



ONE ABBOTT SOLUTION

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ABOUT THE ONE ABBOTT SOLUTION

1. WHAT IS THE ONE ABBOTT SOLUTION?

The One Abbott Solution for ID NOW™ COVID-19 testing is a simple, reliable, and secure end-to-end connectivity and reporting solution for decentralized environments. It offers the speed and performance of ID NOW COVID-19 testing, as well as reporting within 24 hours.

2. WHAT ARE THE COMPONENTS OF THE ONE ABBOTT SOLUTION?

The One Abbott Solution is comprised of the following components:

- **STARLIMS Digital Solution: Captures demographics and reports data**

STARLIMS Digital Solution for Mandated State Reporting collects ordering physician data, patient demographics, and patient questions required per the CARES Act, and reports data to Public Health authorities within 24 hours



- **ID NOW: Tests patients**

ID NOW is the leading molecular point-of-care (POC) platform in the United States, offering the fastest molecular test on the market for COVID-19



- **RALS™ LiNK: Captures results**

RALS LiNK cellular connectivity captures and consolidates patient test results from multiple ID NOW instruments and locations



3. HOW MUCH DOES THE ONE ABBOTT SOLUTION COST?

The pricing for the One Abbott Solution is based on a cost per test. Existing customers may contact their Abbott account manager for pricing information related to adding the One Abbott Solution. New customers may email inquiries to oneabbottsolution@abbott.com, and an Abbott sales team member will respond to discuss needs and solutions.

4. HOW CAN I LEARN MORE ABOUT THE ONE ABBOTT SOLUTION?

Information on the One Abbott Solution is available at:

<https://www.rals.com/us/home/rals-link/one-abbott.html>.

5. WHICH ID NOW BARCODE SCANNER IS COMPATIBLE WITH THE ONE ABBOTT SOLUTION?

The One Abbott Solution is supported with barcode scanner model L22XWU1200 connected to the ID NOW instrument. The older barcode scanner, model OPR2001ZWU1201, is not compatible with the One Abbott Solution. Customers may consult with their Abbott account manager regarding upgrading their ID NOW barcode scanners to the supported model.

6. HOW CAN THE ONE ABBOTT SOLUTION BE USED IF DEMOGRAPHICS DATA IS ALREADY COLLECTED SEPARATELY (SO THAT STAFF WOULD NOT NEED TO ENTER DATA TWICE)?

Customers who collect demographics data in a separate system may use integration options provided by the STARLIMS Digital Solution, to submit data collected from the EMR (Electronic Medical Records) system to STARLIMS Digital Solution, before patient arrival. Once the patient arrives, the provider can quickly search and find the pre-existing request with data already populated. The provider will be given an opportunity (within STARLIMS Digital Solution) to fill in and submit missing data (if any) to continue the testing workflow.

ABOUT RALS LiNK

7. WHAT IS RALS LiNK?

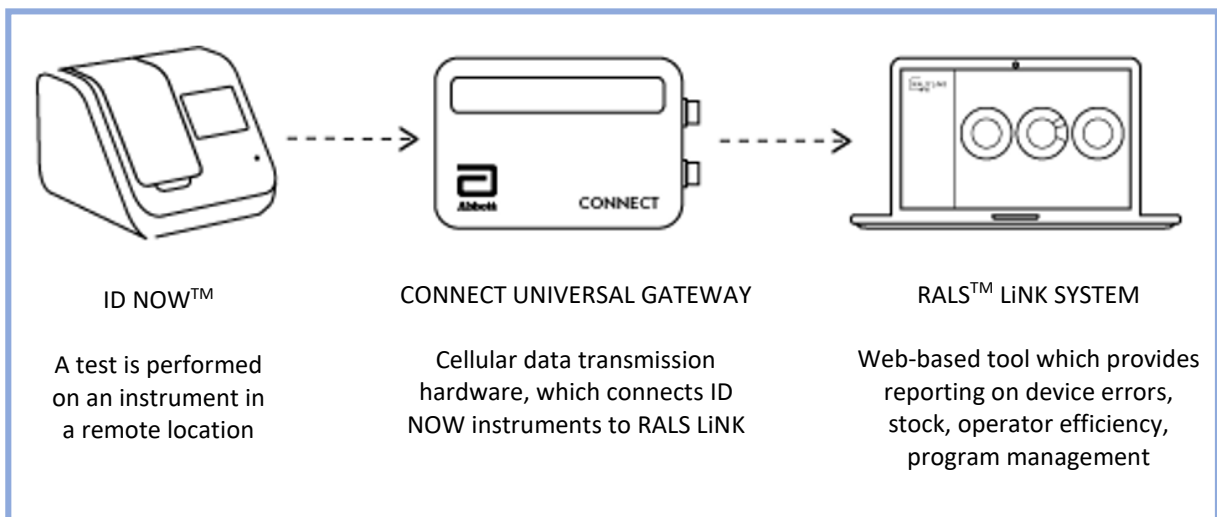
RALS LiNK is a new connectivity solution marketed for the Abbott ID NOW instrument, used for COVID-19 and other tests. It is focused on providing connectivity and results reporting for the patient testing market (Physician Office Laboratories (POL), Retail Health, Urgent Care, Public Health, etc.). RALS LiNK is based on proven technology used in over 40 countries and nearly 5,000 remote clinics.

8. HOW DOES RALS LiNK WORK?

The RALS LiNK system is comprised of two components connected to a point-of-care instrument:

- CONNECT Universal Gateway
- RALS LiNK software

An example of the RALS LiNK data flow with a supported instrument is illustrated below:



9. WHAT DATA DOES RALS LiNK CAPTURE AND TRANSMIT FOR EACH ID NOW RESULT?

RALS LiNK captures and transmits the following data, including but not limited to:

- Cartridge information (cartridge type, lot number, expiry date)
- Sample information (e.g. Sample / order ID)
- Operator ID
- Device (serial number, software version, location)
- Results date, type (patient/QC)
- Results summary:
 - Qualitative results (positive / negative / invalid values)
 - Quantitative results (unique values)

10. WHO IS ABLE TO VIEW THE DATA?

Test results will be made available on a secure, centralized Abbott website. This secure website address will be provided only to customer administrators and authorized users.

11. HOW ARE COVID-19 TEST RESULTS POSTED TO RALS LiNK?

Following test capture on the ID NOW instrument, the test result is sent to the designated CONNECT Universal Gateway and automatically uploaded to the cloud-hosted RALS LiNK service.

12. CAN THE DATA BE SHARED WITH PUBLIC HEALTH?

Yes. Reports can be generated and exported to State and Local Labs as well as to the CDC (United States).

13. DOES THE CONNECT UNIVERSAL GATEWAY USE WI-FI?

At the current time, Wi-Fi is not enabled in the CONNECT Universal Gateway. Each CONNECT Universal Gateway may be connected using an ethernet cable with up to two (2) ID NOW instruments.

14. HOW SECURE IS THE DATA?

Data transmitted from the CONNECT Universal Gateway to RALS LiNK is secured in two ways:

- The mobile SIM card used in the CONNECT Universal Gateway employs a private connection to the data center, which is encrypted using VPN (Virtual Private Network) technology.
- Internet security standards are incorporated, including Secure Sockets Layer (SSL) over TCP/IP (Transmission Control Protocol / Internet Protocol).

15. HOW CAN RALS LiNK BE USED TO MONITOR STOCK LEVELS AND INVENTORY?

Customers having a central location (or person) managing inventory across several sites may record received shipments and quantities into the RALS LiNK dashboard interface. The system will deduct transmitted tests from tracked quantities. This capability enables oversight into how stock levels, instrument utilization, and reagent utilization appear across sites, to allow persons managing inventory to make future shipment allocation decisions.

16. IS RALS LiNK AVAILABLE FOR ID NOW FLU, STREP, OR RSV ASSAYS?

Yes. The following test types are currently supported on RALS LiNK 3.10, with the Abbott ID NOW device:

- ID NOW COVID-19
- ID NOW Influenza A & B 2
- ID NOW RSV
- ID NOW Strep A 2

17. WHERE CAN I FIND OUT MORE ABOUT RALS LiNK?

Information on RALS LiNK is available on the RALS website at:

<https://www.rals.com/us/home/rals/ralslink-idnow.html>

ABOUT STARLIMS DIGITAL SOLUTION

18. WHAT IS THE STARLIMS DIGITAL SOLUTION FOR MANDATED STATE REPORTING?

The STARLIMS Digital Solution for Mandated State Reporting provides a secure web application for collection of patient demographics, ordering physician data, and COVID-19 patient questions required per the U.S. CARES Act. STARLIMS Digital Solution consolidates this data with test results from ID NOW (provided via RALS LiNK) and submits the consolidated data to the AIMS Platform¹ to be reported to public health authorities within 24 hours of the test result. The AIMS Platform will route the submitted data to the state public health authority based on the patient's state of residence.

19. WHAT DATA DOES STARLIMS DIGITAL SOLUTION CAPTURE AND TRANSMIT FOR EACH ID NOW RESULT?

The STARLIMS Digital Solution is designed to collect the fields required by the CARES Act and is updated from time to time as new guidance is released by federal authorities. Customers may refer to the contract for a list of data fields collected.

20. ARE ALL STATES COVERED FOR AUTOMATED PUBLIC HEALTH REPORTING?

Yes, all 50 US states are covered for automated Public Health reporting.

21. HOW DOES STARLIMS DIGITAL SOLUTION ADDRESS ADDITIONAL REPORTING NEEDS FOR NEW YORK?

For the state of New York, the STARLIMS Digital Solution supports Influenza A&B test reporting in addition to COVID-19. Additional questions requested by the state of New York are also supported, including employer & school data.

22. HOW SECURE IS THE DATA WITHIN STARLIMS DIGITAL SOLUTION FOR MANDATED STATE REPORTING?

Data in transit and data at rest is encrypted with 256-bit HTTPS/SSL encryption.

¹ The AIMS Platform is managed by the Association of Public Health Laboratories (APHL).

23. WHO IS ABLE TO VIEW STARLIMS DIGITAL SOLUTIONS DATA?

Authorized site administrators can view COVID-19 testing data on the secure cloud-based STARLIMS Digital Solution Portal. Changes to an organization’s Administrator accounts may be made by notifying Abbott Customer Support (please see Question 30 for Support contact information).

24. HOW LONG WILL DATA BE RETAINED IN STARLIMS DIGITAL SOLUTION?

Abbott will delete the patient demographics & results data (other than de-identified data as provided in the contract), from the STARLIMS Digital Solution after 30 calendar days. The customer is responsible to download their data using the data manager tool provided in the STARLIMS Digital Solution on a routine basis if they wish to retain the Customer Data. Alternatively, customers can leverage the API or HL7 integration to import data to their EMR.

25. CAN STARLIMS DIGITAL SOLUTION INTEGRATE WITH CUSTOMER SYSTEMS, SUCH AS AN EMR?

Yes, the STARLIMS Digital Solution can be integrated with customer systems that manage patient data or patient registration process, such as an Electronic Medical Records (EMR), Electronic Health Records (EHR), or any other clinical patient data system. Abbott will provide integration documentation for STARLIMS Digital Solution, and customers are responsible to work with their IT teams to build the appropriate integration.

STARLIMS Digital Solution can receive patient test orders from an external system with available demographics data (via API, HL7 or CSV file) in order to streamline the testing workflow.

Once testing is complete and results are available, customers may access the consolidated demographics and test results data (via API or HL7 file) to import into the EMR or other clinical patient data system.

26. IS THERE A LIMIT TO THE NUMBER OF ID NOW INSTRUMENTS, USERS, AND SITES THAT CAN BE USED WITH STARLIMS DIGITAL SOLUTION?

There is no limit to the number of users, sites or ID NOW instruments customers can use with STARLIMS Digital Solution.

27. CAN STARLIMS DIGITAL SOLUTION BE USED WITH DESKTOP / LAPTOP COMPUTERS, IN ADDITION TO MOBILE DEVICES?

Yes, customers can use the STARLIMS Digital Solution with desktops and laptops, however, customers wishing to use the driver's license barcode scanning feature will need to purchase a third party external PDF417 barcode scanner. Note: the driver's license scanning feature is provided as a convenience and does not work for all state licenses. Customers should always verify the accuracy of scanned data before submitting. If the scan does not register, then data will need to be manually entered.

IMPLEMENTATION

28. HOW IS THE ONE ABBOTT SOLUTION INSTALLED?

For RALS LiNK, the CONNECT Universal Gateway is delivered pre-configured for the ID NOW device from ARDx Informatics. Customers will receive setup instructions for the CONNECT Universal Gateway, and login information for their RALS LiNK page. The estimated setup time is less than 15 minutes per instrument. Remote assistance is available from ARDx Informatics.

The STARLIMS Digital Solution is accessible from a web URL and therefore requires no installation. Customers will receive administrator credentials to log into the STARLIMS Digital Solution Portal. Administrators will then be able to create user accounts for staff and perform other setup functions such as registering Ordering Physicians and creating additional test sites. Once users are registered on the site, login credentials will be sent via e-mail, which can be used to access the STARLIMS Digital Solution from a smartphone, tablet or a desktop/laptop computer. Customers are also provided with access to short tutorial videos to learn how to use the system. Note: Additional test sites will be activated only after APhL is notified. This process may take a few days.

29. HOW ARE CUSTOMERS TRAINED ON THE ONE ABBOTT SOLUTION?

Remote training is provided by Abbott during the installation process.

30. WHO SHOULD CUSTOMERS CONTACT FOR SUPPORT?

Please contact ID NOW, RALS LiNK & STARLIMS Digital Solution Support:

- Phone: +1 (855) 731-2288
- E-mail: USproductsupport@abbott.com