



MEMORANDUM

Date: March 5, 2021

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

From: C.H. Huckelberry
County Administrator

A handwritten signature in black ink, appearing to be "CHH", is written over the printed name "C.H. Huckelberry".

Re: **COVID-19 Genomic Analysis Protocol**

Supervisor Matt Heinz requested this information at the Board of Health meeting. The attached material discusses in detail the selection of COVID-19 sampling for variant surveillance and genomic monitoring.

If you have any questions regarding the information provided, please contact Health Department Director Dr. Theresa Cullen.

CHH/anc

Attachment

c: Jan Leshar, Chief Deputy County Administrator
Carmine DeBonis, Jr., Deputy County Administrator for Public Works
Francisco García, MD, MPH, Deputy County Administrator & Chief Medical Officer,
Health and Community Services
Terry Cullen, MD, MS, Public Health Director, Pima County Health Department

COVID-19 Genomic Analysis Protocol

2/11/2021

Overview

This PCHD genomic analysis protocol is divided into two processes: (1) surveillance and monitoring and (2) epidemiological investigations. Both can use genomic sequencing and variant-specific PCR testing.

This protocol is supported by PCHD's established relationships between partners: ADHS, CDC, hospitals, PCHD's contracted public PCR testing laboratories (Paradigm, AccuReference, ASU-BioDesign, MicroGenDX for Rescue-me-Wellness, Sonora Quest for El Rio) and genomic sequencing laboratories (State Lab, TGen North, and ASU-BioDesign).

CDC is funding TGen, a genomic sequencing laboratory, to conduct genomic analysis on 5 to 10% of positive samples identified through community COVID-19 PCR testing by commercial laboratories. The gold standard is 10% of positive samples used in the United Kingdom. CDC and ADHS set sampling rates in collaboration with PCHD. Currently TGen collects positive samples in Pima County through Paradigm Laboratories with coordination from PCHD, and SonoraQuest Laboratories with coordination from Banner University Medical Center.

PCHD coordinates with selected hospitals and commercial laboratories that provides the genomic sequencing laboratory with a specific number of positive samples that fills CDC/ADHS weekly allocation for PCHD. PCHD provides selection criteria to the commercial and hospital laboratories to identify and send positive samples to the genomic sequencing laboratory. PCHD's selection criteria is based on the needs of Pima County and the number of positive sample allocated to the county for analysis. The commercial and hospital laboratories need to assure that PCHD selection criteria is met so that the genomic results are representative of Pima County's population and meet PCHD's investigative needs. This may require pop-up testing sites where the commercial laboratory is not testing for COVID-19 or working with other commercial laboratories to assure that the genomic sequencing laboratory receives the samples that meet PCHD selection criteria. The criteria is based on the objectives of the following two processes.

1. Variant surveillance and genomic monitoring

Genomic surveillance and monitoring can be conducted simultaneously using the same samples. Surveillance objective is to identify as quickly as possible the occurrence of known variants that are more contagious and/or pathogenic than the endemic virus. Surveillance can complement epidemiologic investigations such as identifying 'hotspots' in community. Sampling should be representative of the county both geographically and socioeconomically; random sampling¹ from the four geo-socio-economic connected areas (see table below, Sells/Tohono O'odham Nation² is not part of PCHD sampling and analysis). If risk factors are identified from outbreaks then sampling may be weighted to collect more samples from populations with higher risk of the variant emerging or spreading.

¹ Samples collected for this process are classified as "convenience samples." They may not be representative of a population. Randomizing the selection of samples will help reduce additional bias in the selection process.

² PCHD will not selected samples that have residential addresses on tribal land, samples collected on tribal land, nor samples that have been collected under contract by tribal nations.

Monitoring objective is to provide a historic baseline of the evolution of the virus genome and can potentially identify mutations that are occurring in the genome that may pose future risks. Sampling for monitoring can be the same or less intensive that sampling for surveillance for known variants.

PCHD’s Public Health Data Services (Testing Team) advises its partners on testing locations and criteria for selecting SARS-CoV-2 positive samples for genomic analysis. Genomic surveillance of SARS-CoV-2 can use individual and pool sampling for specific variants or sequencing of individual samples. Similarly, the Testing Team advises partners on testing locations to conduct genomic monitoring and sequencing to document changes in genome and identify emergence of new variants.

Laboratories (January 2020 data) that are a potential sources for SARS-CoV-2 positive samples

Laboratories*	Metro Tucson (93%)**	Greater Green Valley (6.1%)	Greater Arivaca-Sasabe (0.1%)	Greater Sells/TON (0.9%)	Greater Ajo (0.3)
AccuReference	2K/wk				
Aegis					30/wk***
ArcPoint	X	X		100/wk	
ASU Biodesign	1.5K/wk				
Bridge Diagnostics		X			
LabCorps	2300/wk	58/wk	<1/wk		<1/wk
MicroGenFX	400/wk - PCHD				
Paradigm	8.6-10K/wk			X	
SonoraQuest	5000/wk	400/wk	3/wk	150/wk	25/wk

* Laboratories may collect samples from people living outside of the area the samples were collected.

** Estimated percent of Pima County population 1,069,000 by geo-socio-economic connected areas.

*** Only testing facility/site in area that sometimes uses SonoraQuest and LabCorp.

2. Epidemiologic investigations

PCHD’s Epidemiology Program (EPI Team) identifies outbreaks and unusual cases for further investigations. Some investigations may need genomic analysis (PCR testing or sequencing) to better understand potential causes and identify mitigation measure. Coordination between and senior leadership, hospitals, and other PCHD’s partners to assist investigations using genomic information as a epidemiologic tool. These investigations complement variant surveillance and genomic monitoring when PCHD epidemiologists identify unusual COVID-19 cases and clusters that are caused by mutant SARS-CoV-2 genomes. These epidemiologic investigations may achieve the following objectives:

- Determine if a mutation is connected with severity (hospital cases)
- Determine if a mutation is connected to an outbreak (contributing factor)
- Identify ‘hotspots’ in community
- Identify potential vaccine breakthrough-infections³,
- Identify persistence infections, and

³ Development of a disease despite a person’s having responded to a vaccine.

- Identify potential re-infections.⁴

Sampling and Shipping Process

ADHS allocated 50 to 75 positive samples per week to be identified in Pima County by PCHD and collected by Paradigm Laboratories. Also, ADHS allocated approximately 100 positive samples per week to be identified by Banner University Medical Center (BUMC) from their COVID-19 positive patients and collected by SonoraQuest Laboratories.

PCHD weekly allocation are divided into positives samples from hospitals patients, from the general population, and for epidemiologic investigation, positive samples collected from people living or working at specific facilities. Hospital samples will likely include those from patients transported from bordering counties and may provide information on variants not yet detected in Pima County.

During weeks with low to moderate COVID-19 hospitalizations a third of the allocation is assigned to non-BUMC hospitals (e.g. 25 of the 75 total allocation), during weeks with high COVID-19 hospitalization up to half of the allocation is assigned to non-BUMC hospitals. The EPI Team coordinates with participating hospitals to assign them the number of positive samples to ship to TGen weekly or week to week.

Pima County COVID-19 ICU patients (February 2021) and non-BUMC hospital patient percentage.

Hospital	COVID-19 ICU patients (2/8/21)	PCR testing laboratory
Banner University Medical Center, South	4	in-house & SonoraQuest
Banner University Medical Center, Tucson	32	in-house & SonoraQuest
Carondelet St Joseph's Hospital	6 (8%)	in-house
Carondelet St Mary's Hospital	12 (15%)	in-house
Northwest Medical Center, Northwest	25 (32%)	in-house
Northwest Medical Center, Oro Valley	8 (10%)	in-house - main lab
Northwest Medical Center, Sahuarita		in-house - main lab
Santa Cruz Valley Regional Hospital, Green Valley		SonoraQuest
Tucson Medical Center	28 (35%)	in-house
VA Medical Center		

Non-hospital samples that meet the requirements described below are selected at random for the community testing site unless the commercial laboratory is instructed otherwise.

Samples must meet the following requirements and shipping instructions:

⁴ **Establishing the diagnosis of reinfection:** This is very challenging and can't be made with molecular testing alone because of the possibility of prolonged (even more than three months!) respiratory shedding of viral RNA following acute infection. Therefore, a repeat positive NAAT in a patient who has recovered from lab-confirmed COVID-19 does not necessarily indicate reinfection. The probability of true reinfection in the setting of a repeat positive PCR result is increased:

- By longer the time interval since the first infection
- By higher the viral load on repeat testing (this requires quantitative PCR with a cycle threshold value is <33)
- If IgG antibody is undetectable at the time of the presumptive reinfection
- If alternative diagnoses are ruled out (e.g., negative respiratory viral panel)

- TGen will accept either the original positive sample (NP swab in sterile saline or viral transport media or saliva) or an aliquot of the sample. Minimum volume is 500ul.
- Select samples with SARS-CoV-2 PCR assay Ct values of <32. This will ensure greater likelihood of sequencing success.
- Remove patient information (name and DOB). Sample tube should only have original laboratory ID or MRN and date of collection.
- Provide TGen (hyaglom@tgen.org) and PCHD (joseph.tabor@pima.gov) each with a line-list that includes ID number, date of collection, county of residence, and Ct value for samples being shipped for sequencing.
- Samples should be stored frozen and batch shipped via FedEx, UPS, or delivered via courier to the address below on dry ice.
- Packages can be received workdays (Monday-Friday) from 9AM-5PM, not holidays. Send packages to
ATTN: TGen North COVID Sequencing 3051 W. Shamrell Blvd Ste. 106, Flagstaff, AZ 86005

Data and Result Reporting

The line list sent to TGen by commercial laboratories is also sent to PCHD and includes the name (minimally the initials), date of birth of the person tested, date sample was collected, and date sample was sent to TGen. Additional information from the commercial laboratory about the person tested is helpful but not required.

TGen will send weekly status reports on the samples being analyzed. If variants of interest are discovered, notification must be immediately sent to PCHD Director. When genomic analysis is completed for a sample, TGen sends a line list of completed samples with results to PCHD.

Line list information from the commercial laboratory and TGen are merged using the commercial laboratory's sample ID number. The merged data provide the person's name, date-of-birth, and county of residence; this information allows retrieval of case and contact information in MEDSIS .

