

ELC ENHANCING DETECTION: ARKANSAS TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Arkansas
Population Size:	3018000

1. Describe the overarching testing strategy in your state or jurisdiction.

A) How you will maximize the use of testing platforms (with an indication of which ones are high throughput), venues, and expanding workforce access across your jurisdiction (e.g. public health labs, private, hospital, commercial, academic, etc.) to rapidly scale testing to accommodate an increased demand for SARS-CoV-2 tests, including utilizing point of care or other rapid results testing for local outbreaks?

The current goal for SARS-CoV-2 testing of the state of Arkansas' population has been established at benchmark of a 2%. This goal has been met using the Arkansas Department of Health Public Health Laboratory's (ADH PHLs) currently available, albeit, limited testing capacity in combination with commercial and academic resources. Current ADH PHL testing capacity is based on semi-automated methodology that is labor-intensive and time consuming based on a combination of manual and automated nucleic acid extraction and nucleic acid amplification using SARS-CoV-2 detection methodology developed and released by the Centers for Disease Control and Prevention.

ADH is on the cusp of initiating high throughput SARS-CoV-2 testing using the Janus and Chemagic platforms (PerkinElmer). With the activation of high throughput SARS-CoV-2 testing, a new benchmark of testing between 3% and 4% of the population per month will be put in place. The new platform will employ fully automated technology (nucleic acid extract and amplification) that will boost processing of clinical specimens from the current level of 200 specimens per day to a minimum of 800-1000 per day. Further increase in APLH testing capacity can be attained by offering specimen processing 24 hours a day during weekdays and is a consideration, should the need arise. The ADH/APLH is seeking to further increase its high throughput SARS-CoV-2 testing capability through the purchase of a Hologic Panther Fusion System. This platform can process up to 500 tests in 8 hours (1000 tests a day).

To further increase ADH PLH testing capacity, ADH has partnered with the clinical laboratory of the John L. McClellan Memorial Veterans Hospital in Little Rock, AR to process additional specimens collected that exceed the current capacity of ADH PHL. ADH is exploring the possibility of contracting specimen processing to the clinical laboratory of the Arkansas Children's Hospital in Little Rock, AR. Such a partnership would further increase the ability to process an additional 500 specimens daily. Three commercial pathology laboratories, located in two different regions of the state, offer the possibility of ADH establishing additional testing partnerships.

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ADH has partnered with community health centers as well as regional and rural community hospitals throughout the state to increase testing for SARS-CoV-2. ADH has provided these venues with the Abbott ID NOW instrument along with test kits and swabs so that these institutions can perform local SARS-CoV-2 testing. In addition, working with the University of Arkansas for Medical Sciences Area Health Education Center, a similar instrument and kits have been provided for community testing in rural part of the state.

Lastly, mobile health unit is available for ADH's use. This unit along paired with the Abbott ID NOW instrument can be used to reach focal areas of a community to target high risk or vulnerable groups for SARS-CoV-2. Communities throughout the state can be reached in this way.

B) Detail your approach to provide testing at non-traditional laboratory sites (e.g. retail sites, community centers, residential medical facilities, or pharmacies).

ADH has 94 local health units (LHUs) distributed in each of the 75 counties in Arkansas. These LHUs have recently been opened as sites for community SARS-CoV-2 testing. Specimens are collected at the LHUs daily on weekdays. Using an extensive network of couriers, specimens are then transport for the LHUs to the APLH for testing. On weekends, specimens collected as part of outbreak investigations at institutions or facilities are transported by the ADH courier network to APLH.

ADH has been advising the University of Arkansas' flagship campus in Fayetteville, AR regarding developing SARS-CoV-2 testing capacity in order to respond to campus outbreaks. This will provide access to testing to the student body of the University of Arkansas at Fayetteville and will inform ADH of any campus outbreaks.

A program to test all staff and high-risk residents housed in congregate living centers in Arkansas has been designed and initiated. Residents of nursing home facilities have been documented to have significantly poor outcome following SARS-CoV-2 testing. ADH has already initiated the process of testing staff and residents of all 250 nursing home facilities in the state.

ADH will test staff and residents of the Arkansas Human Development Centers (HDCs). These are state-run facilities overseen by the Division of Developmental Disabilities Services branch of the Arkansas Department of Human Services. Each HDC provides 24-hour residential, medical, and habilitation services. Greater than 1,000 individuals were served in Arkansas HDCs. Residents of the HDCs have severe intellectual disabilities/mental retardation, autism, cerebral palsy, and epilepsy. Additional concerns include dual diagnosis (co-occurring mental illness and mental retardation), challenging behaviors, fragile health, vision impairment, hearing impairment, and inability to walk. Greater than 60% of residents function at the level of profound mental retardation.

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In order to provide SARS-CoV-2 testing to individuals using homeless shelters in Arkansas ADH has partnered with local EMS services in each of the counties with these shelters. Specimens will be collected at the homeless shelters by local EMS crews and transported to LHUs in the county. From there they will be couriered to the APHL for testing.

ADH has worked with the Arkansas Trucking Association to provide SARS-CoV-2 testing to its 10,000 members at designated sites throughout the state. The ADA is attempting to partner with Walmart and the poultry processing industry. These efforts are nascent and may take the form of employee testing or, potentially, testing of the general public in the case of the former institution.

C) Describe your strategy for serology testing, if applicable.

The first months of the budget period will be devoted to vetting platforms for serologic testing, and developing the methodology for implementing seroprevalence studies. Serology testing platforms will be evaluated with regard to performance (e.g. sensitivity, specificity), ease of implementation, and associated costs. The overall strategy for serology testing will be informed by the questions the CDC and ADH seeks to answer. These may include how much of the population has been infected, how is this changing over time, what characteristics are associated with SARS-CoV-2 infection, how many people experienced mild or asymptomatic infection, and how long can antibodies be found after a COVID-19 infection.

In order to appropriately and accurately generalize findings from seroprevalence studies, careful consideration must be given to methodology and implementation. Therefore, ADH will plan to construct these studies with input from a variety of key stakeholders, including from possible partners like academic institutions or hospital systems. From this input, ADH will develop plans for appropriate sampling, recruitment, testing logistics, data analysis, and other relevant activities. By late summer, ADH, in conjunction with its potential partners, will seek to put these plans into action.

D) Describe how you will communicate, collaborate and coordinate with the broad testing community within your state to ensure alignment in approach and progress toward jurisdictional goals. Plan should include regular outreach to testing partners to monitor test kits, supplies, reagent inventory and staffing levels.

ADH developed a plan that would allow the agency to send large amounts of testing supplies to any provider that will need to test individuals prior to any procedures. A survey form was developed and

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placed on the ADH website for providers to order supplies along with reporting their usage weekly. This link and information was shared amongst many association groups including: Arkansas Hospital Association, Arkansas Medical Society, and Arkansas Dental Association among many others. Once a provider has submitted their order on the online platform, ADH Warehouse packages the supplies and sends them via courier to the local health unit specified for pick up by the requestor.

ADH Warehouse along with ADH Emergency Operations Center (EOC) will continue to monitor the requested supplies and the weekly reporting to ensure that multiple orders from one facility are being used weekly prior to filling their next order. Inventory supplies will be monitored by ADH Warehouse and reported to ADH EOC daily.

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Table #1a: Number of individuals planned to be tested, by month

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Diagnostics*	67,500	75,000							142,500
Serology	0	0							0
TOTAL	67,500	75,000	0	0	0	0	0	0	

Table #1b: Planned expansion of testing jurisdiction-wide

Name of testing entity	Testing venue (select from drop down)	Performing Lab (if different from testing entity)	Daily diagnostic throughput	Daily serologic throughput	Platforms or devices used (list all)	Specific at-risk populations targeted (list all)
Arkansas Dept. of Health	Public health lab		900	0		All at-risk populations, including Nursing Homes, Homeless, Elderly, Prisons, Healthcare workers, disabled

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Arkansas Dept. of Health	Commercial or private lab	AEL Labs, Viracore, UAMS, VA	1,100			All at-risk populations, including Nursing Homes, Homeless, Elderly, Prisons, Healthcare workers, disabled

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2020 Direct Expansion of SARS-COV-2 Testing by Health Departments

2. Describe your public health department's direct impact on testing expansion in your jurisdiction.

Part A)

The Arkansas Department of Health Public Health Laboratory (ADH PHL) will be expanding capacity of SARS-CoV-2 testing by hiring more full-time staff, including at least four microbiologists, two senior microbiologists, two administrative support specialists, a Laboratory Information Management System (LIMS) administrator, and another information technology staff member. All new positions will be in direct support of SARS-CoV-2 by providing testing of specimens, receiving specimens, entering data from test request forms, providing support for inventory supplies and ordering, as well as administrative support for the Molecular Laboratory, Quality Assurance, and Laboratory Budget Administration. These positions are all critical since shift work is required, including nights and weekends, to increase capacity of the laboratory.

ADH PHL has purchased one high-throughput instrument system, the PerkinElmer platform, to increase capacity from several hundred to nearly 1,000 samples a day. Additionally, the laboratory purchased two new ABI 7500 fast DX for RT-PCR analysis. Thus, the laboratory has a total of six ABI 7500 fast DX systems for SARS-CoV-2 analysis. Validation of the PerkinElmer instrument is currently in process.

ADH PHL plans to further increase capacity and redundancy by purchasing a second PerkinElmer system. The second system is necessary for surge capacity during outbreaks, as well as maintaining continued testing capability, if one instrument requires maintenance or service.

In addition to adding capacity within ADH PHL, Arkansas will seek to contract with a large, commercial laboratory to augment the State's efforts. Arkansas will leverage this partnership to ensure testing availability for vulnerable populations within the state, such as nursing home residents. End-to-end logistics will be considered when establishing this relationship to facilitate the most efficient process for not only the actual testing, but also the expeditious reporting of results.

Part B)

Vulnerable populations such as those experiencing homelessness, behavioral health and substance use disorders, and those incarcerated tend to be overlooked during the times of crises. Similarly, at-risk populations such as elderly, those disabled, racial and ethnic minorities, those living in nursing homes and the health care workers caring for them pay the greatest price. Often, vulnerable populations live in congregate settings, thus increasing the risk for rapid spread of COVID-19 and potential outbreaks. At-risk populations tend to have a higher incidence of comorbid conditions that increases their risk of complications, hospitalizations, and potentially excess deaths due to COVID-19. Prioritizing these populations for testing, and implementing mitigation strategies early, can save scores of lives and restore our economy.

Arkansas is the home of 3.02 million Americans based in 2019 US Census estimates. Seventeen percent of them are 65 years of age and older. An estimated 15.7% are African Americans, and 7.7% are Latinx. Approximately 12.5% have some form of disability. Arkansas's median household income is well below

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the national average, and an estimated 17.2% of adults have an income that is below poverty level. In order to avoid disparities among these vulnerable populations, ADH will employ an aggressive testing strategy and a conservative mechanism for determining release from isolation precautions. As an example, all nursing home residents will be tested for COVID-19, and any positive cases will stay on isolation precautions until two negative tests are reported. ADH estimates screening 934,638 vulnerable and at-risk populations, including homeless individuals, nursing home residents, inmates, patients at dialysis centers, residents at other long-term facilities, and minority populations, in Arkansas for COVID-19.

Part C)

Several barriers have been identified to efficient testing at the ADH PHL. Some of these barriers have been overcome with temporary solutions, whereas others, have become permanent.

The laboratory purchased a PerkinElmer Chemagic 360 instrument with a Janus liquid handler to automate RNA extraction and PCR preparation. Also, two more ABI 7500 Fast DX thermocyclers were purchased to accommodate increased sample volume. To meet future needs, the laboratory plans to purchase a second Chemagic 360 and Janus liquid handler to ensure redundancy and continuous testing capacity. If the laboratory is unable to process samples, such as due to reagent availability, the samples will be sent to a contracted laboratory. These contracts are currently in-process.

The laboratory required additional testing analysts, data entry specialists, staff to accept samples, and information technology specialists. The laboratory has hired extra help in temporary positions in some of these needed areas, but is working to hire full-time staff to ensure testing capacity and the ability of the laboratory to function with multiple shifts, including nights and weekends.

Importantly, the laboratory identified a source of inefficiency with data entry. One method to increase efficiency was to utilize current infrastructure by collecting specimens at the ADH's local health units located in each county. The local health units already use an electronic test request system where the patient information is entered at the local health unit. A contracted courier service picks up the samples and delivers to the ADH PHL. Using this system, the laboratory can track specimens in route to the laboratory, as well as report back to the local health unit. Unfortunately, this system can only be used at the local health units. To overcome this barrier, the laboratory is working closely with the Association of Public Health Laboratories (APHL) to create a submitter portal where test request information can be entered by the sample submitter. Thus, the laboratory will reduce the number of paper test request submission. Also, the laboratory will be able to report results through the portal back to the sample submitter without having to use antiquated methods, such as faxing reports. This work with the portal is in the beginning stages and is on-going.

Part D)

As Arkansas enters the next phase of the COVID-19 pandemic, testing for the SARS-COV-2 antibody is an important step in understanding the prevalence of disease and for supporting policy makers in evidence-based decision making.

In the first months of the budget period, ADH plans to investigate a variety of platforms for conducting serology testing. For example, ADH will consider an Evolis platform and the Platelia SARS COV2 Ab test, which has FDA EUA and a sensitivity of 92.2% and specificity of 99.6% in an independent evaluation by

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National Institute of Health (NIH), CDC and Biomedical Advanced Research and Development Authority (BARDA). Other platforms, like Abbott Architect SARS COV 2 IgG, which has a sensitivity of 100% and specificity of 99.6% in an independent evaluation by NIH, CDC and BARDA, will also be evaluated for possible adoption.

During May and June of 2020, ADH will begin developing a methodological approach for conducting seroprevalence studies. Consideration will be given to the specific questions CDC has endeavored to answer, including how much of the population has been infected, how is this changing over time, what characteristics are associated with SARS-CoV-2 infection, how many people experienced mild or asymptomatic infection, and how long can antibodies be found after a COVID-19 infection. Given the potential wide scope for conducting this type of surveillance, and the need to adequately generalize findings to the State's population as a whole, ADH's methodological approach will be carefully considered with input from various stakeholders. These may include, among others, academic institutions.

Part E)

ADH's plan for resource utilization will be informed by community testing indicators and the State's overarching goal of testing between 2.5% and 3% of the population, or approximately 75,000 to 90,000 people, every month for COVID-19. ADH will apply metrics like overall percent positivity, testing rates per capita, incidence rates, percent change in new cases, emergency department syndromic surveillance data, hospitalizations and deaths to community and county-level data to identify areas with a paucity of testing, as well as potential hot-spots. Through the continuous assessment of these indicators, ADH will be positioned to implement rapid, targeted testing to areas of the state that are in most need, and to specific populations that are disproportionately impacted, such as racial and ethnic minorities. In order to operationalize the State's goal of testing between 2.5% and 3% of its population, ADH will expand upon current testing priorities, which include hospitalized patients and healthcare workers, vulnerable patients and other individuals with symptoms consistent with COVID-19. This expansion will include asymptomatic individuals who are at increased risk for infection or severe complications from infection. Direct and household contacts to confirmed COVID-19 cases will be offered testing at their local health units to facilitate timely testing and minimize secondary transmission. Sentinel surveillance for particularly vulnerable populations, including inmates and staff at correctional facilities and nursing home residents and staff, will also be implemented. All inmates will be tested upon intake, as well as release from correctional facilities to detect cases prior to introduction to both the congregate setting and the community, respectively. Nursing home residents and staff will be tested repeatedly to maximize detection of COVID-19 and inform isolation precautions. Given the threat of severe outcomes among residents of nursing homes, ADH will utilize a conservative, testing-based approach for clearing residents from isolation. For each positive nursing home resident, two negative tests, collected at least 24 hours apart, will be required for release from isolation precautions. Collectively, these measures and strategies will facilitate optimal resource utilization.

Part F)

On March 11, 2020, Governor Asa Hutchinson issued Executive Order 20-03 declaring an emergency related to the spread of COVID-19 within Arkansas. As part of this declaration, "provisions of regulating statutes prescribing procedures for conduct of the State Office of Procurement, the State Office of Personnel Management, and all other State departments and agencies are suspended to render

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maximum assistance to the Arkansas Department of Health.” Essentially, the emergency declaration serves to simplify and expedite processes related to procurement and hiring new staff. Among other impacts on procurement, the declaration allows for shorter solicitation timeframes, thus enabling for more rapid selection of qualified vendors. Processes for emergency hiring of new employees and the creation of new positions to support COVID-19 efforts are also facilitated by the emergency declaration.

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Table #2: Planned expansion of testing driven by public health departments

BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Number of additional* staff to meet planned testing levels	1 Microbiologist								0
FOR DIAGNOSTIC TESTING									
How many additional* testing equipment/devices are needed to meet planned testing levels? (provide an estimated number, and include platform details in narrative above)	1 Platform	1 Platform							0
Volume of additional swabs needed to meet planned testing levels ⁺⁺									0
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺	N/A	N/A							0

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BY MONTH:	May-20	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	TOTAL
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	PERKINELMER Extractions = 26,016 & Detection Reagents = 25,920	PERKINELMER Extractions = 26,016 & Detection Reagents = 25,920							
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels	N/A	N/A							0
Volume of additional reagents needed to meet planned testing levels, by testing unit and platform (i.e. 100K/day - Hologic panther; 100k/day - Thermofisher)	N/A	N/A							

* Report new monthly additions only, not cumulative levels

++ For May and June, only include needs beyond the supplies provided by FEMA. Report new monthly additions only, not cumulative levels.