sample Into the QIAstat-Dx Catridge

1. Remove the QIAstat-Dx assay cartridge from its packaging and add the sample to the QIAstat-Dx assay cartridge (refer to the user manual for the respective assay for details such as required sample volume and stability time). Always make sure that sample lids are firmly closed after adding a sample to the QIAstat-Dx assay cartridge.
2. Place a sample barcode on the top right side of the QIAstat-Dx Assay Cartridge. The maximum barcode size is: 22 mm x 35 mm. The label must not be placed beyond 35 mm from the right side of the cartridge.

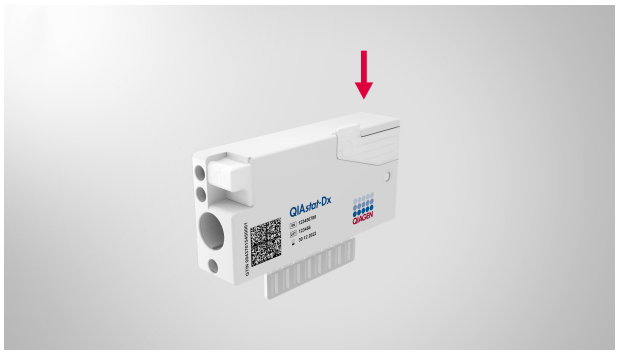

Figure 2. Placing sample ID barcode.

3. Running a Test

1. If there are cartridges in the waste drawer from the previous runs, press **OPEN WASTE DRAWER** to remove used cartridges from previous runs.
2. Press the **OPEN INPUT DRAWER** button and pull the input drawer open to load cartridges.

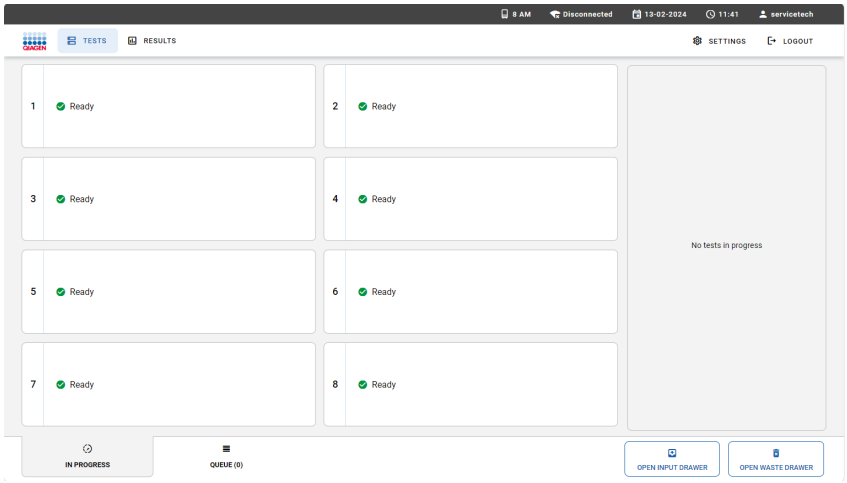

Figure 3. Main Test Screen

The test setup in QIAstat-Dx Rise may differ depending on the HIS/LIS connection status and the Test Orders and Force Orders functionality of the HIS/LIS connection.

HIS/LIS connection	Test Orders	Force Orders	Test setup
No	n/a	n/a	Manual Test Setup
Yes	Disabled	Disabled	Manual Test Setup
Yes	Enabled	Enabled	Test Setup with HIS/LIS connection-LIS orders enforced
Yes	Enabled	Disabled	Test Setup with HIS/LIS connection-LIS orders optional

3.1. Manual Test Setup

1. Scan the sample ID barcode attached to the top of the QIAstat-Dx assay cartridge.

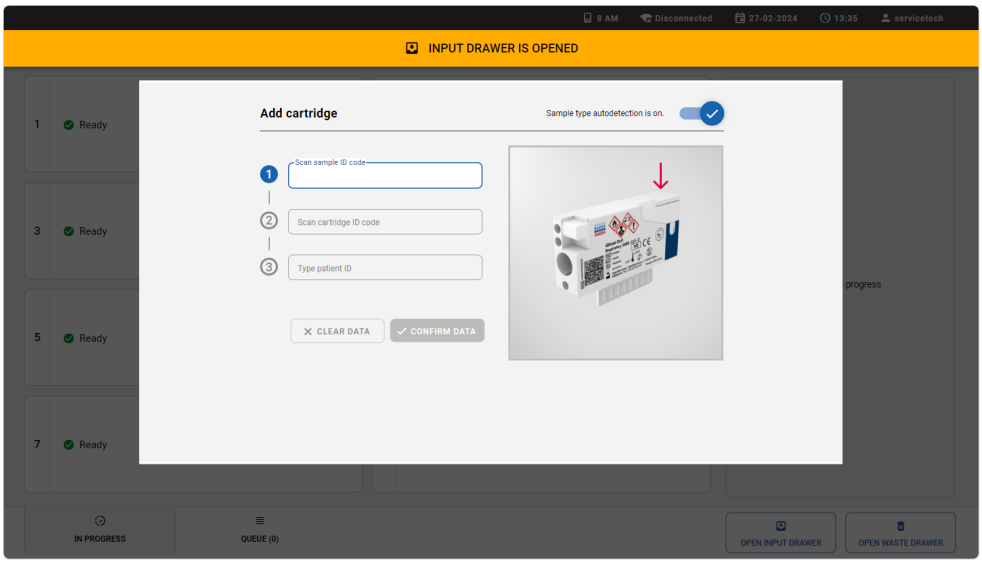

Figure 4. Scan Sample ID Screen.

2. Scan the cartridge ID barcode. The QIAstat-Dx Rise automatically recognizes the assay to be run, based on the QIAstat-Dx assay cartridge barcode.

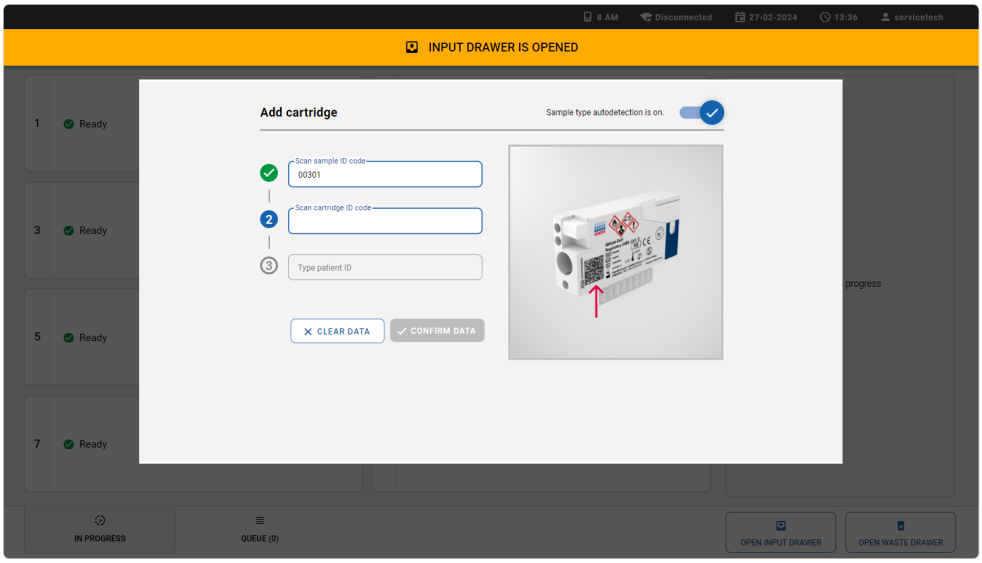

Figure 5. Scan Cartridge ID Screen.

3. Select the appropriate sample type manually if sample type autodetection is set to off.

   Note: Please note that there may be QIAstat-Dx assays for which the QIAstat-Dx Rise cannot automatically detect the sample type. Please check the respective assay handbook accordingly.

4. Type patient ID if applicable.

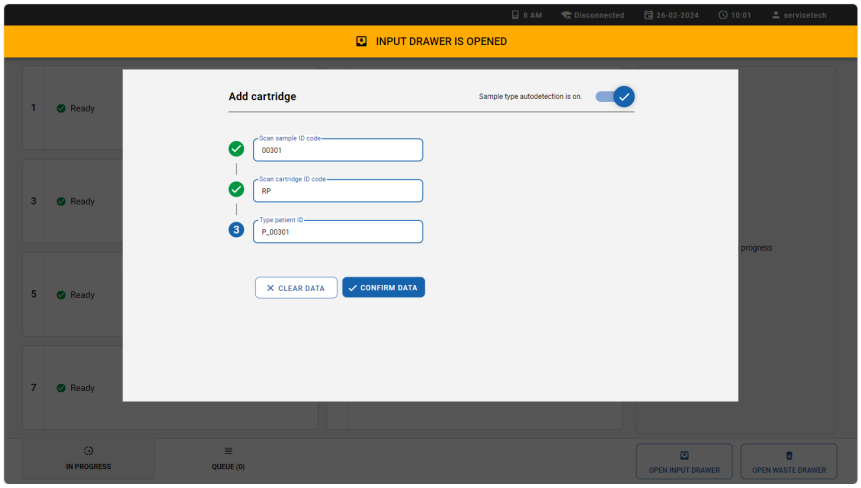

Figure 6. Type patient ID then confirm the data screen

5. Place the cartridge into the input drawer. Ensure that the cartridge is inserted properly into the tray.
6. Repeat steps 1-5 in case more cartridges shall be loaded.
7. Close the input drawer when all cartridges are scanned and inserted. The system will scan the cartridges and prepare a queue. After checking the queue, press the **CONFIRM DATA TO RUN** button and then press the **RUN TEST** button.

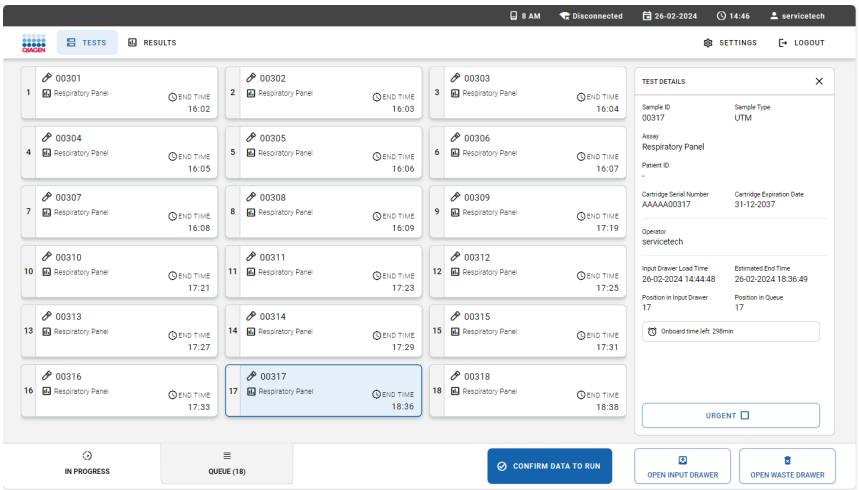

Figure 7. Sample queue screen.

Figure 8. Confirm queue dialog.

8. When the test is complete, the report can be found in the results section.

4. Test Setup With HIS/LIS Connection

4.1. LIS orders enforced

1. Place the cartridges into the input drawer.

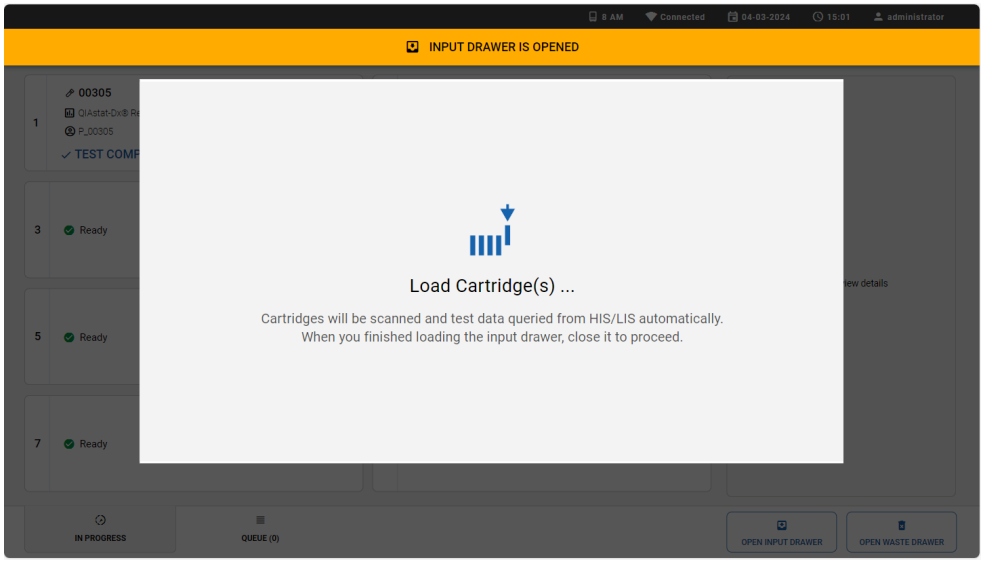

Figure 9. The load cartridge dialog when both test order and force orders are enabled.

2. Close the input drawer when all the cartridges are inserted. The system will scan the sample ID barcode of the cartridges and prepare a queue.
3. After checking the queue, press the **CONFIRM DATA TO RUN** button and then press the **RUN TEST** button.

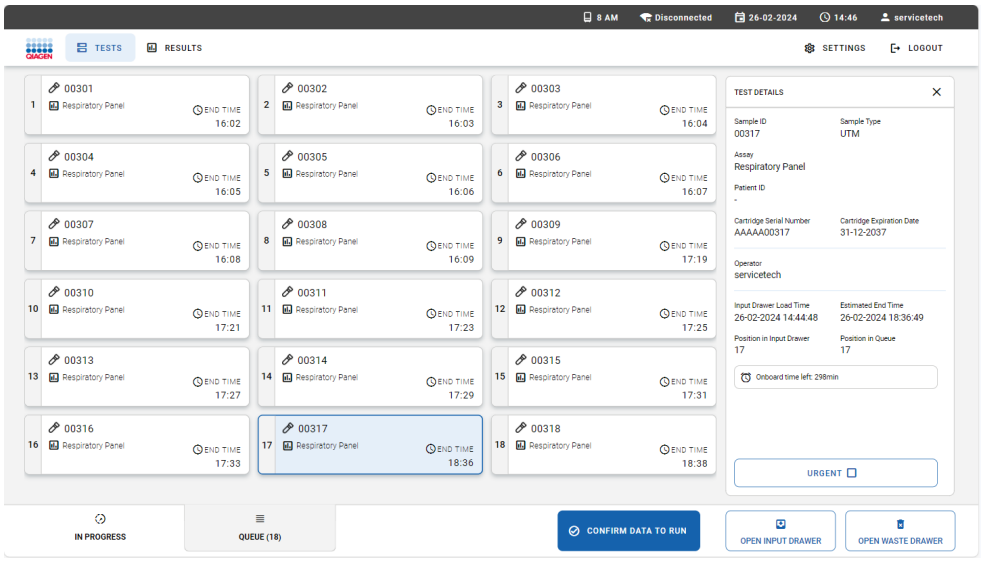

Figure 10. Sample queue screen with selected assay showing additional information.

Note: If Force Orders is enabled and the test order is not successfully retrieved from the LIS, the system will issue an error and not run the test. If a sample must be urgently run for which no test order is created yet, an administrator must temporarily turn off the Force Orders functionality.

4.2. LIS orders optional

When a test order can be retrieved from the LIS system for a sample, the cartridge can be loaded without entering the test data manually.

1. Load the cartridges as described within section LIS orders enforced.

When no test order can be retrieved from the LIS system for a sample, the user can enter the test data manually to run the test.

1. Press the **REGISTER CARTRIDGE MANUALLY** button to switch to manual test setup.

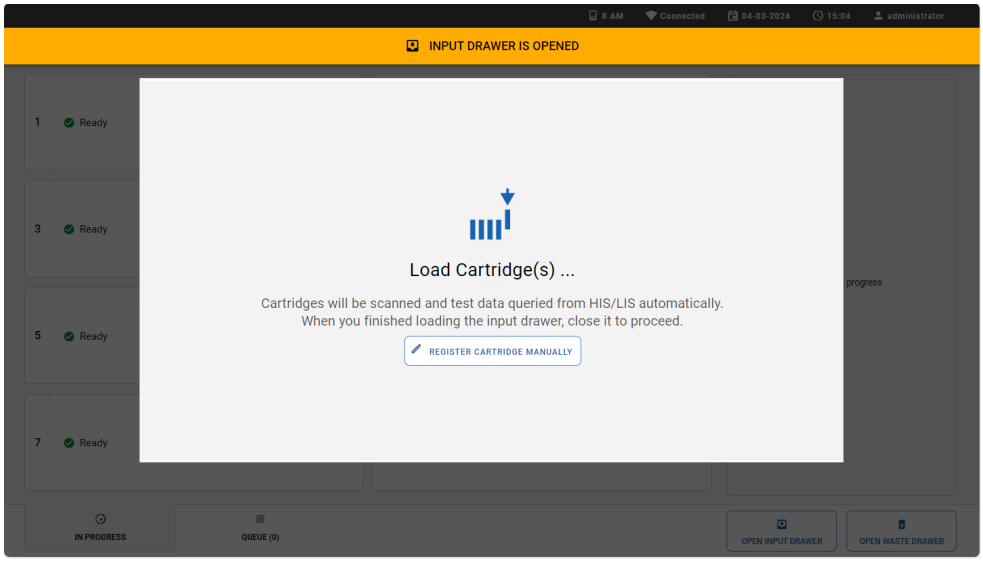

Figure 11. The load cartridge dialog when the test order functionality is enabled and force order disabled

2. Enter the test data and load the cartridges as described within section **MANUAL TEST SETUP**. The system can process tests that were registered manually and tests where the test order is retrieved from LIS in parallel.

   Note: For samples where no test order was created in the HIS/LIS system, the manual data entry is strongly recommended. Otherwise, the time for the queue preparation may take up to 30 minutes depending on the number of loaded cartridges and is therefore not recommended.

5. Viewing Results

The QIAstat-Dx Rise automatically interprets and saves test results. After the run is completed, the results can be seen in the results summary screen.

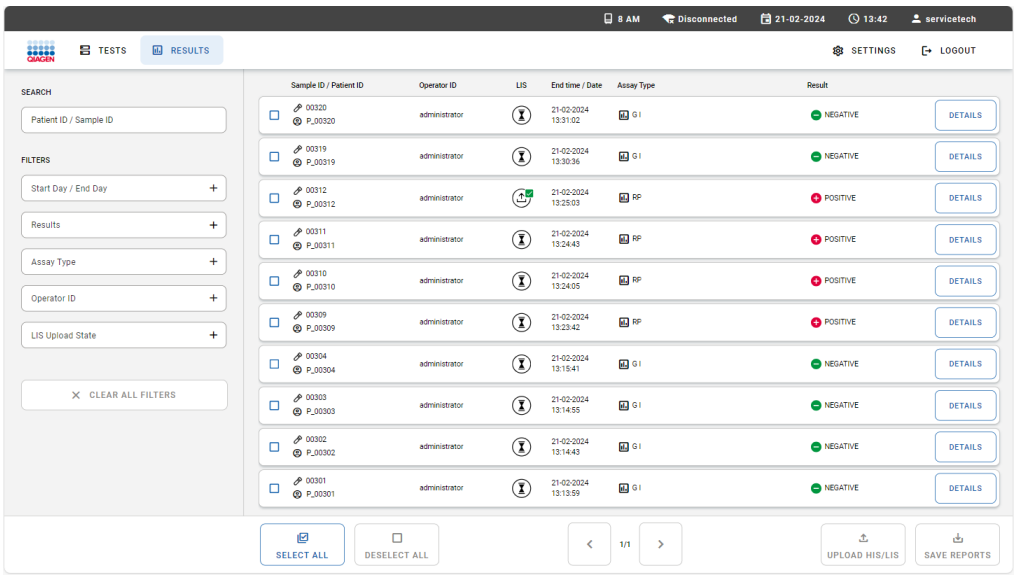

Figure 12. The results summary screen.

- If at least one pathogen is detected in the sample, the term **POSITIVE** is shown in the result column, preceded by a sign.
- If no pathogen is detected, and the internal control is valid, the term **NEGATIVE** is shown in the result column, preceded by a sign.
- If at least one pathogen is detected in the sample, and the internal control was invalid, the term **POSITIVE WITH WARNING** is shown in the result column, preceded by a ! sign.
- If the test did not complete successfully, the term **FAILED** is shown in the result column, proceeded by a sign. When viewing the details of such a test, a specific error code followed by an error message is shown.
- If a test is canceled before running in an AM, the term **NONE** is shown in the result column, proceeded by a sign. When viewing the details of such a test, a specific error message displays the reason for the cancelation and steps how to resolve it. The cartridge of a canceled test can be reloaded into the instrument again within the stability time.
- If a test is aborted before running in an AM, the term **ABORTED** is shown in the result column, proceeded by a sign. When viewing the details of such a test, a specific error message displays the reason for the abortion. The cartridge of an aborted test cannot be reloaded into the instrument.

6. Document revision history

Revision	
Revision 1 May 2024	Initial release of SW2.4