

ELC ENHANCING DETECTION: ARKANSAS TESTING PLAN

2020 Overarching Jurisdictional SARS-COV-2 Testing Strategy

Jurisdiction:	Arkansas
Population Size:	3,018,000

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

Part A)

The goal for SARS-CoV-2 testing in Arkansas was set at 2%, or roughly 60,000 people for the May and June plan. In May, the Arkansas Department of Health Public Health Laboratory (ADH PHL) and its clinical and commercial laboratory partners tested more than 70,000 individuals. In June, ADH reported an average daily testing rate of greater than 6,000 tests. As a result, ADH has updated its testing goal to greater than 6% of the population, or 200,000 individuals, every month.

ADH has initiated high throughput SARS-CoV-2 testing using the Janus and Chemagic platforms (PerkinElmer). The new platform employs fully automated technology (nucleic acid extract and amplification) that will boost processing of clinical specimens to about 700 per day with 24 hours a day service 7 days a week. To further increase capacity at the ADH PHL, a second Chemagic and Janus system has been ordered and will be delivered at the end of June 2020.

ADH has established or is in the process of establishing several partnerships with clinical and commercial laboratories within the state to augment ADH PHL testing capacity. The John L McClellan Memorial Veterans Hospital in Little Rock will continue to process overflow samples collected as part of ADH's nursing home testing strategy. Other clinical laboratories, such as Arkansas Children's Hospital in Little Rock and clinical laboratories in Russellville and Fayetteville, are in negotiations with ADH to conduct testing using the Hologic Panther.

In order to support community health centers and hospitals servicing rural communities in Arkansas, ADH has provided Abbott ID NOW instruments for increasing testing coverage for SARS-CoV-2. In total, 16 of these instruments have been sent into the field, while two remain in the ADH PHL. ADH will continue support entities by sending test kits and other supplies for these machines. Resources are requested through a survey mechanism that is monitored through ADH's emergency operations center.

Finally, ADH is considering using a mobile health unit to further expand the reach of testing within the state. This unit along paired with the Abbott ID NOW instrument can be used to support offsite mass testing events and other focal areas of a community to target high risk or vulnerable groups for SARS-CoV-2.

Part B)

ADH has 94 local health units (LHUs) distributed in each of the 75 counties in Arkansas. These LHUs opened as testing sites in May and have since collected an average of 304 specimens per day. Specimens are collected at the LHUs during business hours are transported to Little Rock for testing using an extensive network of couriers. On weekends, specimens collected as part of outbreak investigations at institutions or facilities are transported by the ADH courier network to ADH PHL.

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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. The University of Arkansas, with ADH support and guidance, will provide testing and conduct contact tracing for its student body should onsite instruction commence in the fall.

The initiative to test all residents and staff at the 250 nursing home facilities in the state began in early June, and was completed on schedule. ADH will also continue its conservative, test-based protocol for releasing PCR positive residents and staff from isolation precautions. These aggressive plans will facilitate the early detection of SAR-CoV-2 within facilities, and could potentially lead to better outcomes.

ADH will continue to test staff and residents of the Arkansas Human Development Centers (HDCs). 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.

Homeless shelters are another congregate setting at high risk for the spread of SARS-CoV-2. ADH has begun 'Operation Compassion', which aims at to test all residents and staff at 96 homeless shelters in Arkansas. ADH is partnering with emergency medical services (EMS) staff to divide the state into response areas and communicate, collect specimens, and transport samples back to ADH.

ADH and its Office of Health Equity has begun implementing mass testing events to support communities and racial/ethnic minorities that have been disproportionately impacted by COVID-19. Over the next two months, ADH will recruit and hire five new positions to support the Office of Health Equity plan for, initiate, and coordinate mass testing throughout the entire state.

Part C)

In the May testing plan, ADH planned to investigate various platforms for performing serology testing. After a thorough review of the available options, ADH plans to purchase two Ortho VITROS 7600 systems serology testing in July. This system satisfied ADH's criterion for serology testing, which included demonstrated performance, scalability and having a FDA EUA.

ADH anticipates initiating serological testing in October. The overarching goal for the state is to estimate the seroprevalence for COVID-19 antibodies among Arkansans at multiple points in time, with more specific objectives including establishing a population-level estimate, estimating seroprevalence within well-defined, congregate settings, and measuring how long antibodies can be found after a COVID-19 infection.

In order to estimate seroprevalence at the state-level, ADH will aim to sample the state's population in way that is reasonably representative in terms of sociodemographic characteristics and geography. A truly random sample is ideal for generalization, but may not be feasible due to limitations in recruitment. ADH plans to utilize resources at local health units and academic partners for the majority of recruitment and testing sample collection. Sample size is not anticipated to be an issue for these studies based on the sample size calculation for prevalence studies (Daniel, 1999).

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ADH also plans to ascertain the spread of COVID-19 within high-risk, congregate settings, like nursing homes and correctional facilities, that have had PCR-positive cases. This strategy will supplement the current understanding surrounding attack rates within these vulnerable populations, as well as help determine characteristics and risk factors associated with SARS-CoV-2 infection. The ADH Healthcare Associated Infections (HAI) program has served as the strike team for these populations throughout the pandemic response. ADH will utilize the HAI program's connections, skill sets, and resources for these seroprevalence studies.

Finally, ADH aims to measure how long antibodies can be found in the body after a COVID-19 infection. This is in-line with the CDC's strategies for serology surveillance. ADH will recruit previous, PCR-positive cases who have recovered from their infection. To facilitate comparisons, various patient characteristics, such as onset date, duration of illness, comorbidities, and demographics, will be taken into consideration.

Part D)

ADH supports a variety of testing facilities throughout the state in order to augment the ADH PHL's capacity. This includes sending Abbott ID NOW systems to community health centers and hospitals that provide testing to underserved areas and populations of Arkansas. In total, 16 Abbott ID NOW systems have been sent to facilities across the state.

To monitor and allocate needed resources to the statewide testing community, 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 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*	8,694	19,067	39,370	39,370	39,370	39,370	39,370	39,370	263,981
Serology						5,000	10,000	10,000	25,000
TOTAL	8,694	19,067	39,370	39,370	39,370	44,370	49,370	49,370	

*Each jurisdiction is expected to expand testing to reach a minimum of 2% of the jurisdictional population.

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 through-put	Daily serologic through-put	Specific at-risk populations targeted (list all)
Aegis	[Select One]				
PathGroup	[Select One]				
Fayetteville Panther	[Select One]				
Russellville Panther	[Select One]				
VA	[Select One]				
UAMS	[Select One]				

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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) has already purchased one high-throughput instrument system, the PerkinElmer platform consisting of a Chemagic 360 and Janus liquid handler, to increase capacity from several hundred to about 700 samples a day for molecular testing. The PerkinElmer platform has been validated and currently in use. The ADH PHL recently purchased two ABI 7500 fast dx for RT-PCR analysis. This provides ADH PHL a total of six ABI 7500 fast dx systems for SARS-CoV-2 analysis. Additionally, the ADH PHL has a BioFire instrument that is used for priority sample analysis, such as during outbreaks, but reagents for SARS-CoV-2 detection have been limited. Lastly, the ADH PHL has already purchased a second PerkinElmer system for further increased capacity and redundancy. This instrument has been delivered and is awaiting assembly. A third Chemagic 360 will be purchased in preparation for the fall influenza season.

To ensure the ADH PHL can utilize both PerkinElmer instruments simultaneously to expand capacity of SARS-CoV-2 PCR analysis, the laboratory will be hiring more full-time staff, including at 4 microbiologists and 2 senior microbiologists. Additionally, 4 laboratory technicians will be hired to support receiving of specimens and data entry of test request forms specific for PCR analysis.

In addition to PCR analysis, the ADH PHL will be purchasing two Ortho VITROS 7600 systems for serology testing. To support this testing, 1 microbiologist and 2 laboratory technicians will be hired. The system will be ordered in early July and testing beginning in the fall 2020.

Lastly, the ADH PHL requires increased staff for other laboratory support functions, such as a Laboratory Information Management System (LIMS) administrator, 2 administrative support specialists, and 1 new position to support quality assurance and the web portal for electronically ordering tests and reporting. All of these new positions will be in direct support of SARS-CoV-2 effort 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.

Part B)

ADH is committed to prioritizing the testing of vulnerable populations for SARS-CoV-2 infection. Specifically, ADH will facilitate testing for racial and ethnic minorities who have been disproportionately impacted, nursing home residents, person's experiencing homelessness and residing in homeless shelters, and inmates at correctional facilities.

ADH plans to utilize its Office of Health Equity and amplify its resources to address the needs of racial and ethnic minorities who have inordinate rates of infection for COVID-19, including Black or African Americans, LatinX and Marshallese. ADH already conducts targeted testing events for these communities and populations. To further expand these endeavors, ADH will recruit and hire five

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positions to initiate, plan and coordinate testing events tailored to address the needs of particular Arkansas communities and populations struggling with high incidence of COVID-19.

ADH completed testing for all nursing home residents and staff for SARS-CoV-2 in late June. As the rest of the year progresses, ADH will maintain its highly conservative approach to testing in nursing homes. Residents who test positive will remain isolated until two negative tests, collected 24 hours apart, are reported. ADH also plans to test new nursing home residents prior to admission to the facility, and continue its current sentinel surveillance strategies.

For persons experiencing homelessness, ADH has partnered with emergency medical services (EMS) staff to test all residents and staff at 96 shelters statewide. Each shelter will be contacted by EMS Staff and will be added to the response schedule. Colleagues from the EMS staff will divide the state into response areas and will be responsible for communication, testing, and transport of samples back to the ADH. No appointments will be needed and all individuals housed at these locations will be tested.

Outbreaks at correctional facilities are particularly challenging to control. Timely testing and isolation precautions are crucial to reducing secondary transmission. ADH will continue its aggressive testing strategy of testing inmates at prisons prior to intake into the facility, as well as release to the community.

Part C)

Several barriers have been identified to efficient testing at the ADH PHL. Some of these barriers have been addressed and overcome with temporary solutions whereas others continue.

To increase efficiency, the ADH PHL 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. All instruments are validated and currently in use for molecular testing. To further increase efficiency and capacity, a second Chemagic 360 and Janus liquid handler has been purchased and expected to be delivered by the end of June 2020. These instrument will ensure redundancy and continuous testing capacity. Additionally, a third Chemagic 360 will be purchased in preparation for the fall influenza season. Although reagents have been in constant supply for the PerkinElmer method, if supplies are limited the laboratory plans to utilize other laboratories, such as pathology groups located within the state with Panther instruments and out-of-state commercial labs, such as AEL and Aegis both located in Tennessee.

The ADH PHL required additional testing analysts, data entry specialists, staff to receive 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 ADH PHL identified a source of inefficiency with data entry. Currently, the ADH PHL and ADH has utilized the current infrastructure by collecting specimens at the Department of Health's local health units (LHU) located in each county. The LHUs already use an electronic test request system where the patient information is entered at the LHU. A courier picks up the samples and delivers to the ADH PHL. Using this system, the ADH PHL can track specimens in route to the laboratory as well as report back to the LHU. Unfortunately, this system can only be used at the LHUs. To overcome this barrier, the ADH PHL is working closely with the Association of Public Health Laboratories (APHL) to create a

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submitter portal where test request information can be entered by the sample submitter. Thus, the ADH PHL will reduce the number of paper test request submissions. Also, the ADH PHL 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 on-going.

Part D)

In the last iteration of its statewide testing plan, ADH proposed to investigate various platforms for performing serology testing. In July, ADH plans to purchase two Ortho VITROS 7600 systems for serology testing. The decision to use this equipment was based on its demonstrated performance (e.g. 100% specificity), scalability, and its FDA EUA.

ADH anticipates initiating serological testing in October. The overarching goal for the state is to estimate the seroprevalence for COVID-19 antibodies among Arkansans at multiple points in time. This can be partitioned into more discrete objectives, which include establishing a population-level estimate at various times, estimating seroprevalence within well-defined, congregate or otherwise high-risk settings (e.g. nursing homes and correctional facilities with low, medium, and high attack rates), and measuring how long antibodies can be detected following COVID-19 infection.

In order to estimate seroprevalence at the state-level, ADH will aim to sample the state's population in way that is reasonably representative in terms of sociodemographic characteristics and geography. A truly random sample is ideal for generalization, but may not be feasible due to limitations in recruitment. ADH plans to utilize resources at LHUs and academic partners for the majority of recruitment and testing sample collection. Sample size is not anticipated to be an issue for these studies based on the sample size calculation for prevalence studies (Daniel, 1999).

ADH also plans to ascertain the spread of COVID-19 within high-risk, congregate settings, such as nursing homes and correctional facilities, that have had PCR-positive cases. This strategy will supplement the current understanding surrounding attack rates within these vulnerable populations, as well as help determine characteristics and risk factors associated with SARS-CoV-2 infection. The ADH Healthcare Associated Infections (HAI) program has served as the strike team for these populations throughout the pandemic response. ADH will utilize the HAI program's connections, skill sets, and resources for these seroprevalence studies.

Finally, ADH aims to measure how long antibodies persist following COVID-19 infection. This is in-line with the CDC's strategies for serology surveillance. ADH will recruit previous, PCR-positive cases who have recovered from their infection. To facilitate comparisons, various patient characteristics, such as onset date, duration of illness, comorbidities, and demographics, will be taken into consideration.

Part E)

ADH plans to continue monitoring community-level indicators for COVID-19 burden and spread. In order to facilitate transparency with the public and stakeholders, and to be able to quickly describe community data, ADH has built an Environmental Systems Research Institute (ESRI)-based, Geographic Information System (GIS) dashboard. This dashboard presents up-to-date data, such as cumulative case counts, active cases, COVID-19 related deaths, percent positivity, testing rates, and case demographics at the county level. In the coming months, ADH plans to expand this dashboard further to include data from syndromic surveillance related to emergency department visits for COVID-like-illness, as well as

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data revolving around hospital impact and capacity. Overall, this dashboard has simplified the process for monitoring community needs for testing and resource allocation.

ADH has updated its testing goal since the last iteration of this plan. ADH now plans to test over 6% of the total population, or 200,000 people, every month. The current average daily testing rate is currently 7,410 tests per day (includes PHL, clinical laboratories, and private/commercial laboratories) for the most recent two weeks (June 19 – July 3). Extrapolating this over a period of a month places this goal in reach with our current approach.

Part F)

The emergency declaration from March 11 (Executive Order 20-03) remains in effect for Arkansas through the end of July. During this time, regulating statutes for procurement and hiring new staff were suspended in order to assist ADH to expeditiously acquire needed resources. Essentially, the emergency declaration has eliminated several layers of approval allowing for rapid delivery of goods and services. As the statewide response to COVID-19 continues and the potential for the expiration of this order arises, ADH will work with political leadership in the legislature and Governor's office to ensure that barriers to procurement and hiring are ameliorated quickly.

References

Daniel WW (1999). *Biostatistics: A Foundation for Analysis in the Health Sciences*. 7th edition. New York: John Wiley & Sons.

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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			10		3				13
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)		2		1					3

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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 swabs needed to meet planned testing levels ⁺⁺									0
Volume of additional media (VTM, MTM, saline, etc.) needed to meet planned testing levels ⁺⁺									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)		20000	45000	45000	45000	45000	45000	45000	
FOR SEROLOGIC TESTING									
Number of additional* equipment and devices to meet planned testing levels					2				2

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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)						5000	10000	10000	

* 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.