



MEMORANDUM

Date: May 1, 2020

To: The Honorable Chairman and Members
Pima County Board of Supervisors

From: C.H. Huckelberry
County Administrator 

Re: **COVID-19 Viral Testing in Pima County**

COVID-19 viral testing in Pima County continues to be a challenge. Attached please find a report from the Health Department that provides an update and overview on this complex issue and how it is playing out in this community.

I note that overall the availability of testing is improving slowly in this community. This reflects greater laboratory capacity on the part of the major laboratory services providers. However what continues to be in short supply is availability of viral collection kits and PPE both of which are essential and needed if we are to improve test coverage locally. Without an adequate supply of both, we cannot begin to reduce the infectious spread of COVID-19.

Since the beginning of the pandemic the Arizona Department of Health Services COVID-19 data dashboard shows 8,456 tests completed from March 11 through April 29. The peak test number of 362 tests in a single day, but the weekday average typically exceeds 250 tests in a day. Notably our Health Department facilitated 2,108 or 27percent of tests reported at the end of last week, by providing viral collection kits and/or processing.

Testing capacity has uniformly been cited as a key component in the decision making process for "reopening the economy," but today there is not a clear federal definition of what adequate community testing levels should be. Federal, state and county resources are invested in testing capacity every day because this information is essential to understand the true extent of COVID-19 infection. Only when sufficient testing is available can we begin to contemplate relaxing the host of mitigation measures in a thoughtful and responsible way.

Attachment

c: Jan Leshar, Chief Deputy County Administrator
Francisco García, MD, MPH, Deputy County Administrator & Chief Medical Officer,
Health and Community Services
Bob England, MD, Director, Health Department

Date: April 30, 2020

To: C.H. Huckelberry County Administrator

From: Bob England 
Interim Director

Via: Francisco Garcia 
Deputy County Administrator

Re: COVID-19 Viral Testing in Pima County

In December 2019, physicians in Wuhan, China identified a novel acute respiratory disease caused by a new strain of coronavirus. This disease was named *coronavirus disease 2019* (COVID-19) and the virus strain was identified as *severe acute respiratory syndrome coronavirus 2* (SARS-CoV-2). The virus spread rapidly and aggressively throughout the world, with over 3,100,000 cases and 216,000 deaths as of April 28, 2020. There is currently no vaccine for this virus and there are no approved therapies or preventative treatments known to cure or avert infection. Treatment is currently limited to symptomatic mitigation and most patients appear to recover after 5-14 days.

Pandemic control measures designed to limit the spread of the disease including infecting tracking and control, social distancing and stay at home orders have been instituted in an attempt to mitigate the surge of infections that would overwhelm the health care infrastructure. Testing methods have been rapidly developed and are a key element in the fight to control COVID-19.

Testing Guidelines

The Centers for Disease Control and Detection have published evolving guidelines recommending specific prioritization of COVID-19 testing. The clinical criteria has been modified based increasing understanding of the actions and spread of the virus. Current priorities of the CDC as of April 28, 2020 are as follows:

High Priority

- Hospitalized patients
- Healthcare facility workers, workers in congregate living settings, and first responders with symptoms
- Residents in long-term care facilities or other congregate living settings, including prisons and shelters, with symptoms
- Persons identified through public health cluster and selected contact investigations

Priority

- Persons with symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea and/or sore throat
- Persons without symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to:
 - Public health monitoring,
 - Sentinel surveillance, or
 - Screening of other asymptomatic individuals according to state and local plans.

Symptoms as discussed in these guidelines include fever and acute respiratory issues of non-productive cough, shortness of breath, or flu-like symptoms in combination with the respiratory issues. These guidelines are in place due to the known characteristics of the virus, the likely health impact of the virus on individuals and communities, and the availability of testing resources. Absent logistical limitations, testing would be more broadly recommended by all public health agencies.

Types of testing

Primary Diagnostics

NAA (nucleic acid amplification) testing is used to diagnose active viral infections, requiring a respiratory sample and specialized laboratory supplies and equipment. NAA is the gold standard for use in the clinical settings, and is generally completed via a process called RT-PCR. A sample is collected by swabbing an area deep in the nose/throat and then placing the swab in a tube containing a special media. The tube is then sent to a lab for processing and analysis. If the virus is present in the sample, this test confirms the patient as COVID-19 infected.

While considered the authoritative testing method, there are limitations. Test results can take 2 to 12 days depending on the location of the lab, and results are reported to the State electronically sometime thereafter. Test kits consisting of specialized swabs, sterile plastic tubes and transport media are required for each test, and the supply chains still have not recovered sufficiently to make these readily available in the numbers required. Additionally, NAA testing does not identify previous or recovered infections – only current, active infection.

Rapid Point of Care Testing

Abbott has developed a rapid testing device that has received an emergency use authorization (EUA) from the Food and Drug Administration for use during the COVID-19 pandemic response. A variation of the NAA testing above, this self-contained apparatus is able to directly receive and process a sample providing results in as little as 15 minutes. The test operator inserts a specimen from a swab as above into the first of two disposable cartridges where it is mixed and then transferred to the second cartridge. Within 15 minutes a clear readout indicates the presence (positive) or absence (negative) of viral material. All three components used are then discarded.

Mr. Huckelberry

Re: COVID-19 Viral Testing in Pima County

April 30, 2020

Page 3

The speed of this test is its greatest advantage, but it may be sacrificing accuracy to accomplish that timeliness. Anecdotal reports are being returned indicating a high false-negative rate such that some clinicians believe this to best be employed as a quick means to confirm a positive case but not a valid exclusion of infection in the negative results. Additionally, the proprietary cartridge design severely limits the available testing supplies to a single manufacturer and an already highly stressed supply chain.

Antibody Testing

To identify previous infection and assumed resistance to subsequent re-infection, clinicians test for the presence of antibodies in their patients' blood. There are two primary methods currently promoted for the detection of these antibodies – serology and lateral flow immunoassay (LFIA).

Serology relies on isolating a sample of the patient's serum (the fluid portion of blood) and subjecting it to laboratory process to detect antibodies in that fluid. Depending on the specific style of serology, results can be binary (yes/no) or can identify specific antibody concentrations. Serology requires a blood draw, specialized supplies and laboratory treatment of the samples to complete testing. Generally, serology can have more accurate and valid results than LFIA, depending on the nature of the serology and how well that specific test has been established.

LFIA, as discussed in this writing, uses a drop of whole blood and a diluent that combine and travel over specially treated membrane. The appearance of colored bands in specific areas of the membrane indicate the presence of IgM antibodies (appearing early post infection), IgG antibodies (appearing later after infection), both or neither. Generally, this test requires only the test kit containing a cassette, a lancet, transfer pipette and diluent, and provides a result within 15 minutes. The advantage of this test method is the rapidity of results, limitation of supplies and skills required to administer and result clarity. With many established infections this methodology is highly valid and accurate. COVID-19, however, is such a new virus that the validity of the multitude of LFIAs manufactured to detect it remains uncertain. As of April 28, 2020 three such tests has received FDA approval under an EUA.

A general concern regarding antibody tests is the applicability of the presence of antibodies to immunity to COVID-19 reinfection and what role this information may play in patient care and for health care workers and first responders. In some cases antibody response provides evidence of immunity to reinfection for a lifetime while other viruses may generate antibodies that are only effective for a shorter period. The novel nature of COVID-19 is such that there is currently no way to know the durability and extent of the protection afforded by the antibodies.

Testing resources in Pima County

Primary Diagnostics

Clinical facilities in Pima County can access COVID-19 testing through their contracted commercial labs including Sonora Quest, LabCorp and others. Those commercial labs, however, have been severely impacted by supply chain weakness and limited availability of the specialized swabs and media required for testing.

Mr. Huckelberry

Re: COVID-19 Viral Testing in Pima County

April 30, 2020

Page 4

To help bridge facilities, particularly smaller venues or those at highest risk for morbidity and mortality (such as long-term care or assisted living facilities), Pima County has established agreements with three additional commercial or research labs and is in the process of adding a fourth. These include the Translational Genomics Research Institute (TGen North) in Flagstaff, Paradigm Labs in Tucson and the Phoenix metro, and the Center for Disease Detection (CDD) in Texas, the contracted provider for the majority of the Pima County Health Department clinical labs. All three of these facilities provide essentially the same service – processing NAA tests. The fourth agency, Accu Reference Medical Lab out of Linden, New Jersey, provides lab analysis but also manages specimen collection, storage and shipment in “pop up” testing sites.

To make use of these resources, Pima County and the partner facilities still need to address the supply chain issue. The Biorepository at the University of Arizona has provided a steady supply of the specialized media and tubes necessary and has procured a supply of functional swabs for specimen collection. To date they have donated over 2,800 collection kits to the testing effort and are working to provide thousands more over the coming weeks, (*see attachment*). The Health Department has distributed nearly 2,000 of these kits to community health centers, long term care facilities and assisted living sites – in some cases performing the actual specimen collection – and intends to continue supporting these facilities as long as the pandemic persists. These kits can be, and are currently, processed at TGen and Sonora Quest.

Paradigm has provided an initial 5,000 test kits and the Health Department will be distributing these in the immediate term. These kits can only be processed by Paradigm. Through a limited initial allocation, CDD will be providing several hundred kits each week based on the rate at which they are consumed. In all, we estimate that the Health Department can help push up to 6,500 primary diagnostic tests per week once all resources are on board.

Rapid Point of Care in Office Testing

The Arizona Department of Health Services (ADHS) has provided Pima County with two Abbott ID Now point of care test devices. As previously indicated, testing supplies for this device are in extremely short supply and at this point only enough for initial set-up, quality control and training have been supplied. ADHS is working with the manufacturer to secure a large and steady supply of the test cartridges but the timeline is as yet uncertain. At this time however, Pima County has only enough cartridges to test fewer than 45 people.

Once the supply shortage is resolved, this will provide an asset to rapidly assess and quarantine infected individuals, a particularly important step in locations serving high-risk populations such as long term care and assisted living facilities.

T53

Antibody Testing

Two methods of antibody testing will soon be available in Pima County. The University of Arizona has developed a serology-based assessment that they are planning to deploy across the state. Initial efforts

Mr. Huckelberry

Re: COVID-19 Viral Testing in Pima County

April 30, 2020

Page 5

will be made to provide testing to high-risk groups such as health care workers and public safety, but they plan to also make serology available to other populations as well.

Pima County is in the final stages of contracting with Cellex Labs, a FDA-approved manufacturer of LFIA tests in the U.S. and expects to bring an initial 25,000 test cassettes into the region in the next month. Additional orders will be placed as the supply chain stabilizes and grows more robust, and other FDA approved tests will also be added to the local test plan as they become available.

Facility-Based and Commercial Testing

Health care facilities and commercial labs are engaged in testing for their patients independent of Pima County efforts. While it has been challenging to get an accurate and committed count of testing capacity, we know that more than 8,456 tests have been resulted in Pima County since the onset of the pandemic. As of end of last week, the Pima County Health Department was directly responsible for distributing 2,108 viral collection kits representing 27% of the testing that has occurred in this county since the beginning of the pandemic.

Hospitals, Community Health Centers (CHCs), and other large ambulatory care settings, are also submitting tests on their patients and represent the balance of the testing in this community. Smaller individual practitioner offices and provider groups, clinical behavioral health entities, long-term care facilities and others are all also able to provide testing, most through contracts with established commercial labs. These types of facilities have the least access to test and PPE supplies and likely do not receive the same prioritization medical supply distributors as larger facilities, there have likely been several hundred tests completed at these smaller scale locations.

LabCorp has received FDA approval for at-home NAA specimen collection and Sonora Quest recently announced the availability of antibody testing at their lab sites with physician order. It is reasonable to expect that other commercial labs will make similar announcements in the coming days.

Aggregate Testing Rate

It is difficult to present an accurate estimate of total testing capacity in Pima County. Facilities capable of ordering and processing COVID-19 tests do not have an obligation to report test numbers to the State or the County (only positive test results are reportable). The ADHS COVID-19 data dashboard shows 8,456 NAA tests completed from March 11 through April 29, with a peak test number of 362 and a weekday average near 250.

An indicator of the adequacy of test coverage in a population is percentage of positive results which in Pima County has hovered between 11 and 17%. Experts suggest that a consistently positive rate below 10% is an indicator of adequate testing coverage.

Federal and state directives to increase testing levels have been echoed in recent days with an expectation of 2-5% of the population tested. Governor Ducey released a plan to test up to 60,000 residents over three weekends starting on May 2, partnering with Banner Health and Walgreens to run drive-through

Mr. Huckelberry

Re: COVID-19 Viral Testing in Pima County

April 30, 2020

Page 6

and onsite testing across the state. Two such sites will be operational in Pima County however broader participation in this effort on the part of other ambulatory care partners is due to the lack of available testing and PPE supplies.

Future Developments

Testing capacity has uniformly been cited as a key component in the decision making process for “reopening the economy” but there is not a clear federal definition of what an adequate level of testing that would be. Federal and state resources are being dedicated to ramping that capacity in order to understand the true spread and nature of the COVID-19 infection and to inform decision makers on the safety of loosening stay at home orders. Robust contact tracing will open the door for phased relaxation of social distancing while still limiting the magnitude and impact of surges in infection.

Alongside testing capacity is the need to understand the level of protection COVID-19 antibodies provide against reinfection. Until that is better clarified the value of antibody testing remains speculative. If the degree of immunity or resistance is determined to be significant, accurate and valid antibody tests will further the support for returning to work and school. Until the successful development of a vaccine – not expected by even the most optimistic timelines before 2021 – this determination will likely be the most significant finding in controlling the spread of COVID-19.

The Pima County Health Department will continue to provide regular updates to County leadership on the receipt and distribution of test resources and will continue to assess community-testing capacity.

Attachment

ATTACHMENT



MEMORANDUM

Public Health Emergency Preparedness COVID-19 Response Team

To: C. H. Huckelberry
County Administrator

Date: April 28, 2020

From: Louie Valenzuela LV
EOC Manager

Spencer Graves SG
Logistics Section Chief

Re: Follow up to **Daily Viral Test Kits Received from Arizona Department of Health Services**

In response to your memo, dated April 24, 2020, please see the attached daily tally of viral test kits received by Pima County Health Department from March 13, 2020 to date.

Please note, to date, there has been one allotment of viral test kits from Arizona Department of Health Services. A total of 201, received on Thursday, April 09, 2020. It is also important to note that test kits purchased from Paradigm are currently undergoing validation, and due for distribution tomorrow.

Health Department has disbursed over 2300 test kits, for use in long term care settings, congregate shelters, and through partnerships with Federally Qualified Health Centers for use in ambulatory clinic settings.

Pima County Health Department will continue to track receipt of test kits and provide updates as requested.

DATE	Arizona Department of Health Services	Paradigm	Sonora Quest	University of Arizona	Grand Total	Disbursed
03/17/20			168		168	168
03/30/20				300	300	300
04/07/20				500	500	500
04/09/20	201				201	201
04/13/20				1000	1000	1000
04/17/20		2500			2500	
04/20/20		2087			2087	
04/22/20		496		1000	1496	139
04/27/20			249		249	
Total	201	5083	417	2800	8,501	2,308