

Frequently Asked Questions – Solana[®]

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

The automatic default setting for Virena ensures that Patient ID and Order Numbers are **not** transmitted or received. In addition, Quidel values the privacy and confidentiality of the information it handles on behalf of its customers and Quidel has taken appropriate measures to safeguard against the transmission of patient-identifiable information transmitted through the Virena database.

What data will be available for an organization to view?

The following fields of data will be available for an organization to view Virena for Solana:

- Run Date
- Facility Name
- Facility Address
- Facility State
- Facility County
- Facility Country
- Storage Date and Time
- Solana Serial Number
- SNOMED Code
- Firmware Revision
- Facility City
- Patient Age (Optional)
- Kit Lot Number
- Router Type
- LOINC Code
- Contact Name
- Test Flag (Final or Resent)
- Patient Status (Optional)
- Assay (Flu, Strep, etc.)
- Analyte Name
- Test Result
- Instrument Type
- Contact E-mail
- Comment
- Study Codes
- Cassette Number
- Assay Type = Assay number
- Transmission Date
- Time Zone
- Contact Phone
- Organization
- Virena Router ID
- Registration Date
- Result Type (Patient, QC, Calibration)

Who is able to see the data?

Access to the Virena website myvirena.com is given only to your organization's administrator and any approved authorized users. Changes to your organization's administrator or authorized users may be made by notifying Quidel by letter or via e-mail. Customer's data access will be limited to only customer's specific data and certain aggregated data, such as mapping and prevalence de-identified data saved on the cloud.

When data is saved with public health, public health agencies will have limited access to de-identified data for surveillance purposes.

What information will public health agencies be able to view?

To provide actionable surveillance information, public health will have access to the following fields of data:

- Run Date
- Facility Name
- Facility Address
- Patient Age
- Assay Type = Assay Number
- SNOMED Code
- Facility City
- Patient Status
- LOINC Code
- Facility State
- Comment
- Analyte Name
- Organization
- Facility County
- Transmission Date
- Test Result
- Time Zone
- Facility Country
- Assay
- Cassette Number

It is recommended for surveillance purposes to include basic demographic information such as age and patient status (in-patient or out-patient). In addition, Solana includes four additional study codes

(limited to 2 numeric values) that may be defined by an organization 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 Virena website?

Myvirena.com is scheduled to update every two hours, UTC.

How is data accessed from the website?

Data is accessed by logging into myvirena.com. With myvirena.com, a customer may generate reports or filter data for printing. In addition, the customer has the ability to export all available data fields via a CSV file format.

Only those users who have been authorized by your organization’s administrator and Quidel will have access to the website. Authorized users will only be able to access data from their own organization.

Who will be responsible for user security? Creating and disabling users?

Quidel requests that any changes with respect to authorized users be in writing from your Hospital/Organization and sent to Quidel. You may e-mail these requests to technicalsupport@quidel.com. The Quidel Administrator will only modify user access upon receipt of written approval from hospital’s designated representative (Organizational Administrator as indicated in the Quidel/Hospital Agreement).

Why share data with Public Health?

The primary goal of our public health surveillance is to provide an early warning system, allowing for intervention, prevention, and containment of disease. By providing patient de-identified data, an organization will be supporting their community, state, and nation’s well-being and safety.

Can customers create custom reports?

There is a report generator tool that allows you to group the results and generate a report based on the filtered groupings. You may also download a CSV file of the data fields to meet your specific reporting needs.

Is there a mapping function in myvirena.com?

Yes, there is a National view and an Organization view. The mapping allows the user to view percent positive rate and number of patients tested based on county (National view) or facility (Organization view).

What analyzers will connect with Virena?

Virena connects to Solana via an Ethernet connection or a static IP address.

How does the Virena router connect to Solana?

If a laboratory has cellular wireless coverage, the standard configuration is to connect the Solana to the Virena router using the provided Ethernet cable. The following are visual depictions showing how a Solana can be connected to a Virena router.

1. Direct cellular transmission of data.

Connect one Solana directly to a Virena router via an Ethernet cable and send encrypted data through a cellular transmission to a secured Virena Cloud (Figure 1).



Figure 1

2. Direct cellular transmission of data from multiple Solana(s).

Connect one or more Solana(s) to a Virena router via a Local Area Network (LAN) (Figure 2) or a network switch (hub) (Figure 3) and send encrypted data through a cellular transmission to a secure Virena Cloud.

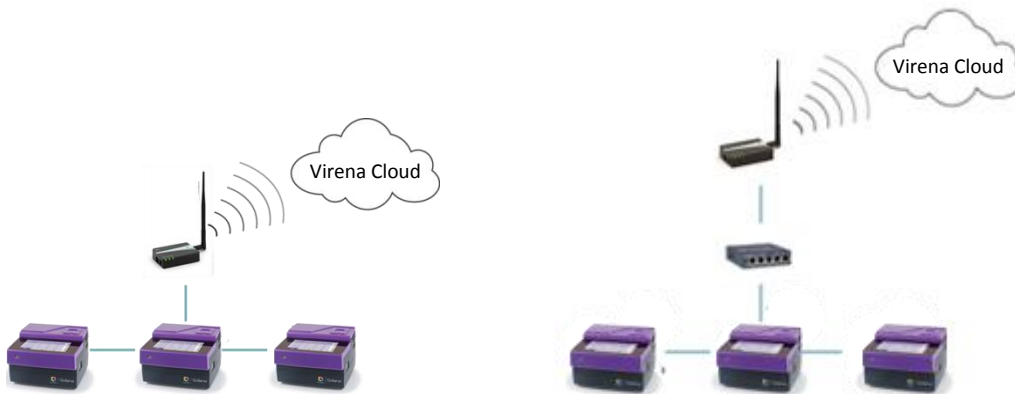
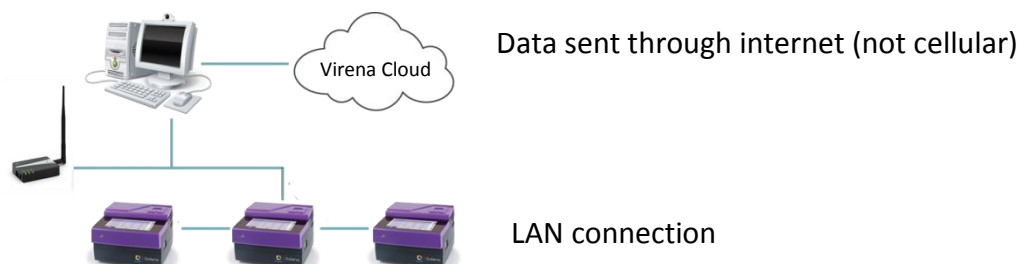


Figure 2

Figure 3

3. Wide Area Network (WAN) transmission of data.

Connect one or more Solana(s) directly to a Virena router via a LAN and send encrypted data through an internet transmission via a facility's WAN to a secured Virena Cloud (Figure 4).



Why use a hub?

The network switch (hub) is for those customers' who have multiple Solanas and want to connect to one Virena, which eliminates the need for having multiple Virena routers. In this case, connect Solana(s) to the network switch (hub). The hub is then connected to the Virena router.

What hubs are recommended for connecting multiple Solanas?

Types of Ethernet Switches tested and recommended:

1. **Netgear:** ProSAFE 5-Port Fast Ethernet Desktop Switch FS105
2. **Linksys:** Autosensing switch
3. **D-Link:** DES-1005E 5-Port 10/100 Desktop Switch

Can one Virena router be used for multiple Solana(s) in different locations?

One Virena router may be linked to multiple Solanas located at different sites (see Figure 4). The Virena router needs a fixed IP address to be assigned by an organization's network administrator. As more Solanas are added through a LAN, you can configure each Solana to communicate directly with the IP address of the Virena router.

What type of connection is used?

In the United States, Virena cellular wireless coverage is currently provided by Verizon or alternatively the Virena can transmit via the facility's internet connection. Quidel has optional carriers available if Verizon coverage is not accessible. Quidel has negotiated for international cellular wireless coverage to be used with the Virena system. The carrier is dependent upon the customer's location.

What if there is no cellular service where the Solana is located?

If a facility does not have cellular coverage, Virena may be installed through a facility's LAN and data will be transmitted via the WAN internet. Alternatively, the Virena router could be moved to a location where there is cellular service or Quidel may offer an alternative cellular carrier.

What wireless protocols are used?

To ensure data security, the cellular wireless communications from the Virena router to Cloud #1 uses Secure Socket Layer (SSL) over TCP/IP.

What happens if our wireless network experiences an outage?

The Virena router uses a cellular wireless system and not the hospital wireless (Wi-Fi) network therefore, this should not be an issue. As mentioned above, the router is able to buffer the data and retransmit upon power reactivity.

Do IT departments need to be involved in the installation?

It depends on the configuration and your organization's policies.

Is this software hosted remotely?

Yes, the software is hosted remotely. You will not need any additional hardware beyond the router.

What assays does Virena transmit to myvirena.com?

All assays available on the Solana platform transmit to the myvirena.com database via the Virena router and are accessible by logging into the myvirena.com.

What, if any, system do they interface with?

There are no interfacing requirements. Transmission is cellular or through the hospitals WAN if requested.

Does Virena transmit results to the LIS?

No, In order to send identified data you need to connect Solana to a middleware or LIS system.

Does using Virena impact workflow?

The Solana and Virena router are pre-configured to require minimum set up time and effort at the user's facility. Results will automatically be sent to the router once completed. The operator does not need to take any action.

What type of Ethernet cable should be used?

Any CAT5 or 6 cable with RJ45 connectors will work properly.

What countries does the cellular service currently support?

At this time Virena can support cellular surveillance in many countries. Please contact Quidel Technical Support for specific information regarding your country.

Does Virena use WIFI?

No. The Virena router does not have WIFI capabilities. The router must be connected by an Ethernet cable or LAN connection to Solana(s).

How secure is the data?

The data coming from Solana to the Virena router is encrypted with a proprietary algorithm. Then, communications from the Virena router are secured again by using standard internet techniques (SSL over TCP/IP).

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

Internet Explorer Browser 9 or above, Safari version 6 running OS X Lion or OS X Mountain Lion.

Is there an upgrade release strategy?

Solana updates are via SD card. No other end user updates are required.

How often will updates occur?

Our estimate is 1-2 times per year.

Will there be a charge for updates?

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

Is there more than one Virena Router available?

Yes, there are 2 types of Virena routers that Quidel offers: WR21 and WR11. The majority of customers in the U.S. will need a WR11 router. The WR21 router will only be needed for limited reasons, including lack of Verizon network in the area and for international customers.

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 technicalsupport@quidel.com if you have any questions regarding Virena or any Quidel product. Our hours of operation are Monday through Friday, 8:00 a.m. to 5:00 p.m. Eastern Time.

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