# APHL/CDC National PHL Call
# 2019-nCoV

April 22, 2020

# Call Summary

**Main Contact Emails**

CDC Emergency Operations Center (EOC) Contact: 770-488-7100
CDC Respiratory Virus inbox: respvirus@cdc.gov
APHL EOC Contact: eoc@aphl.org
APHL Informatics Contact: informatics.support@aphl.org

**Welcome (*Scott Becker, APHL*)**

Happy Lab Week!

On April 21, the White House held a Technical Assistance Call with State and Community Leaders to discuss Expanding COVID-19 testing. On the call, leaders provided an overview of continued expansion of stock within the IRR, which we will discuss more today. Admiral Giroir specifically mentioned expanded availability of Abbott ID NOW kits, swabs and transport media and acknowledged ongoing challenges with stocking extraction reagents. Ambassador Birx described efforts to identify the locations of all equipment within a state that could be used for COVID testing and described states creating a hub and spoke model that would allow them to double or triple their testing capacity. Governors received map of all platforms in their states as well as an extensive excel file of available equipment with contacts for private sector companies.

Also this week, APHL was made aware of an instance where a state received a donation of viral transport media that ended up being contaminated. Please be wary of donations and do your due diligence to check the quality before use.

APHL has been working closely with the IRR and Abbott to address the confusion around the Abbott ID NOW kit ordering. Despite what you might hear from your Abbott representative, PHLs are NOT responsible for odering ID NOW kits for the rest of the state; state and local PHLs are only responsible for ordering kits for those instruments provided by HHS and FEMA.

**Policy Update (*Peter Kyriacopoulos, APHL*)**

The fourth emergency supplemental package should be passed and signed into law shortly. This supplemental package contains $25 billion for the domestic and international COVID-19 response. Of the $25 billion, $11 billion is set aside for state and local entities. Of that $11 billion, a portion will be for Public Health Emergency Preparedness (PHEP), a portion will be distributed based on COVID-19 incidence and another portion will be for the CDC to work on surveillance, epidemiology and data management. Because this is new money, there will also be new obligations, one of which requires the development of a national testing strategy and the development of state level testing plans. Many states are already dong this work. The bill also includes funding for contact tracing and measuring health equity impacts.

This supplemental legistlation contains specific language regarding laboratory capacity, surveillance and contact tracing which is promising. The joint statement that should be out soon will provide additional information.

**Situational Awareness Update (*Greg Armstrong, CDC*)**
The current situation in the US is as follows:

- As of April 21, 2020, the US has roughly 802,000 confirmed cases with 44,000 deaths.
- The US was in the acceration phase in March. Beginning in April, new cases were in a sustained plateau, and as of mid-April, there has been some decrease. It is still too early, however, to say if we are on the other side of the curve. The trends are not uniform across the US.
- CDC is starting to work with states on the next phase of the response. To aid in that effort, CDC is increasing the amount of data on their website. This new data will include information on health care utilization, testing in the commercial sector and hospitals, etc.

**CDC Lab Team Updates *(Wendi Kuhnert, CDC)***
CDC is currently receiving more orders for the Abbott ID NOW kits than there is stock. HHS has been working with Abbott to increase the stock IRR receives and anticipates receiving up to 40,000 tests per week for the next several weeks. Orders for these tests will close at 8 pm EST every Tuesday with shipments leaving Abbott Friday for Monday delivery.

CDC has also been working to increase the IRR's weekly allotment of Cepheid kits. Right now CDC is focusing on getting Cepheid kits to some of the US Affiliated Pacific Island sites since they are unable to perform traditional PCR, but once that situation has stabilized, CDC anticpates having more cartridges available for mainland state and local PHLs.

**CDC Serology Update (*Michelle Owen, CDC*)**
CDC has some initial data on their pan-antibody ELISA assay that utilizes the stabilized spike protein (which matches the protein in the NIH COVID-19 vaccine). CDC has completed longitudinal studies on 14 patients. All 14 patients developed an antibody response post-infection with most of the patients developing a response around day 7/8 and all developing a response by day 22. Microneutralization data shows a good correlation with the ELISA Ig titers, although CDC would like to get additional data from people with lower titers for comparison. CDC has shown that after seroconversion (approximately day 8-10), SARS-CoV-2 can no longer be cultured from patients.

**IRR Update (*Erica Guthrie, CDC*)**
IRR has posted an FAQ under "quick links" on the IRR website. FAQ #12 provides a full list of IRR supplies for COVID testing with links that will take you directly to the product page. The table also lists who is shipping each item and the frequency of shipments. IRR has added an additional customer service line for the alternative distribution sites. When contacting either IRR customer service line, please include specific details regarding your issue such as product number, quote number etc. as this will help ensure the timely resolution of the issue.

IRR has been working closely with Roche to try to resolve the supply chain issues; unforunately, Roche is still unable to provide large quantities of reagents to IRR. Moving forward, IRR will be triaging Roche order requests on a weekly basis. PHLs should place one order a week for these products and IRR will do their best to fulfill what they can. IRR will then close out the order; they are not taking back orders on these or any products right now. IRR is also trying to negotiate shipping directly from the Roche facilitiy, which would decrease the shipping time. Also note that IRR will be changing the Roche catalog numbers from "ER" to "OR". Once this change is made, it will be reflected in the FAQ document.

**FDA Update *(Tim Stenzel, FDA* and *Sara Brenner, FDA*)**
FDA has updated their FAQ page to include a table of all available tests, their regulatory status, and whether they are high, moderate complexity, or waived tests. FDA hopes this resource will help laboratories with their purchasing decisions.

FDA also wanted to make laboratories aware of the following:

- Abbott has amended their ID NOW package insert to remove VTM. The ID NOW is only authorized for use with a direct swab now.
- The interagency effort to evaluate serology tests is underway. FDA and partners are still working out a way to make the results of the testing available to the public.
- FDA has removed the requirement for NP swabs for asymptomatic testing.
- FDA is currently evaluating 3D printed swabs; their performane data is limited. FDA does not have enough information to make a recommendation yet, however, they have received two reports of 3D printed swabs breaking during use, which poses a safety concern.
- FDA continues to work with developers, federal partners and APHL on data harmonization. There is currently a lack of inter-operability that is exacerbating delays for aggregating data. FDA and partners are working to ensure that all of the new tests that come to market are coded the same way. They are developing a cheat-sheet with terminology codes that will address the test and the range of answers generated by each test. If laboratories have questions they can reach out to the FDA at shield-labcodes@fda.hhs.gov.

**HHS Diagnostic Taskforce (*Jessica Roach, HHS*)**
The US has performed 4.69 million tests to date. HHS continues to work with FEMA regional administrators on a testing strategy and with diagnostic manufacturers on supply chain issues. QIAGEN is opening a plant in Germantown, Maryland, which should increase their output. HHS is currently leading an inter-agency team that is evaluating serology assays as well as working to put together an FAQ document that will address some of the questions HHS have received from states.

**PHL Experience: California Statewide Testing Strategy (*Megan Crumpler, Orange County PHL*)**
Governor Newsom established the California COVID-19 Testing Task Force (TTF), a public-private collaboration working group with stakeholders across the state to quickly and significantly boost CA's testing capacity. The TTF's priority is to ensure CA has enough capacity and supplies to administer a significantly greater number of tests statewide. Additional goals include ensuring CA has lab capacity to rapidly turn around test results and increase capacity, working to stand up specimen collection sites - especially in "testing deserts", improving the supply chain, enabling new, high-quality tests to launch, improving the ability to accurately track and evaluate COVID-19 testing capacity, results and reporting, and building the workforce.

At the local level in Orange County, PCR testing is being performed at the PHL and hospital labs. Several locations are using the Abbott ID now and Quest Lab just started performing serology testing. The OCPHL is currently testing inpatients from some local hospitals, residents and staff of skilled nursing facilities, the county jail and juvenile hall, specimens from the county coroner, persons experiencing homelessness, first responders, and healthcare workers.

Additional resources from CA and Orange County:

- CA Data dashboard
- TTF COVID-19 Serology Testing Public Guidance
- TTF Guidance on prioritization of testing
- TTF Evaluation Criteria for COVID-19 Serology Screening
- Orange County COVID-19 Case Counts
- Orange County COVID-19 Testing Network

**Questions & Answers**
**Q:** Are IRR orders being cleared weekly if they are unfilled or are they being rolled over?

**A:** IRR is not taking back orders for any items. Orders that are unfilled will be cleared for that week.

**Q:** If we find manufacturers that are providing false or misleading information about their tests, what should we do?
**A:** Laboratories can report manufacurers that are fraudulently marketing their devices to the FDA's Health Fraud Program. You can also email FDA-COVID-19-Fraudulent-Products@fda.hhs.gov, report the problem through the MedWatch Voluntary Reporting Form, or by emailing CDRH-EUA-Templates@fda.hhs.gov.

**Q:** Can FDA provide clarification on whether point of care tests approved under EUA are considered waived?
**A:** FDA's website has been updated to indicate which tests have been deemed waived.

**Q:** Does CDC know of any sources for verification panels for serology testing?
**A:** At the moment CDC is not aware of anyone selling these yet, but does know a few companies trying to acquire materials to make the panels. Once CDC knows more they will make that information available.

**Q:** Is there an update on the IRR provided collection kits? Our site is still waiting on our order.
**A:** IRR is working with ThermoFisher to build these kits and unfortunately it is taking a bit longer than we had anticipated. CDC is still working through these orders and hopes to have them out soon.

**Q:** Is CDC going to roll out their serology test to PHLs and if so, will it be used for clearing people to return to work?
**A:** CDC has not yet decdied if they will pursue an EUA for their serology assay as there are multiple commercial test coming to market soon. Currently the CDC serology test is only being used for serosurveys.

**Q:** Is CDC serology assay and IgG assay?
**A:** The CDC serology assay is a pan-antibody assay detecting but not distguishing between IgG and IgM and maybe IgA but data are currently limited. We also have the ability to reflex the assay to see if it is specific to IgG, IgM or IgA. The seroconversion data presented earlier in the call was for pan-antibody.

**Q:** Does CDC have guidelines for serology testing?
**A:** CDC does not have detailed guidance on serology yet.

**Q:** Do we have any updates on the Abbott Architect EUA?
**A:** CDC does not have any information on the Abbott Architect; FDA has been made aware of their intent to submit an EUA but does not have any further information at this time.