Cepheid C360

Data-Visualization Features Operator Manual

CE

Cepheid®

Nonmedical-device software
system for disease surveillance

301-3787, Rev. K
March 2022

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1 Introduction

This chapter introduces the *Cepheid C360 Data-Visualization Features Operator Manual* and provides a brief description of the data-visualization features of Cepheid C360.

1.1 About the Cepheid C360 Data-Visualization Tools

Cepheid C360 is a web-based software application for administering Cepheid systems and visualizing medical test data produced by Cepheid instruments. This manual describes the data-visualization features of Cepheid C360. For the administrative tools, see the *Cepheid C360 Administrative Features Operator Manual*.

The data-visualization toolset is used for the following tasks.

- Data aggregation, access and trending.
- Sharing data with other institutions.
- Setting up notifications and alerts.
- Managing instruments.
- Tracking testing efficiency and test performance.

1.2 Related Publications

For information about topics related to Cepheid C360, see the following publications.

For this topic:	See this publication:
The administrative features of Cepheid C360	*Cepheid C360 Administrative Features Operator Manual*
Connecting instruments to Cepheid C360	*C360 Sync Installation and Networking Operator Manual*
Operating and administering the GeneXpert Xpress System	*GeneXpert Xpress System User's Guide*
Operating and administering the GeneXpert Dx System	*GeneXpert Dx System Operator Manual*
Operating and administering the GeneXpert Infinity System	*GeneXpert Infinity System Operator Manual*
Operating and administering the GeneXpert Edge System	*GeneXpert Edge System User’s Guide*

1.3 Technical Assistance

Before contacting Cepheid Technical Support, collect the following information:

- Product name
- Instrument serial number or numbers
- Error messages (if any)
- Software version and, if applicable, Computer Service Tag number

United States Technical Support

Telephone: + 1 888 838 3222
Email: techsupport@cepheid.com

France Technical Support

Telephone: + 33 563 825 319
Email: support@cepheideurope.com

Contact information for other Cepheid offices is available on our website at www.cepheid.com/en/CustomerSupport.

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2 Cepheid C360 Data-Visualization Features Overview

This chapter summarizes the purpose of Cepheid C360, and introduces the features and interface of the Cepheid C360 data-visualization toolset.

Note Cepheid C360 is a supplemental information-management web application that acts as an IT application. It is not used for the diagnosis, treatment or monitoring of patients.

Note Your institution is responsible for ensuring that the uploading of data to the Cepheid C360 server complies with applicable laws and regulations, including those concerning privacy and data-protection.

Note In Cepheid C360, an institution is a single organization that can have a number of labs, institution administrators, lab administrators and assistants, and GeneXpert systems linked to their labs.

A supranational institution is an organization, such as the World Health Organization (WHO), that can issue sharing requests to other institutions and visualize epidemiological trends in the aggregated data.

2.1 Cepheid C360 Interface Overview

The Cepheid C360 data-visualization tools are arranged near the top of the column that runs along the left side of the Cepheid C360 screen. The top-level items for data-visualization are **Medical**, **Instruments**, **Test Results** and **Notifications**. The data-visualization tools are explained in this operator manual.

Further down in the same column, under the word **ADMIN**, there is another set of tools for administrative tasks. They are explained in the *Cepheid C360 Administrative Features Operator Manual*. In most cases, users of the data-visualization tools do not need to use the administrative tools.

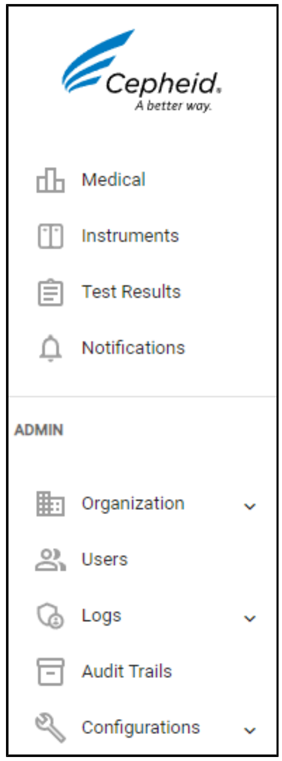

Figure 1. The top-level menu of data-visualization and administrative tools

2.2 Cepheid C360 Data-Visualization Features Overview

This section summarizes the Cepheid C360 data-visualization tools.

The data-visualization tools are split into four categories:

- The **Medical Dashboard** screen, which provides trending of disease incidence.
- The **Instruments** screen, where you view the instruments available to the institution and control their status.
- The **Test Results** screen, which summarizes the positive and negative results of tests administered at your institution.
- The **Notifications** screen, where you set up alerts to receive notifications when the incidence of a disease changes.

Each of these visualization tools is described in detail in this operator manual.

Note Every Cepheid C360 user is assigned a role in the system, such as institution admin, lab admin, or epidemiologist. Some Cepheid C360 features are not visible to users with some roles. The *Cepheid C360 Administrative Features Operator Manual* provides a detailed description of the roles.

2.3 Return to Previous Page

As you drill down into the Cepheid C360 tools, the top of the screen always displays a menu showing the path you've followed. To return to a higher level in the hierarchy, simply click the item you want to return to. For example, on the Instruments screen, when you click an instrument in the table to open a detail screen, the top of the screen builds a path that looks like this:

Figure 2. The menu for retracing your steps

In this example, after reviewing the details of this instrument, click **Instruments Pending Review** to return to the list of instruments ready for review.

Note The browser's back arrow or back command accomplishes the same thing.

2.4 Data Tables

This topic provides general guidance on finding, sorting and exporting data in the Cepheid C360 database.

Many screens in Cepheid C360's data-visualization tools present data in tabular format. In most cases, those tables can be filtered, sorted and exported as CSV files.

Note The CSV format is designed for import into spreadsheet, database and statistical software tools. In the CSV format commas separate each data point and paragraph breaks separate each row of data. For most tables, Cepheid C360 can export up to 3,000 rows as a CSV file. For the **Test Results** table, the export supports up to 300,000 rows.

Search and Filter Data

To search and filter data, look for the pop-up menus that generally appear above the column headers in the table itself. The search and filter menus vary, depending on the type of data in the table. The following example is from the **Test Results** screen. The three menus can filter by the test, the instrument the test ran on, and the result.

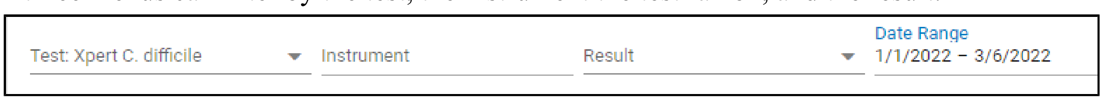

Figure 3. An example of search and filter pop-up menus

Sort Data

Some tables' column headers are active, so that clicking on one sorts the table by the data in that column. In the example shown below, the white arrow next to **Last Name** indicates that the table is currently sorted by last name. The pale arrow next to **Email** appears when the mouse hovers over that column header and indicates that the table could be sorted on that value instead. Not all columns in all tables can sort data.

Figure 4. An example of table column headings for sorting data

Download Data

To determine whether a table can be exported, look for the **Download CSV** icon, which is usually located near the top right corner of the screen.

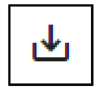

Figure 5. The Download CSV icon

Click the **Download CSV** icon to generate a CSV file and open a save dialog. On the **Test Results** screen the process is slightly different. Click **Export files**, which stores the CSV files you generate in a cache until you are ready to download and save them.

Note The search and filter menus for many Cepheid C360 tables include a field for selecting an institution, but institution personnel only have access to data from the institution where they work, and only their own institution appears in the institution field. The institution field is there for the use of Cepheid Technical Support.

Each section in this operator manual provides appropriate specifics about filtering, sorting and exporting tabular data.

2.5 About Browsers

Because Cepheid C360 runs in a web browser, the exact appearance of the screen may differ slightly depending on which browser you use. However, the features and functions are identical in any browser.

Important **Cepheid C360 is tested with the Chrome, Edge, and Firefox browsers. Cepheid does not test other browsers. Logging in to your Cepheid C360 system with another browser will display a warning message that the browser is not supported.**

2.6 Cybersecurity

Cepheid C360 includes the following data-security and user-authentication safeguards:

- Data encryption during transport and at rest
- Strong password requirements
- Two-factor authentication
- Automatic time-out
- Timed lockout after failed logins
- Role-based access-control
- Audit logs that monitor user interactions

If you experience a cybersecurity event, contact Cepheid Technical Support.

2.7 How to Log In to Cepheid C360

This topic describes how to log in to your Cepheid C360 account.

First Login

When your account was created, you should have received a Welcome email with your user ID and a link to your institution's Cepheid C360 server. Follow the instructions in the email to complete setting up your account.

1. Follow the link in the Welcome email.

Note The Welcome email link is valid for only 24 hours.

2. On the **Welcome to C360** screen create a password that meets the requirements displayed under **Password requirements**.

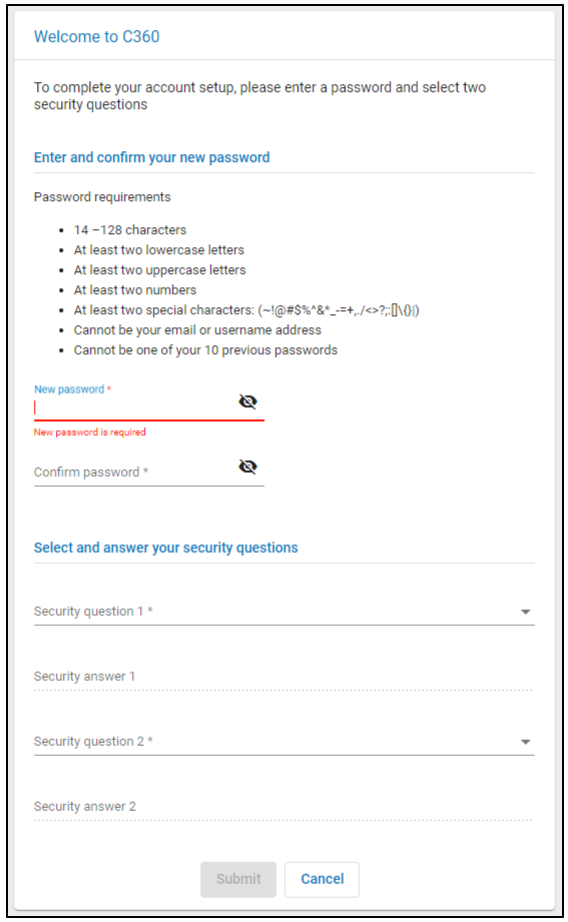

Figure 6. The Welcome login screen

3. Select two security questions under **Select and answer your security questions**. Provide answers for the questions that you will remember and that other people will not know.
4. Click **Submit**. You will be transferred to the regular login screen. Enter your user ID and new password, and your institution's alias. We recommend that you bookmark the Cepheid C360 site.

Note The alias is provided by Cepheid to the institution’s administration and is included in the Welcome email.

Subsequent Logins

After your account is established, logging in to Cepheid C360 is similar to logging in to any system that uses two-factor authentication.

1. In a browser, open the URL for your institution's Cepheid C360 server.

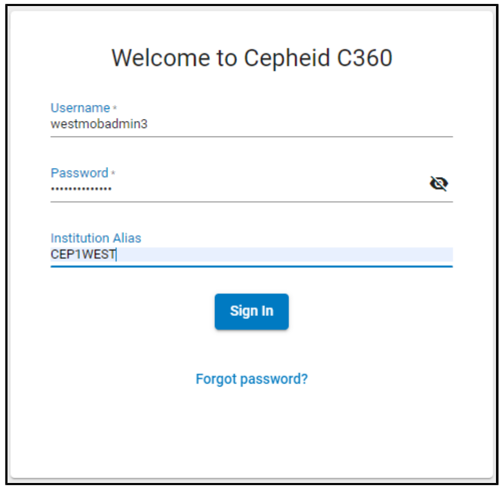

Figure 7. The Cepheid C360 splash screen

2. Enter your user name and the password you created when you completed setting up your account. Passwords are masked by default. To see the password as you enter it, click the eye icon next to the **Password** field. Passwords are case-sensitive, while user names are not.
3. Enter the alias for your institution.

Note If you enter an incorrect password or alias, your login fails but the warning doesn't explain why.

The login screen changes to display the **Code** field.

4. Look in your email or on your phone for a message from *Cepheid C360 team*. Enter the number provided in the email in the **Code** field and click **Login**.

Replace Forgotten Password

If you forget your password you can replace it.

1. Click **Forgot password?** on the splash screen to open the **Forgot Password** screen.

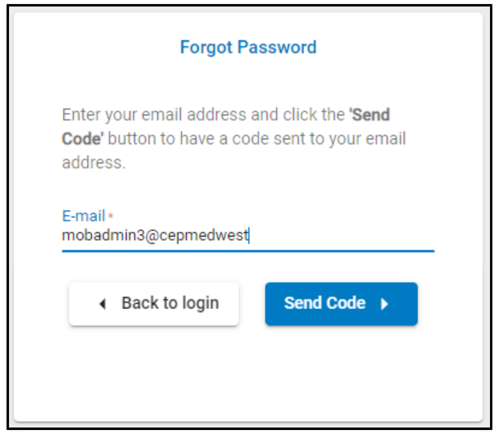

Figure 8. The Forgot Password screen

2. Enter the email address associated with your Cepheid C360 account and click **Send Code**.
3. Look in your email for a message from *Cepheid C360 team*.
4. Enter the code provided in the email and click **Submit Code**.
5. Create a new password, as described later in this manual. When changing your password during login, you do not set new security questions.

2.8 How to Log Out of Cepheid C360

This topic explains how to end a Cepheid C360 session.

To log out of Cepheid C360, click the person icon next to your name, in the upper-right corner of the screen. When the menu displaying **Settings** and **Sign Out** opens, select **Sign Out**.

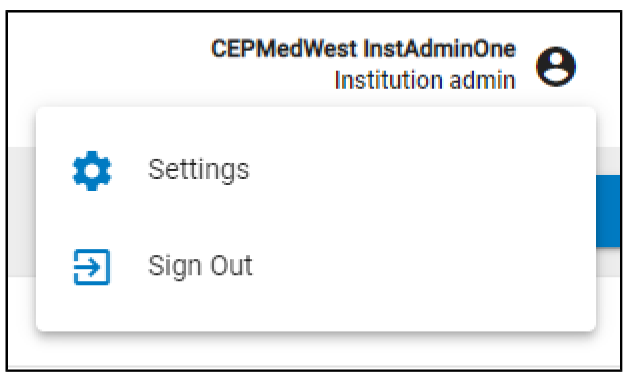

Figure 9. The Settings and Sign Out buttons

Note Cepheid C360 logs you out without a confirmation prompt.

Note

Cepheid C360 logs you out automatically under the following circumstances:

- There has been no activity for 15 minutes.
- The session has been active for more than 24 hours.
- The browser window running the Cepheid C360 session is closed.
- Your username and password are used to log in from another computer or from another browser on the same computer. This could happen if someone else logs in using your credentials, or if you log in from a second computer or browser.

2.9 Account Lockout

If you make three unsuccessful attempts to log in within 30 minutes, the account locks and remains locked for 30 minutes.

2.10 Adjust Your Cepheid C360 Setup

This section explains how to adjust a few basic settings of your Cepheid C360 account.

2.10.1 Change Basic User Settings

This task explains how to change some details on the **User Settings** screen.

1. Click the person icon, then click **Settings**.
   The **User Settings** screen opens, with two buttons: **Change password** and **Edit**.

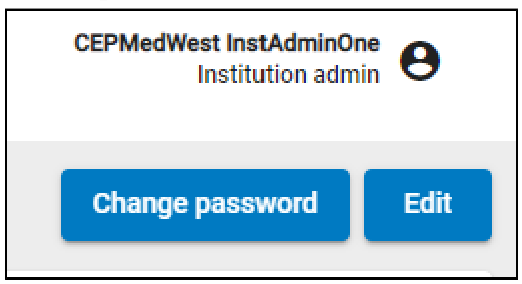

Figure 10. The User Settings buttons

2. Click **Edit**.
   The email address and the phone number fields become editable.

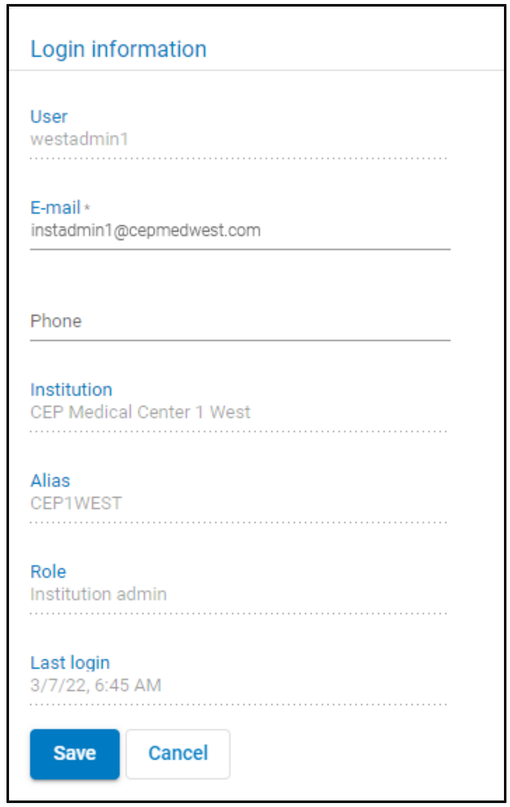

Figure 11. The User Settings screen

Note	The only fields on the **User Settings** screen that can be edited after your account is set up are the email address and the phone number.

3. Make any required changes, then click **Save**. Click **Cancel** instead to revert to the previous email and phone.

2.10.2 Change Security Settings

This topic describes how to change your account password and security questions.

1. Open the **User Settings** screen, then click **Change password** instead of **Edit**. The **Change Password** screen opens.

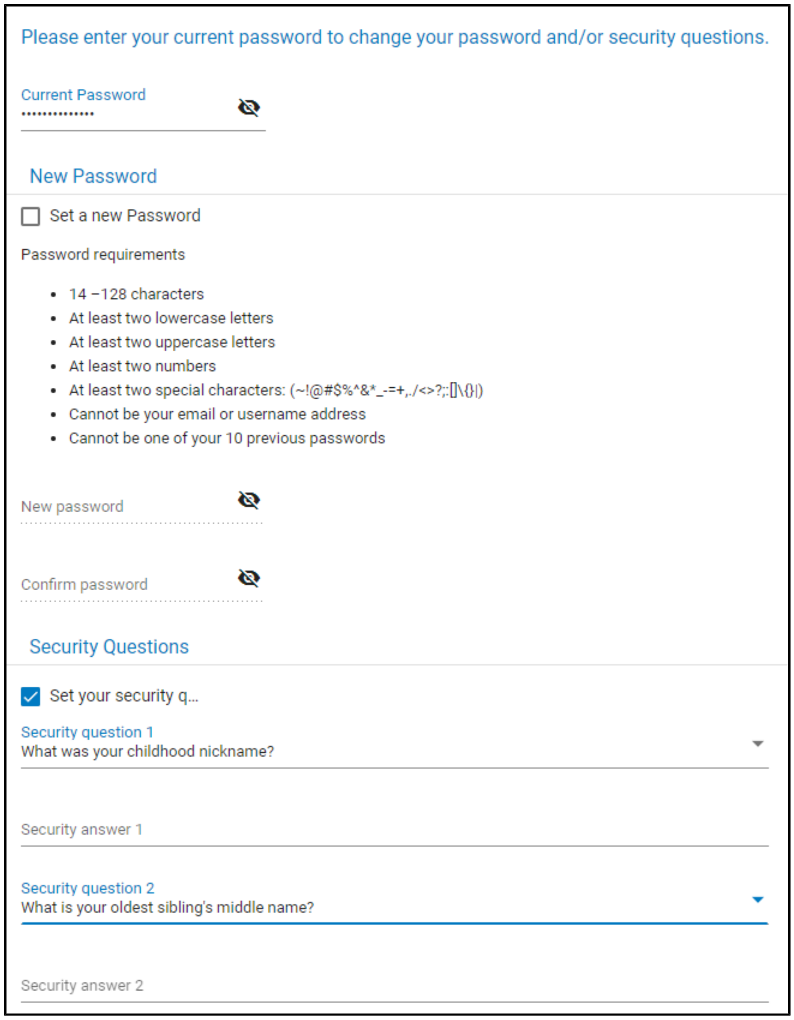

Figure 12. The Change Password screen

2. Enter your current password.
3. Enter a new password, following the required password format shown on the screen. Confirm the new password on the second line.
4. Select or update one or both security questions from the pop-ups. Provide answers for the questions that you will remember and that other people will not know.
5. Click **Save**.

3 Data-Visualization with Cepheid C360

This chapter provides details on Cepheid C360's visualization tools. These include disease surveillance on the **Medical Dashboard** screen, management of instruments on the **Instruments** screen, tracking the performance of labs and instruments on the **Test Results** screen, and incidence alerts on the **Notifications** screen. All four screens are accessed from the top section of the left-hand column.

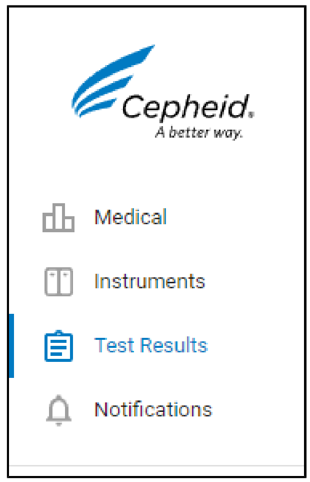

Figure 13. The top-level data-visualization menu

3.1 The Cepheid C360 Medical Dashboard

This topic describes the features of the **Medical Dashboard**. Cepheid C360's **Medical Dashboard** is really the core of the system's data-visualization tools. It aggregates test results, calculates their prevalence, and displays the information in several formats.

In the top pane on the **Medical Dashboard** screen, select an assay from the **Assay** menu, and from the **Definition** menu select the detection rate of interest.

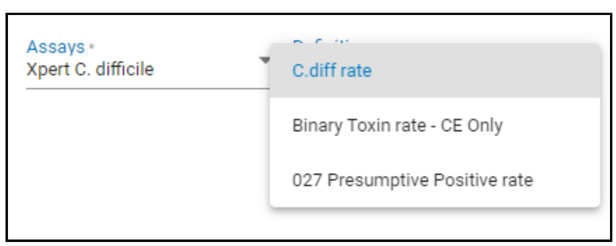

Figure 14. Detail of the Medical Dashboard main menu

Detection rates are defined for each assay depending on the assay targets. For example, for the *Ebola* assay you select from Positivity rate, NP rate or GP rate, while for the *C. difficile* assay you select C. diff rate, Binary Toxin rate, or 027 Presumptive Positive rate. To the right of the assay and rate menus, set a start date and end date, or click one of the preconfigured periods such as This Month or Last Month.

Note Hover over the information icon next to the **Definition** field for details about the definitions associated with whichever assay is selected in the **Assay** field.

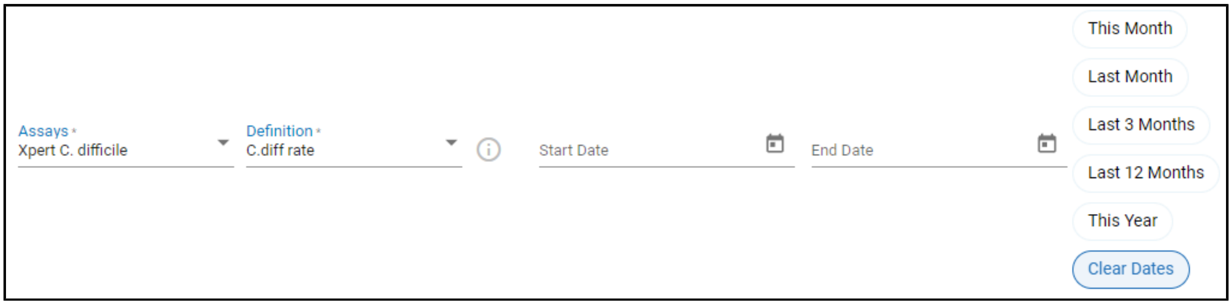

Figure 15. The Medical Dashboard menu

The panes visible below the top pane change depending on which view of the results is selected. When the **Trend Line** or **Map** view is active, a **Search** pane appears on the left side of the screen. This allows you to filter test results by drilling down to a country, a subnational administrative area, a town, or a specific lab.

Note The geographic taxonomy options to define labs and institutions and to search for and aggregate data are different in different countries. For example, the United States has two subnational geographic levels, state and county, while Australia has only one level, and Sweden is granular down to the level of individual cities.

Note The **Test Results** and **Data Grid** views include a table of results. When all columns are visible, the **Search** pane for drilling down to a geographic area or a lab is not visible. Click **Show Less Columns** to display the **Search** pane again.

Note The **Test Results** view of the **Medical Dashboard** screen does not display the same information as the main **Test Results** screen. The **Medical Dashboard** views display data about pathogens detected by assays, while the main **Test Results** screen displays quality-control information about your institution's test performance.

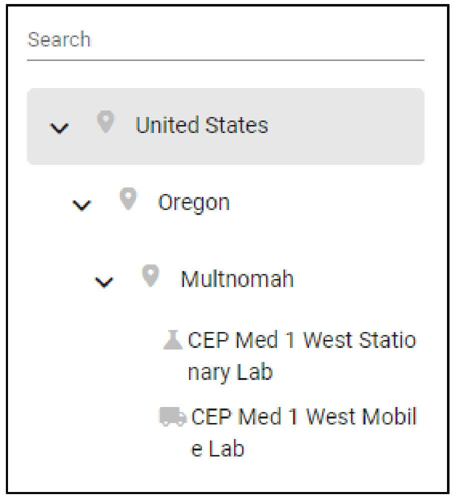

Figure 16. The geographic areas

Between the top pane and the results table, another pane displays a color-coded bar that summarizes how many tests were completed in the selected geographical area or lab, and how many were positive. Click the wrench icon at the right edge of the pane to open the **Thresholds** setting, where you adjust the width of the green, orange and red areas on the summary bar to indicate break points between background incidence, elevated, and highly elevated rates. For example, if you have selected the *Carba-R* assay and its VIM detection rate, you might set the summary bar to appear green if less than 5 percent of test results come back positive, orange if the rate falls between 5 percent and 10 percent, and red when it exceeds 10 percent positives.

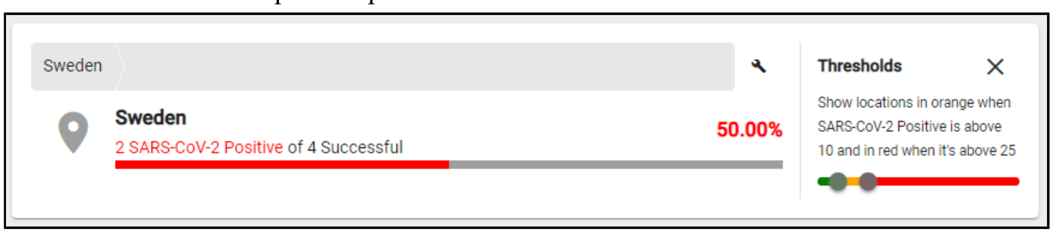

Figure 17. The threshold setting

3.1.1 The Medical Dashboard Results Pane

After you've searched and filtered the results of interest in the **Medical Dashboard**, the Cepheid C360 tools provide four ways to view the data. The **Medical Dashboard**'s bottom pane, the **Results** pane, provides these four views:

- **Trend line**
- **Map**
- **Data Grid**
- **Test Results**

The views update in real time as you change the search and filter parameters.

Figure 18. The Medical Dashboard's four results views

The Trend Line View

When the **Results** pane is set to **Trend line** view it displays the selected test results in a chronological line chart that you can display by day, week, month or quarter, and by percent positive results during each period (typically each week). A separate line appears in the chart for each rate the assay is designed to detect, and the lines can be displayed or hidden independently. The results also appear in table format below the trend line chart. Click the **Download CSV** icon to export the table as a spreadsheet-ready file.

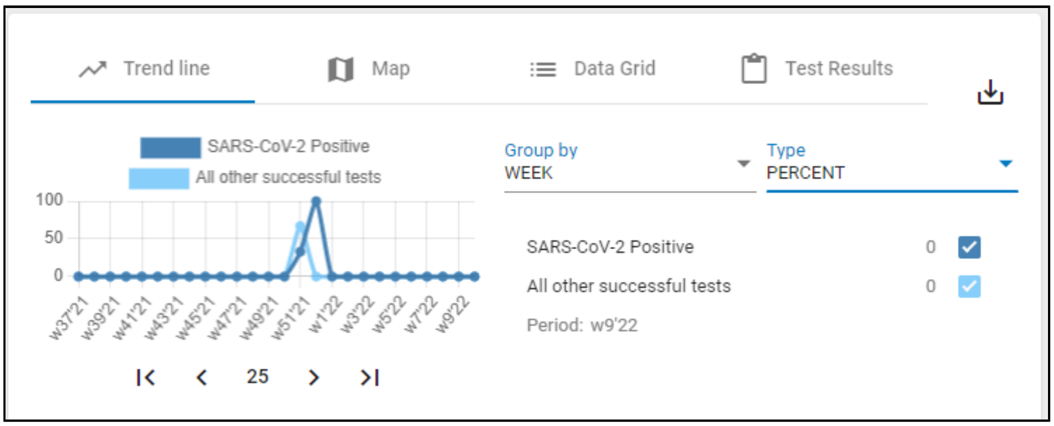

Figure 19. The Trend line view

The Map View

After searching and filtering to include the test results of interest, drill down in the **Search** pane until the map zooms in to the area where your labs or other sites are located. Each area or site appears as a dot on the map—a red dot if the pathogen of interest has been detected there, and a green dot if it has not been detected. Hover over the dots to display the percentage of positive tests at each site.

Note What a dot indicates on the map changes depending on what level of data you are looking at. For example, if you look at countries, any country with test results will appear on the map as a single dot. As you drill down the dots will indicate areas or labs that have recorded test results.

In the area you select, the map view displays all the labs under your institution (or all data-sharing institutions in the case of a supranational institution). When you click on an individual lab, the view changes to the trend line.

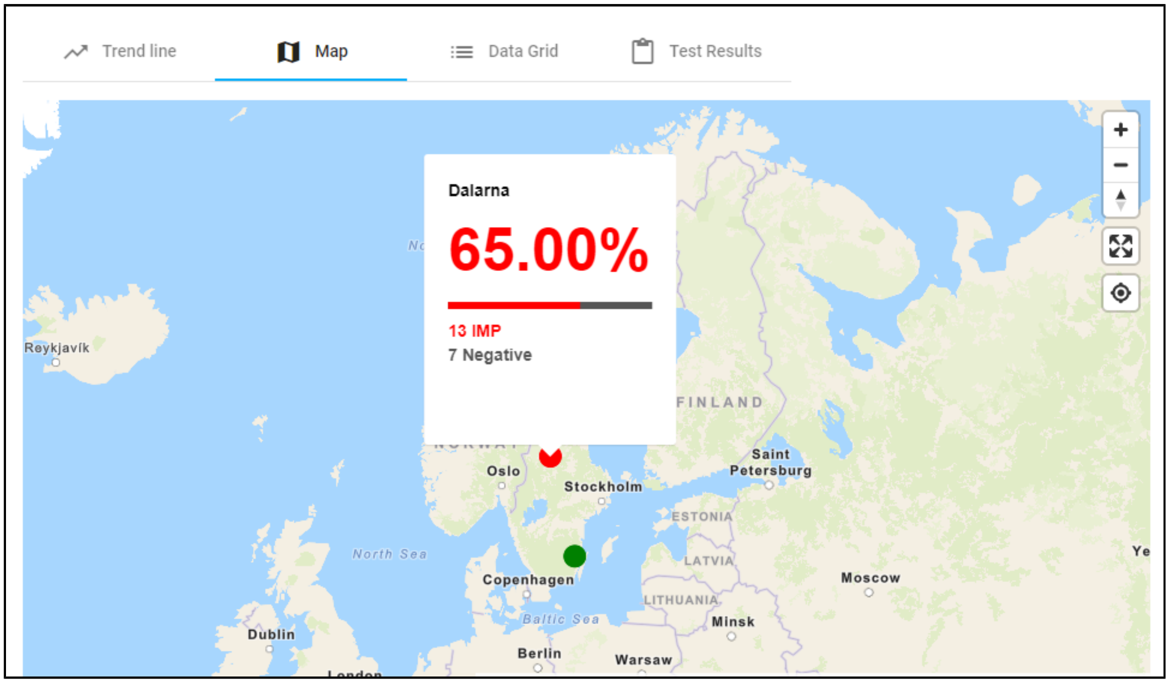

Figure 20. The Map view

The Data Grid View

The **Data Grid** view, when **Show All Columns** is selected, breaks out results by location on the vertical axis and rate on the horizontal axis. When **Show Less Columns** is selected the **Data Grid** view displays a summary of tests and rates. It also collects the five labs with the highest incidence under a separate heading, **Top Laboratories**, that you can click to see the situation at particular hot spots.

Click the **Download CSV** icon to export the data in the **Data Grid** view to a delimited text file.

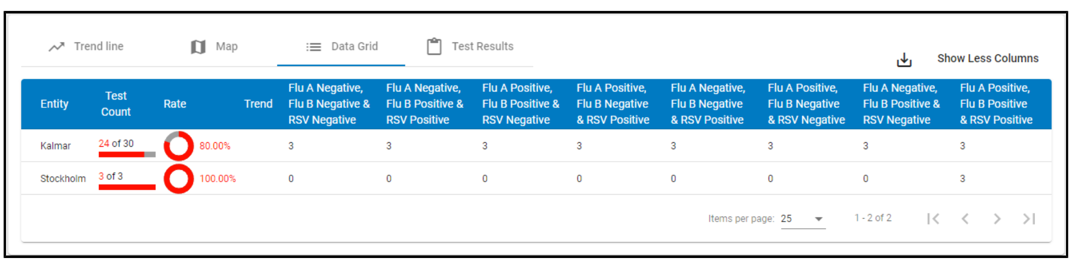

Figure 21. The Data Grid view showing all columns

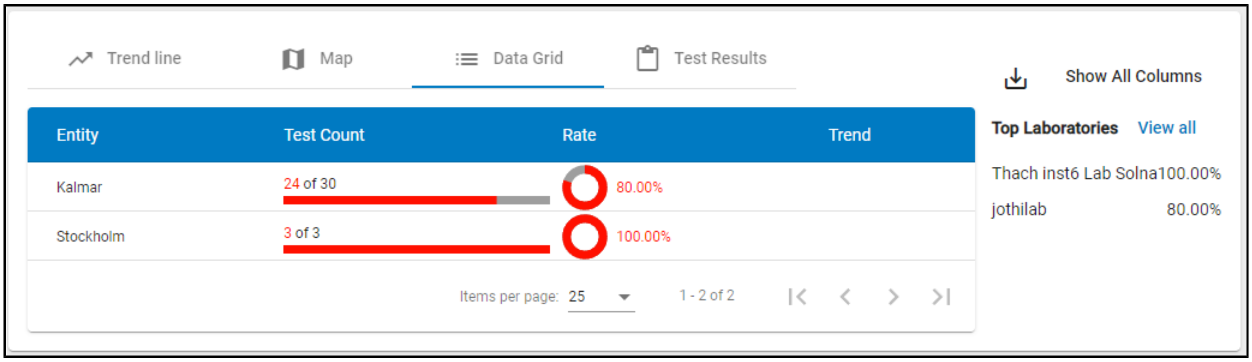

Figure 22. The Data Grid view with the Top Laboratories list

The Test Results View

The final **Medical Dashboard** view, **Test Results**, lists tests with positive results for the rate selected in the **Definition** menu, and only for the selected location and dates. The table can be sorted by most of its column headings, including **Result**, which indicates whether results were positive or negative for all the rates in the assay, and **Reported Result**, which is the raw data returned by the instruments before Cepheid C360 cleans up the data to match rules set by Cepheid under **Assay Groups**.

Note If **Enable Disease Surveillance** is not selected at the time the institution is first configured by Cepheid, the **Test Results** view does not include the reported result information.

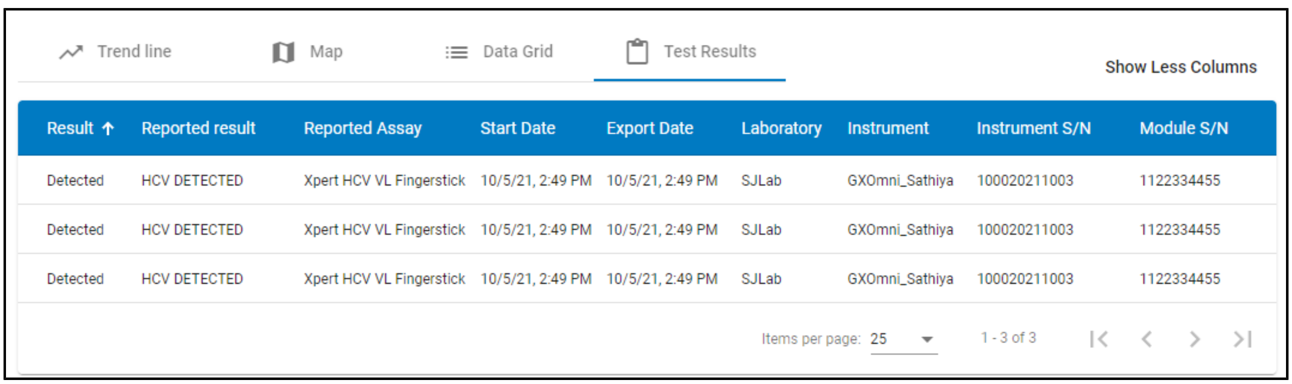

Figure 23. The Test Results view

3.2 Instruments in Cepheid C360

This section explains how to manage instruments when using the Cepheid C360 data-visualization toolset.

The **Instruments** screen allows you to record and modify information about individual instruments, but it does not change the instrument's role or setup in the laboratory. For example, you can give an instrument a meaningful name, such as "GeneXpert IV in TB lab," or record who is in charge of scheduling and maintaining an instrument. This information can be manually updated as an instrument is moved, reassigned, and so on. But it is similar to posting a (very large!) sticky note on an instrument with informal details about it. Information recorded in the **Instruments** screen is separate from the LIS and network configuration and does not affect it.

Note The list of instruments in the **Instruments** table cannot be exported as a CSV file.

New instruments appear in the **Instruments** list when they are added to the Cepheid C360 environment through C360 Sync, as described in *C360 Sync Installation and Networking Operator Manual*. You may need to delete an instrument from the list sometimes. For example, if the PC controlling an instrument is modified, or if the C360 Sync daemon that enables communication between the instrument and the C360 database is removed and reinstalled, the instrument might show up twice, so you would delete the duplicate.

3.2.1 The Instruments Screen

To view the instruments associated with your institution or a lab at your institution, click **Instruments** in the column along the left side of the screen.

The **Instruments** screen has two panes.

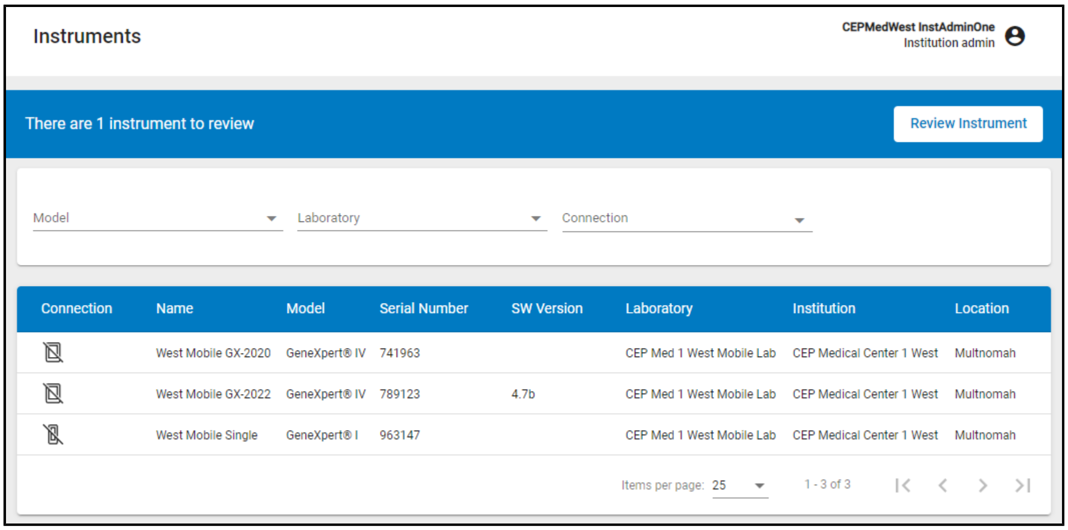

Figure 24. The Instruments screen

The bottom pane lists all the instruments that have been reviewed and approved. The list can be sorted by whether the instruments are connected, their names, models and serial numbers, the software version they are running, and their lab and location.

The top pane provides pop-up menus to filters instruments in the approved list by model and lab. In addition, the **Connection** pop-up menu provides a way to search for instruments that may have dropped off the network. You can configure it to display instruments that have connected within any period from five minutes to two weeks, or to display instruments that have not connected within those same time frames.

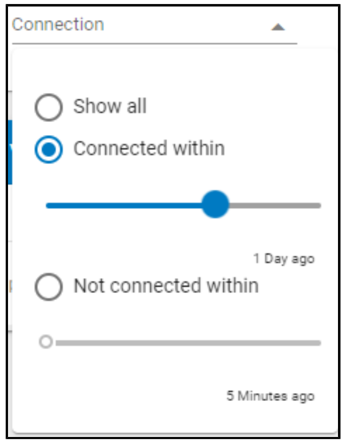

Figure 25. The Connection settings

The top pane also displays a banner listing how many instruments are waiting to be reviewed, and the **Review Instruments** button, which opens a table with the instruments waiting for review.

3.2.2 Review and Approve Instruments

This topic describes how to finalize the installation of instruments.

Instruments are added to your Cepheid C360 system with the Cepheid C360 Sync tool. This is normally an administrative or IT task. (For information on C360 Sync see the *C360 Sync Installation and Networking Operator Manual*.) After an instrument is added to Cepheid C360 it appears in a list on the **Instruments Pending Review** screen, where an institution admin or Cepheid Technical Support finalizes the installation.

1. Click **Review Instruments** in the top pane.
   The **Instruments Pending Review** screen opens, with a table that lists all the unapproved instruments. If there are many instruments listed, you can sort on the following criteria:

   - Whether it is new in the list
   - The instrument's name
   - Its serial number
   - The name of the person responsible for it

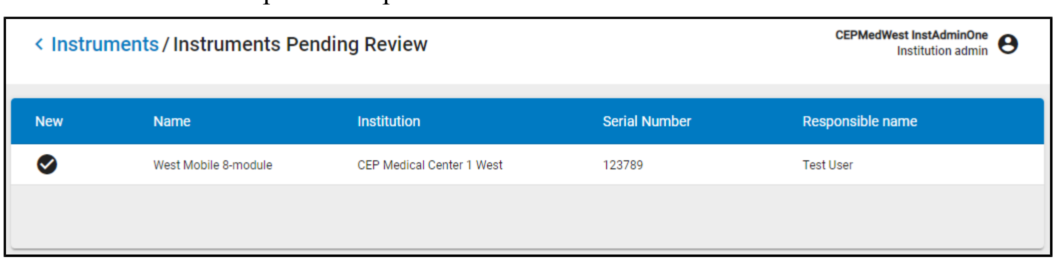

Figure 26. Instruments to review

2. Click an instrument in the list.
   The **Instrument Pending Review Details** screen opens. This screen has three panes.

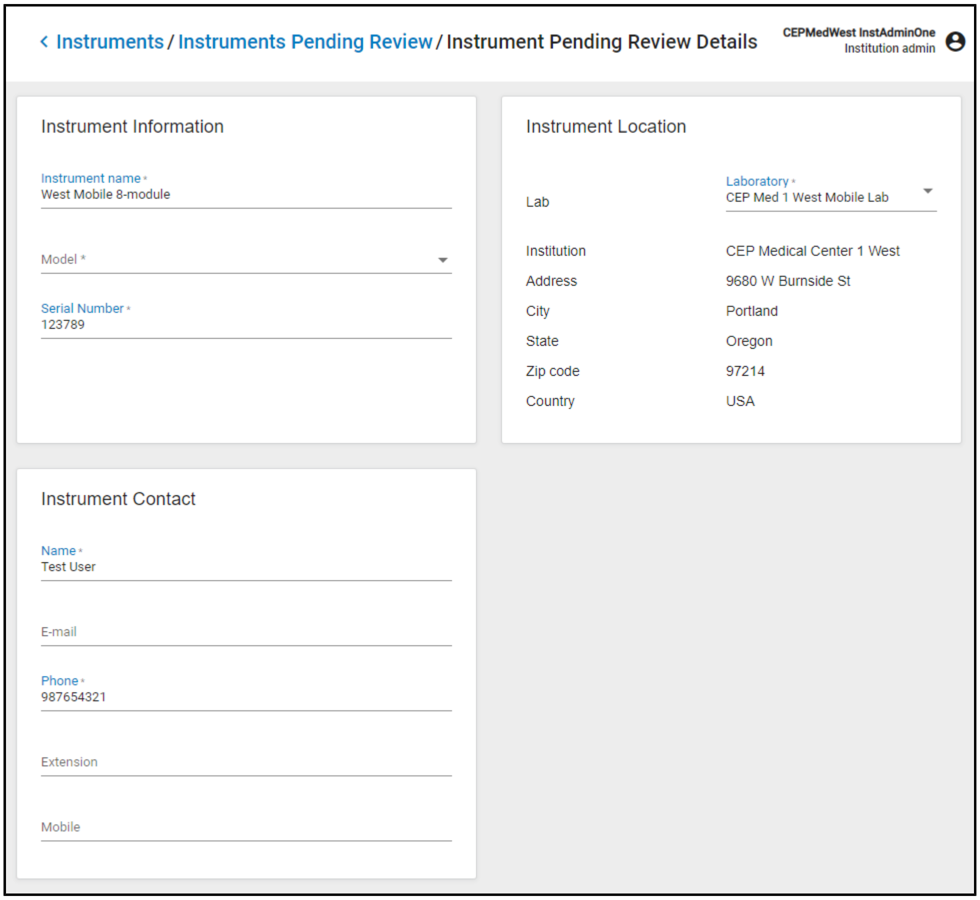

Figure 27. An instrument being reviewed

3. In the **Instrument Information** pane enter the name, model and serial number.

Note Some of this information may have been entered in Cepheid C360 Sync, but you can verify or correct it in the **Instrument Information** pane.

4. Fill in the information in the **Instrument Contact** pane.
5. Complete or update the **Instrument Location** pane.
6. If the instrument you are reviewing is intended for a lab that has not been created yet, you can open the **Create Laboratory** screen from the **Instrument Location** pane. Click the **Laboratory** pop-up menu, then at the bottom of the menu click **Create new laboratory**.

Note Creating laboratories is normally an administrative task and is explained in the *Cepheid C360 Administrative Features Operator Manual*.

7. At the bottom of the screen, click either **Reject** or **Approve and Next**.

Note One scenario in which you would reject instead of approve an instrument is if the C360 Sync operator entered an incorrect registration code. An incorrect registration code might link the instrument to a different institution, which cannot be corrected during the approval process.

3.2.3 Update Cepheid C360 Instruments

After entering information about an instrument and approving it in the **Instrument Pending Review Details** screen, it may be necessary to change some of its information—for example, if it is moved to a different lab or assigned to a different assistant. Make these changes in the **Instrument Details** screen.

The first things to notice about **Instrument Details** is the **Enabled in C360** slider. Push the slider to the left to put the instrument into an inactive state. Inactive instruments remain in the approved list and can be reactivated by pushing the **Enabled in C360** slider back to the right.

Note The disable function displays a confirmation dialog before executing the change.

To delete an instrument from the Cepheid C360 system you must contact Cepheid Technical Support. Generally, you would delete an instrument in the event that it becomes disconnected from the Cepheid C360 environment and you then reinstall it. Because the environment does not support more than one instrument with the same serial number, the old version of the instrument must be deleted when reinstalling it.

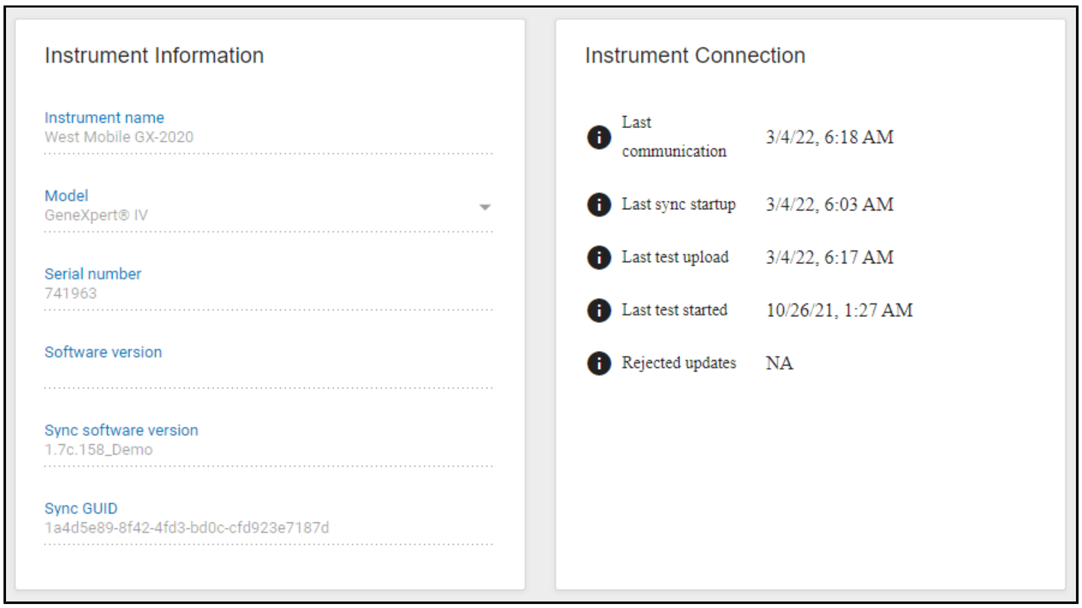

Figure 28. The main panes in the instrument details screen

Next to the **Instrument Information** pane is the **Instrument Connection** pane. This pane simply displays the most recent occurrences of a few events that indicate whether the instrument is able to communicate with Cepheid C360.

There are two additional panes on the **Instrument Details** screen.

- The **Instrument Location & Contact** pane provides the lab where the instrument is installed along with contact information for whoever manages it.

Note To edit information in the **Instrument Location & Contact** pane, click the three vertical dots next to the pane title and select **Edit**. The contact's name, email address and phone numbers are the only editable fields.

- The **Data Collection Policy** pane displays a list of data-collection settings that gather data from the instrument. Click on a project name to open its rules and other settings.

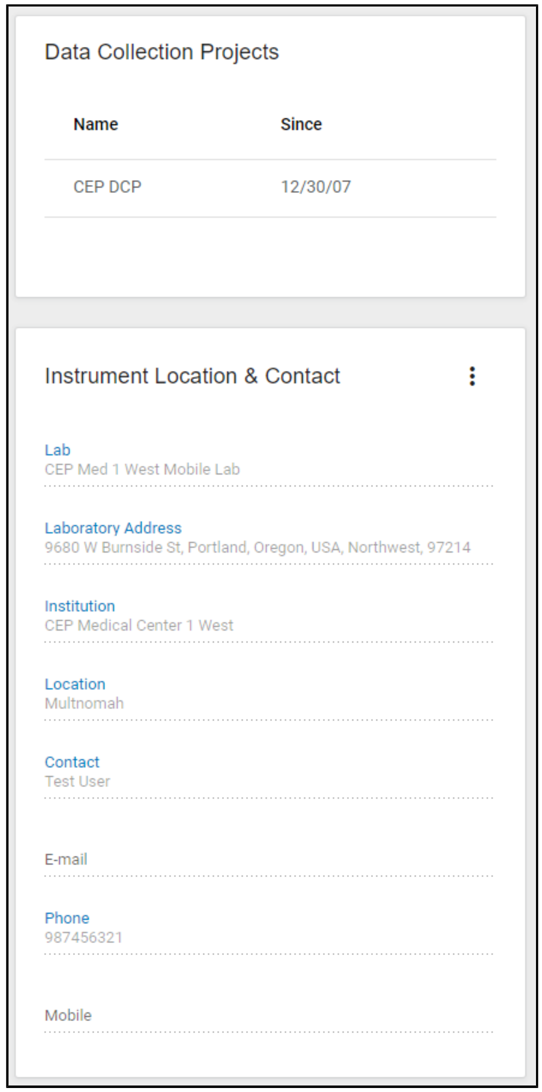

Figure 29. The other panes

3.3 Cepheid C360 Test Results

This topic summarizes the data-visualization features of the **Test Results** screen.

Rather than providing epidemiological information, the **Test Results** tools are designed to track the efficiency and error rate of the testing performed.

Three panes run across the middle of the **Test Results** screen. The leftmost pane, **Result success**, shows how many tests were conducted successfully and how many failed. Note that succeed and fail in this context means how many tests did and did not complete their run—it does not mean whether the test did or did not detect the pathogen.

The middle pane, **Unsuccessful results**, breaks down unsuccessful tests by type. The number of errors, invalid results, and tests with no results can help a lab or institution troubleshoot its procedures.

Finally, the **Cartridge utilization** pane tracks average test time and provides a chart showing how many Xpert Cartridges an organization uses. It can be configured to display cartridge use with the settings under **Date Range**, including the previous week or month, several other ranges, and a manually configured period. This information can be useful for managing inventory and personnel.

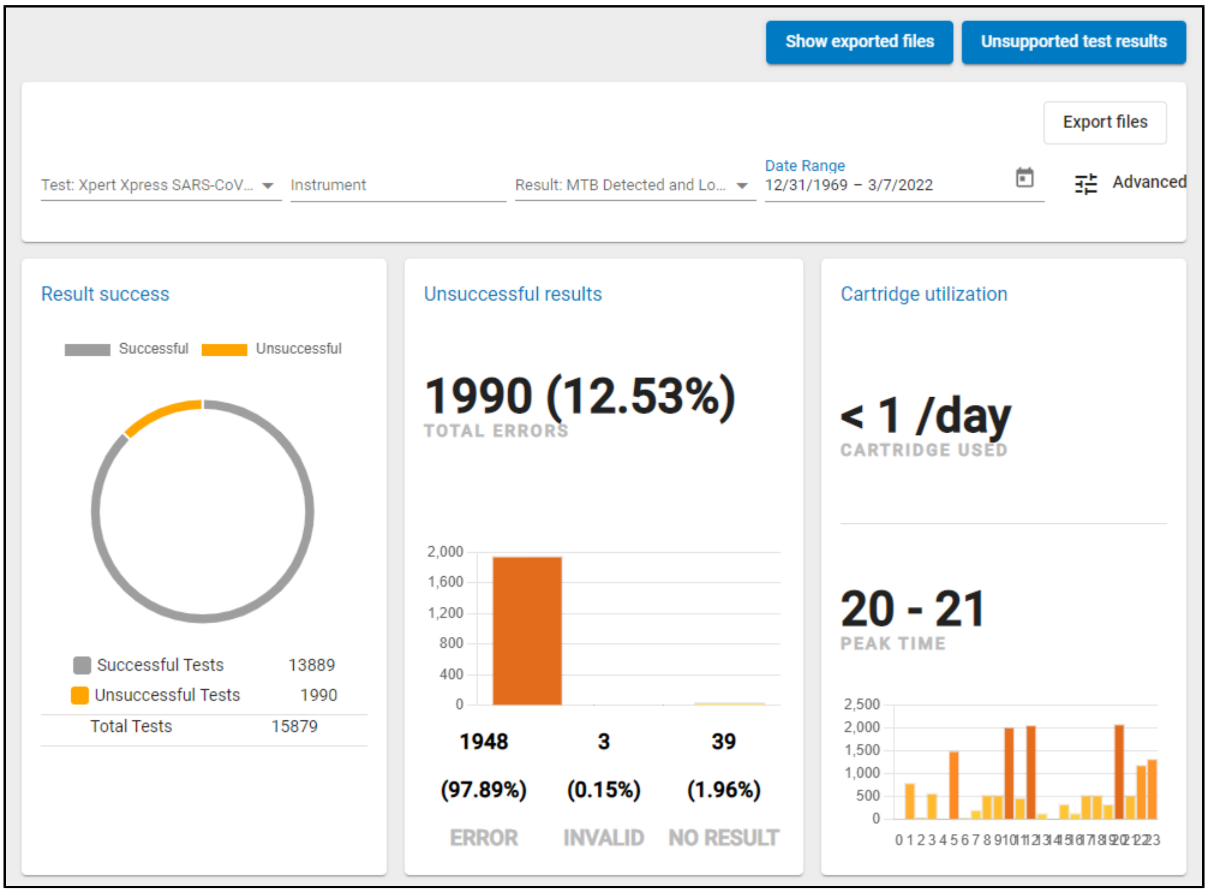

Figure 30. Core features of the Test Results screen

Across the top of the **Test Results** screen, pop-up menus provide settings to filter what test results appear in the results panes. You can choose one or more assays and one or more instruments, enter a date range, and choose which results to include for each assay.

Note Users at supranational institutions cannot apply the same level of granularity as users at other institutions. They can view test results for only one assay at a time, and do not have a menu to select instruments.

The **Result** pop-up menu lists the results tested for in each assay. For example, for the *C. difficile* assay, you can select positive and binary tox; positive and detected; negative; negative and not detected; positive and 027 pressure; and about 10 more results, as well as tests with invalid results, errors or no result. For the *Carba-R* assay, you can select from IMP, NDM and OXA-48 detected; NDM Detected and OXA-48 not detected; IMP, VIM, NDM and OXA-48 detected; and about 20 other combinations.

Note The **Result** pop-up menu defaults to selecting all results an assay tests for. The first checkbox in the **Result** menu switches between **Deselect all** and **Select all**, depending on whether a result has been selected or not.

Note Some result types are tracked by more than one assay. If you select two assays that share a result type and select the same result from both assays, those results are combined in the **Result success** and **Unsuccessful results** charts.

At the far right of the filter tool settings, the **Advanced** pop-up menu provides additional filter settings. The choices include the following:

- The laboratory
- The instrument model name
- The instrument serial number
- The module serial number. (The module is the part of the instrument that holds the Xpert Cartridge and runs the assay. Many instruments have more than one module.)
- The test GUID. (GUID, or globally unique identifier, is a unique number assigned to each test run.)
- Whether to include only specimen tests, only quality-control tests, or both.

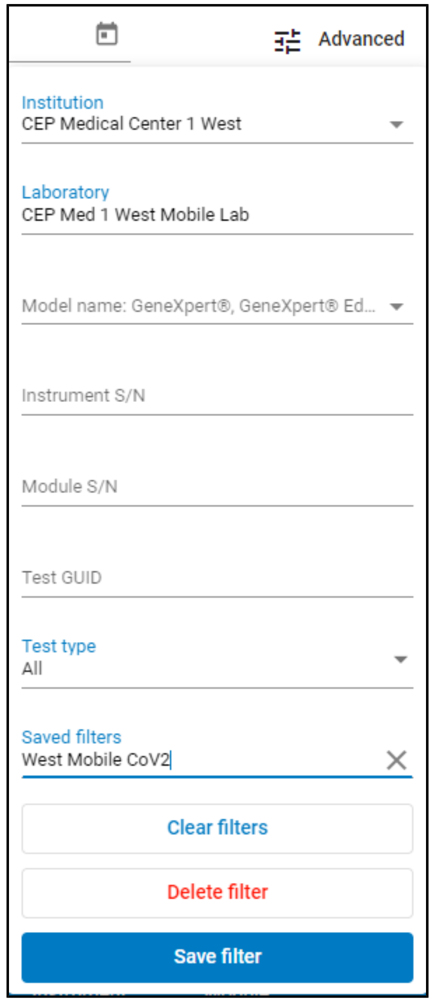

Figure 31. Additional test result filters

Filter settings can be saved with a name and reused. Once you save a filter, it appears in a list each time you click the **Saved filters** pop-up menu.

Filtered results are listed in a table at the bottom of the **Test Results** screen. The list can be sorted by all of the available filters, and individual records in the list can be selected by clicking a checkbox. Click **Export Files**, just above the **Advanced** menu, to convert the filtered and sorted list into a CSV file for import into a spreadsheet or statistical tool.

Note The exported list includes all test results that match the filters if no records are checked, but includes only the checked records if some are checked.

The exported records are converted to a CSV file and saved in Cepheid C360 as a zip file. Click **Show exported files** to open the **Test results downloads** screen, which displays all the stored zip files in a table. Click the download arrow next to each row to open a standard file dialog and save the CSV files on your computer or according to your institution's procedures. Or click the trash can to delete CSV files. (Storing results lists in a table simplifies creating a series of them while looking at the **Test Results** screen. This eliminates the need to stop to download or delete each one as it is generated.)

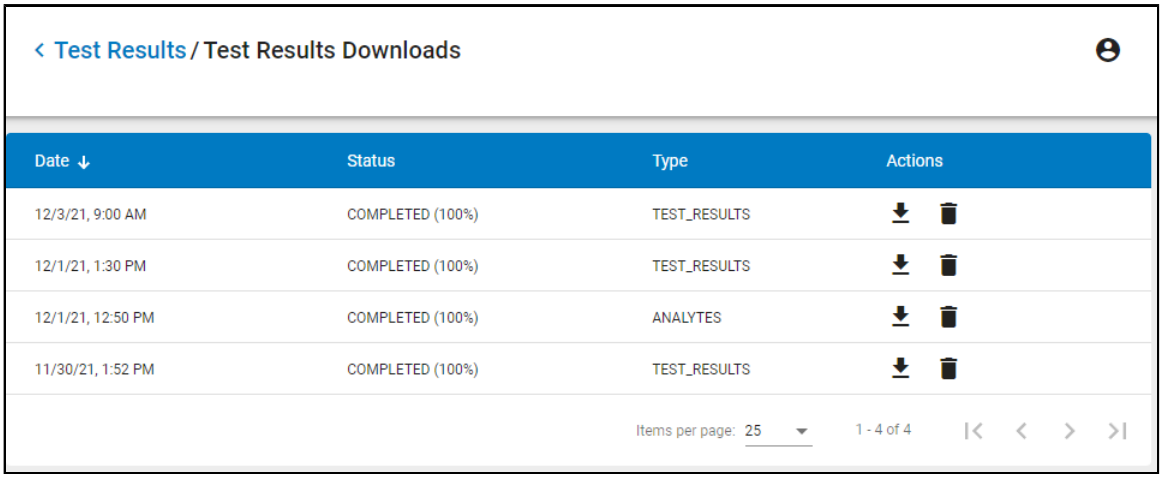

Figure 32. The list of exported CSV files

Click **Unsupported test results** to open the **Review Unsupported Test Results** screen.

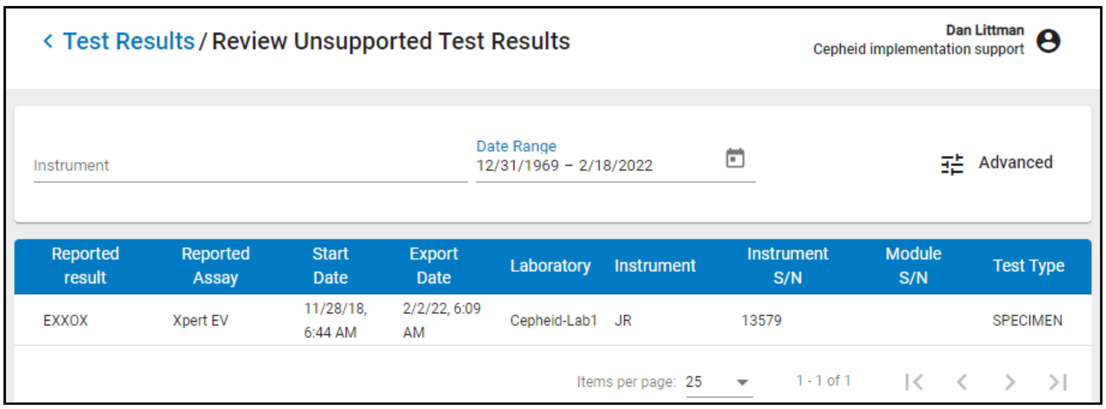

Figure 33. The Unsupported Test Results table

Unsupported test results are results and other data that are captured by an assay but are not part of the reporting rules for that assay. (Reporting rules are established by Cepheid for each assay and cannot be modified by customers.)

The list of unsupported test results can be filtered by selecting an instrument from the **Instrument** pop-up menu and a date range from the **Date Range** pop-up menu. The list can also be sorted by most of the column headings in the table, including the test result, the dates, and so on.

To the right of the **Instrument** and **Date Range** menus, the **Advanced** pop-up menu provides additional filter settings, similar to those in the **Advanced** menu on the main **Test Results** screen.

3.4 Cepheid C360 Notifications

This topic describes how to configure and review notifications.

A notification is an alert triggered by a predefined set of events. For example, you might set one up to email you when your institution records a specified uptick in a particular assay.

Note The notifications feature is not available to supranational institutions. Only people with the institution admin, lab admin and epidemiologist roles can set up a notification, and only the person setting it up receives the alert. The list of notifications sent cannot be exported to a CSV file.

1. To view the **Notifications** screen click **Notifications** in the list of data-visualization tools at the left edge of the main Cepheid C360 screen.
   The **Notifications** screen opens. The default view is the **Notification Sent** table. The **Notification Sent** table lists all events that have triggered a notification.

   You can search the sent notifications on any text term, and filter them by start and end date. You can also sort the list by the date sent and the recipient's name or email address.

Note Only the person who set up a notification receives the alert. However, the Notification Sent table is visible to other users and includes the recipient's email address so that institution admins and Cepheid Technical Support can identify and contact the person. This is useful for planning how to track disease incidence.

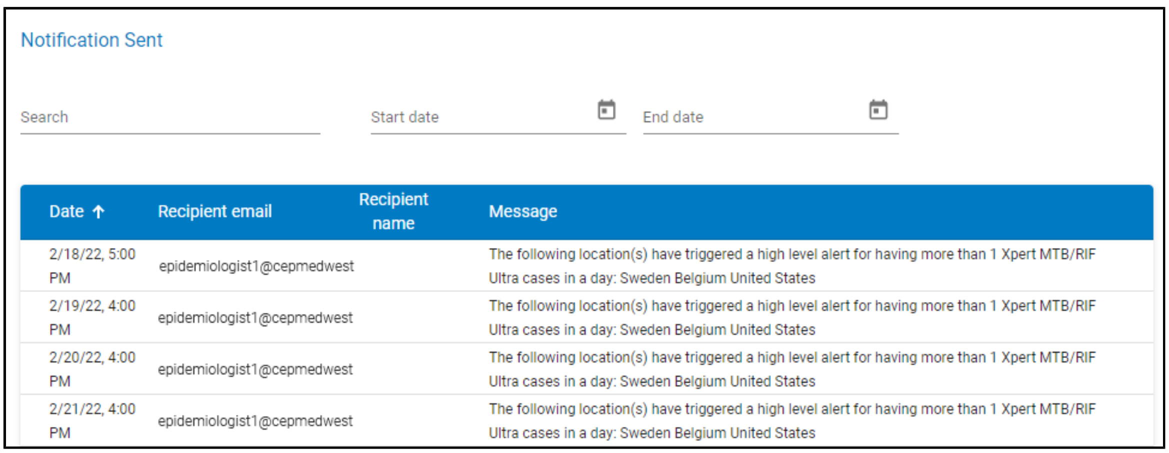

Figure 34. Example notifications

2. To define a notification, click **New Notification** beneath the list of sent notifications. The **New Notification** screen opens.
3. Configure the notification parameters as described below.
   - Choose an assay from the **Assay** pop-up menu.

Note A notification can track only one assay.

   - Set the **Priority** pop-up to high, medium or low.
   - Under **Scope**, select country, region, district, subdistrict or lab to aggregate test data and trigger notifications.

Note The **Scope** geographic setting only triggers notifications from labs in the selected area that belong to your institution. It does not trigger notifications from all institutions' labs in the area.

- In the **Case Count** field, enter the number of cases that you intend to trigger a notification.
- Set a value in the **Notification when threshold is reached for** field, and set a unit in the **consecutive** field. For example, if **Case count** is set to 5, and **Notification when threshold is reached for** and **consecutive** are set for 3 and days, respectively, Cepheid C360 will issue a notification when the designated test returns positive results 5 or more times for 3 days in a row.

4. Click **Save** or **Save and add another**.
The notification is added to the list of active notifications in the **Notification Definition** pane below the **New Notification** button.

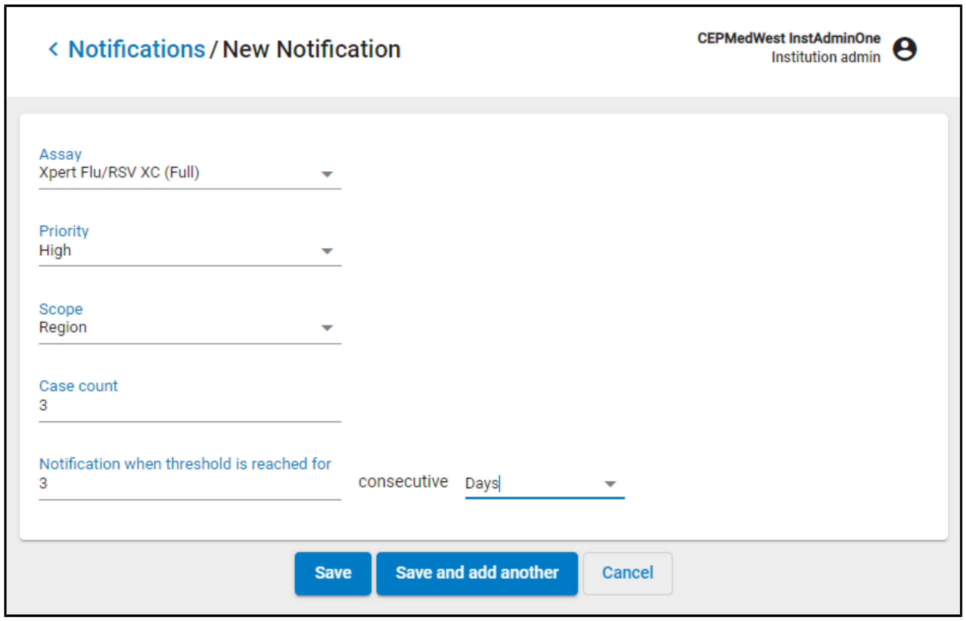

Figure 35. Create a notification

5. The **Notification Definition** pane displays a table that lists the notifications you've created. Each row shows the institution and the notification's priority and the assay it tracks, and provides a summary of the notification's parameters. Sort the list by priority and assay, or filter it by priority.
6. Click a notification in the list to open the **Edit notification** screen. Click **Edit** to change its parameters, or **Delete** if you no longer need that notification.

3.5 Data-Collection Policies

This topic describes what Cepheid C360's data-collection policy feature is for and how to configure policies.

Data-collection policies are useful to narrowly target specific information. For example, you can set up a data-collection policy to extract just the results of one assay conducted in a particular lab or on a particular instrument. Two data-collection policies could gather the same data from the same instruments but return different results based on different **Max Data Category Level** settings.

Data-collection policies are set up by Cepheid Technical Support or institution admins, usually at the request of an epidemiologist, to manage what information generated by instruments is presented in Cepheid C360 for data-visualization purposes. Supranational institutions do not receive data gathered by nonsupranational institutions' data-collection policies.

1. Under **Configurations**, click **Data Collection Policies**.
   The **Data Collection Policies** screen opens, showing a list of your institution's currently active data-collection policies.
2. To create a new data-collection policy, click **New Data Collection Policy**.
   The **New Data Collection Policy** screen opens. The **Data Collection Policy Enabled** slider defaults to being active. To create and implement a data-collection policy, leave the slider as is. You can set up and deploy a data-collection policy, then later make it temporarily inactive by shifting the slider to **Disabled**.

Figure 36. The New Data Collection Policy screen

3. In the **Data Collection Policy Details** pane, give the policy a descriptive name and select the date when you want the policy to go into effect. The **Institution** field defaults to your institution.
   When you complete entering information in the **Data Collection Policy Details** pane, the **Rules** pane opens just beneath it.

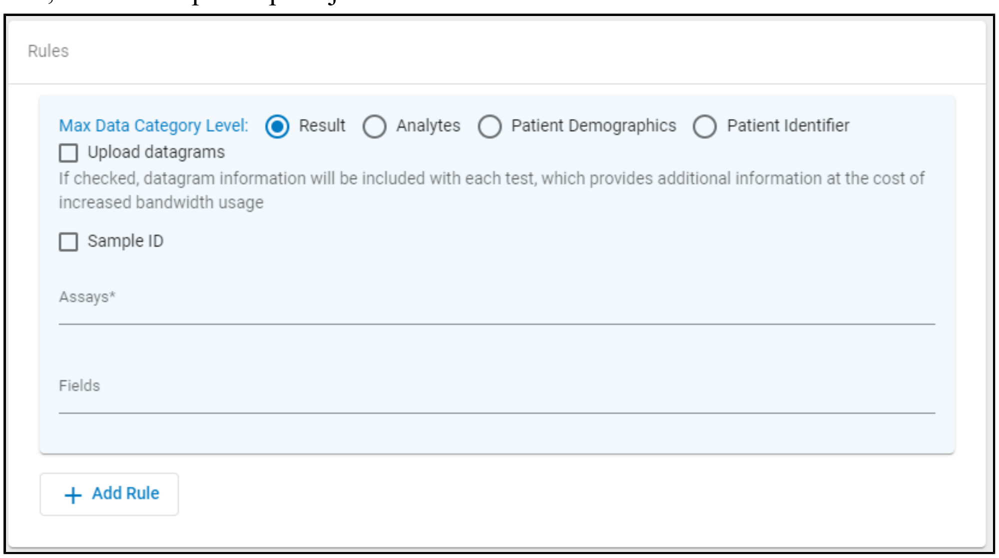

Figure 37. The data-collection policy Rules pane

4. Fill out the fields in the **Rules** pane.

a) Select the level of data to collect. The choices are constrained by the general setting in the **Institution Policy** settings.

b) Check **Upload datagrams** to include datagrams with each test result.

Note Datagrams are a tool used by Cepheid Technical Support to monitor the integrity of data transmissions between instruments and the Cepheid C360 server. We recommend uploading datagrams except in situations of very limited bandwidth.

c) Check **Sample ID** if you intend to collect that information from each test.

Note The **Sample ID** setting may not be visible, depending on how your institution was configured when first created by Cepheid.

d) Click the line under **Assays** to open the list of assays. Choose **Select all** or click the assays you want to include individually. To add individual assays you must click the field line repeatedly to make the menu pop up. To remove an assay after you select it, click the small "X" next to the assay name. To remove them all, click **Select none**.

e) From the **Fields** pop-up menu, choose **Select All**, or pick **Sex**, **Race/Ethnicity**, **Age group**, **Age group CDC** and/or **Patient 3-digit zip**. (Note: When you enter a patient's age, **Age group** or **Age group CDC**, whichever is active based on the setup in C360 Sync Installation and Networking, assigns the patient to standardized age categories for epidemiological purposes.) To select individual fields you must click the field line repeatedly to make the menu pop up. To remove a field after you select it, click the small "X" next to the field name. To remove them all, click **Select none**.

f) Click **Add Rule** to append additional rules to the data-collection policy.

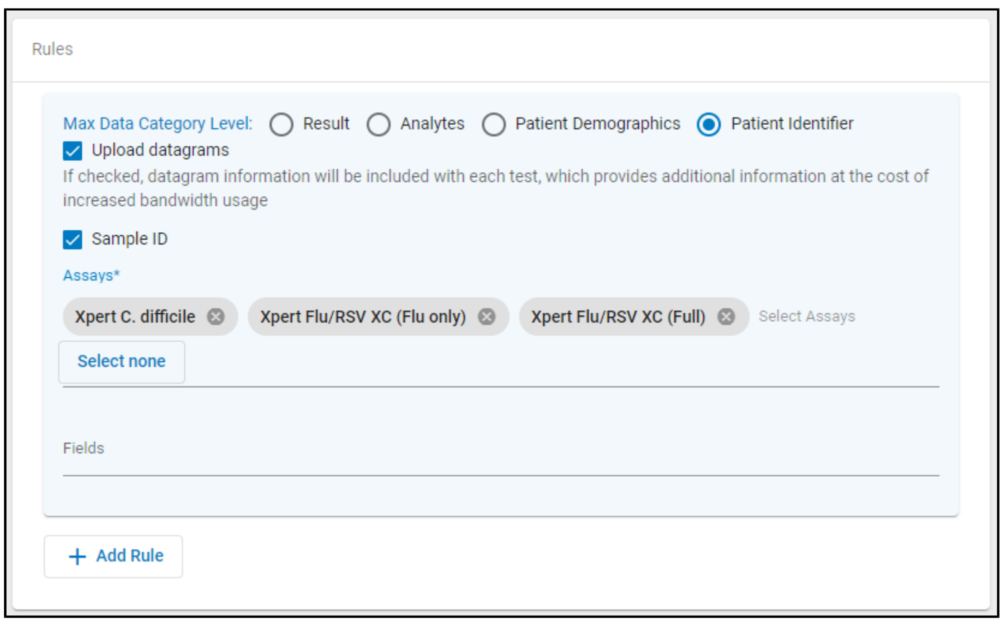

Figure 38. A basic data-collection rule

5. Beneath the **Rules** pane, in the **Applies To** pane, narrow down the results by entering a location, one or more labs, or even specific instruments. The process is similar to adding assays to the data-collection policy.

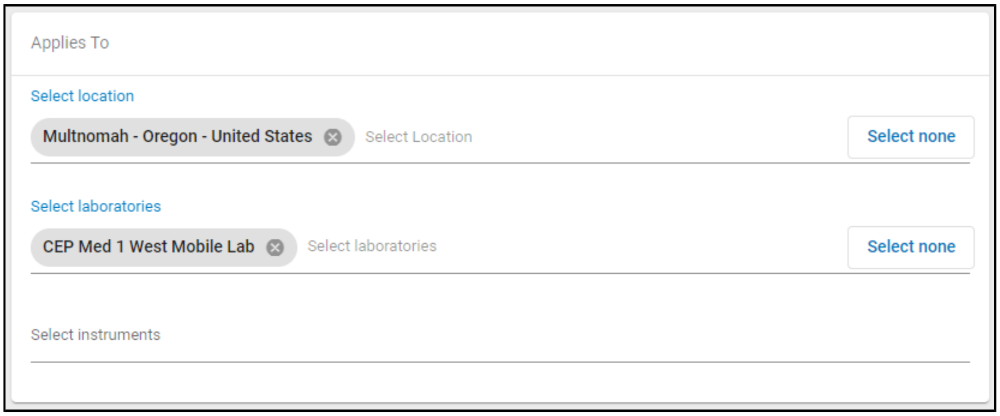

Figure 39. What the data-collection rule applies to

Note A data-collection policy can have as many rules as your institution has assays.

6. Click **Save**.
   The new policy becomes operational and is added to the list of data-collection policies.
7. To modify a data-collection policy, click the one of interest in the **Data Collection Policies** screen.
   The **Data Collection Policy Details** screen opens. You can change all of the policy's settings on this screen in the same way you created them.
8. To delete a data-collection policy, open it from the **Data Collection Policies** screen. At the bottom of the **Data Collection Policy Details** screen click **Delete**.

3.6 Sharing Requests

This topic provides a summary introduction to how institutions can share data.

Institutions can use Cepheid C360 to share and aggregate test-results data for use in tracking epidemiological trends across health-care systems or geographic areas. Institutions designated as supranational initiate requests to receive data from other institutions, which can accept or reject the request. Nonsupranational institutions cannot initiate requests or receive shared data. Administrators at both kinds of institutions need to understand how data-sharing works.

4 Supranational Institutions and Data-Sharing

This chapter describes how supranational institutions set up and send data-sharing requests, and how nonsuprational institutions manage the requests.

An institution defined as supranational in Cepheid C360 is an institution that aggregates medical test data from other medical centers. It may be part of a public-health agency such as the CDC or the WHO, or an entity of a private medical network tasked with gathering and interpreting information from the network's other institutions. Supranational institutions do not operate their own labs. Instead, their administrators request data from other institutions, and their epidemiologists interpret the data.

Note An institution is defined as supranational when Cepheid creates it in Cepheid C360. Once an institution has been defined as supranational it cannot be converted to a regular institution.

Note An institution can be enrolled in Cepheid C360 twice, as a supranational institution and a nonsupranational institution. That would allow it to issue sharing requests and to accept sharing requests from other institutions. To configure two versions of an institution, provide different identifiers and slightly different names. Keep in mind that supranational institutions cannot have laboratories.

To gather medical test data, a supranational institution sends out sharing requests that specify what information it is seeking. A sharing request might specify, for example, the results of a set of assays for a particular date range. The receiving institution or institutions can accept or reject the request. However, only supranational institutions and Cepheid Technical Support can initiate data-sharing requests.

Note The Supranational Admin and Supranational Epidemiologist roles have slightly different privileges in Cepheid C360 than the Institution Admin and Epidemiologist roles have. Generally, the supranational roles do not provide access to features that are internal to an institution, such as adding and inviting new institution personnel, adding and editing labs, viewing instrument configurations, and setting institution policy. In the same way, supranational admins and epidemiologists have a few privileges that institution personnel do not, such as adding and inviting new supranational personnel, and issuing or modifying sharing requests.

Data collected with data-sharing requests becomes available to the Cepheid C360 data-visualization tools. However, the shared data provided to the supranational institution includes only the test results collected by the sharing institution. Lab information, personnel, and other information is not included.

Note A supranational institution cannot distribute data gathered with sharing requests to other institutions.

4.1 Data-Sharing Requests

This topic describes how to create a data-sharing request.

Administrators at nonsupranational institutions and epidemiologists do not generate sharing requests, but they should understand how sharing requests work.

Note For a nonsupranational institution to participate in sharing data, it must be configured to accept sharing requests at the time the institution is created in Cepheid C360. An institution configured to accept data-sharing requests is visible to supranational institutions that may send sharing requests. The institution is not obligated to accept them; it can accept or reject individual sharing requests. An institution not configured to accept data-sharing requests does not appear in the list of potential sharing institutions that supranational institutions draw from.

1. Under **ADMIN**, click the arrow next to the **Configurations** item to expand it. Then click **Sharing Requests**.
   The list of previously created sharing requests opens in a table. The table can be sorted by institution, or alphabetically by each request's name.

Name	Institution	Assays	Periodicity	Data category	Granularity	Data from
BCR 2020s overview	CEP Supranational Medical East	Xpert BCR-ABL Monitor, Xpert BCR-ABL Ultra, Xpert BCR-ABL Ultra p190	Monthly	None	Laboratory	1/1/20
C.Diff Metro Portland	CEP Supranational Medical East	Xpert C. difficile	Daily	None	Test Result with Patient Demographics	1/1/22
Carba-R West	CEP Supranational Medical East	Xpert Carba-R	Real time	None	Laboratory	1/1/21
FII and FV urban areas	CEP Supranational Medical East	Xpert FII & FV	Daily	None	Country	1/31/21
GBS south	CEP Supranational Medical East	Xpert GBS LB, Xpert GBS	Real time	None	Test Result with Patient Demographics	2/14/22
Hemo fever	CEP Supranational Medical East	Xpert Ebola	Daily	None	Laboratory	1/31/22
Multnomah schools	CEP Supranational Medical East	Xpert Norovirus	Daily	None	Test Result with Patient Demographics	1/1/21
Recent STD incidence	CEP Supranational Medical East	Xpert HPV 16_18-45, Xpert HPV HR, Xpert HIV Qual, Xpert HIV Quant	Daily	None	Subdistrict	1/1/22
Recent Throat and Lung	CEP Supranational Medical East	Xpert Flu/RSV XC (Flu only), Xpert Flu, Xpert MRSA/SA Nasal Complete, Xpert MRSA, Xpert Xpress SARS-CoV-2/Flu/RSV, Xpert Xpress Strep A	Daily	None	Test Result with Patient Demographics	1/31/22

Items per page: 25 1 - 9 of 9

Figure 40. Data-sharing request examples

2. Click **Create new sharing request**.
   The **New sharing request** screen opens.

Note Only Cepheid Technical Support and users with the role of Supranational Institution Admin at a supranational institution can initiate sharing requests.

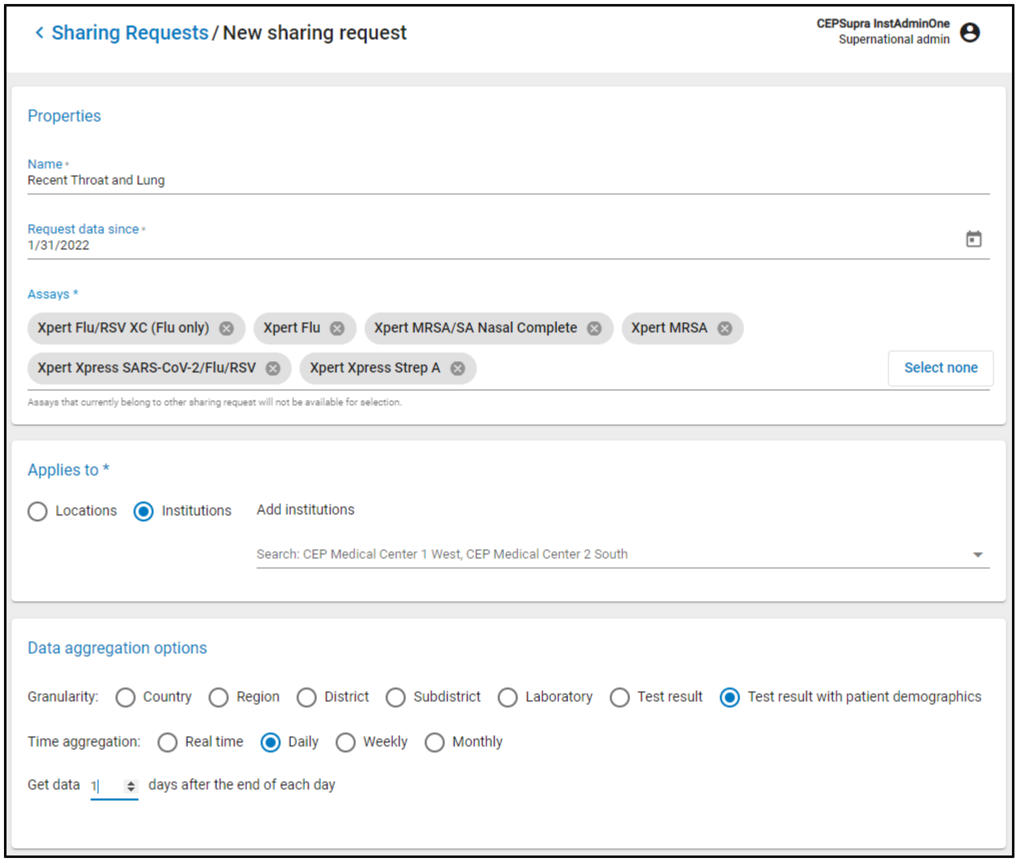

Figure 41. Setting up a data-sharing request

3. Fill out the fields in the **Properties** pane.
   a) Enter a recognizable name for the sharing request in the **Name** field, such as Influenza incidence in metropolitan New York.
   b) Click the calendar icon next to the **Request data since** field and select a start date.
   If the start date is in the past, the sharing request retrieves the data retroactively.
   c) Click in the **Assays** field and select the tests of interest from the menu of choices, or click **Select all** in the menu.

   If you select an assay by mistake, click the small "X" to its right to remove it from the request.

Important **You can send more than one sharing request to the same institution and you can include more than one assay in a request, but each assay can only be included in one request. To retrieve test results for a particular assay from multiple sharing institutions, include them all on the request. We recommend that you plan sharing requests carefully to avoid duplication.**

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4. In the **Applies to** pane select either the **Locations** or the **Institutions** radio button.
   a) Click in the Search field. A menu of locations or institutions opens, depending on which radio button you selected.
   b) Click the checkboxes of the locations or institutions you want to add to the sharing request.You can select multiple locations or institutions. There is no limit to the number of institutions included in a request. If you select by location, only the

institutions in that location and that are configured to accept sharing requests receive the request.

Note If some of the institutions in a sharing request decline the request, data will still be retrieved from those institutions that accept the request.

5. Set the following details in the **Data aggregation options** pane.
   a) Choose one radio button for **Granularity**. The choices are as follows:
      - Country
      - Region
      - District
      - Subdistrict
      - Laboratory
      - Test result
      - Test result with patient demographics

Note If an institution does not collect patient demographics or is set up to prevent sharing that information, it will not be included in the data shared after the request is accepted even if the requesting institution includes that in the sharing request.

Note Not all geographical areas provide the same levels of granularity. For details about your location contact Cepheid Technical Support.

   b) Choose one radio button for **Time aggregation**. The choices are as follow
      - Real time
      - Daily
      - Weekly
      - Monthly
   c) The choices for the final setting, **Get data "X" days after...**, vary depending on the **Time aggregation** setting. For example, if you select the **Weekly** radio button and enter 2 in the **Get data "X" days after...** field, data from institutions that accept the sharing request will be retrieved two days after the end of each week. These settings are visible when the institution admin at the sharing institution reviews the request on the **Sharing Request Details** screen.
6. Click **Save**.
   The sharing request is added to the table of requests at the supranational institution and at the institution or institutions receiving the request. However, it will not be active until the specified institution or institutions accept the request.

Note After a sharing request has been created, a new pane, **Requested acceptance status**, appears at the bottom of the screen. Click the arrow next to the title to see whether the listed institutions have accepted the request.

Figure 42. Sharing request status

4.2 Modify a Sharing Request

This topic describes how a supranational institution modifies a sharing request after it has been created.

After a request has been created, some of the parameters can be changed and some cannot. To change a request, simply open it by clicking it in the table of sharing requests.

The following parameters can be changed:

- The request's name
- The assays requested
- Institutions or locations can be added but not removed.

The following parameters cannot be changed:

- The start date
- Any of the data-aggregation options

Note After a sharing request has been configured to apply to institutions or locations in the **Applies to** pane, that setting cannot be changed.

4.3 Delete a Sharing Request

This topic describes how a supranational institution deletes sharing requests it has created. A sharing request can be deleted whether the receiving institution has accepted the request or not.

1. Open the request by clicking it in the table of sharing requests.
   The sharing request's window opens.

Note Only people with the Supranational Institution Admin role can delete a sharing request.

2. Click **Delete** just above the right side of the **Properties** pane.
3. When the confirmation dialog opens click **Yes**.
   The sharing request is deactivated and removed from the table of requests. Any data received from the sharing institution is removed from the requesting institution’s aggregated data. (Deleting a sharing request does not remove data from the sending

institution's database.) The request also is removed from the table of requests at the sharing institution. This occurs whether or not the institution has accepted the request.

4.4 View and Respond to Sharing Requests

This task describes how institutions that receive sharing requests can view them.

1. Under **ADMIN**, click the arrow next to the **Configurations** item to expand it. Then click **Sharing Requests**.
   The list of pending and accepted sharing requests opens in a table. The table can be sorted by status, alphabetically by each request's name, or by the institution making the request.

Status	Name	Institution	Assays	Periodicity	Data category	Granularity	Data from
PENDING	BCR 2020s overview	CEP Supranational Medical East	Xpert BCR-ABL Monitor, Xpert BCR-ABL Ultra, Xpert BCR-ABL Ultra p190	Monthly	None	Laboratory	1/1/20
PENDING	C.Diff Metro Portland	CEP Supranational Medical East	Xpert C. difficile	Daily	None	Test Result with Patient Demographics	1/1/22
PENDING	Carba-R West	CEP Supranational Medical East	Xpert Carba-R	Real time	None	Laboratory	1/1/21
ACCEPTED	Multnomah schools	CEP Supranational Medical East	Xpert Norovirus	Daily	None	Test Result with Patient Demographics	1/1/21
ACCEPTED	Recent STD incidence	CEP Supranational Medical East	Xpert HPV 16_18-45, Xpert HPV HR, Xpert HIV Qual, Xpert HIV Quant	Daily	None	Subdistrict	1/1/22
PENDING	Recent Throat and Lung	CEP Supranational Medical East	Xpert Flu/RSV XC (Flu only), Xpert Flu, Xpert MRSA/SA Nasal Complete, Xpert MRSA, Xpert Xpress SARS-CoV-2/Flu/RSV, Xpert Xpress Strep A	Daily	None	Test Result with Patient Demographics	1/31/22

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Figure 43. Sharing requests received

2. Click a request in the table to open it. Review what details the requesting supranational institution has asked for.

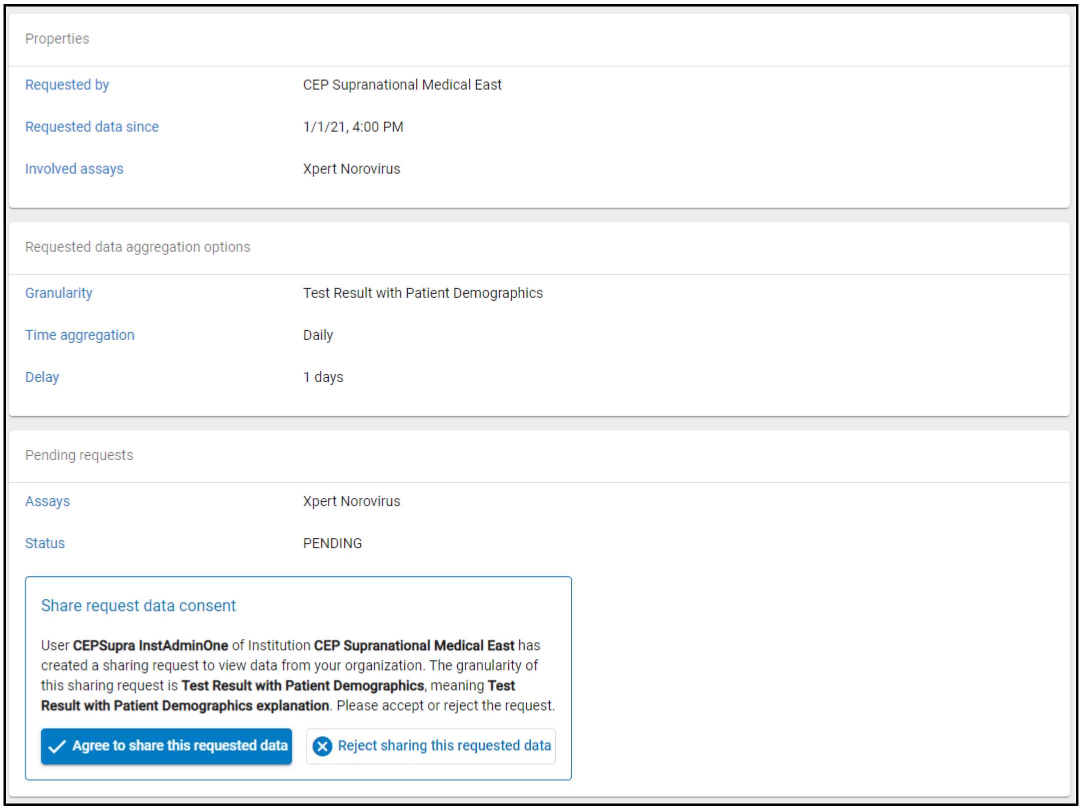

Figure 44. Sharing request details and the accept or reject control

3. At the bottom of the sharing request screen is a box called **Share request data consent**. Click either **Agree to share this requested data** or **Reject sharing this requested data**.

Important **The institution that receives a sharing request is responsible for complying with applicable privacy and data-protection laws.**

4.5 Stop Sharing

This topic describes how an institution that has accepted a sharing request can stop sharing data.

1. Open the request by clicking it in the table of sharing requests.
   The sharing request's window opens.
2. In the **Data being shared** pane at the bottom of the screen click **Stop sharing**.

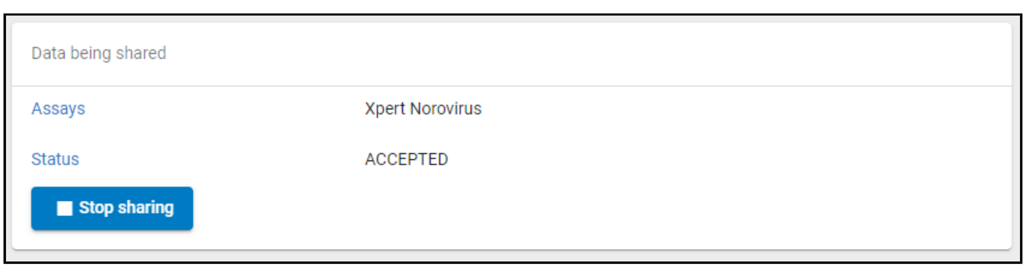

Figure 45. The Stop sharing button

Cepheid C360 stops sending new data to the requesting institution. Data previously shared with the requesting institution is no longer visible to the supranational institution. Stopped sharing requests remain in the list of requests.

4.6 Reinitiate a Stopped Share

This topic describes how to start sharing data again after having stopped a sharing request.

1. Open the request by clicking it in the table of sharing requests.
   The sharing request's window opens. The **Stop sharing** button in the **Data being shared** pane now reads **Start sharing this data**.
2. Click **Start sharing this data**.
   Cepheid C360 begins sending the requested data to the supranational institution that initiated the request. If the request's start date was before or during the period the sharing request was stopped, any missed data is retrieved retroactively.