

Updates on Testing:

1. Current Testing is through Labcorp- This is a RT-PCR. Turnaround time is 1-2 days in most cases.
2. Rapid Testing- ID Now through Abbott is the only platform available for rapid test of swabs. This is an RT-PCR test. This test is 15 minutes and would be amazing. We have a good relationship with Abbott since we already use their ID analyzer for our flu, RSV, and strep tests. Our contacts at Abbott would love to distribute some tests to us; they say we are the 2nd highest volume user of their product in Utah. However, their supply is being used as FEMA directs. Abbott, at this time does not have autonomy to distribute to their clients.

Utah has not seen any of the supply from FEMA, but just this week UDOH got a trickle of supply. UDOH knows that Tanner is up and ready to go with analyzers already and we have been told we are priority to get the small number of tests available.

3. Antibody Testing-

Antibody tests are helpful to healthcare professionals to identify individuals who have overcome an infection in the past and have developed an immune response. **Whether an immune response is long lasting immunity to COVID has not been determined yet.** These would need to be done around 10+ days after an infection. In the future, this may potentially be used to help determine, together with other clinical data, that such individuals are no longer susceptible to infection and can return to work. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

Two types of serology tests in particular are becoming more widely available—laboratory-based enzyme immunoassays on high throughput automated platforms, and/or rapid, point of care (POC) tests, which are similar to a blood glucose test or home pregnancy exam. Even though they are becoming available, the supply/demand issues remain with most of the supply going to the "hotspot" areas within the nation.

1-ARUP is currently validating a serum COVID IgG test, but they're only testing samples from the University Hospital and other frontline hospitals. They are also strict regarding timeline - that it needs to be 7-10 days after the onset of symptoms. ARUP does not have FDA approval for their test. There is one other company with FDA approval to do high throughput testing and it is ORTHO. Reference labs will be picking this up when supply becomes available and giving us options for sending out the COVID IgG level.

2-Rapid antibody tests are in two categories:

FDA Category C: they have shown some performance data in the U.S. with good specificity and sensitivity and the FDA has approved their test. Two tests so far are in this category. One is an antibody test from Cellex, a North Carolina Company. We have been in communication with them, and they do not anticipate being able to distribute

to private clinics for 4 weeks. One other company was approved today, a company called Chembio from New York. They are a familiar global health company that does rapid HIV and rapid Zika testing. They have not listed their options for distribution yet, but we have asked our distributors for access to them. Because of the FDA approval, insurances will pay for these.

FDA Category D: The test has not been reviewed by the FDA, and the FDA does not authorize the use of the test, but they allow these to be sold with disclaimers. There are over 70 tests in this category. Some of these tests are likely very good, but we know some of them are very poor tests with sensitivity around 30%. The highest risk is cross reactivity with other non- pandemic human coronaviruses. Since these tests lack FDA review and authorization and validation data, we are hesitant to use these. Whether these tests would be covered by insurance is also up in the air.