

Frequently Asked Questions

What is Virena?

Virena is an innovative global data management system that aggregates de-identified patient results, quality control results and calibration results from our instruments. This system contains a central application (myvirena.com) and a cellular router (either external or internal) component to transmit the data.

How am I sure that only de-identified data is being transmitted?

Virena

The automatic default setting on the Quidel instrument ensures that the patient ID, order number and other health information data is **not** transmitted.

What data will be available for a customer to view?

The following fields of data will be available for an authorized user to view:

Run Date	Instrument	Serial • Operator ID = Number	 Analyte Name 	Test Result
	Number	in the second se	/	
Facility Name	 SNOMED Code 	LOINC Code	Instrument Type	• Time Zone
Facility Address	• Firmware Revision	Contact Name	Contact E-mail	 Contact Phone
Facility State	• Facility City	 Test Flag (Final or Resent) 	• Study Codes (Optional)	 Organization
Facility County	• Transmission Date	Cassette Lot Number	Cassette Number	Wireless Device ID
Facility Country	• Kit Lot Number	 Result Type (Patient, QC, Calibration) 	• Assay (Flu, Strep, etc.)	 Registration Date
Facility Zip Code	Wireless Device Typ	• Order Number (optional)	 Storage Date and Time 	 Assay Type = Assay number
Patient Status (Empty, In-Patient, Out-Patient	Patient Age (Option	al)		

 Patient Status (Empty, In-Patient, Out-Patient, Proficiency, Confirmatory)

Who is able to see the data?

Access to the myvirena.com is provided only to a customer's administrator and their authorized users. Data access is limited to only customer's specific data. There are some views such as mapping that aggregate data, and hold all customer identification confidential.

With myvirena.com, a customer's authorized user may generate reports, charts and graphs using the report generator tool. In addition, the user may print these reports and/or export all available data fields through a CSV file format. When data is shared with public health agencies, such agencies will have limited access to the de-identified data for surveillance purposes.

What information will public health agencies be able to view?

To provide actionable surveillance information, public health agencies may have access to the following data:

• Run Date

• Assay

- Facility Name
- SNOMED Code Facility Address • Facility City
- Transmission Date
 Cassette Lot Number • Patient Age
- Facility State

• Assay Type = Assay Number • Wireless Device ID

Cassette Number

LOINC Code

- Patient Status (Empty, In-Patient, Out-Patient, Proficiency, Confirmatory)
- Analyte Name
- Organization

Instrument Zip Code

Facility County

- Time Zone
 - Facility Country

Test Result

• Facility Zip Code

It is recommended for surveillance purposes to include basic demographic information such as age and patient status (in-patient, out-patient, proficiency). In addition, the Sofia platform includes four study codes (limited to 2 numeric values) that may be defined by a customer for improved data gathering and analysis. Administrators and users are prohibited from including patient identifiable information in these fields.

How often is data downloaded to the myvirena.com website?

Myvirena.com is scheduled to update once every hour.

Who will be responsible for user security such as creating and disabling users on myvirena.com?

Quidel requires that any changes with respect to authorized users is in writing from the customer's administrator and sent to Quidel. You may e-mail the requests to customerservice@guidel.com. The Quidel system administrator will only modify user access upon receipt and verification of written approval from the customer's administrator as indicated in the Quidel agreement.

Why share data with Public Health?

The primary goal of public health surveillance is to provide an early warning system, allowing for intervention, prevention, and containment of disease. Providing patient de-identified data, supports community, state, and the nation's well-being and safety efforts. Specific state health organizations can and may request the myvirena.com data.

What assays does the instrument transmit to myvirena.com?

All assays available on Quidel instrumented platforms are transmitted to myvirena.com and data are accessible by logging into myvirena.com. Not all assays are aggregated or transmitted to public health.

Is there a mapping function in myvirena.com?

Yes, there is a national view and a customer view. Mapping allows the user to view percent positive rates and the number of patients tested based in a specific county (national view) and facility (customer view).

How do Quidel Instruments connect to Virena?

Quidel Instruments transmit encrypted data through a cellular wireless network to myvirena.com. Only de-identified data is transmitted and stored on myvirena.com.

What type of connection is used?

Quidel has negotiated cellular coverage to be used with the instrument's cellular router. The carrier is dependent upon the customer's location. Some Quidel instruments may transmit via the facility's internet connection, if the customer's policy allows it.

What if there is no cellular service where the Quidel instrument is located?

If the customer facility does not have cellular coverage, the instrument may be moved to a location where there is improved cellular service. Alternatively, the ability to connect via the facility's internet is available on defined Quidel instruments, if the customer's policy allows it.

What wireless protocols are used?

To ensure data security, the cellular communications from the Quidel instruments to myvirena.com Cloud uses Secure Socket Layer (SSL) over TCP/IP.

What happens if our wireless network experiences an outage?

In most cases, Quidel instruments send data via the cellular wireless system and not the customer's wireless (WIFI) network, therefore this should not be an issue. The instruments are able to buffer the data and retransmit upon reestablishing connection.

Do IT departments need to be involved in the installation?

It depends on the customer's requirements and policies.

Is the myvirena.com software hosted remotely?

Yes, the myvirena.com software is hosted remotely on a secure system. You will not need any additional hardware or software.

What, if any, system interface is required?

There are no interface requirements. Transmission is through cellular connection.

Does using the cellular router impact workflow?

No, results are automatically sent to myvirena.com once completed. The operator is not required to take any action.

In what countries is the cellular service currently supported?

At this time, the cellular router can support connectivity in countries served by Quidel's preferred carriers only. Please contact Quidel Technical Support (information provided below) for specific information regarding your country.

Does the cellular router use WIFI?

No. The cellular router does not have WIFI capabilities.

What are the browser and other software requirements to access myvirena.com?

Internet Explorer Browser 9 or above, latest version of Chrome, and the latest version of Safari.

How is software updated?

Myvirena.com is a cloud based system, all updates are managed through the cloud service by Quidel.

Will there be a charge for myvirena.com updates?

Any update that improves a current feature or communication is included in the myvirena.com program. If Quidel offers additional, new features, you may have the option to purchase such features at an additional fee.

How do I reach Technical Support?

Please contact Quidel Technical Support at 800.874.1517 (in the U.S.), 858.552.1100 (outside the U.S.) or <u>technicalsupport@quidel.com</u>. Our hours of operation are Monday through Friday, 7:00 a.m. to 5:00 p.m. Pacific Time.

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