



## **COVID-19 Evidence Accelerator Collaborative**

### **Diagnostics Evidence Accelerator #19**

*Thursday, November 19, 2020, 12:00-1:00PM ET*

#### **Call Summary**

#### **Introduction to Diagnostics Evidence Accelerator Meeting 19**

This week's Diagnostics Evidence Accelerator meeting consisted of 3 presentations.

1. COVID-19 At-Anywhere Diagnostics Design-a-thon (Sara Brenner, FDA/CDRH)
2. COVID-19 Testing at Walgreens (Mike Umbleby, Walgreens)
3. The Power of Data to Drive Early Intervention and Save Lives (Chris Scoggins and Terry Finch, Abbott Rapid Diagnostics)

#### **COVID-19 At- Anywhere Diagnostics Design-a-thon (Sara Brenner, FDA/CDRH)**

Design-a-thon is a public-facing, open-innovation technology sprint with industry that aims to develop device-integrated software for automatic data capture and wireless transmission directly from in vitro diagnostic devices (IVDs). The goal of the design-a-thon is to close the gap between the tests that are being performed and the tests that are being reported and not reported especially from point of care devices. CDRH has authorized the first fully at-home molecular diagnostic COVID-19 test. This test is available by prescription only. The department is addressing test reporting gaps, which are anticipated to grow as more tests become available at point-of-care and in-home, in two ways: 1) through policy and regulation and 2) through innovation and technological solutions.

There are two goals of the COVID-19 At-Anywhere Diagnostics Design-a-thon (DAT). The first goal is to bring together the public and private sector innovators to develop software or digital health tools that integrate with IVDs. They want to have the reporting capabilities already built in to alleviate reporting and data collection burdens. The second goal is to integrate a USG or contractor-developed HHS interface that will exemplify the design principles and provide device/systems-agnostic "docking" between HHS Protect and various reporting systems. This contractor-developed tool will be named "Wireless Automated Transmission for Electronic Reporting Systems" (WATERS). The reporting systems could be IVDs (devices- hardware/software), apps (like the USDS product), LIMS (laboratory information systems), and any other entity that's transmitting/reporting diagnostic data. WATERS will be built by Data Robot during the DAT as the "back end processing" or "docking station" that interfaces and sets the design parameters for all devices to directly report data into HHS Protect. This is a core functionality that enables Federal direct reporting. All DAT products will be designed with these essential interoperability parameters and be capable of direct federal reporting through WATERS.

The outputs of the Design-a-thon will establish and align diagnostics data reporting standards for single core data element defined under the CARES Act, which have been defined by HHS for [lab-based](#) and [non-lab-based](#) tests. The ultimate result would be IVDs that go-to-market with built-in, automated, harmonized data capture and wireless transmission capabilities. The next phase of the Design-a-thon will be for external panel of judges to judge the designs and the winners will go on to an opportunity project which is a 4-6 week commercialization sprint with additional government partners. There is an app developed by the CDC and the USDS called the PRIME Data Input app, which aims to improve test reporting. This app has additional features designed to support workflow, batch testing, scheduling, and check in as well as data reporting. This is being used in facilities that are using the Abbott BinaxNOW and other rapid antigen tests to help providers collect and report data in bulk. With the Design-a-thon products, they envision more harmonization in data and direct reporting to states and HHS. To sign up for the Design-a-thon, accelerators can join at <https://waters.crowdcity.com/>.

### **COVID-19 Testing at Walgreens (Mike Umbleby, Walgreens)**

Walgreens is making a direct impact on the COVID-19 pandemic through strengthening their partnership with HHS and delivering on their vision of health testing. Walgreen has administered over 2 million COVID-19 tests which counts for 44% of HHS COVID-19 testing. There are 794 sites in 49 states, DC, and Puerto Rico. 70% of Walgreens sites are located in underserved areas. Walgreens has digital capabilities including admin portal, appointment scheduler, and insurance capture. Walgreens has the ability to deliver more than 50,000 tests per day. The test manufacturer for 79% of the tests administered was Abbott IDNOW and 21% of the tests administered were LabCorp RT-PCR.

Abbott IDNOW is a rapid point of care test which contains FDA approved CLIA waived instrument. The sample is collected via nasal swab and the molecular system uses isothermal technology for RNA amplification. This test provides results in 13 minutes which is available through drive up and drive thru. This presents a challenge for Walgreens to balance dispensing prescriptions and tests, however, this does allow more sites across the country to spread out the testing demand. The use cases for this test is both diagnostics and screening and Walgreen has administered more than 1.1 million Abbott IDNOW tests. Also, Walgreens has a swab and send test which is an RT-PCR lab test for qualitative detection of nucleic acid from SARS-CoV-2. The sample is collected via nasal swab and processed at a lab. The self-administered test provides result in 1-5 days. The patient provides the sample in the drive thru, puts it in a container, and leaves the sample in a drop box as they leave the drive thru.

Walgreens is working on acquiring the Abbot BinaxNOW which is a rapid point of care antigen test which provides results in 15 minutes. The sample for this test is collected via a nasal swab and it uses extraction reagent on Ag Card to detect proteins from SARS-CoV-2, visibly displays test result on Ag Card. Walgreens is in the process of discussing how they can assist in distributing the test to states since the tests were distributed by HHS. Pharmacist are able to order and administer tests, therefore they are sending testing data to the State Health Department. Before the pandemic, Walgreens was discussing expanding testing across their pharmacies and the partnership with Abbott has accelerated this process. Legislation was passed in Florida that allows pharmacists to prescribe Tamiflu for a positive flu patient which reduces time to therapy. Walgreens does not have the capability to share and integrate results with an EHR, however, they do provide the results to the patients and ask them to share the results with their physician. The test results do show manufacturer test name on the result.

### **The Power of Data to Drive Early Intervention and Save Lives (Chris Scoggins and Terry Finch, Abbott Rapid Diagnostics)**

Abbott is a global healthcare company that has over 100,000 employees around the world and serves more than 160 countries. Their technology expands across all of healthcare. They have medical devices, diagnostics, nutritional, and medications. Abbott is a first responder in U.S. testing and data reporting solutions for COVID-19. They have created over 9 COVID tests. The tools that they have in their toolbox are diagnostic antibody tests, molecular laboratory tests, rapid diagnostic testing, and connectivity capability. They are continually evaluating how to move forward faster. Interventions are driven by test data. Testing is occurring in more locations, as COVID-19 has elevated the need for distributed and decentralized testing. The pandemic also pointed out the lack of infrastructure to be able to take decentralized testing to centralized reporting and tracking, which needed to happen simultaneously. In order to bend the curve for COVID-19, it is important to have data on the hotspots so resources such as tests and equipment can be deployed to those hotspots.

The ID NOW platform plus RALS LiNK solution enables test data collection for public health reporting. The RALS LiNK enabled the connection between the tests. They created an information management system called STARLIMS which automatically retrieves patient test results, demographics, ordering physician information and patient questions for COVID-19 testing. This eliminates manual data entry errors of patient test results. Abbott received an EUA for BinaxNOW COVID-19 Ag CARD. The features of the test include a unique card format, no need for additional instrumentation (which enables decentralized testing), rapid results, and a complementary NAVICA digital solution. This allowed them to create a mobile ecosystem where the test result could be connected to the product and the digital app was simple, scalable, trustable, and had integrity. The NAVICA applications are free of charge to the patient. Patients can opt to allow their test information to be shared with their schools and employer.

The unique combination of NAVICA and the BinaxNOW™ test allows COVID-19 test results to be quickly displayed and securely shared. This capability will be added to other Abbott tests soon to allow for informed decisions. NAVICA displays results from the 15-minute Abbott BinaxNOW™ COVID-19 Ag Card that helps individuals make informed decisions. This technology is highly secure. Support for Public Health Reporting from another Abbott tool, NAVICA Connect, will be launching in December 2020. NAVICA Connect is intended to help organizations performing tests to meet their state and federal government public health reporting requirements outlined under CARES Act. In conclusion, both presenters mentioned that testing is less valuable without reporting data to make informed resource allocation decisions.

### **From the Chat Box**

- The links to join the Design-A-Thon through the Crowdcity event platform <https://waters.crowdcity.com/> and <https://www.hhs.gov/coronavirus/covid-19-at-anywhere-diagnostics-design-a-thon/index.html>
- An accelerator stated that be interesting to see understanding and acceptance of such data transmission by the end-user- the public.
  - Another accelerator agreed about the public aspect and acceptance.
  - An accelerator stated that it is fair to consider that there is >1 end-user: 1) Public Health; and 2) the person being tested/testing themselves. Need to consider secure message transmission to protect PHI.
- An accelerator said that incentives to not share results with employer, school, etc. are barriers. People may not buy into contact tracing of friends, family, others. People at parties may not want to disclose who was at party. Public health interests collide with private interests.

- A caller asked what does this look at from a legal release? How much fine print and are people actually aware?
- An accelerator asked if the presenter can submit the results to the EHR of each patient? Can they assure that the results are being successfully transmitted?
  - The presenter responded by stating they do not have that capability yet, however, they do provide the results to the patient and ask the patient to share the results with their primary care physician.
- Another accelerator asked what does the reimbursement for these tests look like?
- A participant asked the presenter if they can describe the mechanism by which you do the reporting to public health? Does that include the manufacturer name, sample type?
  - Excel spreadsheets were used earlier in the pandemic, but as more states acquire the capability to report real time data, Walgreens is doing that in partnership with the states.
- A participant stated that they think one of the large pharmacy chains does have an arrangement with epic to return information to the health information exchange.
- An accelerator asked if the data reporting happen from the lab partner back to Walgreens and then on to others or does it go from the lab partner directly or maybe if it is reported from both entities, how do we manage duplicate records?
- A participant asked if the test results and test information returned back to insurance payers?
- A caller stated that as a pharmacist, this is brilliant thank you for this work. If you made this test an NDC and called it a 'drug' it could adjudicate quickly behind the scenes.
  - Another caller agreed. The problem is that we do not have unique, universal identifiers by lot and version for diagnostic tests, and therefore we do not know the predictive value of each one of the multiple diagnostic tests in use.
- An accelerator asked did Walgreens create a de-novo process for reporting or did you leverage the NAVICA platform for reporting? Are you storing data that is not reported, including the manufacturer, sample type, supply chain, etc
- An accelerator asked the presenter to correct her if she is wrong, but the reporting piece varies depending on the test. Those run by LabCorp are reported by LabCorp, those managed through PWN are reported by PWN, and those done by Walgreens directly are reported by Walgreens. There is not duplicate reporting of these tests.
  - The presenter stated that this is correct. Some of this depends on who is the ordering provider (PWN or WAG) as well as who is performing the test (lab or Walgreens). We provide all of the relevant data that is required from a regulatory perspective and sync up with all providers to ensure there is no duplication of reporting.
- A caller stated that failing an automatic, embedded system/process, how can we entice patients to self-report their results of home test kits?
- An accelerator asked can BinaxNOW be self-administered by adults 18+ if they complete the 4 training modules?
- Another accelerator asked what are the additional tests being considered added to the platform?
- The presenter states that the data they report are patient demographic information (age, sex, etc.), race, ethnicity, contact info, test type, screening criteria responses, test time, test result, and provider information
- An accelerator stated that we need the link to the EHR data, so these diagnostic data would not remain largely unlinked to important patient data and therefore underused.
- A participant stated that clinical reference labs generally assume an incoming lab orders data feed that includes the ordering physician, the lab test/panel, the LOINC code, the ICD-10-CM code, and patient identifiers. How different is Walgreen's approach?

- Another accelerator asked don't you think participants would report back to their health care providers.

**Next Steps**

- Continue making data connections through the Evidence Accelerator.

**Next Meeting: Thursday, December 3<sup>rd</sup>, 2020 12-1 pm ET**