

myvirena.com
User Manual / Training Guide

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Introduction

Virena is a wireless cloud-based system that allows you to manage patient de-identified data, in near real-time, for improved operational efficiencies. Virena is simple, secure, HIPAA compliant, and available with Quidel automated testing platforms. Virena connects Sofia, Sofia 2 and/or Solana instruments to the Quidel cloud (myvirena.com) via a secure, cellular 4G LTE network. As tests are run throughout the day, Virena transmits de-identified data, in near real-time, to the Quidel cloud (myvirena.com) where it is stored, processed and made available to your organization.



Registering as a New User

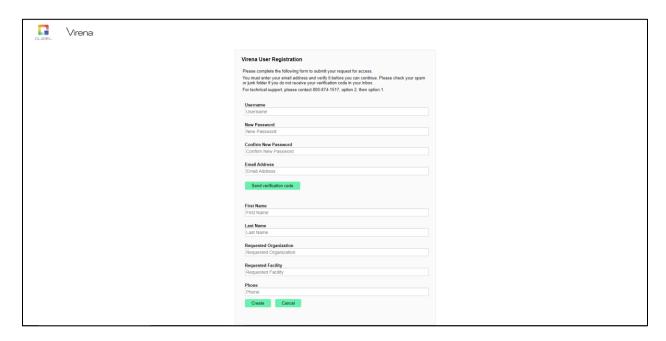
Using one of the following internet browsers:

- Internet Explorer version 11 or above
- Chrome latest Version on Windows 10.

Enter the URL https://www.myvirena.com in the address bar and press enter. On the resulting log-in page, click "Sign up now"



This will take you to the user registration page.



On this page, enter your personal information including the username and password you would like to use to access the website.

- Username
- Password
- Email Address
- First Name
- Last name
- Requested Organization (The organization is the parent company and the facilities are the satellite offices where the instruments are located).
- Requested Facility (location you are at)
- Phone

For security purposes, we need to verify your e-mail address. A verification code will be sent to the entered e-mail address. In case you do not receive the e-mail immediately, please check your spam folder. The e-mail with the verification code is sent from "Microsoft on behalf of myVirena Prod msonlineservicesteam@microsoftonline.com"

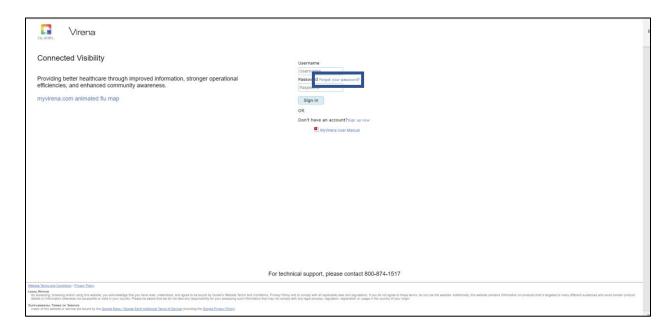
Once you submit the request, an administrator will verify this information and then formally assign you to the appropriate organization and facility within the system. Once your request has been approved, you will receive an e-mail within 2-3 business days containing a link to activate your account.

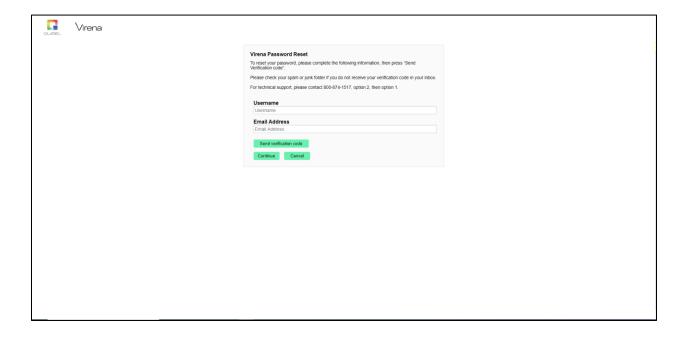
Activate your account by clicking on the link. You will now be able to log-in to the website using the username and password you entered above.

Reset password/change e-mail address

If needed, your password and e-mail address can be changed. A valid user name and the associated e-mail address are required. If you do not know your user name and/or e-mail address, please contact your Organizational Administrator or Quidel Technical Support.

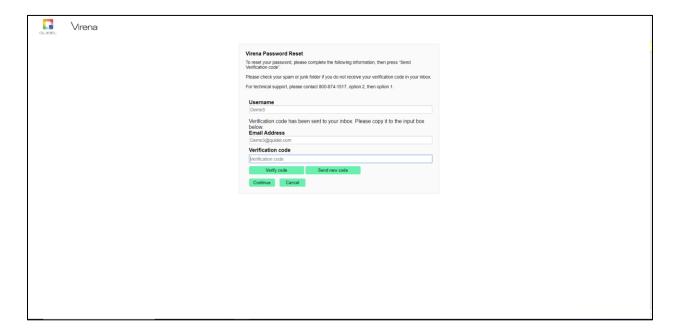
To change your password please click on the "Forgot your password?" link on the log-in screen.





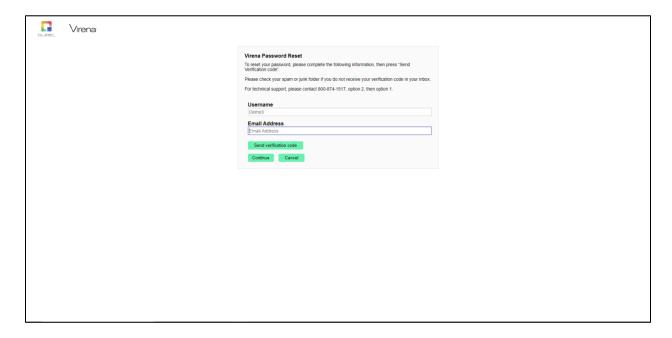
Please enter your "username" and e-mail address, then click "Send verification code." If the user name and the e-mail address do not match, an error message will be displayed. An e-mail with the verification code (valid for 5 minutes) will be sent to the entered e-mail address.

We use a verification code to confirm that the e-mail address is valid for additional security.



Enter the verification code.

On the next screen click "Change e-mail" to change your e-mail address (this will trigger another verification code) or click "Continue", to reset your password.



Enter and confirm new password and click "Continue."



Once the new password has been confirmed, it can be used to log-in to myvirena.com.

User Roles

When you are granted access to the website, the Quidel Administrator will assign you a role depending upon your organizational affiliation and intended use of the website. The list of participating facilities, user roles and associated contact names for each role are documented within the customer agreement. If you would like to add or delete users, the Organizational Administrator (identified on the contract) must contact Quidel Technical Support via an e-mail or phone call to technicalsupport@quidel.com or 800.874.1517. When adding or deleting an authorized user, please provide the authorized user's first name, last name, e-mail, phone number and facility name.

We have divided the roles into two categories: Healthcare Provider and Public Health.

Healthcare Provider Roles

Organizational Administrator

Defined in the customer agreement, this is the key contact person for each healthcare organization.; This person determines the member facilities and authorized users for the customer organization. Any changes to the organization's facilities or users must be made in writing or via e-mail to Quidel. Users in the Organizational Administrator's role are able to see all the test results that originated from facilities owned by the organization to which the user belongs.

Authorized User

Defined in the customer agreement, these users are authorized by the Organizational Administrator to access the data generated by the organization. Authorized users are only able to see the test results that originated from facilities owned by the organization to which the user belongs.

Public Health Roles

De-identified results are automatically sent to myvirena.com which are then forwarded to registered Public Health agencies nightly. Public Health agencies also have the option to log-in to myvirena.com to gather public health data. Public Health roles are limited to viewing de-identified patient results and cannot view quality control, calibration or invalid results. Data from customers who "opt out" of data sharing are not provided or made available to public health agencies.

Country

Users in the Country role are only able to see those results that originated from facilities within the user's country.

State

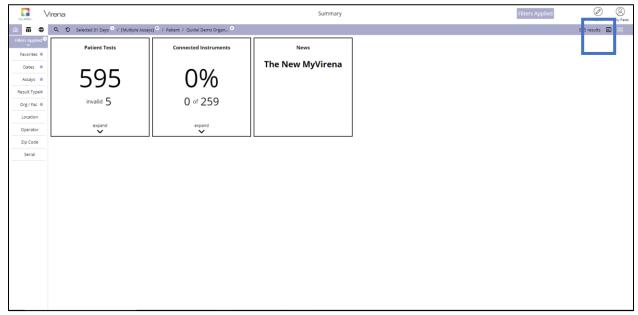
Only users located in the United States and its Territories can be in the State role. These users can only see results originated from facilities within the user's state or territory. The users will not be able to see the names of other organizations contributing to the data.

County

Only users located in the United States can be in the County role. These users are only able to see those results that originated from facilities within the user's county.

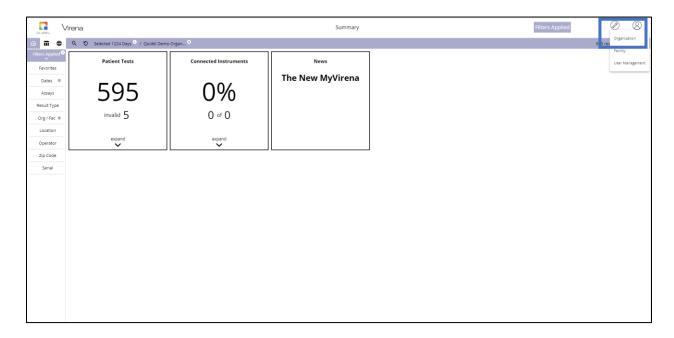
Managing My Organization

The Organizational Administrator can manage organizational information (e.g. address), facilities and users. The information is found in the *Admin Tab*.



Manage Organizations

By selecting "Organization" the list of all organizations that you have access to administer will be displayed.



By clicking on the facility name, you will be able to edit the facility information.

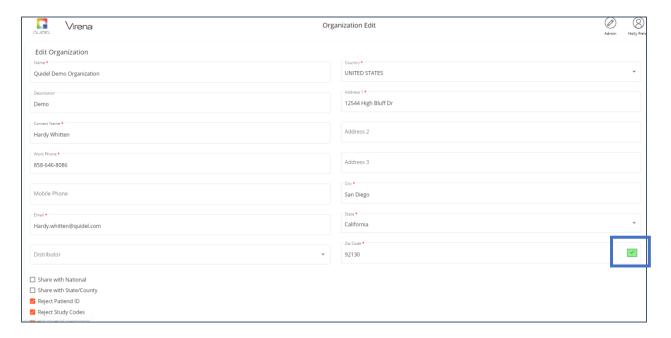


The following information on the screen can be edited:

- Name of the facility
- Description of the Organization
- Contact Name
- Work Phone
- Mobile Phone
- E-mail
- Address

The other fields can only be updated by contacting Quidel Customer Service.

To ensure that correct address is entered, an address validation is provided by clicking on the *Verified* button next to the zip code. Once click it will turn green to show it is verified.



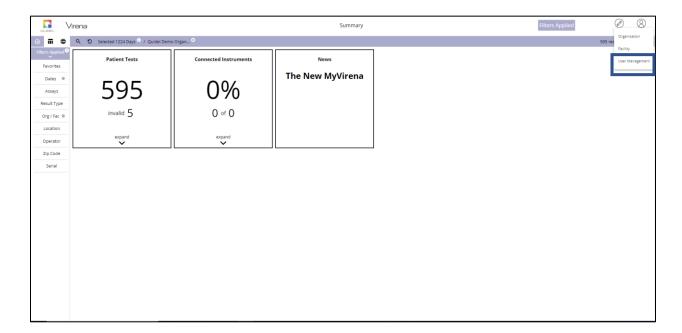
After updating and saving changes, a note will be shown indicating that all transmitted test results associated with this organization will be updated accordingly to ensure data consistency.

After the address is verified, the button color will change to green.

After updating and saving changes, a note will be shown indicating that all transmitted test results associated with this organization will be updated accordingly to ensure data consistency.

Manage Users

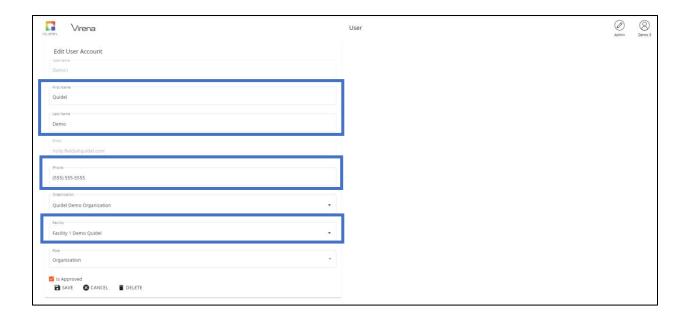
If the organization has multiple users, the Organizational Administrator can manage and approve user accounts by clicking on "User Management"



To find user type in their name in the search bar.



By clicking on the "Name" the user detail will be displayed and can be edited.



The following fields can be updated:

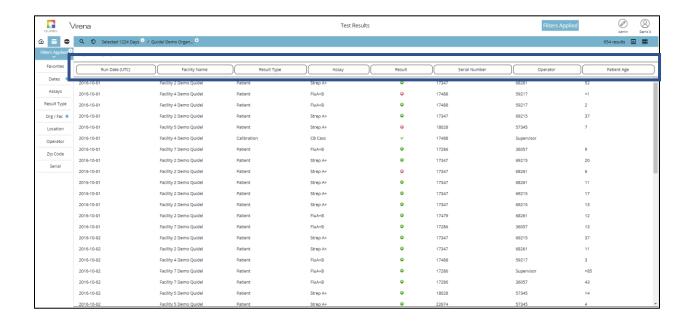
- First Name
- Last Name
- Phone
- Facility
- Active status

Accessing Test Result Data



Initial log in will take you to the home page. To access the test result data, simply click the icon

By selecting a filter and dragging it into the bar above the filters, you can select which filter type to use.



Search Criteria Basics

Criteria available for searching are in the "Filter" section above the results. Any criteria in which you enter or select a value for will return matching results.

Searching by Time-period

To search for results for a specific time period, choose "Dates" option on the left column and fill in the time-period information.

Searching by Assay(s), Result Type(s) and Facilities

These criteria are special in that you can select more than one at a time. To select multiple criteria, simply Select the filter for the desired criteria and drag to the filter bar above the filter list. To unselect items, simply click the X.

Additional Filters

Additional Filters can be chosen from the filter bar. Country, State, County, Organization Assay, Serial number, Operator and Patient age can be selected.

Executing a Search

After entering your search criteria, you may initiate the search by clicking the *Search for Results* icon located on the top blue bar. This will retrieve all the results that match the criteria you entered and display them in the results grid, located below the search panel.



Resetting the Search Criteria

To quickly clear your results and reset all search criteria, you may click the *Reset Search Filter* icon on the top blue bar.



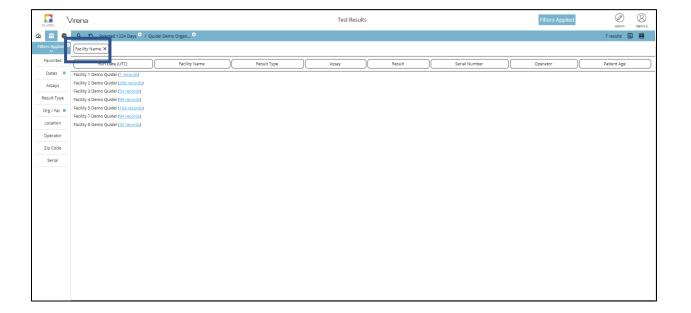
Reset Search Filter icon

Viewing Results

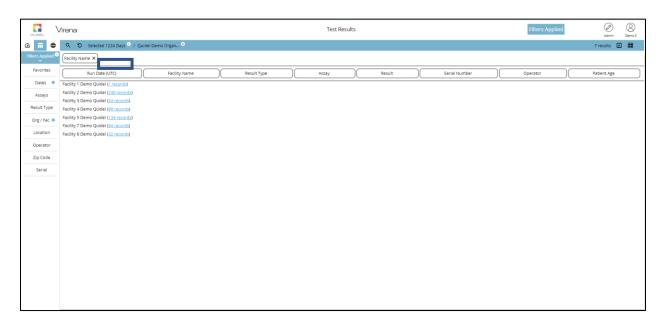
Once you have retrieved a set of results, you can view more detail by clicking on the results.

Viewing Result Details

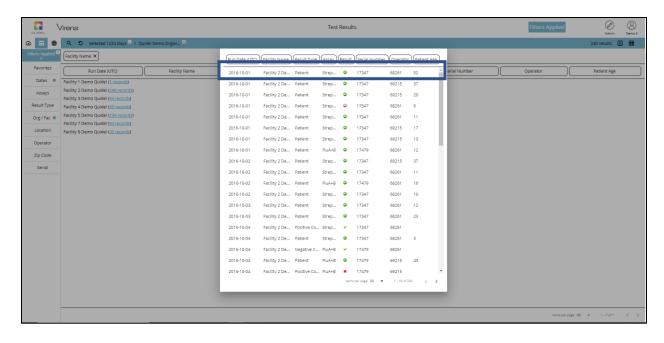
Clicking on any part of the selected result entry will reveal result details .



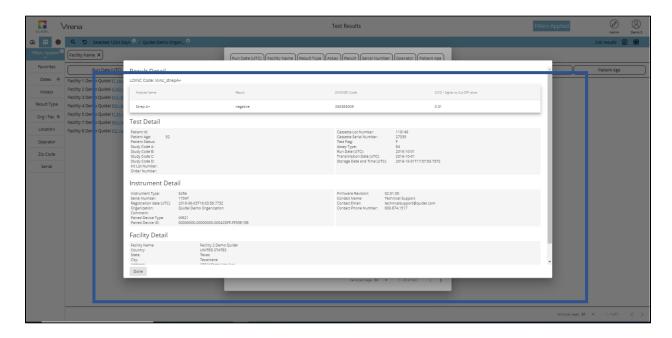
This will bring up a list of tests run.



Clicking on the test results will bring up a list of the test run at that facility.

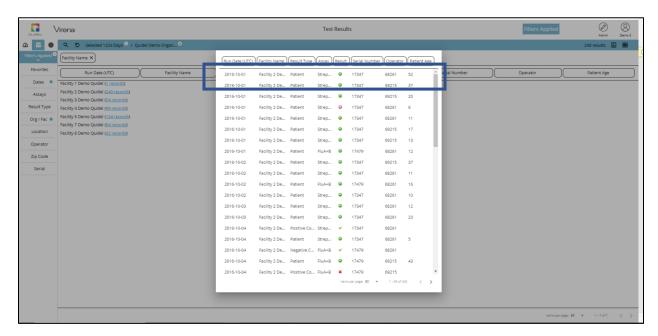


After clicking on the test, the result and additional information will appear.



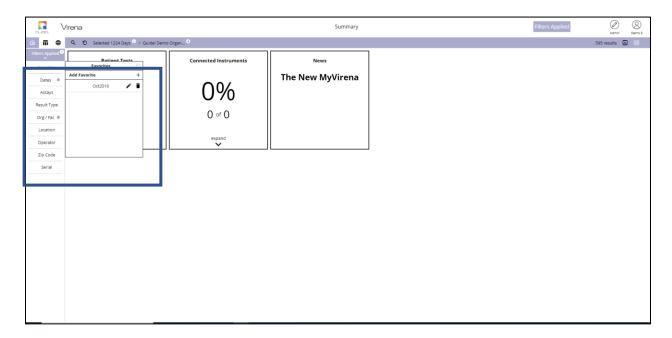
Sorting Results

The results grid can be sorted by filter. To sort by a column in ascending order, click the filter. To sort in descending order, click the filter again.



Managing Result Filters

It is possible to add, delete or edit search "Favorites" so you can run those searches again in the future. First select the filter parameters that you would like to place into your report. Select "Favorites" from the left option column then "Add Favorite". This will create a new report.



Share filter in your organization and schedule reports

It is possible to share filters and schedule reports exports with authorized users in your organization. When adding a "New Favorite", a new screen will appear. On this screen you can choose to share with your Organization.

Schedule an automated export or report to be sent to a user

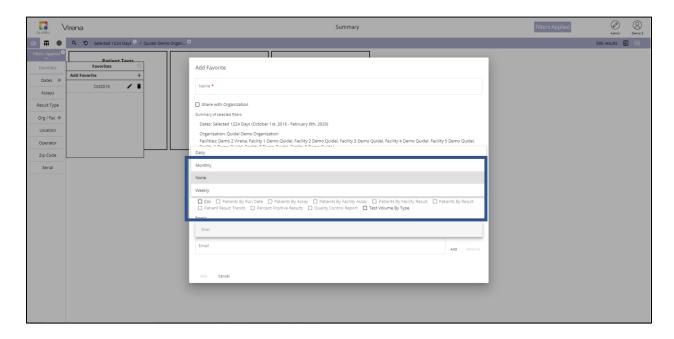
The selected filter can be used to generate a scheduled CSV Export or a chart. Select "schedule" by using the dropdown arrow.





Then choose the frequency.

- Daily –every night
- Weekly –Sunday night so it is available on Monday
- Monthly Every first of the month



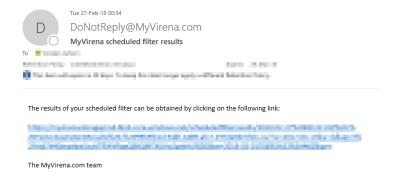
Then choose the report type.



Then enter the email address.



The report will be sent as an e-mail, originating from DoNotReply@MyVirena.com and containing a link to download the CSV export or an image of the chart. If you do not receive an e-mail, please review your spam folder or contact your IT department to whitelist the e-mail address.

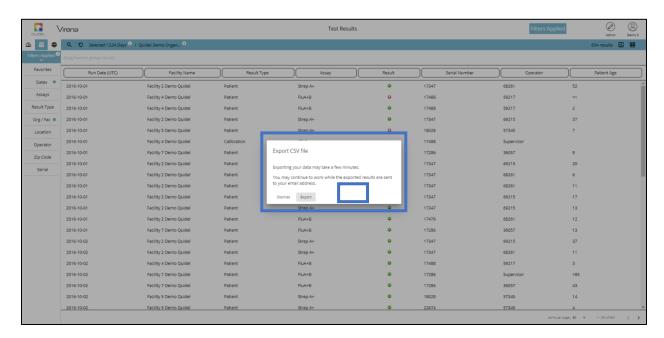


Reporting Results

You can easily generate a report from any view you have created in the "Filtered" page. Once you have filtered as desired, click the *View as Report* icon in the upper left of the "Browse Test Results" page.

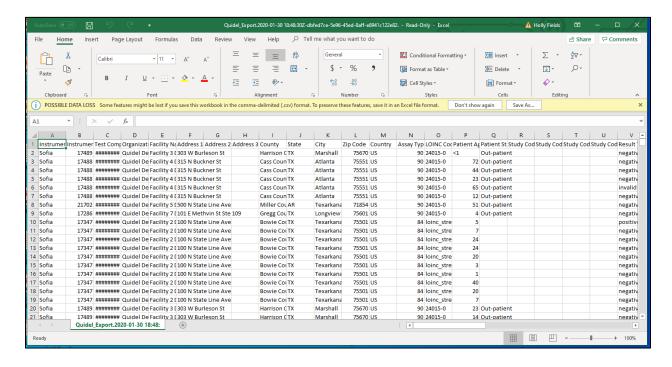


Once selected you can export the file.



Report Examples

Reported will be exported as a csv file.

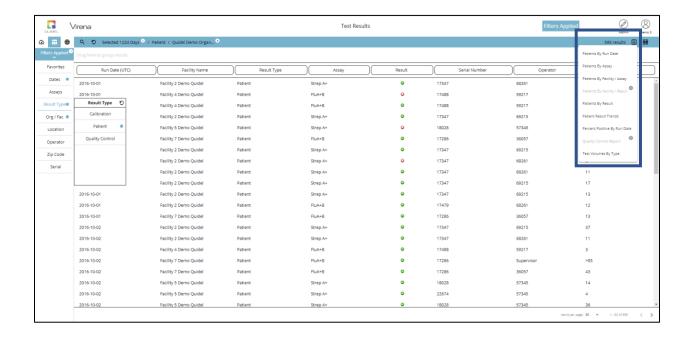


Charting Test Results

In myvirena.com, there are several charts available for analyzing your result data. As with reporting and exporting, charts are also accessed from the "Browse Test Results" page (shown below) and the chart data comes from your search criteria.

When you select a chart from the *Chart icon*, a new browser window opens and renders the selected chart.

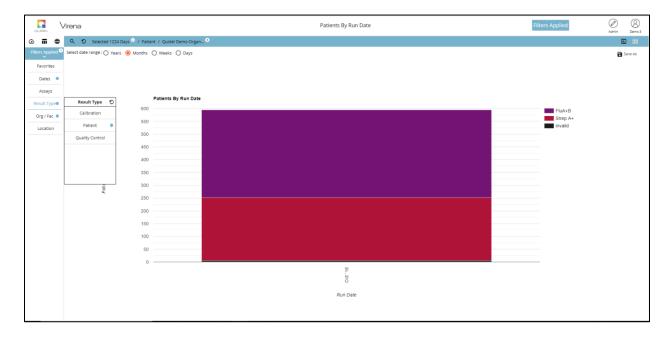




Patients by Run Date Chart

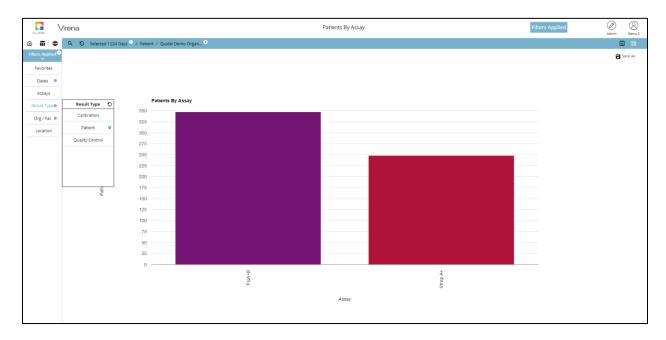
The "Patients by Run Date" chart is a stacked column chart that shows the number of patient tests run for each assay over a period and matching the search criteria. The numbers of tests for each assay are represented as a segment in each column of the chart.

The columns in this chart can be aggregated by day, week, month and year using the aggregation selector in the lower left of the page.



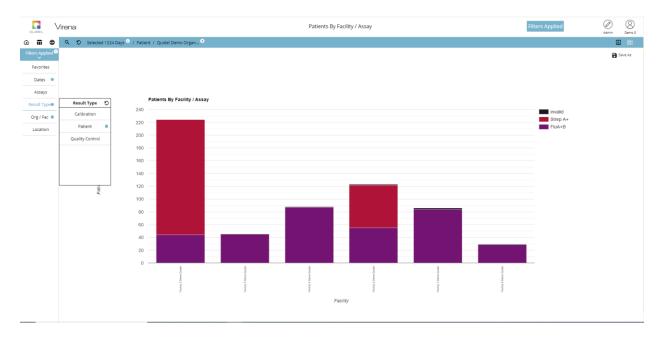
Patients by Assay Chart

The "Patients by Assay" chart is a column chart that shows the total number of patient tests run for each assay over a period and matching the search criteria. The total number of tests for each assay is represented as a column.



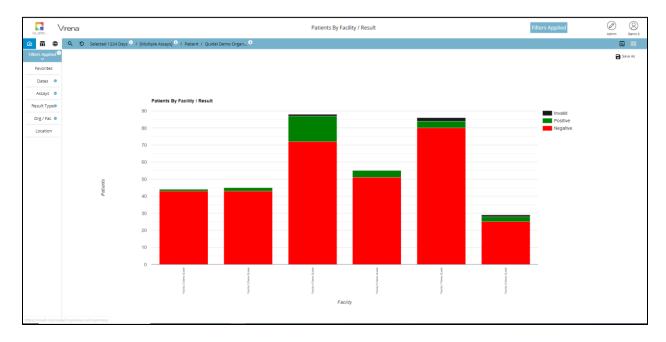
Patients by Facility / Assay Chart

The "Patients by Facility / Assay" chart is a stacked column chart that shows the number of patients tested for each facility by assay matching the search criteria. The total numbers of tests for each assay are represented as a segment in each column of the chart.



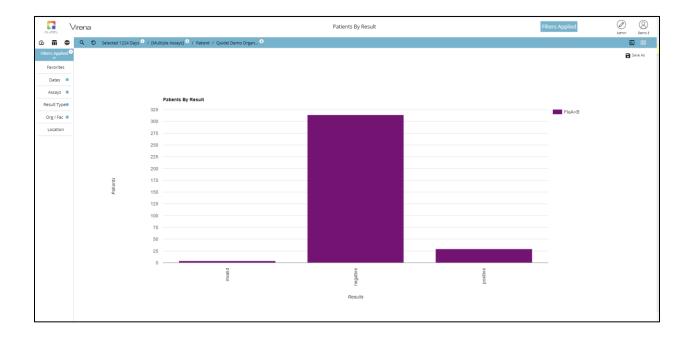
Patients by Facility / Result Chart

The "Patients by Facility / Result" chart is a stacked column chart that shows the number of patients tested for each facility by result (pos/neg) matching the search criteria. The total number of tests for each result are represented as a segment in each column of the chart.



Patients by Result Chart

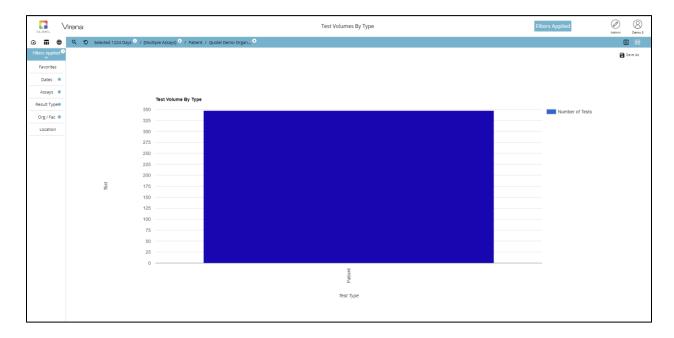
The "Patients by Result" chart is a stacked column chart that shows the total number of patient tests run by each result matching the search criteria. The number of tests for each assay within a result is represented as a segment of the result column.



Test Volumes by Type Chart

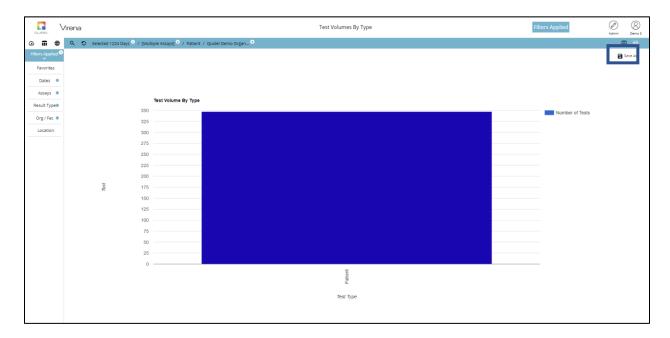
The "Test Volumes by Type" chart is a column chart that shows the total number of tests run of each test type (Patient, Quality Control and Calibration) over a period that match the search criteria. Calibrations are not specific to an assay; therefore, to view calibrations, do not select a specific assay in your search criteria (Note below, there is no assay selected).

If you would like to determine the volume of patients and controls per assay, select these as your search criteria. The calibration bar will result in a 0 value, since calibration is not associated with a specific assay.

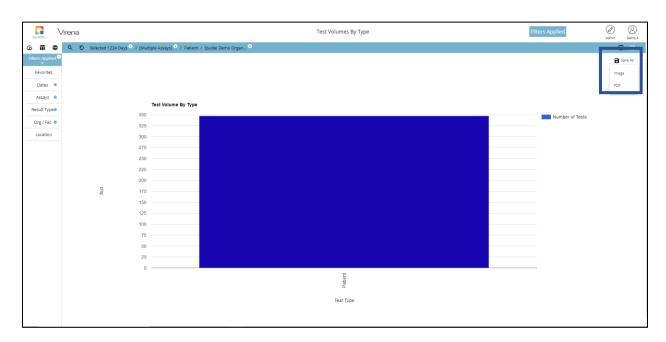


Saving Chart

Select save as on the right-hand side of the chart.

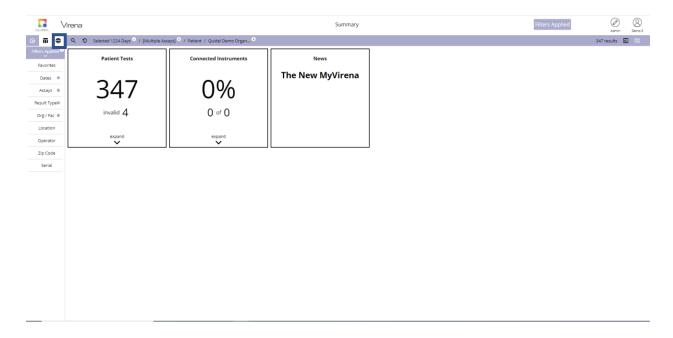


Once the save as button is clicked an option to save as an image or a PDF will appear. Select the desired format.



Mapping Results

To Map your results, choose the Map Results tab.

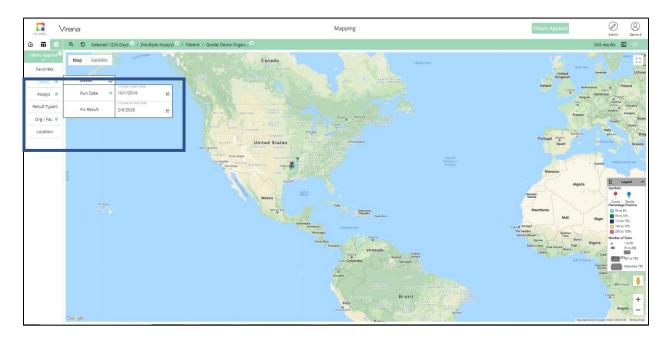


Mapping Criteria Basics

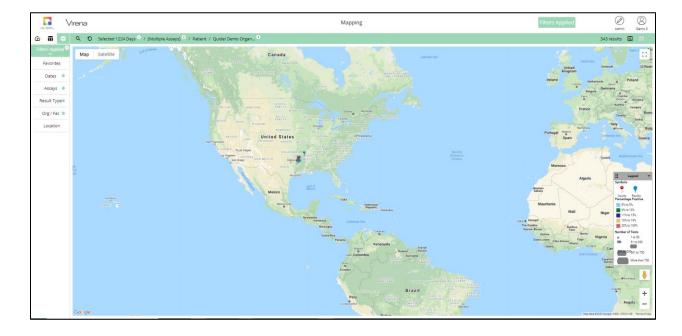
Mapping provides a National View of all connected Instruments. To view the National landscape, leave the filter for the Organization blank. To view your Organization's data only, choose your Organization as the filter criteria.

Searching by Time-period

To search for results that were run during a period, choose "Dates" then either Run date or Fix Result option and fill in the corresponding time-period information. Note that if you leave the date criteria blank, the system will attempt to retrieve results within 90 days.



Note: To minimize the date selections click on Date again and this will close the selections.



Searching by Assay(s), Organization and/or Facility

The search criteria for the mapping application only allows you to access one assay and one organization at a time.

All other search criteria work as described on the section titled, "Searching for Results."

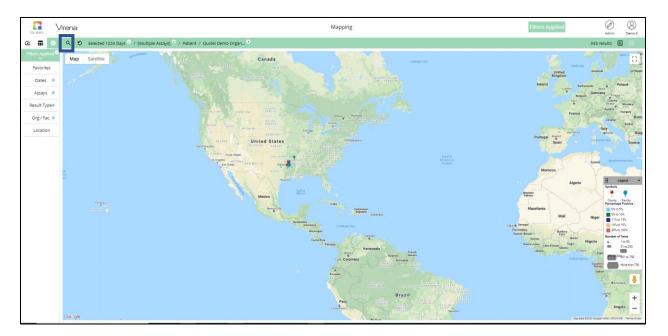
Executing a Map Search

After entering your filter criteria, you may initiate the search by clicking the *Search* Icon button. This will retrieve all the results that match the criteria you entered and display them on the map, located below the search panel.



Resetting the Map Criteria

To quickly clear your results and reset all search criteria, you may click the Reset Search Filter Icon.



Viewing Maps

Mapping provides a National View of all connected instruments as well as an Organization view.

Viewing Map Full Screen

To view a full screen map, click on the *Full Screen* Icon in the upper left corner of the screen under the Function Tabs.

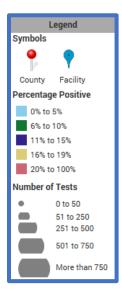


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Minimize Icon: To exit from the full screen view.

Map Legend

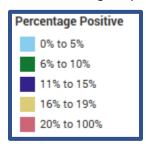
The Legend contains three pieces of information: Symbols, Percent Positives, and Number of Tests.



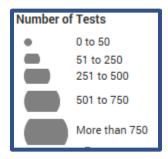
Symbols: The symbol represents county or facility location.



Percent Positive: A range of percent positive is indicated by color coding.

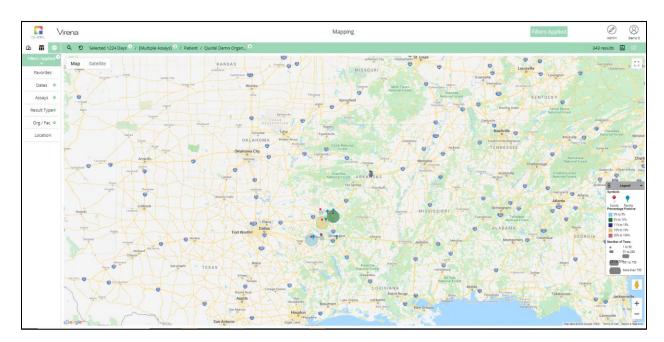


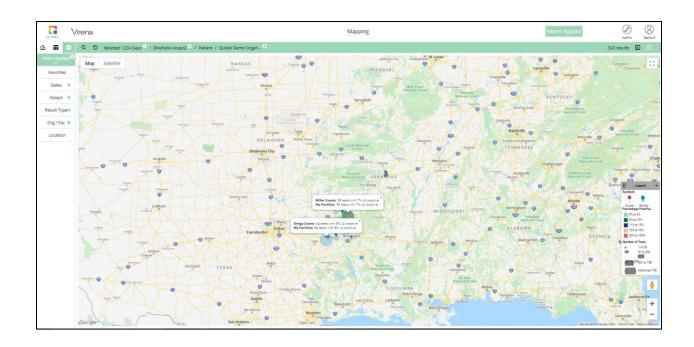
Number of Tests: The number of tests performed in that county.



County and Facility Information

By clicking on the facility marker, you will be able to see detailed information about your facility and for a county. By clicking on a county pin, you will be able to see the test results and the positivity rate for this county. If you have facilities located in the selected county, additional information will be visible. All test results of the county will be displayed and compared with the test results for "My Facilities" located in the county.





Terms

Analyte A substance being measured; e.g. Flu A is an analyte.

Assay A qualitative or quantitative analysis of a substance. For example, Sofia

Influenza A+B is an assay.

Assay Type The numbering system Quidel uses for each assay. For example, for Flu A+B the

assay type is 90.

Authorized Users Users who are authorized by the Organizational Administrator to access the

data being generated by the Organization. The Authorized Users are given access to all Organization data but are not able to edit settings or provide

authority to other users for administrative purposes.

Cassette Number The unique identifying number included on the barcode of each Test Cassette.

Cassette Lot Number The manufacturing lot number of the cassette as indicated in its bar code.

Contact Name Contact name is the Organizational Administrator.

Country User Public health role that associates a user with a specific country. A user with the

Country User role is only able to see results that originated from facilities within

the user's country.

County User Public health role that associates a user with a specific U.S. county. A user with

the County User role is only able to see those results that originated from

facilities within the user's county.

.CSV File Comma-Separated Value file. An electronic data file where individual pieces of

data are separated by commas. The file can be readily interpreted by many

software applications, including Microsoft Excel.

Facility Name A site or location that is part of the customer/organization where a Quidel

instrument is located. Facilities are "children" to the parent organization.

Firmware Revision The version identifier of the instrument firmware (software).

Grouping Bar An area on the screen where column headers can be dragged and dropped to

group results by the chosen column(s).

Instrument Run Date The date the test was run, as generated by the instrument.

Inst. Serial Number The serial number of the instrument that transmitted the result.

Instrument Type The type of analyzer measuring the assay; e.g. Sofia.

Kit Lot Number The unique identifying number for all assay test kits manufactured in a single

lot. Only transmitted with QC results, not with patient results.

LOINC Code Logical Observation Identifiers Names and Codes. A universal code system for

identifying laboratory and clinical observations. A LOINC code is associated with

each assay.

Operator ID Same as User ID

Administrator

Operator Name Same as User Name

Operator Number Operator Number is the only field transmitted to myvirena.com, if populated

(on Sofia). If this field is not populated, no Operator/User ID or Operator/User

name is transmitted.

Order Number Order number is limited to 20 characters (on Sofia). The supervisor may enable

or disable the transmission of order number to the Virena cloud.

Organization A customer/organization may have satellite facilities or locations where an

instrument(s) and/or Virena router(s) are located. The facilities are locations

that are part of a larger organization or customer.

Organizational Healthcare user who is an authorized user and is also the primary contact for

the organization relative to Virena. The Organizational Administrator notifies Quidel of the addition or deletion of member facilities and authorized users for

the organization.

Patient Age Patient Age is indicated by years. Patients older than 85 will be displayed as >85

in myvirena.com. Patients younger than 1 year of age will be displayed as <1. Patient age is an optional input when running the instrument, but strongly

recommended.

Patient Status Patient status is an optional toggle field allowing the user to define the patient

as in-patient or out-patient status. This is also used to distinguish proficiency

tests from patient results.

Public Health The County, State and National public health agencies that participate in the

Virena surveillance program.

Registration Date The date the router or modem was registered.

Result Type The type of result generated from the instrument. It can be a patient, quality

control or calibration type of result.

Router Type The type of router used to transmit data to myvirena.com.

Router ID Used with Sofia, the router has a device ID, similar to, but not the serial number.

Test Result Indication of test result as positive, negative or invalid. For QC and Calibration

results, the indicator is pass, fail, and invalid.

Site Name A site name is the facility entered to show where the Sofia is located. This is not

required to be entered into the Sofia and is not transmitted (Rev 2.0 software)

to myvirena.com.

SNOMED Code Systematized Nomenclature of Medicine. A comprehensive clinical terminology

for identifying patient problems (diseases and conditions).

State User Public health role that associates a user with a specific state within the United

States and its Territories. A user with the State User role is only able to see the

results that originated from facilities within the user's state or territory.

Storage Date The date and time that a test result was stored in the Virena database.

Study Codes There are four open and optional Study Codes labeled: Study Code A, Study

Code B, Study Code C, and Study Code D. Each field is limited to 2 numbers and

can be used for informational purposes as deemed necessary by the

Organizational Administrator. No protected health information (PHI) or user-

identifiable data must be placed in these fields.

Test Flag Indicates whether a test result was stored from the first transmission from the

instrument ("F") or whether it was stored from a retransmission ("R").

Time Zone Time zone of the instrument that transmitted the result.

Transmission Date The date the instrument transmitted the result to the Virena router.

User ID Same as Operator ID. This is an optional field in the Sofia which allows the

instrument operator/user to enter a unique identifier using the numeric keypad or barcode scanner. User ID must be numeric and at least 4 digits. In Sofia Firmware 2.0, the operator ID is not transmitted. It is replaced by the Operator #

provided it is entered.

User Name Same as Operator Name. You may add a User name connected with the User ID.

Use the numeric keys or barcode scanner to enter the ID number. The User name is displayed on the screen, printout (if printed) and sent to the LIS. The

User Name is not transmitted to myvirena.com.

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