COVID-19 Antibodies Testing for Arkansas

MAY 12, 2020

UAMS Health

Arkansas Children's
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Executive Summary

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. A team of investigators at UAMS, working with the Arkansas Department of Health and Arkansas Children's, outlined a three-phased approach to establish statewide antibody testing for COVID-19.

In the first phase of the study, we will develop and assess the specificity and sensitivity of a newly developed UAMS SARS-CoV-2 antibody test. To accomplish this goal, we will partner with the UAMS Clinical Laboratory to compare the newly developed test to the UAMS Clinical Laboratory SARS-CoV-2 IgG commercial assay using existing blood samples from UAMS patients that would otherwise be wasted. We also will examine the relationship of antibody responses to COVID-19 in patients hospitalized with evidence of COVID-19, in non-hospitalized patients with evidence of COVID-19, and in asymptomatic individuals from the general population.

In the second phase of the study, we will conduct adult and pediatric seroprevalence studies to determine the prevalence of COVID-19 antibodies among the Arkansas population. This work will include three waves of testing, with adult and pediatric samples collected and analyzed in June/July, followed by samples in August/September, and samples in October/November. A systematic randomized sampling of the state adult population will be employed to ensure the results are a true representation of the prevalence of COVID-19 antibodies among adults. The pediatric study will be a convenience sample providing a sense of prevalence among children. The information from the seroprevalence study will provide policy-makers with valid data on which to make decisions impacting the health and welfare of all Arkansans and will help Arkansas prepare for the future.

The final phase of the project is to provide the infrastructure for additional capacity for low-cost antibody testing for the state of Arkansas. To accomplish this goal, we will acquire a robotic-assisted immunoassay machine, to be delivered mid-July and operational by early August. This will provide us with the capacity to conduct up to 3,000 tests per day. We anticipate that 5-10% of machine capacity will be needed for research and surveillance, thereby providing capacity for more than 2,500 samples/day for workplace/school/community testing. The UAMS Clinical Laboratory will then evaluate the assay for performance, ease of use, and logistics before establishment of a laboratory-developed test with oversight by the FDA.

Overall, we believe that this approach will be an important strategy for better understanding how much of the Arkansas population has been infected with SARS-CoV-2 and how the virus is spreading throughout Arkansas communities over time.

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The **Co**rona**vi**rus **Di**sease of 20**19** (**COVID-19**) pandemic in Arkansas became apparent March 13, 2020, when the first patient was diagnosed in Pine Bluff. Since that time, Arkansans have faced a number of unknowns and experienced unprecedented public health actions in an effort to stem the spread of the infection. For some, sheltering in place in their homes has been a new, if not trying experience. The economic consequences of the pandemic have been especially harsh for many Arkansans, especially those who own or are employed by small businesses. Restaurants, schools and retail stores have largely been closed for weeks. These types of public health actions have significantly changed the lives of Arkansans.

Because laboratory tests that assess current infection were largely unavailable early in the timeline of the epidemic, there are many who have been infected. Yet, there is no test to provide laboratory evidence of past infections in the community. A secondary problem is the emerging knowledge that some infected persons may never have symptoms and may never be tested. Consequently, we know almost nothing about the prevalence of the virus in Arkansas and how many have been exposed to the virus to date.

Being able to test for and determine the point prevalence of COVID-19 in Arkansas is a vital step to inform and support policy-makers as they plan for reopening Arkansas' businesses and schools. This information is desperately needed to help policy-makers plan for the health care needs of the state. Specifically, we believe there are three goals for Arkansas (Table 1A) and three immediate questions (Table 1B) to be answered as reopening begins and two important future questions. As Anthony Fauci, M.D., Director of the National Institute of Allergy and Infectious Disease, said recently about national measures to stem the tide of the pandemic, "[S]erosurveillance is going to play a major role in...a framework for getting back to normal...(1)"

Table 1A. Key Goals or Arkansas Regarding Serologic Testing for COVID-19	Table 1B. Key Questions for Serologic Testing for COVID-19
1. Improve the safety and general welfare of all Arkansans. 2. Inform plans to help Arkansas reopen businesses, schools and public areas. 3. Prepare for a potential second wave of COVID-19 cases	Immediate: 1. What percentage of Arkansans have antibodies to COVID-19 and do they differ for important sub-groups of the Arkansas population. 2. What is the relationship between antibody levels and COVID-19 disease severity? 3. What are the effects of comorbidities, demographic factors, and geographic locales on the generation of antibodies to COVID-19? Future: 4. Are antibodies to COVID-19 protective and how long do they last? 5. How can we prepare now for the next pandemic that will affect Arkansas?

The purpose of this study is to provide state and local leaders with valid information on which to make informed decisions affecting the health and welfare of all Arkansans and prepare Arkansas for the future. Informed public health decisions for COVID-19 are dependent on two types of information. First, a valid and reliable test for COVID-19 antibody detection is needed. Second, valid and reliable estimates of the rates of detection of COVID-19 antibodies in Arkansas are needed. To provide this information, **the aims of this study are two-fold. Aim 1 is to develop and assess the analytic specificity and sensitivity of a newly developed UAMS COVID-19 antibody test. Aim 2 is to estimate the prevalence of COVID-19 antibodies among the Arkansas population.** We will implement the study in two concurrent and complementary components: The Laboratory Component and the Prevalence Component. Because of possible supply chain disruptions, relying on current tests may create significant delays now and in the future as states compete for all the materials needed to conduct tests. Arkansas has the opportunity to create its own test and be less reliant on national supply chain constraints. Finally, with a scientifically credible test and new robotic-assisted immunoassay machine, we will provide Arkansas with the capacity to conduct up to 3,000 COVID-19 tests per day.

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The Laboratory Component

This new coronavirus, Severe Acute Respiratory Syndrome (SARS) Coronavirus (CoV)-2, has challenged all existing diagnostic systems and approaches in the United States. While initial diagnostic methodologies to identify SARS-CoV-2 (hereafter referred to as COVID-19) centered around detection of genetic material (viral genomic RNA), scientists also assessed the value of serology (Immunoglobulin (Ig) M and G antibody levels) to measure exposure and immunity to the virus in those who were symptomatic, mildly symptomatic, and asymptomatic during the pandemic. Serologic (or antibody-based) approaches to the detection of infection have existed since 1896 (2) and rely on knowledge of the body's immune response to a foreign pathogen, such as a virus (**Figure 1**).

Numerous private companies quickly developed rapid IgM- and IgG-based tests to detect antibody responses to COVID-19. However, the relevance and reliability of these point-of-care tests in the assessment and management of patients remains unclear (3). Various reports, including information from New York released on April 23, 2020, suggest the percentage of individuals with an antibody response to COVID-19, but without obvious symptoms of illness, may be as high as 20%. Other data from select populations (pregnant women, cruise ship passengers) suggest rates of 14% to 18% (4, 5). A study of older residents from a long-term care facility conducted by the Centers for Disease Control found half of the infected individuals who tested positive for antibodies to COVID-19 were asymptomatic or pre-symptomatic (6). Locally, a study with Adult and Teen Challenge in Hot Springs found only 3 out of 26 people who tested positive by a polymerase chain reaction (PCR) test were symptomatic (7). The significance of these findings is that **the rate of asymptomatic COVID-19 carriers likely exceeds rates for influenza or other common viral pathogens. These asymptomatic carriers may harbor infection and pass it on to people with high-risk conditions.**

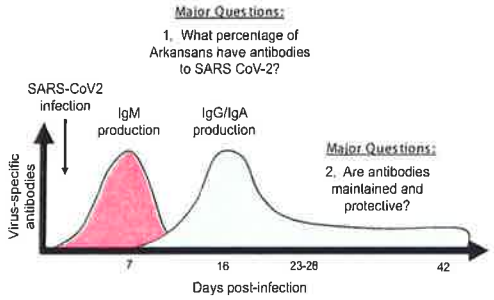

Figure 1. Development of IgM and IgG antibodies during COVID-19. *Following viral infection, B cells generate antibodies that are specific for the virus. The first form of antibody to develop, IgM, is detectable within 1 week. During the next 7-10 days higher affinity forms antibody, IgG and IgA, are generated. Antibody responses wane once the infection is controlled (typically 3-4 weeks after infection). Memory B cells that are part of the "immune memory" are generated throughout the antibody development process and facilitate rapid responses to re-exposure to the virus.*

Drs. Boehme, Forrest, and Kennedy at UAMS recently developed an assay to detect IgM and IgG that recognizes the viral S "spike" protein in blood samples of UAMS hospitalized patients with known COVID-19 infection. Components of the assay were gifted to UAMS by Dr. Florian Krammer at Mount Sinai (8, 9). The Mount Sinai test received Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) on April 15, 2020 and has been scaled for screening as many people as possible in New York (10). The specificity and sensitivity of this test are currently not listed; however, early data supports specificity to COVID-19 of 98.5%.

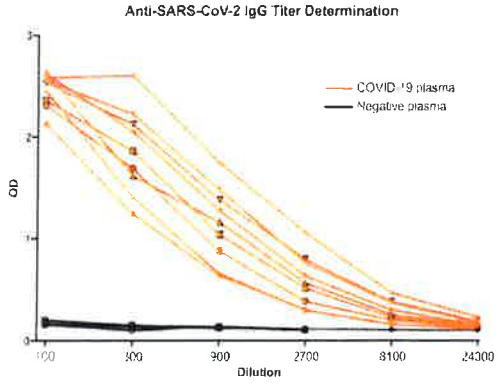

Figure 2: Quantification of IgG in UAMS 1 in UAMS hospital patients. *Three-fold serial dilutions of plasma from control patients (black lines) were screened using ELISA for the capacity to bind the RBD from SARS CoV-2. Data are presented as optical density.*

As shown in **Figure 2**, RBD-specific IgG antibody levels from patients that tested PCR positive for COVID-19 are substantially higher than the levels detected in samples from control patients (taken prior to the COVID-19 pandemic). Moreover, the readings for IgG in the COVID-19 patients did not return to the baseline until very dilute solutions were prepared. These data will inform our basic approach to evaluate populations in Arkansas for exposure to COVID-19 infection. While the UAMS test does not have Emergency Use Authorization, it is very similar to the Krammer ELISA test, as the components of the test are the same, and we anticipate quick authorization. Drs. Kennedy, Boehme, and Forrest can manufacture the RBD protein at UAMS, so UAMS will no longer rely on the Krammer laboratory or other supply chains to provide the protein. These advances also will lower the per-sample cost compared to other commercial rapid assays.

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Building on current work, considering key goals for the State of Arkansas (**Table 1A**), and questions surrounding antibody response to COVID-19 (**Table 1B**), we propose the following approach to develop a strategy to evaluate the role of serologic testing for COVID-19 in Arkansas.

Approach. The first part of the work is to build the evidence base for the value of the UAMS test for use in Arkansas in health care and private industry settings. Initially, we will examine analytic sensitivity and specificity of the test. To do this, we will use existing blood samples from UAMS patients with RT-PCR evidence of COVID-19 and measure antibody responses in these samples. We will compare the antibody responses to clinical symptoms of COVID-19. Existing COVID-19 screening data, demographic and clinical data, and COVID-19 RT-PCR data are available in the enterprise data warehouse at UAMS. Second, we will prospectively obtain samples from non-hospitalized patients with COVID-19 infection (using UAMS clinics and other approaches) and asymptomatic individuals from the general population (working with our eight community campuses located throughout rural regions of Arkansas). Third, we will examine the relationship of IgG profiles over time to known comorbid risk factors (chronic lung disease, diabetes mellitus, cardiac disease, chronic kidney disease, and immunosuppression) and as a function of age, gender, race, ethnicity, and geographic location in Arkansas (11). We will also evaluate the performance of the UAMS assay against the Beckman Coulter IgG assay that will have FDA EUA clearance (anticipated May 15, 2020), which will be utilized in the UAMS Clinical Laboratory. In the event that the UAMS assay does not meet standards, Dr. Olgaard has agreed to run all seroprevalence blood samples on the Beckman Coulter instrument as an alternative approach.

While the above data demonstrate our ability to quantify antibody responses, we recognize the need for large scale testing which will require robotics-enabled technology. We will purchase a Tecan EVO, which has the capacity for large throughput ELISA testing. The analysis of these data and comparison of antibody profiles with known risk factors and demographic data will require advanced informatics and data analysis support, all available within the Departments of Biomedical Informatics and Biostatistics at UAMS. Analysis of these data will allow us to address our initial questions in Table 1B and will inform our approach to evaluate future questions. For example, understanding the persistence of IgG in the population will inform future decisions, especially when COVID-19 vaccines are available. In addition, we recognize the importance of building a blood and respiratory sample biobank with secure, protected linkage to clinical and laboratory data. We will follow established models already in existence at UAMS to build a biobank and data repository, which will support future questions about pandemics and inform state-based approaches to emergency preparedness.

The Prevalence Component

The Prevalence Component will provide blood samples from two groups: a representative sample of Arkansans and a convenience sample of children. To conduct the prevalence study of adults, we will implement a prospective panel study. A prospective panel study design is considered best when using a test to screen asymptomatic individuals (12). The panel study will consist of three waves of randomly selected adults. The first wave will collect 1,500 blood samples between June 1 and July 15 among adults and 300 blood samples among children less than 18-years-old. The second wave will collect 3,000 blood samples from adults between August 1 and September 15, including oversampling of African-Americans, Latinos, and Marshallese. We will obtain 600 samples from children over this time period. The third wave will also collect 3,000 blood samples from adults and 600 samples from children between October 1 and November 15. The dates for collecting wave samples was determined based on a long-term forecast model of the course of the pandemic in Arkansas developed by the UAMS College of Public Health.

While it is recognized there are many challenges to collecting blood samples from children, the importance of understanding antibody responses in children demands inclusion of children in the seroprevalence study. The pediatric prevalence study will be conducted using a convenience sample of children presenting to pediatric clinics around the state. This component will use waste blood samples and the number of children included will be proportionate to the pediatric population in Arkansas.

Creating a random sample of Arkansas Adults. To build a representative sample of adult Arkansans, we will first begin by telephoning a random sample of residents until desired numbers are reached for each wave. The surveys will be implemented as part of an on-going study of the health, financial, and food security of Arkansans (The Arkansas Pandemic Poll). We are currently collecting data from 300 Arkansans every two weeks for the poll. To achieve the number of blood samples required for the Laboratory Component, we will increase the number of random calls to 1,200 calls every week for each wave.

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We will build wave samples by calling a random sample of mixed telephone ground line and targeted cell phone numbers in Arkansas. Land lines are a sample based upon all known land lines in Arkansas. Cell phone numbers will be targeted according to volume of calls and locations where the phone is most used. Targeting will eliminate cell numbers not currently in use or used outside the state. The mixed sample of ground and cell phones will be created by a company having access to these data and experience conducting polling in Arkansas. New call samples will be provided by the survey research company every two weeks.

Trained research assistants will call telephone numbers using a provided list. If an eligible person answers the call, the research assistant will explain that he/she is calling from UAMS and would like to ask him/her a short series of questions. If the person refuses the invitation to answer questions, the research assistant thanks him/her and proceeds to the next number. Calling will continue until each wave sample is reached.

Prior experience suggests about 7% of respondents will be Spanish-speaking only. In the event the person reached on the phone is Spanish-speaking, a phone caller fluent in Spanish will speak with the respondent. To oversample African-American and Latino Arkansans, the company providing phone numbers will provide a larger sample of phone numbers from counties with large numbers of African-Americans and Latinos. This will maintain the randomness of the sample drawn, while increasing the numbers of each racial/ethnic group. To draw our sample from the state's large Marshallese population, we will work with UAMS Northwest located in Fayetteville. Researchers at UAMS Northwest have a strong collaborative partnership with the Marshallese community. Our goal is to have a representative sample from 100 Marshallese in Waves 2 and 3.

Eligibility for adults. To be eligible to participate in the project, a called respondent must be: 18 years of age or older; a resident of Arkansas; able to understand and speak English or Spanish; and able to provide informed consent. If the respondent is eligible and agrees to participate in the project, he/she will be informed about the study and asked if he/she prefers to have a nurse visit his/her home, travel to a local UAMS clinic, or visit a local community site to have a blood sample collected. If the respondent agrees to participate, she/he will be asked over the phone for initial verbal informed consent and for personal information, such as address and phone numbers. To encourage participation in numbers sufficient to conduct the study, individuals will be offered a $40 Walmart gift card for their time devoted to this project.

To increase information about the study in local communities, important community leaders, such as local physicians, ministers, and political officials will receive information about the study and why it is important. We will ask these leaders to inform their local constituencies about the study and the date and location of community blood sample collection sites. In addition, the UAMS Office of Communications and Marketing will prepare news releases and other announcements about the study and its purpose.

Collecting blood samples and personal data from adults. Blood samples and some demographic and health history data will be collected by trained personnel, many of whom will be UAMS nurses. Nurses will collect blood samples in UAMS regional programs, pediatric clinics, and community sites such as churches, utilizing established collaborations among UAMS faculty and community partners. Nurses will travel to either the local clinic or community site and will receive training on human subjects research, cultural sensitivity and community based research at the beginning of the study.

When the participant arrives at the local clinic or community site, the nurse will again explain the study in detail using a script providing information about the study. The nurse will answer all questions to the participant's satisfaction. The nurse will then again ask the participant for his/her consent to proceed, and ask him/her to sign a written consent form. The participant will be given a copy of the informed consent form, which will include UAMS telephone numbers where study investigators may be contacted if there are other questions.

After written consent, the nurse will ask the respondent a brief series of questions and collect a blood sample. The questions will include gender, age, race/ethnicity, income, chronic medical conditions, recent symptoms, and recent travel. Responses to questions will be recorded on a paper/pencil form. The paper form will have a unique identification number. Afterwards, a blood sample will be collected and stored in a gold top tube. The tube will be clearly marked with the unique identification number and the date the sample was collected. Once collected, the tube will be placed in an insulated cooler to be transported to a UAMS regional clinic, if the blood is collected at the participant's home.

When the nurse arrives at the clinic, the blood sample will be spun and packaged for overnight shipping to the lab at UAMS Little Rock. If the sample cannot be shipped until the next day, the sample will be refrigerated and shipped at the earliest possible time. The signature page of the informed consent will be scanned and emailed to the Department of Epidemiology at UAMS Little Rock. The nurse will record responses to survey questions in a pre-programmed web-based database. Responses

will be checked by a research assistant in the Department of Epidemiology within 24 hours. If data are found to be incomplete, the research assistant will call the nurse during the same business day to attempt to collect missing data.

All emailed and web-based forms will use UAMS encrypted systems. The systems are HIPAA compliant.

Once delivered to the UAMS lab (Kennedy lab), the sample will be aliquoted into three parts, including the sample to be analyzed in the Kennedy laboratory, the sample to be analyzed by the UAMS Clinical laboratory (Beckman assay) and remaining samples will be stored and frozen for future analysis.

Participants will not be informed of personal test results. However, each participant will be provided the aggregate study results in easy-to-follow language. Results will be shared by mail.

Creating a sample of Arkansas children. We will use a convenience sampling design to collect blood samples from children from pediatric clinics around the state. Clinics will include UAMS and Arkansas Children's Hospital (ACH) clinics and facilities. The number of blood samples collected will be proportional to the pediatric population of the state. While not representative, the sample will provide a sense of true prevalence of COVID-19 in children in different regions of the state.

Eligibility for children. To be eligible to provide a blood sample for the pediatric prevalence study, children must be less than 18 years of age and a resident of Arkansas. Information about the study will be shared with UAMS and ACH pediatric clinics around the state. The requirement for informed consent will be determined by the UAMS institutional review board.

Collecting pediatric blood samples. Pediatric blood samples will be collected at the same time the adult waves are collected and will rely on waste blood samples, defined as any remaining blood samples available after clinical laboratory tests have been completed. We will collect 300 pediatric blood samples in the first wave and 600 in waves 2 and 3, respectively, for a total of 1,500 pediatric samples.

Blood samples collected from children will be excess or waste blood from blood samples collected for other reasons. Pediatric samples will be shipped on ice to the Kennedy laboratory for processing. Blood samples will be identified by unique number and accompanied by minimal data, including age, gender, race/ethnicity, and county in which the blood was collected. Accompanying data will be recorded on a brief form. The form will be sent to UAMS with the blood sample.

Analyses. Adult survey and blood data will be merged by unique ID number. No personal identifiers will be used for data analysis. Adult and pediatric data will be analyzed separately. We expect adult data will provide a true representation of COVID-19 prevalence in Arkansas. Pediatric data will provide a suggestion of true prevalence among children in Arkansas.

First we will assess how accurately the population of Arkansas has been represented in a sample. It is our expectation, using the mixed telephone polling methods, the resulting samples will be proportionately representative of the population living in Arkansas. If the sample needs to be adjusted, a biostatistician will develop population weights to make the sample representative of Arkansans. Second, demographic characteristics will be assessed from sample to sample to assess if there are differences among them. We expect no significant differences. Data will also allow us to make assessments of adult seroprevalence by race/ethnicity, income group, size of family, age, county, urban/rural residence, reported comorbidities, and so forth. From wave to wave, we will also plot trend lines to determine if infection rates are increasing, decreasing, or staying the same.

The adult and pediatric samples collected during waves 1 to 3 will provide sufficient power for all planned analyses and will allow a valid and reliable estimate of the prevalence of COVID-19 in Arkansas (12, 13).

Building A Pandemic Support System and Infrastructure for Arkansas

By building the capacity to process up to 3,000 tests/day per machine with a scientifically credible assay, Arkansas will be able to track the COVID-19 pandemic as we resume public activities. We also will be prepared to meet any future pandemics. However, building a system requires more than a machine. It requires a system for ensuring that time-sensitive samples get to the processing labs. We will develop a training program for how blood should be collected by nurses who are drawing blood. Blood samples (gold top tubes- 5mL) will be collected by trained nurses. These blood samples will be placed in a biohazard sealable and impervious bag and then placed in the refrigerator prior to shipping via courier service. Samples will be shipped on ice to the Boehme/Kennedy/Forrest laboratory where they will be aliquoted per plans. We will develop a system for communicating back results. Further work on building the Pandemic Support System will be achieved in future projects as we build the infrastructure and basic system components.

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Time Line of Major Activities/Deliverables

June

Week 1:	Purchase large-scale immunoassay machine to conduct scientifically credible rapid testing in support of Arkansas employers and citizens (delivery in 11 weeks)
Week 1:	Hire contract nurses across state and develop blood sample collection strategy, train nurses, order all field blood sample collection supplies
Weeks 1 - 4:	Complete 80% of Wave 1 random sample of blood sera from 1,500 adult Arkansans and deliver to UAMS Clinical Laboratory for immunoassay testing to assess coronavirus prevalence in Arkansas
Weeks 1 – 4:	Collect 300 blood samples from children
Weeks 1 - 4:	Complete immunoassays in UAMS Clinical Laboratory to describe those Arkansans sero-positive for Covid19 antibodies
Weeks 3 & 4:	Begin epidemiological analysis and briefing report to Governor and Secretary of Health

July

Week 1 - 2:	Finish Wave 1 random sample of blood sera from 1,500 adult Arkansans and deliver to UAMS Clinical Laboratory for immunoassay testing to assess COVID-19 virus prevalence in Arkansas
Weeks 1 - 2:	Finish immunoassays in UAMS Clinical Laboratory to describe those Arkansans sero-positive for COVID-19 antibodies
Weeks 1-2:	Finish epidemiological analysis and briefing report to Governor and Secretary of Health
Week 3:	Brief Governor and Secretary of Health on Wave 1 seroprevalence findings
Weeks 1 - 4:	Build evidence for UAMS immunoassay as "best in class"

August

Weeks 1 - 4:	Install and complete operational testing on new rapid testing machine for UAMS projects
Weeks 3 - 4:	Begin Wave 2 random sample of bloods from 3,000 adults in Arkansas and deliver to UAMS labs for immunoassay testing
Week 4:	Release UAMS immunoassay test to Arkansas health care community for clinical testing (a successful CLIA inspection)
Week 4:	Brief Governor and Secretary of Health on new capacity in Arkansas

September

Weeks 1 - 3:	Complete Wave 2 random sample of blood from 3,000 adults and children in Arkansas and deliver to UAMS labs for immunoassay testing
Week 3:	Complete all immunoassays in UAMS labs using the new rapid testing machine to describe those Arkansans infected with coronavirus
Weeks 3 & 4:	Conduct epidemiological analysis and prepare report for Governor and Secretary of Health
Weeks 4:	Brief Governor and Secretary of Health on Wave 2 seroprevalence findings

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October

Weeks 1 - 4:	Publish results in scientific journals to lend credibility to work and brand Arkansas as leader in mitigating pandemic
Weeks 1-4:	Build components of Pandemic Support System and infrastructure to protect Arkansans and our businesses
Weeks 1 - 4:	Begin Wave 3 random sample of blood sera from 3,000 adults and children in Arkansas and deliver to UAMS labs for immunoassay testing
Weeks 2 - 4:	Begin immunoassays in UAMS labs using the new rapid testing machine to describe those Arkansans infected with corona virus
Weeks 3 & 4:	Conduct epidemiological analysis and prepare report for Governor and Secretary of Health
Week 4:	Brief Governor and Secretary of Health on new capacity in Arkansas

November

Weeks 1 - 2:	Complete Wave 3 random sample of blood from 3,000 adults and children in Arkansas and deliver to UAMS labs for immunoassay testing
Week 3:	Complete all immunoassays in UAMS labs using the new rapid testing machine to describe those Arkansans infected with corona virus
Weeks 3 & 4:	Finish epidemiological analysis and prepare report for Governor and Secretary of Health

December

Week 1:	Brief Governor and Secretary of Health on Wave 3 seroprevalence findings

References

1. Abbasi J. "The promise and peril of antibody tests for COVID-19." **JAMA**. Apr 17, 2020. Online publication. [https://jamanetwork.com/journals/jama/fullarticle/2764954].
2. Gruber-Widal Reaction for Typhoid fever.
3. Coronavirus antibody tests: Can you trust the results? **New York Times**. Apr 24, 2020. Online publication. [https://www.nytimes.com/2020/04/24/health/coronavirus-antibodytests.html?referringSource=articleShare].
4. Sutton D, Fuchs K, D'Alton M, Goffman D. Universal screening for SARS-CoV-2 in women admitted for delivery. **New Engl J Med**. Apr 13, 2020. Online publication. [https://www.nejm.org/doi/full/10.1056/NEJMc2009316].
5. Mizumoto K, Kagaya K, Zarebski A, Chowell G. Estimating the asymptomatic proportion of coronavirus disease 2019 (COVID-19) cases on board the Diamond Princess cruise ship, Yokohama, Japan, 2020. **Euro Surveill**. 2020; 25(10):2000180.
6. Kimball, et al. Asymptomatic and presymptomatic SARS-CoV-2 infections in residents of a long-term care skilled nursing facility — King County, Washington, March 2020. **Morbidity and Mortality Weekly Report**. Apr 3, 2020. Online publication. [https://www.cdc.gov/mmwr/volumes/69/wr/mm6913e1.htm]
7. "26 test positive for COVID-19 at Adult and Teen Challenge." **The Sentinel Record**. [Hot Springs, AR]. Apr 18, 2020. Online publication. [https://www.hotsr.com/news/2020/apr/18/26-test-positive-for-covid-19-at-adult-/]
8. Stadlbauer, et al. A detailed protocol for a serologic assay to detect SARS-CoV-2 seroconversion in humans: antigen production and setup. Apr 2020. Online Publication. [https://labs.icahn.mssm.edu/krammerlab/wp-content/uploads/sites/68/2020/03/Stadlbauer-and-Amanat-COVID19-antigen-expression-and-serology-protocol-3_22_20.pdf].
9. Amanat, et al. A serological assay to detect SARS-CoV-2 seroconversion in humans." **MedRxIV**. Mar 2020. Online publication. [https://www.medrxiv.org/content/10.1101/2020.03.17.20037713v2].
10. Food and Drug Administration EUA. Apr 15, 2020. [https://www.fda.gov/media/137032/download].
11. Package Insert. [https://www.fda.gov/media/136625/download]
12. Obuchowski N, Zhou X. Prospective studies of diagnostic test accuracy when disease prevalence is low. **Biostat** 2002; 3(4), 477-492.
13. Arya R, Antonisamy B., Kumar S. Sample size estimation in prevalence studies. **Indian J Pediatr** November 2012; 79(11):1482-1488.

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UAMS COPH BUDGET

DETAIL BUDGET FOR INITITAL BUDGET PERIOD DIRECT COSTS ONLY						FROM 5/1/2020	THROUGH 10/31/2020	
PERSONNEL (Applicant Organization Only)		Months Devoted To Project						
NAME	ROLE ON PROJECT	% effort	Acad. Mnths	Sum. Months	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Victor Cardenas	PD/PI	50.00%			$ 133,547	$ 38,951	$ 11,295.79	$ 50,247
Lori Fischbach		50.00%			$ 136,653	$ 39,857	$ 11,558.57	$ 51,416
James Selig		10.00%			$ 144,125	$ 8,407	$ 2,438.11	$ 10,845
Ben Amick		5.00%			$ 245,000	$ 7,146	$ 2,072.29	$ 9,218
TBN Graduate Assistant		50.00%			$ 30,000	$ 8,750	$ -	$ 8,750
TBN Graduate Assistant		50.00%			$ 30,000	$ 8,750	$ -	$ 8,750
10 -TBN Call Center Interviewers		100.00%			$ 45,760	$ 266,928	$ 77,409	$ 344,337
Jay Gandy	PD/PI	5.00%			$ 252,500	$ 7,365	$ 2,135.73	$ 9,500
TBN: Marshallese Data Collector		25.00%			$ 38,200	$ 3,183	$ 827.67	$ 4,011
TBN: Marshallese Data Collector		25.00%			$ 42,000	$ 3,500	$ 910.00	$ 4,410
TBN: Clinic/Project Manager		15.00%			$ 65,000	$ 3,250	$ 845.00	$ 4,095
Ted Brasfield		10.00%			$ 77,992	$ 4,550	$ 1,319	$ 5,869
SUBTOTALS →→						**$ 400,637**	**$ 110,812**	**$ 511,448**

CONSULTANT COSTS			$ -
EQUIPMENT (Itemize)			$ -
SUPPLIES (Itemize by Category) office supplies miscellanous supplies			$ 1,500
TRAVEL mileage (Dr. Amick to Fayetteville) lodging & meals		1176 1050	$ 2,226
PATIENT CARE COSTS	INPATIENT		$ -
	OUTPATIENT		$ -
ALTERATIONS AND RENOVATIONS (Itemize by category)			$ -
OTHER EXPENSES (Itemize by category) Open access journals Dynata Corporation Random Digit Dial list of call numbers		9000 14000	$ 23,000
CONSORTIUM/CONTRACTUAL COSTS		Direct	$ -
		SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	$ 538,174
CONSORTIUM/CONTRACTUAL COSTS		Indirect	$ -
		TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	$ 538,174

Josh Kennedy/Jeff Moran research laboratory and LDT

		Cost	% Effort/Allocation		Actual Annual Cost		Monthly Cost
Personnel							
1 Analyst Salary and fringe (TBD)			100%	$	85,000.00	$	7,083.33
1 Analyst Salary and fringe (TBD)			100%	$	85,000.00	$	7,083.33
1 Laboratory Technician (TBD)			100%	$	50,000.00	$	4,166.67
Laboratory Technical Lead (TBD) - reviews test results			45%	$	100,000.00	$	8,333.33
Laboratory Director Salary and fringe (TBD) - generally Pathologist			10%	$	250,000.00	$	20,833.33
QA/QC Officer Salary and Fringe (TBD)			20%	$	100,000.00	$	8,333.33
redCAP and informatics support			50%	$	98,000.00	$	8,166.67
Data integration/management			30%	$	25,500.00	$	2,125.00
Jeff Moran, PhD (Consultant)			10%	$	30,000.00	$	2,500.00
			Subtotal based on %	$	823,500.00		
Equipment							
EVO 150 for Sample Accessioning (3,000 samples per week)							
TECAN Freedom EVO - Robiotic System for ELISA testing (3,000 samples per week)	$	300,000	100%	$	300,000.00	$	25,000.00
Protein manufacturing/purification	$	35,000		$	35,000.00		
Consumable Supplies							
Laboratory Consumable Supplies - Estimated at $1.50 per sample (pipet tips, glassware, general lab equipment, gases, ppe, etc.)	$	150,000	100%	$	150,000.00	$	12,500.00
Sub-Total	$	485,000		$	1,308,500.00	$	106,125.00
Total Costs	$	485,000.00		$	1,308,500.00	$	106,125.00

ACRI Budget

Pediatric Convenience Sample Collection

DETAIL BUDGET FOR INITITAL BUDGET PERIOD DIRECT COSTS ONLY						FROM 6/1/2020	THROUGH 5/30/2021	
PERSONNEL (Applicant Organization Only)		Months Devoted To Project						
NAME	ROLE ON PROJECT	% effort	Acad. Mnths	Sum. Months	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Heather Young	PD/PI	10.00%			$ 145,000	$ 14,500	$ 4,205.00	$ 18,705
Sandi McCullough (laboratory assoc)		30.00%			$ 52,000	$ 15,600	$ 4,992.00	$ 20,592
Administrative support		40.00%			$ 55,000	$ 22,000	$ 4,387.00	$ 26,387
SUBTOTALS →→						**$ 52,100**	**$ 13,584**	**$ 65,684**
CONSULTANT COSTS Research Coordinator Hours: 2750 hrs X 65/hour								$ 178,750
EQUIPMENT (Itemize)								$ -
SUPPLIES (Itemize by Category) Shipping supplies and shipping								$ 110,897
TRAVEL Local travel to pediatric sites								$ 500
PATIENT CARE COSTS	INPATIENT							$ -
	OUTPATIENT							$ -
ALTERATIONS AND RENOVATIONS (Itemize by category)								$ -
OTHER EXPENSES (Itemize by category) Patient incentives								$ 60,000
CONSORTIUM/CONTRACTUAL COSTS						Direct		$ -
						SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		$ 415,831
CONSORTIUM/CONTRACTUAL COSTS						Indirect		$ -
						TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		$ 415,831

Sample Collection - Adults

DETAIL BUDGET FOR INITITAL BUDGET PERIOD DIRECT COSTS ONLY						FROM 5/1/2020	THROUGH 10/31/2020	
PERSONNEL (Applicant Organization Only)		Months Devoted To Project						
NAME	ROLE ON PROJECT	% effort	Acad. Mnths	Sum. Months	INST. BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTALS
	PD/PI					$ -	$ -	$ -
Nursing support		100.00%				$ 318,229	$98,650.90	$ 416,880
						$ -	$ -	$ -
						$ -	$ -	$ -
						$ -	$ -	$ -
						$ -	$ -	$ -
						$ -	$ -	$ -
SUBTOTALS →→						$ 318,229	$ 98,651	$ 416,880
CONSULTANT COSTS								$ -
EQUIPMENT (Itemize)								$ -
SUPPLIES (Itemize by Category)								
serum gel tube or a red top tube	$0.22	12000	$2,607.60					
masks	$0.60	10000	$6,000.00					
gloves	$0.27	20000	$5,400.00					
face shields--box of 20	$106.00	225	$23,850.00					
gowns	$0.22	1000	$224.75					
Igloo 6 pack container	$15.00	100	$1,500.00					
Ice packs--box of 24	$50.00	4	$200.00					
shipping container	$26.00	7500	$195,000.00					
shipping cost	$13.10	7500	$98,250.00					
								$ 333,032
TRAVEL								
Travel 50 miles roundtrip			$115,625.00					
Community event/advertisement/coordination			$99,000					$ 214,625
PATIENT CARE COSTS	INPATIENT							$ -
	OUTPATIENT							$ -
ALTERATIONS AND RENOVATIONS (Itemize by category)								$ -
OTHER EXPENSES (Itemize by category) Incentives: $20.00 gift cards x 7500		150000						$ 150,000
CONSORTIUM/CONTRACTUAL COSTS					Direct			$ -
					SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD			$ 1,114,537
CONSORTIUM/CONTRACTUAL COSTS					Indirect			$ -
					TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD			$ 1,114,537

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD (DIRECT COSTS ONLY)

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD (from Form Page 4)				
PERSONNEL: Salary & fringe benefits. Applicant organization only		$ 1,817,511.93			
CONSULTANT COSTS		$ 178,750.00			
EQUIPMENT		$335,000			
SUPPLIES		$ 595,429.35			
TRAVEL		$ 217,351.00			
PATIENT CARE COSTS INPATIENT		$ -			
PATIENT CARE COSTS OUTPATIENT		$ -			
ALTERATIONS AND RENOVATIONS		$ -			
OTHER EXPENSES		$ 233,000.00			
CONSORTIUM/CONTRACTUAL COSTS DIRECT		$ -			
SUBTOTAL DIRECT COSTS		$ 3,377,042.28			
		$ -			
CONSORTIUM/CONTRACTUAL COSTS F&A		$ -			
TOTAL DIRECT COSTS		$ 3,377,042.28			

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PERIOD OF SUPPORT

JUSTIFICATION: Follow the budget justification instructions exactly. Use continuation page as needed.