



COMMONWEALTH OF VIRGINIA
STANDARD CONTRACT

Contract No. UCPJMU5954

This contract entered into this 19th day of February 2021, by Motir Services, Inc., hereinafter called the "Contractor" and Commonwealth of Virginia, James Madison University called the "Purchasing Agency".

WITNESSETH that the Contractor and the Purchasing Agency, in consideration of the mutual covenants, promises and agreements herein contained, agree as follows:

SCOPE OF CONTRACT: The Contractor shall provide the services to the Purchasing Agency as set forth in the Contract Documents.

PERIOD OF PERFORMANCE: From February 19, 2021 through February 18, 2022 with two one-year renewal options.

The contract documents shall consist of:

- (1) This signed form;
- (2) The following portions of the Request for Proposal FDC-1101 dated December 11, 2020:
 - (a) The Statement of Needs,
 - (b) The General Terms and Conditions,
 - (c) The Special Terms and Conditions together with any negotiated modifications of those Special Conditions;
 - (d) Addendum One, dated January 5, 2021;
- (3) The Contractor's Proposal dated January 12, 2021 and the following negotiated modification to the Proposal, all of which documents are incorporated herein.
 - (a) Negotiations Summary, dated February 5, 2021.

IN WITNESS WHEREOF, the parties have caused this Contract to be duly executed intending to be bound thereby.

CONTRACTOR:

By: Emmanuel O. Irono
(Signature)

Emmanuel O. Irono
(Printed Name)

Title: President & CEO

PURCHASING AGENCY:

By: Doug Chester
(Signature)

Doug Chester
(Printed Name)

Title: Buyer Senior

**RFP # FDC-1101, Clinical Staffing and Services for COVID Testing/Vaccinations
Negotiation Summary for Motir Service, Inc.**

February 5, 2021

1. Parties agree that items within this Negotiation Summary modify RFP# FDC-1101 and the Contractor's response to RFP# FDC-1101 and that this Negotiation Summary takes precedence in conflict.
2. The rate schedule is as follows:

Motir Services, Inc. Testing Capacity: 1,000 Tests per day (8-hours)				
Positions	Number of Positions	Hour/Day	Billing Rate	Bill - Per Day/1,000
Clinical Director	1	8	\$75.00	\$600.00
RN's including Quality Control	8	8	\$65.00	\$4,160.00
Logistics	3	8	\$39.00	\$936.00
Licensed Practical Nurse	4	8	\$46.00	\$1,472.00
Certified Nursing Assistant (C.N.A.) or Medical Assistant (MA)	4	8	\$32.00	\$1,024.00
IT (Network Support)	1	8	\$52.00	\$416.00
Security	2	8	\$38.00	\$608.00
Data Management	2	8	\$44.00	\$704.00
TOTAL	25	64		\$9,920.00
PPE & Other Related Material Cost - Reimbursable				
	Cost	Cost including Admin Fee (13%)	Minimum Tests Per Day	Bill/Day
Reimbursable Material Cost	\$430.00	\$485.90	1,000	\$485.90
Subscribed User Fee	\$2.00	\$2.26	1,000	\$2,260.00
Administering Cost of Vaccination	\$1.50	\$1.70	1,000	\$1,695.00
Cost of capacity testing site per person	\$2.99	\$3.38	1,000	\$3,378.70
Initial Deployment Cost	\$1,200.00	\$1,356.00	1,000	\$1,356.00
Refrigerated/Freezer Transportation for Vaccination	\$360.00	\$406.80	1,000	\$406.80
Site Network/Server	\$650.00	\$734.50	1,000	\$734.50
Logistics	\$1,235.00	\$1,415.89	1,000	\$1,415.89
PPE	\$650.00	\$734.50	1,000	\$734.50
Other Supplies	\$300.00	\$339.00	1,000	\$339.00
TOTAL	\$4,849.49	\$5,334.44		\$12,806.29
TOTAL COST/DAY/1,000 PERSON				\$22,726.29
COST PER PERSON				\$22.73

Motir Services, Inc. Vaccination Capacity: 1,000 Tests per day (8-hours)				
Positions	Number of Positions	Hour/Day	Billing Rate	Bill - Per Day/1,000
Clinical Director	1	8	\$75.00	\$600.00
RN's including Quality Control	8	8	\$65.00	\$4,160.00
Logistics	3	8	\$39.00	\$936.00
Licensed Practical Nurse	4	8	\$46.00	\$1,472.00
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TOTAL COST/DAY/1,000 PERSON				\$22,726.29
COST PER PERSON				\$22.73

Testing and vaccination pricing is based on minimum 1,000 people per day. MOTIR can scale up to 2,000 or 3,000 based on needs and budget.

- Should travel be required during the term of this contract, all travel expenses shall be in accordance with the U.S. General Services Administration (GSA) allowance for lodging, meals, and incidentals.

<http://www.gsa.gov/portal/content/104877>

<http://www.gsa.gov/portal/content/101518>

4. Contractor agrees that all exceptions taken within their initial response to RFP# FDC-1101 that are not specifically addressed within this negotiation summary are null and void.
5. Contractor has disclosed all potential fees. Additional charges will not be accepted.



JAMES MADISON UNIVERSITY

Clinical Staffing and Services for COVID Testing/Vaccinations Clinics

RFP# FDC-1101



Submitted By:

Dr. Emmanuel O. Irono
President & CEO
Motir Services, Inc.
1508 East Capitol Street, NE
Washington DC, 20003
P: (202) 371-9393
F: (202) 289-1611
Email: eirono@motirservices.com
Website: www.motirservices.com

Submitted To:

Doug Chester, Buyer Senior-Procurement
Services,
Commonwealth of Virginia
James Madison University
Procurement Services MSC 5720
752 Ott Street, Wine Price Building
First Floor, Suite 1023
Harrisonburg, VA 22807
P: 540-568-4272;
Email: chestefd@jmu.edu

PROPOSAL

January 12, 2020 at 2:00 p.m.



This data furnished pursuant to this solicitation shall not be disclosed outside James Madison University be duplicated, or used, in whole or in part, for any purpose other than to evaluate the offer.

January 12, 2021

Doug Chester
Commonwealth of Virginia
James Madison University
Procurement Services MSC 5720
752 Ott Street, Wine Price Building
First Floor, Suite 1023
Harrisonburg, VA 22807

RE: Clinical Staffing and Services for COVID Testing/Vaccinations Clinics

Dear Mr. Chester:

Motir Services, Inc. (“MOTIR”) is pleased to leverage its twenty-seven (27) years of specialized clinical staffing and other clinical demonstrated services experience responding to emergency infectious disease crises, managing and operating educational institutions clinics, government agencies’ clinics and private organization employment clinics to provide clinical support services to *mitigate risks towards the eradication* of coronavirus disease (COVID-19), Flu, and other infectious diseases. During this global public health crisis MOTIR has pulled together faith-based community organizations and organizations representing several minority groups within targeted communities across the DMV area to be tested for the COVID-19 virus and assist with educating about the COVID-19 vaccine. As a 27-year old, full-service support services company located in Washington, DC, Prince George’s, Maryland, and Atlanta, Georgia MOTIR is pleased to submit this proposal for the Large Scale Testing/Vaccinating of clients of James Madison University for COVID-19 and any other clinical services upon request.

MOTIR Medical Staffing Division whose service philosophy and dedication to quality have attracted attention for COVID-19 related services, since the pandemic throughout the DMV area. Founded in 1994, MOTIR is an experienced, successful provider of support services to our government and commercial clients local and internationally. MOTIR is a Small Business Administration 8(a) graduate and twenty-five (25) year United States Department of Transportation (DOT) Certified Disadvantaged Business Enterprise and Capital Region Minority Supplier Diversity Council (CRMSDC) Minority Owned Business (MBE). Our experience successfully delivering a customized array of services to government, military, commercial, and private sector clients includes, medical staffing, environmental & biohazard cleaning services, operations and maintenance support.

MOTIR Medical Staffing, a division of MOTIR, specializes in the delivery of quality, experienced professionals to support the needs of our government, military and private sector clients. For over two decades, MOTIR Medical Staffing has provided outstanding clinical staff which has helped to shaped successful, clinical and technological innovation health system for our clients.

MOTIR’s demonstrated experience in the quick response and ongoing transformation in clinical staffing and services due to the current pandemic has made us nationally recognized for redefining clinical staffing by:

- Putting our employees, clients, community and stakeholders at the center of everything we do and creating a staffing model that ensures that every client gets the quality staff, timely, superb customer service everytime.
- Harnessing our integrated capabilities to deliver both superb services and care for our clients while maintaining high value to our stakeholders.
- Partnering with our local and community universities in employing undergraduates and graduates who have attained advance understanding of disease, its prevention, treatment, and cure.
- Fueling the development of new business within the surrounding communities in spite of the current business environment. With this ongoing catalyst and driver of economic development local residents benefit from employment which is provided.
- Serving the underserved and disadvantaged as we have positioned MOTIR to assist our clients in advancing excellence and innovation within the healthcare system.
- MOTIR medical staffing support has been instrumental in responding to emergency infectious disease crises, critical community medical needs and urgent, 24/7/365 weather events, and is strategically positioned to provide guidance in the wake of this novel coronavirus crisis. Our experience has enabled us to recommend solutions for this COVID-19 public health crisis to provide *100% safeguards to save lives, slow the continued spread of novel coronavirus (SARS-CoV-2), mitigate the infiltration and recontamination in spaces and partnered with the AFRICIAN AMERICAN HEALTH PROGRAM (AAHP), MONTGOMERY COUNTY DEPARTMENT OF HEALTH (DHH) and CIAN Diagnostic to provide COVID-19 off-site and clinic testing.*

MOTIR stands ready to provide the personnel, management, technical, fiscal, and administrative support necessary to successfully provide COVID-19 related services to James Madison University. Please do not hesitate to call or email me directly if you have questions or need any additional information from our team at 202.371.9393 or eirono@motirservices.com.

Thank you for welcoming this update and review of our capability!

Sincerely,



Dr. Emmanuel O. Irono
President and CEO
Motir Services, Inc.

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Executive Summary

COVID-19 has been declared a Pandemic by the World Health Organization (WHO) and a Public Health Emergency (PHE) by the U.S. Government. A pandemic, as defined by the WHO, is a worldwide spread of a new disease; occurring over a wide geographic area and affecting an exceptionally high proportion of the population. Current evidence shows that the virus has infected over 22 million Americans, with over 375,000 confirmed dead. The Commonwealth of Virginia has reported over 403,000 confirmed cases, with 5,393 deaths.

MOTIR has provided throughout its existence comprehensive resources for setting up and running all types of vaccination clinics. This includes practical help including phone and text messages for patient outreach. Data analytics for deliverables and outcomes of vaccination clinics. During a pandemic, staff is usually unavailable due to sickness, injury or taking care of loved ones. MOTIR prides its continued success in this area due to its Corporate Incident Command Center (CIC) which has created a contingency plan which anticipates personnel shortages and minimizes their impact of the pandemic. This plan includes efforts to ensure that staff members remain healthy and able to perform to the best of their ability and that their families are supported. MOTIR's Compassion Fatigue Program provides training in self-care and self-resilience.

MOTIR continuously acquires and maintains an adequate, skilled and trained workforce and understands the importance of managing and providing the client with staff upon request. MOTIR not only provides the clinical staff to administer, test/vaccinate, we also partner with the client in effective deployment of vaccine and the use of various vaccination strategies depending on where the clinics are located and the population served.

Illness Severity

The complete clinical picture of COVID-19 is not fully known at this time. Reported illnesses range from very mild (including some with no reported symptoms) to severe including illness resulting in death). While information suggests that most COVID-19 illness is mild, a report out of China suggests serious illness occurs in approximately 16 percent of cases (Dr. Nancy Messonnier, Director of the National Center for Immunization and Respiratory Diseases (NCIRD) cited this in a recent telebriefing. <https://www.cdc.gov/media/releases/2020/t0303-COVID-19-update.html>). Older people and people of all ages with severe underlying health conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of developing serious COVID-19 illness.

Risk Assessment

Risk depends on characteristics of the virus, including how well it spreads between people; the severity of resulting illness, the medical or other measures available to control the impact of the virus (for example, vaccines or medications that can treat the illness) and the relative success of these measures. In the absence of a vaccine or treatment medications, nonpharmaceutical interventions become the most important response strategy; these include community interventions that can reduce the impact of disease.

Risk from COVID-19 can be broken down into risk of exposure versus risk of serious illness and death:

- Risk of Exposure is increased for:
- People in places of reported, ongoing community spread of the virus that causes COVID-19, with the level of risk dependent on the location

- Healthcare workers caring for patients with COVID-19
- Close contacts of persons with COVID-19
- Travelers returning from affected international/local locations where community spread is occurring, with level of risk dependent on where they traveled
- Risk of Severe Illness is increased for:
- Older adults, with risk increasing by age
- People who have serious chronic medical conditions, such as: heart disease, diabetes, lung disease, and hypertension

The focus of MOTIR's preparedness model has been to maintain an "all service COVID-19" core high response capability for all of our clients. MOTIR is ensuring active partnership between JMU and MOTIR Medical Staffing Division. MOTIR will coordinate activities with JMU team to:

- Limit the spread of COVID-19 infection among Commonwealth of Virginia's residents
- Provide care for those infected with COVID-19,
- Provide education about the COVID-19 vaccine.

MOTIR's plan will outline response activities for COVID-19 testing/vaccinating. MOTIR will conduct all activities necessary to protect and reduce the spread of COVID-19 among the targeted population and ensure continuity of access to and delivery of healthcare service and COVID-19 informative information as appropriate. Also, as stated in the transmittal letter, MOTIR will perform all related COVID-19 services required under this RFP.

Corporate Overview

Motir Services, Inc. (MOTIR) has over 27 years of demonstrated experience delivering comprehensive support services to its customers and is strategically positioned to offer testing/vaccinating for JMU clinics across the Commonwealth of Virginia. Throughout the COVID-19 pandemic, MOTIR has successfully executed its *rapid response containment, decontamination, medical monitoring and continuous sanitization solutions* to government and commercial clients seeking to eradicate *coronavirus*. From containment support for infectious disease control of methicillin-resistant Staphylococcus aureus (MRSA) to treating, air scrubbing and wipe-down cleaning of *Sarcoptes scabiei* (scabies), MOTIR has a demonstrated track record of successful responsiveness to public health emergencies. Working in both classified and unclassified environments.

MOTIR Medical Staffing Division COVID-19 Capability Response Plan

The Capability and Response Plan approved January 2020, provides strategic guidance for the coordination of MOTIR Services during this pandemic breakout, a focus on viral pandemic pathogens. Our plan incorporates Center for Disease Control and Prevention(CDC), States and local Health Departments, Occupational Health and Safety Administration (OSHA) and James Madison University recommendations.

Over the past year MOTIR has set up and run walk-thru clinics so that patients can get their flu vaccination while adhering to the recommended social distancing and congregation guidelines, ensuring separation between sick and healthy patients, and helping to limit traffic flow through clinic.

Corporate Level Roles and Responsibilities

The corporate office coordinates RFP scope of work, support and consequence management. Corporate supports MOTIR Medical Staffing Division, as requested, to assist medical staff, logistic team, program management and partner with preparedness, and response activities. As defined below:

- Corporate will provide PPE fit-testing, medical screening, and training for all staff and other response personnel.
- Provide corporate staff as liaisons to field staff in the Incident Management Center deploying to the county targeted areas testing centers.
- Provide clinic guidance and logistical blueprint of setup of clinic.

MOTIR follows CDC revised Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations. To facilitate the most efficient and safe delivery of available vaccine via large community clinics, MOTIR follows these recommendations and guidelines which have been developed to assist with planning large-scale vaccination clinics for public and private clients. Ideally, plans from private and public groups should be shared to identify best practices, avoid unnecessary overlapping of services, and maximize the effective and efficient delivery of vaccinations.

SET UP AND ADMINISTRATION OF STAFFING AND SERVICES (RFP C1)

Resources are available for hosting a vaccination clinic outside of traditional medical setting, including a step-by-step guide to help clinic coordinators/supervisors who oversee vaccination clinics at temporary, off-site or satellite settings. These resources follow CDC guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation.

OUTDOOR TESTING	LESS THAN 100 RESIDENTS SCHEDULED FOR TESTING	ASSESSMENTS
LOCATION Personnel	<p>Large Parking lot (2 separate entrances referred.)</p> <p>8 Medical Personnel: 1— Registered Nurse: Will provide supervision for the oversight for the entire testing program to ensure proper infectious disease and proper chain of custody procedures are followed. Will provide on site guidance for residents actively showing symptoms and provide resident follow-up and COVID-19 planning for any residents testing positive. Continuous link to medical facilities, hospitals, ER with Motir Medical Directors and Area physicians for active. acceptance and admission and management of COVID and comorbidities. Ensures collected specimens are picked up in good time by couriers.</p> <p>3 Licensed Practical Nurses: Will administer the testing while the residents remain in their vehicles. 2 at any time testing while the 3rd one engages in product specifications and availability, communication, and feedback to RN. The specimen tube needs to be completely labeled: full name, DOB, type of swab, date and time of collection, name of person collecting.</p> <p>2 Certified Nursing Assistants: Will gather resident information and screen residents prior to seeing the LPN</p> <p>1 Certified Nursing Assistant: Will take completed tests from LPN's and ensure there is no cross contamination and the proper chain of custody is followed.</p>	<p>-Entrance and Exit. Limited grass. No sands. Cleared a day prior -Ready area physicians for treatments/ advancement of care known ahead of exercise -Assess weather forecasts -Traffic director by the Client -Incentive packages encouraged</p>
Equipment	<p>Drive-up Tents Covered Tables: longitudinal PPE Test kits (to be provided by client) Safety Barriers Medical Waste bags. Signage Cones Coolers. Ice packs Sanitization Stations for Cleaning, Disinfection, Sterilization. Thermometers</p>	<p>Space to be assessed by MOTIR for installations with assessment of sizes of tents to space</p>
Procedures	<p>Kits refrigerated in coolers with ice packs. "Shorter" regular Q tip looking swabs for nasal swabs, longer ones for pharyngeal swabs. Nasals go back into the nares, both sides, down to half the stick part so pretty far, but does not need to go to nasopharynx. (Must be done by licensed Motir staff) The "longer, thinner" swab is the nasopharyngeal swab and needs to go all the way back until you hit the back, but only on one side. Like most viral swabs if individual can "sit in place" for a bit the sampling is improved.</p>	

NEEDS OF THE TESTING SITE (RFP C2)

1. Clinic Logistics:

- Leadership Roles
- Human Resource Needs
- Vaccination Clinic Location
- Clinic Lay-out and Specifications
- Crowd Management Outside of the Clinic
- Crowd Management Inside of the Clinic
- Clinic Security
- Clinic Advertising

2. Vaccine Storage, Handling, and Administration:

1. Vaccine Storage and Handling
2. Vaccine Administration
3. Vaccine Documentation

3. Leadership Roles

- Designate local clinic leaders for overall vaccination campaign operations, and leaders for communications systems from both the public and private sectors.
- Designate a clinic manager and a team leader each for supplies, logistics, medical personnel, support functions and their respective backups.
- Designate a leader to oversee infection control at the clinic, which includes ensuring that healthcare personnel who are preparing and administering the vaccinations are appropriately trained on safe injection practices.

4. Human Resource Needs

- Secure staff to fill the positions of greeters-educators, priority client screeners, registration personnel, medical screeners, form/payment collectors, clinic flow controllers, vaccination assistants, vaccination administrators, security and emergency medical personnel.
- Meet the language needs of the community using multi-lingual staff.
- Prepare staff members to know and execute their responsibilities and be able to correctly answer questions from clients.
- Ensure clinic staff are trained and have demonstrated knowledge in the proper vaccine storage, handling and administration of vaccines.
 - Vaccine Storage& Handling Toolkit 2.74 MB, 49 pages]
 - Vaccine Administration Recommendations and Guidelines
- Cross-train staff members, if possible, to enable flexibility in meeting needs at various stations as demands fluctuate.
- Make provisions for surge capacity staffing, particularly at clinic opening time, where pre-scheduling will not be done or large numbers of unscheduled clients are anticipated.

5. Clinic Lay-Out and Specifications

Set up for unidirectional client flow from an external gathering area → eligibility screening area (multiple stations) → clinic entrance → facility waiting area(s) → registration/question and

answer/form completion area (multiple stations) → medical screening/treatment area (as needed) → Medicare and other payment area (multiple stations) → vaccination area (multiple stations) → exit at a location distant from the entrance.

- Clinics should also have a designated area for vaccine preparation. Vaccines should not be prepared (including drawing up) at the individual vaccination stations.
- Use liberal amounts of rope, stands and signs in multiple languages, as needed, in outside waiting area(s) and inside clinic to delineate routes for clients to follow from station to station.
- Provide adequate number of copies of Vaccine Information Statements in the Question and Answer area. Staff should be trained to answer common questions.
- Provide seating for clients and the person administering the vaccine at each vaccination station and have one or more vaccination stations with surrounding screens where over-clothed clients can discreetly bare their arms for vaccination. Each station must also have adequate administration supplies.
- Section off private area(s) where clients who experience acute adverse events after vaccination or who have medical problems can be evaluated and treated.
- Adequate number of computers/tablets and internet access to determine immunization history in the state or regional Immunization Information system of clients presenting for vaccination.
- Ensure the presence of an onsite emergency medical kit and a designated trained physician, emergency medical technician (EMT), pharmacist, or nurse certified in basic cardiopulmonary resuscitation who can administer treatment for allergic reactions and address urgent medical problems
- Clinics should submit information on vaccinations administered to the jurisdiction's immunization information system (IIS) or vaccine registry. Consult your jurisdiction or state immunization program for more information as requirements and specifics may vary.

6. Crowd Management Outside of the Clinic

- Schedule staff to arrive 1 to 2 hours before clinic opening time to welcome and screen clients for vaccine eligibility, indications and contraindications and for insurance, if insurance will be billed for the vaccination, even if pre-scheduling is being used.
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) for expedited access into the clinic.
- Direct arriving clients into several lines and use numerous signs and announcements to clarify who falls into high-risk groups.
- Communicate the number of vaccine doses available at the clinic to the clients.
- Instruct clients to assess their eligibility to receive vaccination by reviewing the CDC, or similar, self-screening form and ensure staff administering vaccines review the forms with the clients prior to vaccination.
 - Provide all clients with an up-to-date vaccine information statement (VIS).
 - Provide language translation services where necessary.
 - Update clients on their estimated waiting times to be screened.
 - Schedule at least 2 screeners per line to reduce crowd size and waiting times by rapidly identifying and retaining prioritized clients and letting others know about vaccination priorities of the clinic.
 - Consider distributing sequentially numbered tickets, VIS or other forms in appropriate languages that permit entry into the clinic to persons in prioritized patient groups only.
 - Provide clients who cannot be served for lack of vaccine an up-to-date listing of alternative clinics providing vaccinations.

7. Crowd Management Inside of the Clinic

- Vaccinate clients in the order of their numbered tickets.
- Arrange accommodations for special-needs clients (e.g., persons with disabilities, very advanced age or fragility) to receive expedited vaccination – consider a dedicated vaccination line.
- Communicate clinic updates and wait times for vaccination so that clients are free to leave and return to be vaccinated.
- Assist clients in completing required forms (e.g., consent forms and/or vaccination cards) by having sufficient registration staff available.
- Maintain a steady flow of clients through the clinic so that vaccinators are never without a client at their stations; redirect clients who create bottlenecks.
- Provide adequate facilities (e.g., waiting areas, restrooms, water) to meet the needs of the clients.

8. Clinic Security

- Require all staff to wear identification cards color coded for their job functions.
- Consider using uniformed presence to act as security and assist in managing crowds.
- Employ security personnel to monitor the mood of waiting crowds and communicate deteriorating situations to the clinic manager.
- Secure the vaccine and protect clinic staff and their valuables.
- Recruit local volunteers familiar to clinic customers since they may be especially effective in diffusing crowd-related tension.

9. Staff and Team Pre-selection.

10. Suppliers of product selection to supplement MOTIR's bank of resources, ensuring no break in testing exercise.

11. Invitations and Request for any Information from clients about their intended groups.

12. Develop documents that include additional requirements or changes in testing plans such that considers weather changes and forecasts.

ACTIVE CONTINUOUS SESSIONS

1. Determine indoors or outdoors appropriateness.
2. Set ups and product considerations

DETERMINING NUMBER OF TEST/VACCINATIONS TO BE PROVIDED & ESTIMATED NUMBER OF TESTS PER DAY (RFP C3, C9)

MOTIR has the capability to test up to 500 students, staff and employees per day. We have the capability to vaccinate up to 500 students, staff and employees per day.

Monitor response of population. Assess and evaluate testing success. Assess sensitization of group done at different times during testing.

Post Testing surveillance. Establish system for continuous monitoring and of assessment of groups. Testing results and professional handling of deliverance with Identification and Notification. Clients feedback and end user feedback.

Staff Education on improper administration of vaccines will be conducted All personnel who will administer vaccines will receive comprehensive, competency-based training regarding vaccine administration policies and procedures before administering vaccines. Staff knowledge and skills regarding vaccine administration are validated prior to assignment.

NUMBER AND TYPE OF STAFF (RFP C4)

Role	# of Staff	Responsibilities
Clinical Director	1	The Site Lead is responsible for all aspects of the Site, including quickly developing incident objectives, managing all operations, application of resources, as well as responsibility for all persons involved.
Registered Nurse	9	The RN is responsible for the effective and efficient processing of participants through the test Site. Serves as a backup to the Swabber at the Sample Station, as required. The RN monitors incident operations and advises Site Lead on all matters relating to operational safety, including the health and safety of emergency responder personnel.
Data Management	2	Responsible for executing tasks that require accessing Patients data, including creating the Requisition Kits and troubleshooting issues like data mismatch or incorrect appointment information. Management of Command Center In proximity to supplies and staff area. Verify biometrics data is correct.
Security	2	Checkpoint staff is responsible for providing initial traffic control support to the Site, redirecting non-participants off Site, and ensuring participants present appointment information to downstream Checkpoints.
(CNA) Certified Nursing Assistant	8	CNA is responsible for distributing Requisition Kits to participants, confirming participant information matches the requisition, providing traffic control support to Sample Station and redirecting non-participants off Site.

(LPN) Licensed Practical Nurses	1	LPN is responsible for confirming participant information, performing nasopharyngeal swab, or assisting in mid-turbinate swab collection, preparing and labeling the sample test kit for delivery to test vendors, performing sample reconciliation, and completing decontamination procedures in the hot zone. LPN is also responsible for providing traffic control support to direct participants off site.
Logistics	2	Coordinating and moving resources – people, materials, inventory, and equipment –at the desired destination. focuses on planning, optimizing, and executing the use of vehicles to move goods between warehouses, retail locations and customers
Security	2	Assist in participant flow and traffic control through the Site, Traffic Controller.

TRAINING & LICENSES AND CERTS REQUIRED OF STAFF (RFP C5, C6)

Staff Education on improper administration of vaccines will be conducted All personnel who will administer vaccines will receive comprehensive, competency-based training regarding vaccine administration policies and procedures before administering vaccines. Staff knowledge and skills regarding vaccine administration are validated prior to assignment. Staff will receive HIPPA and FERPA training, background checks, and drug screenings.

PPE FOR STAFF (RFP C7)

MOTIR will provide all staff and personnel at each site to wear facial masks that shields the nose and mouth, facial shields and protective garmets.

PROTOCOLS TO ENSURE STAFF IS NOT COVID-19 POSITIVE (RFP C8)

MOTIR performs regular screening of all personnel to ensure there are no COVID-19 positive staff members.

TEST REPORTING BY 10AM & REPORTING TO VDH (RFP C10, C15)

MOTIR has the capability to provide test results reporting by 10am the following day. Please see Appendix B for MOTIR's Daily Status Call Report.

SITE SUPERVISION (RFP C11)

MOTIR provides supervision at each testing site. Please see Appendix A for the Project Daily Status Report to understand MOTIR's supervision of each testing site.

FEES PER TYPE OF STAFF (RFP C12)

Please see the Pricing Schedule.

BINAXNOW (RFP C13, C17, C18)

MOTIR adheres to the BinaxNow method of testing. Please see Appendix C for our BinaxNOW Procedures.

POSITIVE TEST RESULTS WITHIN THE TIME PERIOD (RFP C14)

MOTIR has the capability to provide positive test results to the individual and the designated University representative on a real time basis. Please see Appendix B for MOTIR's Daily Call Report.

SETUP AND MAINTAIN MULTIPLE LOCATIONS (RFP C16)

MOTIR has the capability to maintain up to five (5) sites simultaneously.

RELEVANT PAST PERFORMANCE (RFP. IV.B.)

CONTRACT REFERENCE 1	
Contract	20-PO-0012 AAHP COVID-19 Testing for Montgomery County
Estimated Annual Dollar Amount	\$2,400,000
Contract Term	October 2020 – June 2021
Point of Contact	Beatrice Miller, Executive Committee Chair Phone: 240-848-5575 Email: nurse@aahpcovid.com
Type of Contract/Services Provided	MOTIR provided clinic and non-clinical, staff to administer PCR COVID-19 testing for different types of clinical setting, indoor and outdoor. Mass scale and small scale. Tested over 5000 residents in two months.

CONTRACT REFERENCE 2	
Contract	PO594374, DC Health Immunization Program for Pediatric & Adults
Estimated Annual Dollar Amount	\$300,000
Contract Term	2007 - 2019
Point of Contact	Vivian Walker Phone: 202-442-5955 Email: Vivian.walker@dc.gov
Type of Contract/Services Provided	MOTIR provides nurses and other medical personnel to help reduce the spread of vaccine preventable diseases to resident, visitors and those working or doing business in the District. MOTIR's nurses provide patients with evidence -based information about vaccine safety, potential side effects, and the importance of immunization. MOTIR's nurses administer vaccines to infants, children and adults for 8 hours or more in a day.

CONTRACT REFERENCE 3	
Contract	CW81602 Medical Doctors and Nurses, COVID-19
Estimated Annual Dollar Amount	\$1,100,000.00
Contract Term	2020
Point of Contact	Dena Hasan Phone: 202-442-5955 Email: dena.hassan@dc.gov
Type of Contract/Services Provided	MOTIR provided Licensed Practical Nurses (LPN's) to provide COVID-19 screening and testing services in 5 homeless shelters in the District of Columbia. MOTIR tested approximately 600 people per day.

CONTRACT REFERENCE 4	
Contract	LCISS17D0033 Registered Nurses & Nurse Practitioners at Library of Congress
Estimated Annual Dollar Amount	\$300,000.00
Contract Term	2007 - 2018
Point of Contact	Dr. Sandra Charles Phone: 202-707-5000
Type of Contract/Services Provided	MOTIR provided Registered Nurses with a specialization in occupational health to independently monitor, assess, and diagnose the health status of LOC staff in accordance with Medical Directives to improve an inter-disciplinary approach to healthcare and prevention-oriented interventions (eg stress management, smoking cessations, fitness/nutrition, etc.); treat infectious disease, provide immunization, preventive care and health coordination, counseling, screening, referrals and case management.

CONTRACT REFERENCE 5	
Contract	3011523, Government Printing Office (GPO) Occupational Health Nurses
Estimated Annual Dollar Amount	\$300,000.00
Contract Term	2008 - 2018
Point of Contact	Beverly Williams Phone: 202-512-2061
Type of Contract/Services Provided	MOTIR provided Registered Nurses with a specialization in occupational health to independently monitor, assess, and diagnose the health status of 1,800 GPO staff in accordance with Medical Directives to improve employees health and safety 24 hours a day. MOTIR's OHN provide an inter-disciplinary approach to healthcare and prevention-oriented interventions (eg stress management, smoking cessations, fitness/nutrition, etc.); treat infectious disease, provide immunization, preventive care and health coordination, counseling, screening, referrals and case management.

REQUEST FOR PROPOSAL

RFP# FDC-1101

Issue Date: 12/11/2020
Title: Clinical Staffing and Services for COVID Testing/Vaccinations Clinics
Issuing Agency: Commonwealth of Virginia
James Madison University
Procurement Services MSC 5720
752 Ott Street, Wine Price Building
First Floor, Suite 1023
Harrisonburg, VA 22807

Period of Contract: From Date of Award Through One Year (Renewable)

Sealed Proposals Will Be Received Until 2:00 PM on January 12, 2021 for Furnishing The Services Described Herein.

SEALED PROPOSALS MAY BE MAILED, EXPRESS MAILED, OR HAND DELIVERED DIRECTLY TO THE ISSUING AGENCY SHOWN ABOVE.

All Inquiries For Information And Clarification Should Be Directed To: Doug Chester, Buyer Senior, Procurement Services, chestefd@jmu.edu; 540-568-4272; (Fax) 540-568-7935 not later than December 18th.

NOTE: James Madison University will be closed for winter break from Tuesday, December 22, 2020 through Friday, January 1, 2021

NOTE: THE SIGNED PROPOSAL AND ALL ATTACHMENTS SHALL BE RETURNED.

In compliance with this Request for Proposal and to all the conditions imposed herein, the undersigned offers and agrees to furnish the goods/services in accordance with the attached signed proposal or as mutually agreed upon by subsequent negotiation.

Name and Address of Firm:

Motir Services, Inc.

1508 East Capitol Street, NE

Washington, DC 20003

By:


(Signature in Ink)

Name: Emmanuel O. Irono

(Please Print)

Date: January 12, 2021

Title: President & CEO

Web Address: www.motirservices.com

Phone: 202-371-9393

Email: eirono@motirservices.com

Fax #: 202-289-1611

ACKNOWLEDGE RECEIPT OF ADDENDUM: #1 EL #2 _____ #3 _____ #4 _____ #5 _____ (please initial)

SMALL, WOMAN OR MINORITY OWNED BUSINESS:

☒ YES; ☐ NO; *IF YES* ⇒ ☒ SMALL; ☐ WOMAN; ☒ MINORITY *IF MINORITY:* ☒ AA; ☐ HA; ☐ AsA; ☐ NW; ☐ Micro

Note: This public body does not discriminate against faith-based organizations in accordance with the Code of Virginia, § 2.2-4343.1 or against an offeror because of race, religion, color, sex, national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment.



Attachment A

ATTACHMENT A

OFFEROR DATA SHEET

TO BE COMPLETED BY OFFEROR

1. **QUALIFICATIONS OF OFFEROR:** Offerors must have the capability and capacity in all respects to fully satisfy the contractual requirements.
2. **YEARS IN BUSINESS:** Indicate the length of time you have been in business providing these types of goods and services.

Years 27 Months _____

3. **REFERENCES:** Indicate below a listing of at least five (5) organizations, either commercial or governmental/educational, that your agency is servicing. Include the name and address of the person the purchasing agency has your permission to contact.

CLIENT	LENGTH OF SERVICE	ADDRESS	CONTACT PERSON/PHONE #
African American Health Program (AAHP)	Since 2020	1401 Rockville Pike Rockville, MD 20852	Beatrice Miller 240-848-5575
DC Health	Since 2007	899 North Capitol Street, NE Washington, DC 20002	Vivan Walker 202-442-5955
DC Department of Health	Since 2020	899 North Capitol Street, NE Washington, DC 20002	Dena Hasan 202-442-5955
Library of Congress	Since 2007	101 Independence Ave, SE Washington, DC 20540	Dr. Sandra Charles 202-707-5000
Government Printing Office (GPO)	Since 2008	732 North Capitol Street, NW Washington, DC 20401	Beverly Williams 202-512-2061

4. List full names and addresses of Offeror and any branch offices which may be responsible for administering the contract.

Motir Services, Inc., 1508 East Capitol Street, NE, Washington, DC 20003

5. **RELATIONSHIP WITH THE COMMONWEALTH OF VIRGINIA:** Is any member of the firm an employee of the Commonwealth of Virginia who has a personal interest in this contract pursuant to the [CODE OF VIRGINIA](#), SECTION 2.2-3100 – 3131?

[] YES [X] NO

IF YES, EXPLAIN: N/A



Attachment B

ATTACHMENT B

Small, Women and Minority-owned Businesses (SWaM) Utilization Plan

Offeror Name: Motir Services, Inc. **Preparer Name:** Emmanuel Irono

Date: January 12, 2021

Is your firm a **Small Business Enterprise** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes X No

If yes, certification number: 940 Certification date: 1/1/2008

Is your firm a **Woman-owned Business Enterprise** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes No X

If yes, certification number: Certification date:

Is your firm a **Minority-Owned Business Enterprise** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes X No

If yes, certification number: 940 Certification date: 1/1/2008

Is your firm a **Micro Business** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes No X

If yes, certification number: Certification date:

Instructions: *Populate the table below to show your firm's plans for utilization of small, women-owned and minority-owned business enterprises in the performance of the contract. Describe plans to utilize SWAMs businesses as part of joint ventures, partnerships, subcontractors, suppliers, etc.*

Small Business: "Small business " means a business, independently owned or operated by one or more persons who are citizens of the United States or non-citizens who are in full compliance with United States immigration law, which, together with affiliates, has 250 or fewer employees, or average annual gross receipts of \$10 million or less averaged over the previous three years.

Woman-Owned Business Enterprise: A business concern which is at least 51 percent owned by one or more women who are U.S. citizens or legal resident aliens, or in the case of a corporation, partnership or limited liability company or other entity, at least 51 percent of the equity ownership interest in which is owned by one or more women, and whose management and daily business operations are controlled by one or more of such individuals. **For purposes of the SWAM Program, all certified women-owned businesses are also a small business enterprise.**

Minority-Owned Business Enterprise: A business concern which is at least 51 percent owned by one or more minorities or in the case of a corporation, partnership or limited liability company or other entity, at least 51 percent of the equity ownership interest in which is owned by one or more minorities and whose management and daily business operations are controlled by one or more of such individuals. **For purposes of the SWAM Program, all certified minority-owned businesses are also a small business enterprise.**

Micro Business is a certified Small Business under the SWaM Program and has no more than twenty-five (25) employees AND no more than \$3 million in average annual revenue over the three-year period prior to their certification.

All small, women, and minority owned businesses must be certified by the Commonwealth of Virginia Department of Small Business and Supplier Diversity (SBSD) to be counted in the SWAM program. Certification applications are available through SBSD at 800-223-0671 in Virginia, 804-786-6585 outside Virginia, or online at <http://www.sbsd.virginia.gov/> (Customer Service).

RETURN OF THIS PAGE IS REQUIRED

ATTACHMENT B (CNT'D)

Small, Women and Minority-owned Businesses (SWaM) Utilization Plan

Procurement Name and Number: FDC-1101

Date Form Completed: January 12, 2021

Listing of Sub-Contractors, to include, Small, Woman Owned and Minority Owned Businesses
for this Proposal and Subsequent Contract

Offeror / Proposer:

Motir Services, Inc.
Firm

1508 East Capitol Street, NE, Washington, DC 20003
Address

Emmanuel Irono, 202-371-9393
Contact Person/No.

Sub-Contractor's Name and Address	Contact Person & Phone Number	SBSD Certification Number	Services or Materials Provided	Total Subcontractor Contract Amount (to include change orders)	Total Dollars Paid Subcontractor to date (to be submitted with request for payment from JMU)
MOTIR, a small minority owned business will self perform all services on this contract.					

(Form shall be submitted with proposal and if awarded, again with submission of each request for payment)

RETURN OF THIS PAGE IS REQUIRED

VASCUPP

MOTIR does not have company sales with VASCUPP.

Pricing

Financial Budget RFP# FDC-1101 JMU FY 2021			January 2021 - May 2021			
Costs for Community Testing and Vaccination- Staffing						* Assumed 173 hrs. a month
Positions	No. of positions	Hours/day	Billing Rate	Bill-Per Day	Bill /month *	Billing Budget for 5 months
Clinical Director	1	8.00	75.00	600.00	12,975.00	64,875.00
Registered Nurse	2	8.00	65.00	1,040.00	11,245.00	56,225.00
(LPN) Licensed Practical Nurses	1	8.00	46.00	368.00	7,958.00	39,790.00
(CNA) Certified Nursing Assistant	1	8.00	32.00	256.00	5,536.00	27,680.00
IT (Network Systems)	1	8.00	52.00	416.00	8,996.00	44,980.00
Security	2	8.00	39.00	624.00	6,747.00	33,735.00
Data Management	2	8.00	44.00	704.00	7,612.00	38,060.00
Logistics	2	8.00	39.00	624.00	6,747.00	33,735.00
Total	12	64.00		\$ 4,632.00	-	\$ 339,080.00
Costs for Community Testing - Equipment, Supplies and Resources						
	Cost	Cost including Admin Fee 15%	Tests Per Day	Bill/Day	Bill/Month	Billing Budget for 5 months
Reimbursable Material Cost	\$ 215.00	\$ 247.25	60	\$ 247.25	\$ 7,417.50	\$ 37,087.50
Subscribed User Fee	\$ 2.00	\$ 2.30	60	\$ 138.00	\$ 4,140.00	\$ 20,700.00
Administering Cost of Vaccination	\$ 1.50	\$ 1.73	60	\$ 103.50	\$ 3,105.00	\$ 15,525.00
Cost of capacity testing site per person	\$ 2.99	\$ 3.44	60	\$ 206.31	\$ 6,189.30	\$ 30,946.50
Initial Deployment Cost	\$ 1,200.00	\$ 1,380.00	60	\$ 1,380.00	\$ 41,400.00	\$ 207,000.00
Refrigerated/ Freezer Transport for Vaccination	\$ 360.00	\$ 414.00	60	\$ 414.00	\$ 12,420.00	\$ 62,100.00
Site Network/Server	\$ 650.00	\$ 747.50	60	\$ 747.50	\$ 22,425.00	\$ 112,125.00
Logistics	\$ 1,253.00	\$ 1,440.95	60	\$ 1,440.95	\$ 43,228.50	\$ 216,142.50
PPE	\$ 3,699.20	\$ 4,254.08	60	\$ 354.51	\$ 10,635.20	\$ 53,176.00
Other supplies	\$ 300.00	\$ 345.00	60	\$ 345.00	\$ 10,350.00	\$ 51,750.00
Total	\$ 7,683.69	\$ 8,836.24		\$ 8,836.24	\$ 161,310.50	\$ 806,552.50
Total Budget - 5 months						\$ 1,145,632.50

Appendix A – Project Daily Status Report



STATUS REPORTING DAILY COVID-19 TESTING ACTIVITY

COVID-19 TESTING
PROJECT



STATUS SUMMARY

DAILY RESULT CALLING ON TRACK ?



WHAT IS THE TOTAL DAILY
CALLS?

HOW MANY RESIDENTS
WERE TESTED

HOW MANY RESIDENTS ON EACH CALL LIST
FOR NURSE NAVIGATOR

EDNA

MARAGRET

STEPHANIE

ANN

JENIA

NOELIA

PROGRESS

SINCE LAST TESTING DATE THE FOLLOWING WERE ACHIEVED AND
PROGRESS SINCE LAST STATUS UPDATE WAS GIVEN

TOTAL NUMBER OF DAILY TEST

- SITE LOCATION-
INDOOR/OUTDOOR
- NUMBER OF TEST DONE.

TOTAL NUMBER OF CALLS MADE

- TOTAL NUMBER OF
SUCCESSFUL CONTACTS
- TOTAL NUMBER OF
UNDELIVERED RESULTS

ATTENTION AREAS

LIST OF PROBLEMS/BARRIERS TO SUCCESSFULLY DELIVERING RESULT

- LANGUAGE
- NON-WORKING NUMBERS
- NO AVAILABLE VOICE MAIL SET UP

MAKE SURE YOU UNDERSTAND

- Issues that are causing delays or impending progress
- Why problem was not anticipated

TECHNOLOGY

List Technical Problems That Have Been Solved

List Outstanding Technical Issues That Need To Be Solved

Summarize their impact on the project

List Any Dubious Technological Dependencies For Project

Indicate source of doubt

Summarize action being taken for backup plan

RESOURCES

SUMMARIZE PROJECT RESOURCES

- Dedicated (full-time) resources
- Part-time resources
- If project is constrained by lack of resources, suggest alternatives

UNDERSTAND WHAT CUSTOMERS WANT

Customers may want to be assured that all possible resources are being used, but in such a way that costs will be properly managed

GOALS FOR NEXT REVIEW

DATE OF NEXT STATUS UPDATE

LIST GOALS FOR NEXT REVIEW

- Specific items that will be done
- Issues that will be resolved
- Issues that will be resolved
- Issues that will be resolved

ACTION PLAN REVIEW

- Make sure anyone involved in project understands action plan

Appendix B – Daily Status Call Report



STATUS REPORTING DAILY COVID-19 TESTING ACTIVITY

COVID-19 TESTING
PROJECT



STATUS SUMMARY

DAILY RESULT CALLING ON TRACK ?



WHAT IS THE TOTAL DAILY
CALLS?

HOW MANY RESIDENTS
WERE TESTED

HOW MANY RESIDENTS ON EACH CALL LIST
FOR NURSE NAVIGATOR

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STEPHANIE

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INDOOR/OUTDOOR
- NUMBER OF TEST DONE.

TOTAL NUMBER OF CALLS MADE

- TOTAL NUMBER OF
SUCCESSFUL CONTACTS
- TOTAL NUMBER OF
UNDELIVERED RESULTS

ATTENTION AREAS

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- LANGUAGE
- NON-WORKING NUMBERS
- NO AVAILABLE VOICE MAIL SET UP

MAKE SURE YOU UNDERSTAND

- Issues that are causing delays or impending progress
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UNDERSTAND WHAT CUSTOMERS WANT

Customers may want to be assured that all possible resources are being used, but in such a way that costs will be properly managed

GOALS FOR NEXT REVIEW

DATE OF NEXT STATUS UPDATE

LIST GOALS FOR NEXT REVIEW

- Specific items that will be done
- Issues that will be resolved
- Issues that will be resolved
- Issues that will be resolved

ACTION PLAN REVIEW

- Make sure anyone involved in project understands action plan

Appendix C – BinaxNOW Procedures

PROCEDURE CARD

For Use Under an Emergency Use Authorization (EUA) Only.

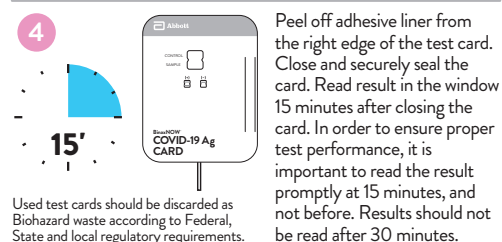
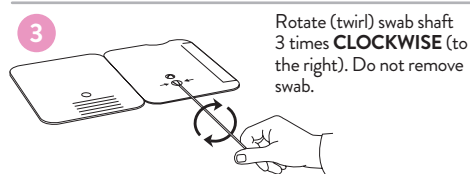
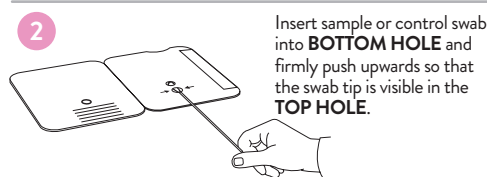
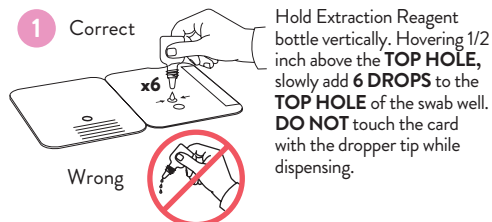
The BinaxNOW COVID-19 Ag Card is a lateral flow immunoassay for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 directly from anterior nasal (nares) swab specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within seven days of the onset of symptoms.

IMPORTANT: See Product Insert, including QC section, for complete use instructions, warnings, precautions and limitations.

False negative results may occur if specimens are tested past 1 hour of collection. Specimens should be tested as quickly as possible after specimen collection. Open the test card just prior to use, lay it flat, and perform assay as follows.

Part 1 - Sample Test Procedure

Patient Samples require 6 drops of Extraction Reagent.



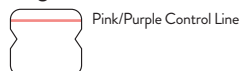
In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Part 2 - Result Interpretation

A **negative specimen** will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

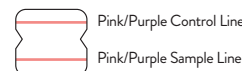
Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.

Negative Result



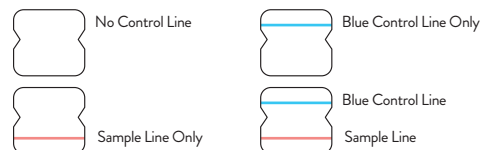
A **positive specimen** will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.

Positive Result



If no lines are seen, or if just the Sample Line is seen, the assay is invalid. Invalid tests should be repeated.

Invalid Result

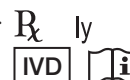


Procedure for External Quality Control Testing

External Controls require 8 drops of Extraction Reagent

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.
2. Follow Steps 2 – 4 of the Test Procedure shown.

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.globalpointofcare.abbott



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IN195001 Rev. 2 2020/12

Abbott
BinaxNOW
COVID-19 Ag

ProCard

Size:
5.5" x 8.0"

Printed Colors



Incoming Inspection Colors (For Reference Only) Colors below are not used for printing



PN: IN195001
Rev: 2

Date of Last Revision:
2.2 2020/12/12

BINAXNOW COVID-19 AG CARD (PN 195-000) – INSTRUCTIONS FOR USE

BinaxNOW™ COVID-19 Ag CARD

For Use Under an Emergency Use Authorization (EUA) Only

For use with anterior nasal (nares) swab specimens

For *in vitro* Diagnostic Use Only

Rx Only

INTENDED USE

The BinaxNOW™ COVID-19 Ag Card is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

The BinaxNOW™ COVID-19 Ag Card does not differentiate between SARS-CoV and SARS-CoV-2.

Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

The BinaxNOW™ COVID-19 Ag Card is intended for use by medical professionals or trained operators who are proficient in performing rapid lateral flow tests. BinaxNOW™ COVID-19 Ag Card is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION OF THE TEST

Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to

severe respiratory illness and has spread globally, including the United States.

BinaxNOW™ COVID-19 Ag Card is a rapid lateral flow immunoassay for the qualitative detection and diagnosis of SARS-CoV-2 directly from nasal swabs, without viral transport media. The BinaxNOW™ COVID-19 Ag Card kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLES OF THE PROCEDURE

The BinaxNOW™ COVID-19 Ag Card is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2 nucleocapsid protein from nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other reagents/pads to construct a test strip. This test strip and a well to hold the swab specimen are mounted on opposite sides of a cardboard, book-shaped hinged test card.

To perform the test, a nasal swab specimen is collected from the patient, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually at 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes.

REAGENTS AND MATERIALS

Materials Provided

Test Cards (40): A cardboard, book-shaped hinged test card containing the test strip

Extraction Reagent (1): Bottle containing 7.5 mL of extraction reagent

Nasal Swabs (40): Sterile swabs for use with BinaxNOW™ COVID-19 Ag Card test

Positive Control Swab (1) : Non-infectious recombinant SARS-CoV-2 nucleocapsid antigen dried onto a swab

Negative Control Swab: The use of a sterile patient swab ensures appropriate negative results are obtained

Product Insert (1)

Procedure Card (1)

Materials Required but not Provided

Clock, timer or stopwatch

Materials Available as an Optional Accessory

Swab Transport Tube Accessory Pack

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement

Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate, high or waived complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. This product has been authorized only for the detection of proteins from SARS- CoV-2, not for any other viruses or pathogens
5. This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
6. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
7. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
8. Proper sample collection, storage and transport are essential for correct results.
9. Leave test card sealed in its foil pouch until just before use. Do not use if pouch is damaged or open.
10. Do not use kit past its expiration date.
11. Do not mix components from different kit lots.
12. Do not reuse the used test card.
13. Inadequate or inappropriate sample collection, storage, and transport may yield false test results.
14. Do not store or test specimens in viral transport media, as it may result in false positive or false negative results.
15. All components of this kit should be discarded as Biohazard waste according to Federal, State and local regulatory requirements.
16. Solutions used to make the positive control swab are non-infectious. However, patient samples, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
17. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens. Change gloves between handling of specimens suspected of COVID-19.
18. INVALID RESULTS can occur when an insufficient volume of extraction reagent is added to the test card. To ensure delivery of adequate volume, hold vial vertically, 1/2 inch above the swab well, and add drops slowly.
19. False Negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.
20. Swabs in the kit are approved for use with BinaxNOW™ COVID-19 Ag Card. **Do not use other swabs.**
21. The Extraction Reagent packaged in this kit contains saline, detergents and preservatives that will inactivate cells and virus particles. Samples eluted in this solution are not suitable for culture.
22. Do not store the swab after specimen collection in the original paper packaging, if storage is needed use a plastic tube with cap.

STORAGE AND STABILITY

Store kit at 2-30°C. The BinaxNOW™ COVID-19 Ag Card kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

QUALITY CONTROL

BinaxNOW™ COVID-19 Ag Card has built-in procedural controls. For daily quality control, Abbott suggests that you record these controls for each test run.

Procedural Controls:

- A. The pink-to-purple line at the “Control” position is an internal procedural control. If the test flows and the reagents work, this line will always appear.
- B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. BinaxNOW™ COVID-19 Ag Card kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab’s standard Quality Control procedures.

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

SPECIMEN COLLECTION AND HANDLING

Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Anterior Nasal (Nares) Swab

Only the swab provided in the kit is to be used for nasal swab collection.

To collect a nasal swab sample, carefully insert the entire absorbent tip of the swab (usually ½ to ¾ of an inch (1 to 1.5 cm) into the nostril. Firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall 5 times or more for a total of 15 seconds, then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

SPECIMEN TRANSPORT AND STORAGE

Do not return the nasal swab to the original paper packaging.

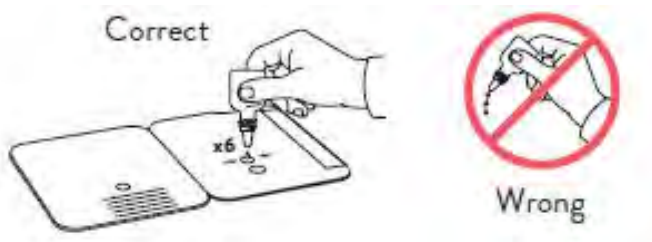
For best performance, direct nasal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance and avoid possible contamination, it is highly recommended the nasal swab is placed in a clean, unused plastic tube labeled with patient information, preserving sample integrity, and capped tightly at room temperature (15-30°C) for up to (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than 1 hour delay occurs, dispose of sample. A new sample must be collected for testing.

TEST PROCEDURE

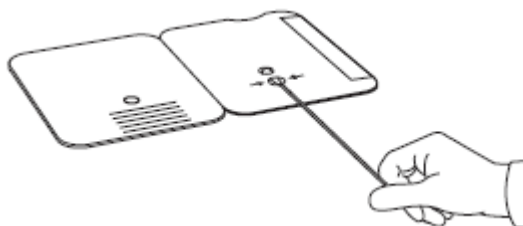
Procedure for Patient Specimens

Open the test card just prior to use, **lay it flat**, and perform assay as follows. **The test card must be flat when performing testing, do not perform testing with the test card in any other position.**

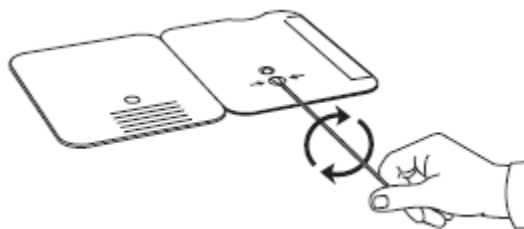
1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **6 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



2. Insert sample into **BOTTOM HOLE** and firmly push upwards so that the swab tip is visible in the **TOP HOLE**.

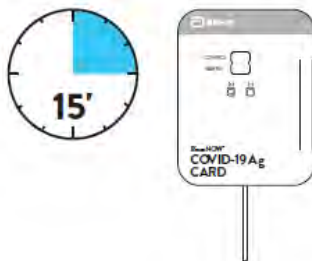


3. Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab.



Note: False negative results can occur if the sample swab is not rotated (twirled) prior to closing the card.

4. Peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in the window 15 minutes after closing the card. In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes.



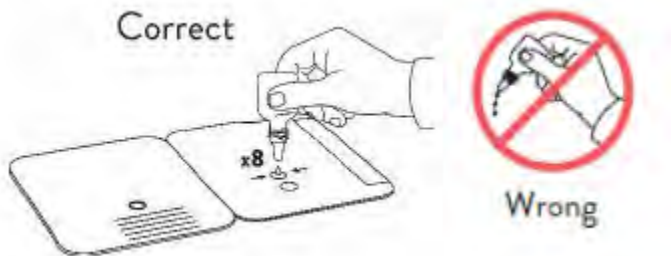
Note: False negative results can occur if test results are read before 15 minutes.

Note: When reading test results, tilt the card to reduce glare on the result window if necessary. Individuals with color-impaired vision may not be able to adequately interpret test results.

Procedure for BinaxNOW™ Swab Controls

Open the test card just prior to use, lay it flat, and perform assay as follows.

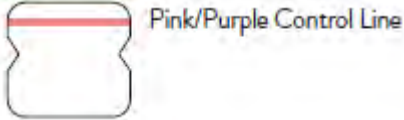
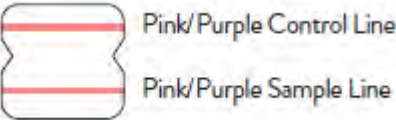

1. Hold Extraction Reagent bottle vertically. Hovering 1/2 inch above the **TOP HOLE**, slowly add **8 DROPS** to the **TOP HOLE** of the swab well. **DO NOT** touch the card with the dropper tip while dispensing.



2. Follow Steps 2 – 4 of the Test Procedure for Patient Specimens.

RESULT INTERPRETATION

Note: In an untested BinaxNOW COVID-19 Ag Card there will be a blue line present at the Control Line position. In a valid, tested device, the blue line washes away and a pink/purple line appears, confirming that the sample has flowed through the test strip and the reagents are working. If the blue line is not present at the Control Line position prior to running the test, do not use and discard the test card.

<p>Negative</p> <p>A negative specimen will give a single pink/purple colored Control Line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.</p>	
<p>Positive</p> <p>A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. Any visible pink/purple colored line is positive.</p>	
<p>Invalid</p> <p>If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.</p>	<p>Invalid Result</p> 

LIMITATIONS

- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- The performance of the BinaxNOW™ COVID-19 Ag Card was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- False negative results may occur if a specimen is improperly collected, transported, or handled.
- False results may occur if specimens are tested past 1 hour of collection. Specimens should be test as quickly as possible after specimen collection.
- False negative results may occur if inadequate extraction buffer is used (e.g., <6 drops).
- False negative results may occur if specimen swabs are not twirled within the test card.
- False negative results may occur if swabs are stored in their paper sheath after specimen

collection.

- Positive test results do not rule out co-infections with other pathogens.
- False negative results are more likely after eight days or more of symptoms.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
- The presence of mupirocin may interfere with the BinaxNOW™ COVID-19 Ag test and may cause false negative results.
- Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
- If the differentiation of specific SARS viruses and strains is needed, additional testing, in consultation with state or local public health departments, is required.

CONDITIONS of AUTHORIZATION for LABORATORY and PATIENT CARE SETTINGS

The BinaxNOW™ COVID-19 Ag Card Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>.

However, to assist clinical laboratories using the BinaxNOW™ COVID-19 Ag Card, the relevant Conditions of Authorization are listed below:

- Authorized laboratories¹ using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using your product must use your product as outlined in the “BinaxNOW™ COVID-19 Ag Card” Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott Diagnostics Scarborough, Inc. (via email: ts.scr@abbott.com, or via phone by contacting Abbott Diagnostics Scarborough, Inc. Technical Service at 1-800-257-9525) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.
- Abbott Diagnostics Scarborough, Inc., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are

maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

¹ The letter of authorization refers to, “Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.” as “authorized laboratories.”

PERFORMANCE CHARACTERISTICS

CLINICAL PERFORMANCE

Clinical performance characteristics of BinaxNOW™ COVID-19 Ag Card was evaluated in a multi-site prospective study in the U.S in which patients were sequentially enrolled and tested. A total of ten (10) investigational sites throughout the U.S. participated in the study. Testing was performed by operators with no laboratory experience and who are representative of the intended users at CLIA waived testing sites. In this study testing was conducted by sixty-two (62) intended users. To be enrolled in the study, patients had to be presenting at the participating study centers with suspected COVID-19. Patients who presented within 7 days of symptom onset were included in the initial primary analysis. Two nasal swabs were collected from patients and tested using the BinaxNOW™ COVID-19 Ag Card at all study sites. An FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assay for the detection of SARS-CoV-2 was utilized as the comparator method for this study.

At all sites, one nasal swab was tested directly in the BinaxNOW™ COVID-19 Ag Card test according to product instructions and the other swab was eluted in viral transport media (VTM). Swabs were randomly assigned to testing with the BinaxNOW or RT-PCR testing and were tested by minimally trained operators who were blinded to the RT-PCR test result. All sites shipped the VTM sample to a central testing laboratory for RT-PCR.

External control testing, using BinaxNOW™ COVID-19 Ag Card Positive and Negative Controls, was performed prior to sample testing each day, at all study sites.

The performance of BinaxNOW™ COVID-19 Ag Card was established with 460 nasal swabs collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19.

BinaxNOW™ COVID-19 Ag Card Performance within 7 days of symptom onset against the Comparator Method

BinaxNOW™ COVID 19 Ag Card	Comparator Method		
	Positive	Negative	Total
Positive	99	5	104
Negative	18*	338	356
Total	117	343	460
Positive Agreement: 99/117 84.6% (95% CI: 76.8% - 90.6%)			
Negative Agreement: 338/343 98.5% (95% CI: 96.6% - 99.5%)			

*14 of the discrepant samples had high Ct values (>33) when tested by the comparator method.

The following data is provided for informational purposes:

The performance of BinaxNOW™ COVID-19 Ag Card with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. As presented in the table below, the positive agreement of the BinaxNOW™ COVID-19 Ag Card is higher with samples of a Ct count <33.

BinaxNOW™ COVID-19 Ag Card Performance against the Comparator Method – by Cycle Threshold Counts

BinaxNOW™ COVID 19 Ag Card	All Subjects*	
	Comparator Method (POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ≥ 33)
Positive	116	17
Negative	12	28
Total	128	45
Positive Agreement (95% CI)	90.6 (84.2, 95.1)	37.8 (23.8, 53.5)

*In patients presenting within seven (7) days of symptom onset, BinaxNOW COVID-19 Ag Card achieved 95.6% (86/90) positive percent agreement for samples with Ct < 33

Patient Demographics

Patient demographics (gender and age) are available for the 460 samples used in the analysis of patients with symptom onset within the previous seven (7) days. The table below shows the positive results broken down by age of the patient:

Age	Comparator Method		
	Total #	Positive	Prevalence
≤ 5 years	0	-	-
6 to 21 years	17	3	17.6%
22 to 59 years	312	79	25.3%
≥ 60 years	131	35	25.4%

Patient demographics, time elapsed since onset of symptoms for all patients enrolled, are presented in the table below. Positive results broken down by days since symptom onset:

Days Since Symptom Onset	Cumulative RT PCR Positive (+)	Cumulative BinaxNOW COVID 19 Ag Card Positive (+)	PPA	95 % Confidence Interval	
1	12	10	83.3%	51.6%	97.9%
2	34	28	82.4%	65.5%	93.2%
3	50	41	82.0%	68.6%	91.4%
4	63	50	79.4%	67.3%	88.5%
5	78	63	80.8%	70.3%	88.8%
6	90	75	83.3%	74.0%	90.4%
7	117	99	84.6%	76.8%	90.6%
8 to 10	144	118	81.9%	74.7%	87.9%
11 to 14	161	126	78.3%	71.1%	84.4%
All specimens	167	129	77.2%	70.1%	83.4%

A cohort of patients who presented with symptom onset greater than seven days were enrolled in the clinical study (n = 161). The positive agreement in patients with symptoms greater than seven days was 60% (30/50) and negative agreement was 98% (109/111). Therefore, negative results in patients with symptom onset greater than seven days should be interpreted with caution, as the sensitivity of the assay decreases over time.

ANALYTICAL PERFORMANCE

Limit of Detection (Analytical Sensitivity)

BinaxNOW™ COVID-19 Ag Card limit of detection (LOD) was determined by evaluating different concentrations of heat inactivated SARS-CoV-2 virus. Presumed negative natural nasal swab specimens were eluted in PBS. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Inactivated SARS-CoV-2 virus was diluted in this natural nasal swab matrix pool to generate virus dilutions for testing.

Contrived nasal swab samples were prepared by absorbing 20 microliters of each virus dilution onto the swab. The contrived swab samples were tested according to the test procedure.

The LOD was determined as the lowest virus concentration that was detected $\geq 95\%$ of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The BinaxNOW™ COVID-19 Ag Card LOD in natural nasal swab matrix was confirmed as 140.6 TCID₅₀/mL.

Limit of Detection (LoD) Study Results

Concentration TCID ₅₀ /mL	Number Positive/Total	% Detected
140.6	20/20	100%

Cross Reactivity (Analytical Specificity) and Microbial Interference

Cross reactivity and potential interference of BinaxNOW™ COVID-19 Ag Card was evaluated by testing 37 commensal and pathogenic microorganisms (8 bacteria, 14 viruses, 1 yeast and pooled human nasal wash) that may be present in the nasal cavity. Each of the organism, viruses, and yeast were tested in triplicate in the absence or presence of heat inactivated SARS-CoV-2 virus (45 TCID₅₀/swab). No cross-reactivity or interference was seen with the following microorganisms when tested at the concentration presented in the table below.

Potential Cross Reactant		Test Concentration
Virus	Adenovirus	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human metapneumovirus (hMPV)	1.0 x 10 ⁵ TCID ₅₀ /mL
	Rhinovirus	1.0 x 10 ⁵ PFU/mL
	Enterovirus/Coxsackievirus B4	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human coronavirus OC43	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human coronavirus 229E	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human coronavirus NL63	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 1	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 2	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 3	1.0 x 10 ⁵ TCID ₅₀ /mL
	Human parainfluenza virus 4	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza A	1.0 x 10 ⁵ TCID ₅₀ /mL
	Influenza B	1.0 x 10 ⁵ TCID ₅₀ /mL
	Respiratory Syncytial Virus A	1.0 x 10 ⁵ PFU/mL
Bacteria	<i>Bordetella pertussis</i>	1.0 x 10 ⁶ cells/mL
	<i>Chlamydia pneumoniae</i>	1.0 x 10 ⁶ IFU/mL
	<i>Haemophilus influenzae</i>	1.0 x 10 ⁶ cells/mL
	<i>Legionella pneumophila</i>	1.0 x 10 ⁶ cells/mL
	<i>Mycoplasma pneumoniae</i>	1.0 x 10 ⁶ U/mL
	<i>Streptococcus pneumoniae</i>	1.0 x 10 ⁶ cells/mL
	<i>Streptococcus pyogenes (group A)</i>	1.0 x 10 ⁶ cells/mL
	<i>Mycobacterium tuberculosis</i>	1.0 x 10 ⁶ cells/mL
	<i>Staphylococcus aureus</i>	1.0 x 10 ⁶ org/mL
	<i>Staphylococcus epidermidis</i>	1.0 x 10 ⁶ org/mL
	Pooled human nasal wash	N/A
Yeast	<i>Candida albicans</i>	1.0 x 10 ⁶ cells/mL

To estimate the likelihood of cross-reactivity with SARS-CoV-2 virus in the presence of organisms that were not available for wet testing, *In silico* analysis using the Basic Local Alignment Search Tool (BLAST) managed by the National Center for Biotechnology Information (NCBI) was used to assess the degree of protein sequence homology.

- For *P. jirovecii* one area of sequence similarity shows 45% homology across 18% of the sequence, making cross-reactivity in the BinaxNOW™ COVID-19 Ag Card highly unlikely.
- No protein sequence homology was found between *M. tuberculosis*, and thus homology-based cross-reactivity can be ruled out.
- The comparison between SARS-CoV-2 nucleocapsid protein, MERS-CoV and human coronavirus HKU1 revealed that cross-reactivity cannot be ruled out. Homology for HKU1 and MERS-CoV is relatively low, at 37.8% across 95% of the sequence and 57.14% across 87% of the sequence, respectively.

High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.6×10^5 TCID₅₀/mL of heat inactivated SARS-CoV-2 virus with the BinaxNOW™ COVID-19 Ag Card.


Endogenous Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with the BinaxNOW™ COVID-19 Ag Card at the concentrations listed below and were found not to affect test performance.

Substance	Active Ingredient	Concentration
Endogenous	Mucin	2% w/v
	Whole Blood	1% v/v
OTC Nasal Drops	Phenylephrine	15% v/v
OTC Nasal Gel	Sodium Chloride (i.e. NeilMed)	5% v/v
OTC Nasal Spray 1	Cromolyn	15% v/v
OTC Nasal Spray 2	Oxymetazoline	15% v/v
OTC Nasal Spray 3	Fluconazole	5% w/v
Throat Lozenge	Benzocaine, Menthol	0.15% w/v
OTC Homeopathic Nasal Spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC Homeopathic Nasal Spray 2	Zincum gluconium (i.e., Zicam)	5% w/v
OTC Homeopathic Nasal Spray 3	Alkalol	10% v/v
OTC Homeopathic Nasal Spray 4	Fluticasone Propionate	5% v/v
Sore Throat Phenol Spray	Phenol	15% v/v
Anti-viral Drug	Tamiflu (Oseltamivir Phosphate)	0.5% w/v
Antibiotic, Nasal Ointment	Mupirocin ¹	0.25% w/v
Antibacterial, Systemic	Tobramycin	0.0004% w/v

¹ Testing demonstrated false negative results at concentrations of 5 mg/mL (0.5% w/v). Standard dose of nasal ointment: 20 mg (2% w/w) of mupirocin in single-use 1-gram tubes.

SYMBOLS

 Only	Prescription Only
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ORDERING AND CONTACT INFORMATION

Reorder Numbers:

195-000: BinaxNOW™ COVID-19 Ag Card (40 Tests)

195-080: BinaxNOW™ COVID-19 Ag Control Swab Kit

US +1 877 441 7440

Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

US

+ 1 800 257 9525

ts.scr@abbott.com



Abbott Diagnostics Scarborough, Inc.

10 Southgate Road
Scarborough, Maine 04074 USA

www.abbott.com/poct

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IN195000 Rev. 2 2020/12



Appendix D – Off Site Checklist




CHECKLIST of

Best Practices FOR Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

This checklist is a step-by-step guide to help clinic coordinators/supervisors overseeing vaccination clinics held at satellite, temporary, or off-site locations follow Centers for Disease Control and Prevention (CDC) guidelines and best practices for vaccine shipment, transport, storage, handling, preparation, administration, and documentation. These CDC guidelines and best practices are essential for patient safety and vaccine effectiveness. This checklist should be used in any non-traditional vaccination clinic settings, such as workplaces, community centers, schools, makeshift clinics in remote areas, and medical facilities when vaccination occurs in the public areas or classrooms. Temporary clinics also include mass vaccination events, walk-through, curbside, and drive-through clinics, and vaccination clinics held during pandemic preparedness exercises. **A clinic coordinator/supervisor at the site should complete, sign, and date this checklist EACH TIME a vaccination clinic is held.** To meet accountability and quality assurance standards, all signed checklists should be kept on file by the company that provided clinic staffing.

This document also contains sections, marked in red, that outline best practices for vaccination during the COVID-19 pandemic. For continued up-to-date guidance, please visit www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html.

INSTRUCTIONS

1. A staff member who will be at the vaccination clinic should be designated as the clinic coordinator/supervisor. This person will be responsible for completing the steps below and will be referred to as “you” in these instructions.
2. Review this checklist during the planning stage of the vaccination clinic—well in advance of the date(s) when the clinic will be held. This checklist includes sections to be completed before, during, and after the clinic.
3. **Critical guidelines for patient safety and vaccine effectiveness are identified by the stop sign icon: . If you check “NO” in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic. Follow your organization’s protocols and/or contact your state or local health department for guidance BEFORE proceeding with the clinic. Do not administer any vaccine until you have confirmed you can move forward with the clinic.**
4. Contact your organization and/or health department if you have any concerns about whether vaccine was transported, stored, handled, or administered correctly, whether patients’ personal information was protected appropriately, or other responses that you have marked as “NO” in rows that do not have the .
5. This checklist should be used in conjunction with CDC’s *Vaccine Storage and Handling Toolkit*: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. For information about specific vaccines, consult the vaccine manufacturer’s package insert.
6. **This checklist applies ONLY to vaccines stored at REFRIGERATED temperatures** (i.e., between 2–8° Celsius or 36–46° Fahrenheit).
7. Sign and date the checklist upon completion of the clinic or completion of your shift (whichever comes first). *(If more than one clinic coordinator/supervisor is responsible for different aspects of the clinic, you should complete only the section(s) for which you were responsible.)*
8. Attach the staff sign-in sheet (with shift times and date) to the checklist (or checklists if more than one clinic supervisor is overseeing different shifts) and submit the checklist(s) to your organization to be kept on file for accountability.

Name and credentials of clinic coordinator/supervisor:

Name of facility where clinic was held:

Address where clinic was held (street, city, state):

Time and date of vaccination clinic shift (the portion you oversaw):

Time (AM/PM)

Date (MM/DD/YYYY)

Time and date when form was completed:

Time (AM/PM)

Date (MM/DD/YYYY)

Signature of clinic coordinator/supervisor:



**U.S. Department of
Health and Human Services**
Centers for Disease
Control and Prevention

BEFORE THE CLINIC (Please complete each item before the clinic starts.)**VACCINE SHIPMENT**

YES NO N.A.

☐ ☐ ☐ Vaccine was shipped directly to the facility/clinic site, where adequate storage is available. (*Direct shipment is preferred for cold chain integrity.*)

VACCINE TRANSPORT (IF IT WAS NOT POSSIBLE TO SHIP VACCINES DIRECTLY TO THE FACILITY/CLINIC SITE)

YES NO N.A.

☐ ☐ ☐ **Vaccines were transported using a portable vaccine refrigerator or qualified container and packout designed to transport vaccines** within the temperature range recommended by the manufacturers (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines). Coolers available at general merchandise stores or coolers used to transport food are NOT ACCEPTABLE. See CDC's Vaccine Storage and Handling Toolkit for information on qualified containers and packouts: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.

☐ ☐ ☐ The person transporting the vaccines confirmed that manufacturer instructions for packing configuration and proper conditioning of coolants were followed. (*Your qualified container and packout should include packing instructions. If not, contact the company for instructions on proper packing procedures.*)

☐ ☐ ☐ The person transporting the vaccines confirmed that all vaccines were transported in the passenger compartment of the vehicle (NOT in the vehicle trunk).

☐ ☐ ☐ A digital data logger with a buffered probe and a current and valid Certificate of Calibration Testing was placed directly with the vaccines and used to monitor vaccine temperature during transport.

☐ ☐ ☐ The amount of vaccine transported was limited to the amount needed for the workday.

VACCINE STORAGE AND HANDLING (UPON ARRIVAL AT FACILITY/CLINIC)

YES NO N.A.

☐ ☐ ☐ If vaccines were shipped, the shipment arrived within the appropriate time frame (according to manufacturer or distributor guidelines) and in good condition.

☐ ☐ ☐ If the vaccine shipment contained a cold chain monitor (CCM), it was checked upon arrival at the facility/clinic, and there was no indication of a temperature excursion (i.e., out-of-range temperature) during transit. CCMs are stored in a separate compartment of the shipping container (a CCM may not be included when vaccines are shipped directly from the manufacturer). *Note: CCMs are for one-time use and should be thrown away after being checked.*

☐ ☐ ☐ Upon arrival at the facility/clinic (either by shipment or transport), vaccines were immediately unpacked and placed in proper storage equipment (i.e., a portable vaccine refrigerator or qualified container and packout specifically designed and tested to maintain the manufacturer-recommended temperature range). *Follow the guidance for unpacking and storing vaccines specified in CDC's Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf.*

☐ ☐ ☐ Upon arrival at the facility/clinic, vaccines were still within the manufacturer-recommended temperature range (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines).

☐ ☐ ☐ Upon arrival at the facility/clinic, vaccines remained protected from light (per manufacturer's package insert) until ready for use at the vaccination clinic.

☐ ☐ ☐ Upon arrival at the facility/clinic, expiration dates of vaccines and any medical equipment (syringes, needles, alcohol wipes) being used were checked, and they had not expired.

CLINIC PREPARATION AND SUPPLIES

YES NO N.A.

☐ ☐ ☐ A contingency plan is in place in case vaccines need to be replaced. The plan addresses scenarios for vaccine compromised before arrival at the clinic and for vaccine compromised during clinic hours.

☐ ☐ ☐ An emergency medical kit (including epinephrine and equipment for maintaining an airway) is at the site for the duration of the clinic.

☐ ☐ ☐ All vaccination providers at the site are certified in cardiopulmonary resuscitation (CPR), are familiar with the signs and symptoms of anaphylaxis, know their role in an emergency, and know the location of epinephrine and are trained in its indications and use.

☐ ☐ ☐ There is a designated area at the site for management of patients with urgent medical problems (e.g., fainting).

☐ ☐ ☐ Adequate infection control supplies are provided, including biohazard containers and supplies for hand hygiene. If administering injectable vaccines, adhesive bandages, individually packaged sterile alcohol wipes, and a sufficient number of sterile needles and syringes and a sharps container are provided.

☐ ☐ ☐ Staff members administering vaccines have reviewed vaccine manufacturer instructions for administration before the vaccination clinic.

☐ ☐ ☐ If using a standing order protocol, the protocol is current and available at the clinic/facility site.

☐ ☐ ☐ A process for screening for contraindications and precautions is in place.

☐ ☐ ☐ A sufficient number of vaccine information statements (VISs or Emergency Use Authorization [EUA]) forms, if required) for each vaccine being offered is available at the clinic/facility site.

If you check "NO" in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic.

- » Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- » Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A designated clean area for vaccine preparation has been identified and set up prior to the clinic.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A qualified individual has been designated to oversee infection control at the clinic.

PREVENTING TRANSMISSION OF COVID-19 AT THE CLINIC

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient supply of PPE for staff is available, including face masks, gloves, and, if appropriate, eye shields.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient supply of face coverings is available for visitors and patients who may not have one.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient hand sanitizer is available so that staff and patients can repeatedly practice hand hygiene.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cleaning supplies are available so workspaces can be cleaned regularly (note the amount needed may be more than normally required). (See EPA's Registered Antimicrobial Products for Use Against Novel Coronavirus SARS-CoV-2 the virus that causes COVID-19.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Additional controls, such as counters and plastic shields, are in place to minimize contact where patients and staff interact (e.g., registration or screening areas).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Signs, barriers, and floor markers to instruct patients to remain 6 feet apart from other patients and clinic staff have been set up before the clinic.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sufficient supply of thermometers to check patient temperatures prior to entering the vaccination clinic and COVID symptom checklists.

DURING THE CLINIC (Please complete each item while the clinic is occurring and review at the end of your shift.)

VACCINE STORAGE AND HANDLING (AT FACILITY/CLINIC)

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being kept in proper storage equipment that maintains the manufacturer-recommended temperature range (<i>i.e.</i> , a portable vaccine refrigerator or qualified container and packout specifically designed and tested to maintain correct temperatures when opened and closed during the clinic).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccine temperature is being monitored during the clinic using a digital data logger with a buffered probe (placed directly with vaccines) and a current and valid Certificate of Calibration Testing. Follow the monitoring guidance specified in CDC's Vaccine Storage and Handling Toolkit: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf .
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccines are being stored in a storage unit at the site, vaccine temperature data are being reviewed and documented a minimum of 2 times during each clinic workday (preferably at the beginning and middle of an 8-hour shift) to ensure they remain at correct temperatures (<i>i.e.</i> , between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines). If you are a VFC provider, check with your state immunization program for specific requirements for vaccine temperature monitoring during mass vaccination clinics.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccines cannot be stored in a storage unit at the site, they are being kept in the portable vaccine refrigerator or qualified packout with a temperature monitoring device (with a probe in a thermal buffer) placed as close as possible to the vaccines, and temperatures are being read and recorded at least once an hour. The container is being kept closed as much as possible.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being protected from light during the vaccination clinic per the manufacturer's package insert.

VACCINE PREPARATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Expiration dates of vaccines (and diluents, if applicable) are being checked again during preparation, and only vaccines that have not expired are being administered. (Note: If you are using multidose vials, be sure to review beyond use dates, along with expiration dates.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being prepared in a clean, designated medication area, away from any potentially contaminated items.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If using reconstituted vaccines, they are being prepared according to the manufacturer's guidelines.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being prepared at the time of administration.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccines are predrawn from a multidose vial, only the contents of 1 multidose vial are being drawn up at one time by each staff member administering vaccines (the maximum number of doses per vial is described in the package insert).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If using single-dose or multidose vials, syringes are being labeled with the name of the vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Once drawn up, vaccines are being kept in the recommended temperature range. (Questions about specific time limits for being out of the recommended temperature range should be referred to the manufacturer.)

VACCINE ADMINISTRATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccine information statements (VISs or Emergency Use Authorization [EUA] forms, if required) are being provided to every patient, parent, or guardian before vaccination (as required by federal law).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All patients are being screened for contraindications and precautions for the specific vaccine(s) in use before receiving that vaccine(s).

If you check "NO" in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic.

- » Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- » Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is using proper hygiene techniques to clean hands before vaccine administration, between patients, and anytime hands become soiled. www.cdc.gov/handhygiene/providers/index.html
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If gloves are being worn by staff administering vaccines, they are being changed and hands are being cleaned using proper hygiene techniques between patients.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is triple-checking labels, contents, and expiration dates or beyond use dates (as noted in the manufacturer's package insert, if applicable) before administering vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are normal in appearance (i.e., not discolored, without precipitate, and easily resuspended when shaken).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Each staff member is administering only the vaccines they have prepared.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If more than one vaccine type is being administered, separate preparation stations are set up for each vaccine type to prevent medication errors.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being administered using aseptic technique.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is administering vaccine to the correct patient (e.g., if a parent/guardian and child or two siblings are at the vaccination station at the same time, patient's name and date of birth are verified prior to vaccination).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is administering vaccines using the correct route per manufacturer instructions.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is administering the correct dosage (volume) of vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff has checked age indications for the vaccines and is administering vaccines to the correct age groups.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For vaccines requiring more than 1 dose, staff is administering the current dose at the correct interval. <i>Follow the recommended guidelines in Table 3-1 of the General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html#t-01.</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If vaccine administration errors are observed, corrective action is being taken immediately.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any persons with a needlestick injury, a vaccine administration error, or an urgent medical problem are being evaluated immediately and referred for additional medical care if needed.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Patients are being encouraged to stay at the clinic for 15 minutes after vaccination to be monitored for adverse events. This is especially critical at drive-through or curbside clinics where drivers are being vaccinated.

ADMINISTRATION OF INJECTABLE VACCINES (In this section, N.A. is ONLY an option if the clinic is EXCLUSIVELY using non-injectable vaccines, such as live, attenuated influenza vaccine.)

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A new needle and new syringe are being used for each injection. (Needles and syringes should never be used to administer vaccine to more than one person.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Single-dose vials or manufacturer-filled syringes are being used for only one patient.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are being administered following safe injection practices.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For walk-through clinics, seats are provided so staff and patients are at the same level for optimal positioning of anatomic site and injection angle to ensure correct vaccine administration.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is identifying injection site correctly. (For intramuscular route: deltoid muscle of arm [preferred] or vastus lateralis muscle of anterolateral thigh for adults, adolescents, and children aged ≥3 years; vastus lateralis muscle of anterolateral thigh [preferred] or deltoid muscle of arm for children aged 1–2 years; vastus lateralis muscle of anterolateral thigh for infants aged ≤12 months. For subcutaneous route: thigh for infants aged <12 months; upper outer triceps of arm for children aged ≥1 year and adults [can be used for infants if necessary].)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Staff is inserting needles quickly at the appropriate angle: 90° for intramuscular injections (e.g., injectable influenza vaccines) or 45° for subcutaneous injections (e.g., measles, mumps, rubella vaccine).
YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Multidose vials are being used only for the number of doses approved by the manufacturer.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccines are never being transferred from one syringe to another.

If you check "NO" in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic.

- » Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- » Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Used needles and syringes are being immediately placed in a sharps container following administration. (Needles are NOT being recapped.)

VACCINE DOCUMENTATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Each vaccination is being fully documented with name of person vaccinated; vaccination date; vaccine type, lot number, manufacturer; patient receipt of vaccine information statement (VISs or Emergency Use Authorization [EUA] form), including edition date and date VIS was provided; injection site; vaccination route; dosage; and name, title, and office/company address of person who administered the vaccine.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Your state's immunization information system (IIS) was used to document vaccinations administered. (<i>CDC recommends using your state's IIS to document vaccinations.</i>)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Patients are receiving documentation for their personal records and to share with their medical providers.

PREVENTING TRANSMISSION OF COVID-19 AT THE CLINIC

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All staff and patients have their temperature checked before entering the clinic and are answering the COVID screening questions before entering the clinic .
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All patients are wearing a face covering. Face masks should not be placed on children under age 2, anyone who has trouble breathing, or anyone who is unconscious, incapacitated, or otherwise unable to remove the mask without assistance.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All staff is wearing recommended personal protective equipment (PPE), including face masks, gloves (optional for subcutaneous and intramuscular injections, required for intranasal and oral vaccinations), and eye protection (based on level of community transmission). See www.cdc.gov/vaccines/pandemic-guidance/index.html for current guidance.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Social distancing guidance is being followed, including signs, banners, and floor markers to instruct staff and patients where to stand, shields as appropriate when the 6-foot minimum distance cannot be observed, and one-way traffic flow.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All areas are being wiped down and cleaned more frequently than normal cleaning that takes place during vaccine preparation and administration and between patients.

AFTER THE CLINIC (Please complete each item after the clinic is over.)

POST-CLINIC ACTIONS

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Temperature of remaining vaccine was checked and recorded at the end of clinic. If not still at manufacturer-recommended temperature (i.e., between 2–8° Celsius or 36–46° Fahrenheit for ALL refrigerated vaccines), follow your organization's protocols and/or contact your state or local health department for guidance.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any remaining vaccine in provider predrawn syringes, opened multidose vials, or activated manufacturer-filled syringes (MFSs) was properly discarded. <i>An MFS is activated when the sterile seal is broken (i.e., cap removed from needle or needle added to the syringe). If absolutely necessary, a partially used multidose vial may be transported to or from an off-site/satellite facility operated by the same provider, as long as the cold chain is properly maintained, the vaccine is normal in appearance, and the maximum number of doses per vial indicated by the manufacturer has not already been withdrawn, or the beyond use date indicated by the manufacturer has not been met. However, a partially used vial cannot be transferred from one provider to another or across state lines or returned to the supplier for credit.</i>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Viable, unused vaccine was placed back in proper storage equipment that maintains the manufacturer-recommended temperature range at the end of the clinic day and was not stored in a dormitory-style or bar-style combined refrigerator/freezer unit under any circumstances. (This includes vaccine transported for a multi-day clinic to a remote location where adequate storage at the site is not available.)
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any needlestick injuries were recorded in a sharps injury log and reported to all appropriate entities (e.g., local health department and your organization).
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any vaccine administration errors were reported to all appropriate entities.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All biohazardous material was disposed of properly.

POST-CLINIC DOCUMENTATION

YES	NO	N.A.	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Vaccinations were recorded in the jurisdiction's immunization information system (IIS) where available.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If not submitted to an IIS, vaccination information was sent to primary health care providers as directed by an established procedure based on state or jurisdiction regulations.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Any adverse events were reported to the Vaccine Adverse Event Reporting System (VAERS): vaers.hhs.gov/index .
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All patient medical information was placed in a secured storage location for privacy protection.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The staff sign-in sheet was attached to this document (with shift times, clinic location, and date).

N.A. means Not Applicable.

This checklist was adapted from materials created by the California Department of Public Health, the Centers for Disease Control and Prevention, and the Immunization Action Coalition.

If you check "NO" in ONE OR MORE answer boxes that contain a , DO NOT move forward with the clinic.

- » Follow your organization's protocols and/or contact your state or local health department for guidance *before* proceeding with the clinic.
- » Do not administer any vaccine until you have confirmed that it is acceptable to move forward with the clinic.

ADDITIONAL INFORMATION AND RESOURCES

If you are concerned that CDC guidelines were not followed during your vaccination clinic held at a satellite, temporary, or off-site location, contact your organization and/or state or local health department for further guidance.

COVID-19 information can be found at:

- www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html

- » CDC's guidelines and resources for vaccine storage, handling, administration, and safety:
 - Vaccine storage and handling: www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf
 - Vaccine administration:
 - www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html
 - www.cdc.gov/vaccines/hcp/admin/admin-protocols.html
 - www.cdc.gov/vaccines/hcp/admin/resource-library.html
 - Injection safety: www.cdc.gov/injectionsafety/providers.html
 - Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/
 - Videos on preparing and administering vaccines. www.cdc.gov/vaccines/hcp/admin/resource-library.html (includes videos on intramuscular injections and administration of live, attenuated influenza vaccine)
- » The Immunization Action Coalition has a skills checklist for staff administering vaccines: www.immunize.org/catg.d/p7010.pdf.
- » The Immunization Action Coalition and the Alliance for Immunization in Michigan have patient education materials available:
 - Screening tools: <http://www.immunize.org/handouts/screening-vaccines.asp>
 - Vaccination after-care:
 - Children: www.immunize.org/catg.d/p4015.pdf
 - Adults: www.aimtoolkit.org/docs/vax.pdf
- » The Immunization Action Coalition has information on the medical management of vaccine reactions:
 - Children and adolescents: www.immunize.org/catg.d/p3082a.pdf
 - Adults: www.immunize.org/catg.d/p3082.pdf
- » Manufacturers' product information and package inserts with specific, detailed storage and handling protocols for individual vaccines: www.immunize.org/packageinserts/pi_influenza.asp

This checklist is a valuable resource for use in temporary mass vaccination clinics and other vaccination exercises, such as those conducted at vaccine points of dispensing (PODs) or vaccination and dispensing clinics (VDCs) as part of public health emergency preparedness (PHEP) program activities.

Medical waste disposal is regulated by state environmental agencies. Contact your state immunization program or state environmental agency to ensure that your disposal procedures comply with state and federal regulations.

States have laws on documentation of vaccinations, use of immunization information systems (IISs), and types of health care providers who can administer vaccines.



Request for Proposal

RFP# FDC-1101

**Clinical Staffing and Services for COVID
Testing/Vaccinations Clinics**

**NOTE: James Madison University will be closed for winter break from
Tuesday, December 22, 2020 through Friday, January 1, 2021**

12/11/2020



REQUEST FOR PROPOSAL

RFP# FDC-1101

Issue Date: 12/11/2020

Title: Clinical Staffing and Services for COVID Testing/Vaccinations Clinics

Issuing Agency: Commonwealth of Virginia
James Madison University
Procurement Services MSC 5720
752 Ott Street, Wine Price Building
First Floor, Suite 1023
Harrisonburg, VA 22807

Period of Contract: From Date of Award Through One Year (Renewable)

Sealed Proposals Will Be Received Until 2:00 PM on January 12, 2021 for Furnishing The Services Described Herein.

SEALED PROPOSALS MAY BE MAILED, EXPRESS MAILED, OR HAND DELIVERED DIRECTLY TO THE ISSUING AGENCY SHOWN ABOVE.

All Inquiries For Information And Clarification Should Be Directed To: Doug Chester, Buyer Senior, Procurement Services, chestefd@jmu.edu; 540-568-4272; (Fax) 540-568-7935 not later than December 18th.

NOTE: James Madison University will be closed for winter break from Tuesday, December 22, 2020 through Friday, January 1, 2021

NOTE: THE SIGNED PROPOSAL AND ALL ATTACHMENTS SHALL BE RETURNED.

In compliance with this Request for Proposal and to all the conditions imposed herein, the undersigned offers and agrees to furnish the goods/services in accordance with the attached signed proposal or as mutually agreed upon by subsequent negotiation.

Name and Address of Firm:

By: _____
(Signature in Ink)

Name: _____
(Please Print)

Date: _____

Title: _____

Web Address: _____

Phone: _____

Email: _____

Fax #: _____

ACKNOWLEDGE RECEIPT OF ADDENDUM: #1_____ #2_____ #3_____ #4_____ #5_____ (please initial)

SMALL, WOMAN OR MINORITY OWNED BUSINESS:

ÿ YES; ÿ NO; IF YES ÿ SMALL; ÿ WOMAN; ÿ MINORITY **IF MINORITY:** ÿ AA; ÿ HA; ÿ AsA; ÿ NW; ÿ Micro

Note: This public body does not discriminate against faith-based organizations in accordance with the Code of Virginia, § 2.2-4343.1 or against an offeror because of race, religion, color, sex, national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment.

REQUEST FOR PROPOSAL

RFP # FDC-1101

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I. PURPOSE

The purpose of this Request for Proposal (RFP) is to solicit sealed proposals from qualified sources to enter into a contract to provide clinical staffing and clinic site services for COVID-19 testing and vaccination clinics for James Madison University (JMU), an agency of the Commonwealth of Virginia. Initial contract shall be for one (1) year with an option to renew for two (2) additional one-year periods.

II. BACKGROUND

James Madison University and other institutions of the Commonwealth plan to provide the contractor with Abbott BinaxNow COVID tests (allocated to us by the Commonwealth of Virginia or tests purchased directly by the institution). JMU currently needs to administer 6,000 of these tests between January 2020 and May 2020. This will mean multiple large-scale clinics. Additional BinaxNow clinics may be needed throughout the year. In addition, JMU (and multiple other institutions in the Commonwealth) are anticipating the future need of clinics to administer COVID vaccinations.

James Madison University will determine the need for external staffing and services related to testing and vaccination clinics on an as needed basis.

III. SMALL, WOMAN-OWNED AND MINORITY PARTICIPATION

It is the policy of the Commonwealth of Virginia to contribute to the establishment, preservation, and strengthening of small businesses and businesses owned by women and minorities, and to encourage their participation in State procurement activities. The Commonwealth encourages contractors to provide for the participation of small businesses and businesses owned by women and minorities through partnerships, joint ventures, subcontracts, and other contractual opportunities. Attachment B contains information on reporting spend data with subcontractors.

IV. STATEMENT OF NEEDS

A. General

1. James Madison University seeks established firms to provide turnkey services for testing and vaccination clinics. Currently, James Madison University anticipates providing the BinaxNow testing for upcoming clinics. James Madison intends to award multiple contracts and therefore no guarantees are given for the quantity of work your firm may or may not receive from a possible resulting contract. Contract award(s) will be made to the most qualified firms for providing staffing suitable for testing and vaccination clinics. Contractor shall furnish all necessary labor, resources, equipment and materials as may be required to fulfill James Madison University's needs and will clearly identify specific resources or equipment that must be provided by the university.
2. James Madison University reserves the right to obtain other cost estimates prior to authorizing work and to solicit any services apart from the resulting contract(s) as may be deemed in the best interest of the university.
3. No work is to be undertaken by the contractor until a written purchase order has been received.

- B.** Specify at least three (3) clients, preferably from a higher education institution, for similar staffing and services related to testing and/or vaccination clinics. Include the date(s) and

services furnished. Provide client name, address, contact name, phone number, and email address for each clinic that JMU may contact.

- C. Provide a detailed response to each of the following:
1. Describe your firm's ability and experiences related to the set up and administration of staffing and services for testing and/or vaccination clinics.
 2. Describe the needs of the testing site and contractor versus institution responsibilities (site, security, crowd control, equipment, privacy curtains, signage, staffing to checking in, staffing to administer the test or vaccine, etc.)
 3. Provide information on the suggested number of tests/vaccinations to be provided at each clinic and your methodology to process that number of testing/vaccination participants.
 4. Provide information on number and type of staff the contractor recommends for those scenarios. Include specific information on qualifications of staffing utilized for testing clinics versus vaccination clinics.
 5. Describe training (specifically HIPPA/FERPA), breaks, background checks, drug screenings, etc that will be provided to the staffing utilized/hired by the contractor.
 6. Describe licenses or certifications contractor shall require of staffing for testing and/or vaccination clinics.
 7. Describe Personal Protective Equipment (PPE) that the contractor will provide to all staffing. Contractor's employees and temporary staff performing the tests shall wear at all times a facial mask that covers both the nose and mouth, and protective garment covering.
 8. Describe protocols that will ensure that those individuals performing the tests each day are not infected with the COVID-19 virus.
 9. Describe the estimated number of tests that your staff could perform on a daily basis.
 10. Describe ability to provide test results reporting by 10:00 a.m. EST on the day after testing has been performed. Reporting shall be provided to the school in an Excel format that shall list the results of all the test performed during day. The structure and contents of the report shall be agreed upon between the Contractor and school prior to the start of testing.
 11. Describe contractor's supervision of each testing/vaccination clinic.
 12. Describe the fees per type of staffing; any fee for collection or administering of the test/vaccine, PPE, mileage, etc. as identified by the contractor.
 13. Describe your firm's ability to provide clinic staffing for both testing and vaccination clinics – firms may be awarded even if they are only suited for one or the other. JMU is providing the BinaxNow testing in the current situation, but we may be interested if the firm's ability to offer clinics and work with other testing and vaccination providers.
 14. Positive tests results shall be provided to the individual and the designated University representative on a real time basis. Describe your firm's ability to meet this requirement.
 15. Contractor shall report to the Virginia Department of Health (VDH) test results in accordance with VDH requirements within the time period as required. Describe your firm's ability to meet this requirement.
 16. Describe you firm's ability to setup and maintain multiple locations that may be geographically distant from each other.
 17. The Contractor shall ensure all employees and/or temporary staff performing the testing have been properly trained in administering the BinaxNOW test. Confirmation of successful training shall be provided to the designated school representative no later than

three (3) days prior to commencement of testing. Describe your firm's ability to comply with this requirement.

18. If BinaxNOW is not made available as anticipated, or provided in lesser quantities, describe options for your own testing solution. This would entail providing the test kits and required testing equipment. Contractor, at the time, would work in good faith through the specific institutions' protocols related to FERPA, Business Associate Agreements, SOC II, etc as necessary based on the type of testing made available. Additional requirements may be needed for providing testing that may not be needed for a staffing only situation.
19. Provide any other information regarding services that you firm would like us to consider to that is unique to your firm or methodology.

V. PROPOSAL PREPARATION AND SUBMISSION

A. GENERAL INSTRUCTIONS

To ensure timely and adequate consideration of your proposal, offerors are to limit all contact, whether verbal or written, pertaining to this RFP to the James Madison University Procurement Office for the duration of this Proposal process. Failure to do so may jeopardize further consideration of Offeror's proposal.

1. RFP Response: In order to be considered for selection, the **Offeror shall submit a complete response to this RFP**; and shall submit to the issuing Purchasing Agency:
 - a. **One (1) original and three (3) copies** of the entire proposal, INCLUDING ALL ATTACHMENTS. Any proprietary information should be clearly marked in accordance with 3.f. below.
 - b. **One (1) electronic copy in WORD format or searchable PDF (*flash drive*)** of the entire proposal, INCLUDING ALL ATTACHMENTS. Any proprietary information should be clearly marked in accordance with 3.f. below.
 - c. Should the proposal contain **proprietary information**, provide **one (1) redacted hard copy** of the proposal and all attachments with **proprietary portions removed or blacked out**. This copy should be clearly marked "*Redacted Copy*" on the front cover. The classification of an entire proposal document, line item prices, and/or total proposal prices as proprietary or trade secrets is not acceptable. JMU shall not be responsible for the Contractor's failure to exclude proprietary information from this redacted copy.

No other distribution of the proposal shall be made by the Offeror.

2. The version of the solicitation issued by JMU Procurement Services, as amended by an addenda, is the mandatory controlling version of the document. Any modification of, or additions to, the solicitation by the Offeror shall not modify the official version of the solicitation issued by JMU Procurement services unless accepted in writing by the University. Such modifications or additions to the solicitation by the Offeror may be cause for rejection of the proposal; however, JMU reserves the right to decide, on a case-by-case basis in its sole discretion, whether to reject such a proposal. If the modification or additions are not identified until after the award of the contract, the controlling version of the solicitation document shall still be the official state form issued by Procurement Services.

3. Proposal Preparation

- a. Proposals shall be signed by an authorized representative of the Offeror. All information requested should be submitted. Failure to submit all information requested may result in the purchasing agency requiring prompt submissions of missing information and/or giving a lowered evaluation of the proposal. Proposals which are substantially incomplete or lack key information may be rejected by the purchasing agency. Mandatory requirements are those required by law or regulation or are such that they cannot be waived and are not subject to negotiation.
- b. Proposals shall be prepared simply and economically, providing a straightforward, concise description of capabilities to satisfy the requirements of the RFP. Emphasis should be placed on completeness and clarity of content.
- c. Proposals should be organized in the order in which the requirements are presented in the RFP. All pages of the proposal should be numbered. Each paragraph in the proposal should reference the paragraph number of the corresponding section of the RFP. It is also helpful to cite the paragraph number, sub letter, and repeat the text of the requirement as it appears in the RFP. If a response covers more than one page, the paragraph number and sub letter should be repeated at the top of the next page. The proposal should contain a table of contents which cross references the RFP requirements. Information which the offeror desires to present that does not fall within any of the requirements of the RFP should be inserted at the appropriate place or be attached at the end of the proposal and designated as additional material. Proposals that are not organized in this manner risk elimination from consideration if the evaluators are unable to find where the RFP requirements are specifically addressed.
- d. As used in this RFP, the terms “must”, “shall”, “should” and “may” identify the criticality of requirements. “Must” and “shall” identify requirements whose absence will have a major negative impact on the suitability of the proposed solution. Items labeled as “should” or “may” are highly desirable, although their absence will not have a large impact and would be useful, but are not necessary. Depending on the overall response to the RFP, some individual “must” and “shall” items may not be fully satisfied, but it is the intent to satisfy most, if not all, “must” and “shall” requirements. The inability of an offeror to satisfy a “must” or “shall” requirement does not automatically remove that offeror from consideration; however, it may seriously affect the overall rating of the offeror’s proposal.
- e. Each copy of the proposal should be bound or contained in a single volume where practical. All documentation submitted with the proposal should be contained in that single volume.
- f. Ownership of all data, materials and documentation originated and prepared for the State pursuant to the RFP shall belong exclusively to the State and be subject to public inspection in accordance with the Virginia Freedom of Information Act. Trade secrets or proprietary information submitted by the offeror shall not be subject to public disclosure under the Virginia Freedom of Information Act; however, the offeror must invoke the protection of Section 2.2-4342F of the Code of Virginia, in writing, either before or at the time the data is submitted. The written notice must specifically identify the data or materials to be protected and state the reasons why protection is necessary. The proprietary or trade secret materials submitted must be identified by some distinct method such as highlighting or underlining and must indicate only the specific words, figures, or paragraphs that constitute trade secret or proprietary information. The

classification of an entire proposal document, line item prices and/or total proposal prices as proprietary or trade secrets is not acceptable and will result in rejection and return of the proposal.

4. Oral Presentation: Offerors who submit a proposal in response to this RFP may be required to give an oral presentation of their proposal to James Madison University. This provides an opportunity for the Offeror to clarify or elaborate on the proposal. This is a fact-finding and explanation session only and does not include negotiation. James Madison University will schedule the time and location of these presentations. Oral presentations are an option of the University and may or may not be conducted. Therefore, proposals should be complete.

B. SPECIFIC PROPOSAL INSTRUCTIONS

Proposals should be as thorough and detailed as possible so that James Madison University may properly evaluate your capabilities to provide the required services. Offerors are required to submit the following items as a complete proposal:

1. Return RFP cover sheet and all addenda acknowledgements, if any, signed and filled out as required.
2. Plan and methodology for providing the goods/services as described in Section IV. Statement of Needs of this Request for Proposal.
3. A written narrative statement to include, but not be limited to, the expertise, qualifications, and experience of the firm and resumes of specific personnel to be assigned to perform the work.
4. Offeror Data Sheet, included as *Attachment A* to this RFP.
5. Small Business Subcontracting Plan, included as *Attachment B* to this RFP. Offeror shall provide a Small Business Subcontracting plan which summarizes the planned utilization of Department of Small Business and Supplier Diversity (SBSD)-certified small businesses which include businesses owned by women and minorities, when they have received Department of Small Business and Supplier Diversity (SBSD) small business certification, under the contract to be awarded as a result of this solicitation. This is a requirement for all prime contracts in excess of \$100,000 unless no subcontracting opportunities exist.
6. Identify the amount of sales your company had during the last twelve months with each VASCUPP Member Institution. A list of VASCUPP Members can be found at: www.VASCUPP.org.
7. Proposed Cost. See Section X. Pricing Schedule of this Request for Proposal.

VI. **EVALUATION AND AWARD CRITERIA**

A. EVALUATION CRITERIA

Proposals shall be evaluated by James Madison University using the following criteria:

- | | |
|---|---------------------------------|
| 1. Quality of products/services offered and suitability for intended purposes | <div>Points</div> <div>20</div> |
|---|---------------------------------|

2. Qualifications and experience of Offeror in providing the goods/services	30
3. Specific plans or methodology to be used to perform the services	25
4. Participation of Small, Women-Owned, & Minority (SWaM) Businesses	10
5. Cost	15
	<hr/> 100

- B. AWARD: Selection shall be made of two or more offerors deemed to be fully qualified and best suited among those submitting proposals on the basis of the evaluation factors included in the Request for Proposals, including price, if so stated in the Request for Proposals. Negotiations shall be conducted with the offerors so selected. Price shall be considered, but need not be the sole determining factor. After negotiations have been conducted with each offeror so selected, the agency shall select the offeror which, in its opinion, has made the best proposal, and shall award the contract to that offeror. The Commonwealth may cancel this Request for Proposals or reject proposals at any time prior to an award, and is not required to furnish a statement of the reasons why a particular proposal was not deemed to be the most advantageous. Should the Commonwealth determine in writing and in its sole discretion that only one offeror is fully qualified, or that one offeror is clearly more highly qualified than the others under consideration, a contract may be negotiated and awarded to that offeror. The award document will be a contract incorporating by reference all the requirements, terms and conditions of the solicitation and the contractor's proposal as negotiated.

VII. GENERAL TERMS AND CONDITIONS

- A. PURCHASING MANUAL: This solicitation is subject to the provisions of the Commonwealth of Virginia's Purchasing Manual for Institutions of Higher Education and Their Vendors and any revisions thereto, which are hereby incorporated into this contract in their entirety. A copy of the manual is available for review at the purchasing office. In addition, the manual may be accessed electronically at <http://www.jmu.edu/procurement> or a copy can be obtained by calling Procurement Services at (540) 568-3145.
- B. APPLICABLE LAWS AND COURTS: This solicitation and any resulting contract shall be governed in all respects by the laws of the Commonwealth of Virginia and any litigation with respect thereto shall be brought in the courts of the Commonwealth. The Contractor shall comply with applicable federal, state and local laws and regulations.
- C. ANTI-DISCRIMINATION: By submitting their proposals, offerors certify to the Commonwealth that they will conform to the provisions of the Federal Civil Rights Act of 1964, as amended, as well as the Virginia Fair Employment Contracting Act of 1975, as amended, where applicable, the Virginians With Disabilities Act, the Americans With Disabilities Act and §10 of the Rules Governing Procurement, Chapter 2, Exhibit J, Attachment 1 (available for review at <http://www.jmu.edu/procurement>). If the award is made to a faith-based organization, the organization shall not discriminate against any recipient of goods, services, or disbursements made pursuant to the contract on the basis of the recipient's religion, religious belief, refusal to participate in a religious practice, or on the basis of race, age, color, gender, sexual orientation, gender identity, or national origin and shall be subject to the same rules as other organizations that contract with public bodies to account for the use of the funds provided; however, if the faith-based organization segregates public funds into separate accounts, only the accounts and programs funded with public funds shall be subject to audit by the public body. (*§6 of the Rules Governing Procurement*).

In every contract over \$10,000 the provisions in 1. and 2. below apply:

1. During the performance of this contract, the contractor agrees as follows:
 - a. The contractor will not discriminate against any employee or applicant for employment because of race, religion, color, sex, sexual orientation, gender identity, national origin, age, disability, or any other basis prohibited by state law relating to discrimination in employment, except where there is a bona fide occupational qualification reasonably necessary to the normal operation of the contractor. The contractor agrees to post in conspicuous places, available to employees and applicants for employment, notices setting forth the provisions of this nondiscrimination clause.
 - b. The contractor, in all solicitations or advertisements for employees placed by or on behalf of the contractor, will state that such contractor is an equal opportunity employer.
 - c. Notices, advertisements, and solicitations placed in accordance with federal law, rule, or regulation shall be deemed sufficient for the purpose of meeting these requirements.
 2. The contractor will include the provisions of 1. above in every subcontract or purchase order over \$10,000, so that the provisions will be binding upon each subcontractor or vendor.
- D. ETHICS IN PUBLIC CONTRACTING: By submitting their proposals, offerors certify that their proposals are made without collusion or fraud and that they have not offered or received any kickbacks or inducements from any other offeror, supplier, manufacturer or subcontractor in connection with their proposal, and that they have not conferred on any public employee having official responsibility for this procurement transaction any payment, loan, subscription, advance, deposit of money, services or anything of more than nominal value, present or promised, unless consideration of substantially equal or greater value was exchanged.
- E. IMMIGRATION REFORM AND CONTROL ACT OF 1986: By entering into a written contract with the Commonwealth of Virginia, the Contractor certifies that the Contractor does not, and shall not during the performance of the contract for goods and services in the Commonwealth, knowingly employ an unauthorized alien as defined in the federal Immigration Reform and Control Act of 1986.
- F. DEBARMENT STATUS: By submitting their proposals, offerors certify that they are not currently debarred by the Commonwealth of Virginia from submitting proposals on contracts for the type of goods and/or services covered by this solicitation, nor are they an agent of any person or entity that is currently so debarred.
- G. ANTITRUST: By entering into a contract, the contractor conveys, sells, assigns, and transfers to the Commonwealth of Virginia all rights, title and interest in and to all causes of action it may now have or hereafter acquire under the antitrust laws of the United States and the Commonwealth of Virginia, relating to the particular goods or services purchased or acquired by the Commonwealth of Virginia under said contract.
- H. MANDATORY USE OF STATE FORM AND TERMS AND CONDITIONS RFPs: Failure to submit a proposal on the official state form provided for that purpose may be a cause for rejection of the proposal. Modification of or additions to the General Terms and Conditions of the solicitation may be cause for rejection of the proposal; however, the Commonwealth reserves the right to decide, on a case by case basis, in its sole discretion, whether to reject such a proposal.

I. CLARIFICATION OF TERMS: If any prospective offeror has questions about the specifications or other solicitation documents, the prospective offeror should contact the buyer whose name appears on the face of the solicitation no later than five working days before the due date. Any revisions to the solicitation will be made only by addendum issued by the buyer.

J. PAYMENT:

1. To Prime Contractor:

- a. Invoices for items ordered, delivered and accepted shall be submitted by the contractor directly to the payment address shown on the purchase order/contract. All invoices shall show the state contract number and/or purchase order number; social security number (for individual contractors) or the federal employer identification number (for proprietorships, partnerships, and corporations).
- b. Any payment terms requiring payment in less than 30 days will be regarded as requiring payment 30 days after invoice or delivery, whichever occurs last. This shall not affect offers of discounts for payment in less than 30 days, however.
- c. All goods or services provided under this contract or purchase order, that are to be paid for with public funds, shall be billed by the contractor at the contract price, regardless of which public agency is being billed.
- d. The following shall be deemed to be the date of payment: the date of postmark in all cases where payment is made by mail, or the date of offset when offset proceedings have been instituted as authorized under the Virginia Debt Collection Act.
- e. Unreasonable Charges. Under certain emergency procurements and for most time and material purchases, final job costs cannot be accurately determined at the time orders are placed. In such cases, contractors should be put on notice that final payment in full is contingent on a determination of reasonableness with respect to all invoiced charges. Charges which appear to be unreasonable will be researched and challenged, and that portion of the invoice held in abeyance until a settlement can be reached. Upon determining that invoiced charges are not reasonable, the Commonwealth shall promptly notify the contractor, in writing, as to those charges which it considers unreasonable and the basis for the determination. A contractor may not institute legal action unless a settlement cannot be reached within thirty (30) days of notification. The provisions of this section do not relieve an agency of its prompt payment obligations with respect to those charges which are not in dispute (*Rules Governing Procurement, Chapter 2, Exhibit J, Attachment 1 § 53; available for review at <http://www.jmu.edu/procurement>*).

2. To Subcontractors:

a. A contractor awarded a contract under this solicitation is hereby obligated:

- (1) To pay the subcontractor(s) within seven (7) days of the contractor's receipt of payment from the Commonwealth for the proportionate share of the payment received for work performed by the subcontractor(s) under the contract; or

- (2) To notify the agency and the subcontractors, in writing, of the contractor's intention to withhold payment and the reason.
 - b. The contractor is obligated to pay the subcontractor(s) interest at the rate of one percent per month (unless otherwise provided under the terms of the contract) on all amounts owed by the contractor that remain unpaid seven (7) days following receipt of payment from the Commonwealth, except for amounts withheld as stated in (2) above. The date of mailing of any payment by U. S. Mail is deemed to be payment to the addressee. These provisions apply to each sub-tier contractor performing under the primary contract. A contractor's obligation to pay an interest charge to a subcontractor may not be construed to be an obligation of the Commonwealth.
 3. Each prime contractor who wins an award in which provision of a SWAM procurement plan is a condition to the award, shall deliver to the contracting agency or institution, on or before request for final payment, evidence and certification of compliance (subject only to insubstantial shortfalls and to shortfalls arising from subcontractor default) with the SWAM procurement plan. Final payment under the contract in question may be withheld until such certification is delivered and, if necessary, confirmed by the agency or institution, or other appropriate penalties may be assessed in lieu of withholding such payment.
 4. The Commonwealth of Virginia encourages contractors and subcontractors to accept electronic and credit card payments.
- K. PRECEDENCE OF TERMS: Paragraphs A through J of these General Terms and Conditions and the Commonwealth of Virginia Purchasing Manual for Institutions of Higher Education and their Vendors, shall apply in all instances. In the event there is a conflict between any of the other General Terms and Conditions and any Special Terms and Conditions in this solicitation, the Special Terms and Conditions shall apply.
- L. QUALIFICATIONS OF OFFERORS: The Commonwealth may make such reasonable investigations as deemed proper and necessary to determine the ability of the offeror to perform the services/furnish the goods and the offeror shall furnish to the Commonwealth all such information and data for this purpose as may be requested. The Commonwealth reserves the right to inspect offeror's physical facilities prior to award to satisfy questions regarding the offeror's capabilities. The Commonwealth further reserves the right to reject any proposal if the evidence submitted by, or investigations of, such offeror fails to satisfy the Commonwealth that such offeror is properly qualified to carry out the obligations of the contract and to provide the services and/or furnish the goods contemplated therein.
- M. TESTING AND INSPECTION: The Commonwealth reserves the right to conduct any test/inspection it may deem advisable to assure goods and services conform to the specifications.
- N. ASSIGNMENT OF CONTRACT: A contract shall not be assignable by the contractor in whole or in part without the written consent of the Commonwealth.
- O. CHANGES TO THE CONTRACT: Changes can be made to the contract in any of the following ways:
1. The parties may agree in writing to modify the scope of the contract. An increase or decrease in the price of the contract resulting from such modification shall be agreed to by the parties as a part of their written agreement to modify the scope of the contract.

2. The Purchasing Agency may order changes within the general scope of the contract at any time by written notice to the contractor. Changes within the scope of the contract include, but are not limited to, things such as the number of or frequency of COVID-19 tests, testing locations, reporting of test results (format and frequency), the type of testing provided, services to be performed, the method of packing or shipment, and the place of delivery or installation. The contractor shall comply with the notice upon receipt. The contractor shall be compensated for any additional costs incurred as the result of such order and shall give the Purchasing Agency a credit for any savings. Said compensation shall be determined by one of the following methods:
 - a. By mutual agreement between the parties in writing; or
 - b. By agreeing upon a unit price or using a unit price set forth in the contract, if the work to be done can be expressed in units, and the contractor accounts for the number of units of work performed, subject to the Purchasing Agency's right to audit the contractor's records and/or to determine the correct number of units independently; or
 - c. By ordering the contractor to proceed with the work and keep a record of all costs incurred and savings realized. A markup for overhead and profit may be allowed if provided by the contract. The same markup shall be used for determining a decrease in price as the result of savings realized. The contractor shall present the Purchasing Agency with all vouchers and records of expenses incurred and savings realized. The Purchasing Agency shall have the right to audit the records of the contractor as it deems necessary to determine costs or savings. Any claim for an adjustment in price under this provision must be asserted by written notice to the Purchasing Agency within thirty (30) days from the date of receipt of the written order from the Purchasing Agency. If the parties fail to agree on an amount of adjustment, the question of an increase or decrease in the contract price or time for performance shall be resolved in accordance with the procedures for resolving disputes provided by the Disputes Clause of this contract or, if there is none, in accordance with the disputes provisions of the Commonwealth of Virginia Purchasing Manual for Institutions of Higher Education and their Vendors. Neither the existence of a claim nor a dispute resolution process, litigation or any other provision of this contract shall excuse the contractor from promptly complying with the changes ordered by the Purchasing Agency or with the performance of the contract generally.
- P. DEFAULT: In case of failure to deliver goods or services in accordance with the contract terms and conditions, the Commonwealth, after due oral or written notice, may procure them from other sources and hold the contractor responsible for any resulting additional purchase and administrative costs. This remedy shall be in addition to any other remedies which the Commonwealth may have.
- Q. INSURANCE: By signing and submitting a proposal under this solicitation, the offeror certifies that if awarded the contract, it will have the following insurance coverage at the time the contract is awarded. For construction contracts, if any subcontractors are involved, the subcontractor will have workers' compensation insurance in accordance with § 25 of the Rules Governing Procurement – Chapter 2, Exhibit J, Attachment 1, and 65.2-800 et. Seq. of the Code of Virginia (available for review at <http://www.jmu.edu/procurement>) The offeror further certifies that the contractor and any subcontractors will maintain these insurance coverage during the entire term of the contract and that all insurance coverage will be provided by insurance companies authorized to sell insurance in Virginia by the Virginia State Corporation Commission.

MINIMUM INSURANCE COVERAGES AND LIMITS REQUIRED FOR MOST CONTRACTS:

1. Workers' Compensation: Statutory requirements and benefits. Coverage is compulsory for employers of three or more employees, to include the employer. Contractors who fail to notify the Commonwealth of increases in the number of employees that change their workers' compensation requirement under the Code of Virginia during the course of the contract shall be in noncompliance with the contract.
 2. Employer's Liability: \$100,000
 3. Commercial General Liability: \$1,000,000 per occurrence and \$2,000,000 in the aggregate. Commercial General Liability is to include bodily injury and property damage, personal injury and advertising injury, products and completed operations coverage. The Commonwealth of Virginia must be named as an additional insured and so endorsed on the policy.
 4. Automobile Liability: \$1,000,000 combined single limit. *(Required only if a motor vehicle not owned by the Commonwealth is to be used in the contract. Contractor must assure that the required coverage is maintained by the Contractor (or third party owner of such motor vehicle.)*
- R. ANNOUNCEMENT OF AWARD: Upon the award or the announcement of the decision to award a contract over \$100,000, as a result of this solicitation, the purchasing agency will publicly post such notice on the DGS/DPS eVA web site (www.eva.virginia.gov) for a minimum of 10 days.
- S. DRUG-FREE WORKPLACE: During the performance of this contract, the contractor agrees to (i) provide a drug-free workplace for the contractor's employees; (ii) post in conspicuous places, available to employees and applicants for employment, a statement notifying employees that the unlawful manufacture, sale, distribution, dispensation, possession, or use of a controlled substance or marijuana is prohibited in the contractor's workplace and specifying the actions that will be taken against employees for violations of such prohibition; (iii) state in all solicitations or advertisements for employees placed by or on behalf of the contractor that the contractor maintains a drug-free workplace; and (iv) include the provisions of the foregoing clauses in every subcontract or purchase order of over \$10,000, so that the provisions will be binding upon each subcontractor or vendor.
- For the purposes of this section, "drug-free workplace" means a site for the performance of work done in connection with a specific contract awarded to a contractor, the employees of whom are prohibited from engaging in the unlawful manufacture, sale, distribution, dispensation, possession or use of any controlled substance or marijuana during the performance of the contract.
- T. NONDISCRIMINATION OF CONTRACTORS: An offeror, or contractor shall not be discriminated against in the solicitation or award of this contract because of race, religion, color, sex, sexual orientation, gender identity, national origin, age, disability, faith-based organizational status, any other basis prohibited by state law relating to discrimination in employment or because the offeror employs ex-offenders unless the state agency, department or institution has made a written determination that employing ex-offenders on the specific contract is not in its best interest. If the award of this contract is made to a faith-based organization and an individual, who applies for or receives goods, services, or disbursements provided pursuant to this contract objects to the religious character of the faith-based organization from which the individual receives or would receive the goods, services, or disbursements, the public body shall offer the individual, within a reasonable period of time after the date of his objection, access to equivalent goods, services, or disbursements from an alternative provider.

- U. **eVA BUSINESS TO GOVERNMENT VENDOR REGISTRATION, CONTRACTS, AND ORDERS:** The eVA Internet electronic procurement solution, website portal www.eVA.virginia.gov, streamlines and automates government purchasing activities in the Commonwealth. The eVA portal is the gateway for vendors to conduct business with state agencies and public bodies. All vendors desiring to provide goods and/or services to the Commonwealth shall participate in the eVA Internet eprocurement solution by completing the free eVA Vendor Registration. All offerors must register in eVA and pay the Vendor Transaction Fees specified below; failure to register will result in the proposal being rejected. Vendor transaction fees are determined by the date the original purchase order is issued and the current fees are as follows:

Vendor transaction fees are determined by the date the original purchase order is issued and the current fees are as follows:

1. For orders issued July 1, 2014 and after, the Vendor Transaction Fee is:
 - a. Department of Small Business and Supplier Diversity (SBSD) certified Small Businesses: 1% capped at \$500 per order.
 - b. Businesses that are not Department of Small Business and Supplier Diversity (SBSD) certified Small Businesses: 1% capped at \$1,500 per order.
 2. For orders issued prior to July 1, 2014 the vendor transaction fees can be found at www.eVA.virginia.gov.
 3. The specified vendor transaction fee will be invoiced by the Commonwealth of Virginia Department of General Services approximately 60 days after the corresponding purchase order is issued and payable 30 days after the invoice date. Any adjustments (increases/decreases) will be handled through purchase order changes.
- V. **AVAILABILITY OF FUNDS:** It is understood and agreed between the parties herein that the Commonwealth of Virginia shall be bound hereunder only to the extent of the funds available or which may hereafter become available for the purpose of this agreement.
- W. **PRICING CURRENCY:** Unless stated otherwise in the solicitation, offerors shall state offered prices in U.S. dollars.
- X. **E-VERIFY REQUIREMENT OF ANY CONTRACTOR:** Any employer with more than an average of 50 employees for the previous 12 months entering into a contract in excess of \$50,000 with James Madison University to perform work or provide services pursuant to such contract shall register and participate in the E-Verify program to verify information and work authorization of its newly hired employees performing work pursuant to any awarded contract.
- Y. **CIVILITY IN STATE WORKPLACES:** The contractor shall take all reasonable steps to ensure that no individual, while performing work on behalf of the contractor or any subcontractor in connection with this agreement (each, a "Contract Worker"), shall engage in 1) harassment (including sexual harassment), bullying, cyber-bullying, or threatening or violent conduct, or 2) discriminatory behavior on the basis of race, sex, color, national origin, religious belief, sexual orientation, gender identity or expression, age, political affiliation, veteran status, or disability.

The contractor shall provide each Contract Worker with a copy of this Section and will require Contract Workers to participate in training on civility in the State workplace. Upon request, the contractor shall provide documentation that each Contract Worker has received such training.

For purposes of this Section, “State workplace” includes any location, permanent or temporary, where a Commonwealth employee performs any work-related duty or is representing his or her agency, as well as surrounding perimeters, parking lots, outside meeting locations, and means of travel to and from these locations. Communications are deemed to occur in a State workplace if the Contract Worker reasonably should know that the phone number, email, or other method of communication is associated with a State workplace or is associated with a person who is a State employee.

The Commonwealth of Virginia may require, at its sole discretion, the removal and replacement of any Contract Worker who the Commonwealth reasonably believes to have violated this Section.

This Section creates obligations solely on the part of the contractor. Employees or other third parties may benefit incidentally from this Section and from training materials or other communications distributed on this topic, but the Parties to this agreement intend this Section to be enforceable solely by the Commonwealth and not by employees or other third parties.

VIII. SPECIAL TERMS AND CONDITIONS

- A. **AUDIT:** The Contractor hereby agrees to retain all books, records, systems, and other documents relative to this contract for five (5) years after final payment, or until audited by the Commonwealth of Virginia, whichever is sooner. The Commonwealth of Virginia, its authorized agents, and/or State auditors shall have full access to and the right to examine any of said materials during said period.
- B. **CANCELLATION OF CONTRACT:** James Madison University reserves the right to cancel and terminate any resulting contract, in part or in whole, without penalty, upon 60 days written notice to the contractor. In the event the initial contract period is for more than 12 months, the resulting contract may be terminated by either party, without penalty, after the initial 12 months of the contract period upon 60 days written notice to the other party. Any contract cancellation notice shall not relieve the contractor of the obligation to deliver and/or perform on all outstanding orders issued prior to the effective date of cancellation.

In the event that the University, at their sole discretion, determines that the campus must transition to a wholly online or majority online teaching model, and that the majority of students will not be residing on campus, any purchase order or agreement for specific clinics/locations shall immediately terminate upon written notice of that determination to Contractor. The Contractor will be entitled to receive full compensation for the operation of the Clinic(s) and for any tests that were provided to individuals prior to the termination date at the price specified within this Contract. Contractor shall not be entitled to, and hereby waives claims for, including, but not limited to payment for the continued operation of the clinic, scheduled tests, lost profits and all other damages and expenses.

- C. **IDENTIFICATION OF PROPOSAL ENVELOPE:** The signed proposal should be returned in a separate envelope or package, sealed and identified as follows:

From:	<hr/>		
	Name of Offeror	Due Date	Time
	<hr/>		
	Street or Box No.	RFP #	
	<hr/>		
	City, State, Zip Code	RFP Title	
	<hr/>		
	Name of Purchasing Officer:		
	<hr/>		

The envelope should be addressed as directed on the title page of the solicitation.

The Offeror takes the risk that if the envelope is not marked as described above, it may be inadvertently opened and the information compromised, which may cause the proposal to be disqualified. Proposals may be hand-delivered to the designated location in the office issuing the solicitation. No other correspondence or other proposals should be placed in the envelope.

- D. **LATE PROPOSALS:** To be considered for selection, proposals must be received by the issuing office by the designated date and hour. The official time used in the receipt of proposals is that time on the automatic time stamp machine in the issuing office. Proposals received in the issuing office after the date and hour designated are automatically non responsive and will not be considered. The University is not responsible for delays in the delivery of mail by the U.S. Postal Service, private couriers, or the intra university mail system. It is the sole responsibility of the Offeror to ensure that its proposal reaches the issuing office by the designated date and hour.
- E. **UNDERSTANDING OF REQUIREMENTS:** It is the responsibility of each offeror to inquire about and clarify any requirements of this solicitation that is not understood. The University will not be bound by oral explanations as to the meaning of specifications or language contained in this solicitation. Therefore, all inquiries deemed to be substantive in nature must be in writing and submitted to the responsible buyer in the Procurement Services Office. Offerors must ensure that written inquiries reach the buyer at least five (5) days prior to the time set for receipt of offerors proposals. A copy of all queries and the respective response will be provided in the form of an addendum to all offerors who have indicated an interest in responding to this solicitation. Your signature on your Offer certifies that you fully understand all facets of this solicitation. These questions may be sent by Fax to 540/568-7935.
- F. **RENEWAL OF CONTRACT:** This contract may be renewed by the Commonwealth for a period of two (2) successive one-year periods under the terms and conditions of the original contract except as stated in 1. and 2. below. Price increases may be negotiated only at the time of renewal. Written notice of the Commonwealth's intention to renew shall be given approximately 90 days prior to the expiration date of each contract period.
1. If the Commonwealth elects to exercise the option to renew the contract for an additional one-year period, the contract price(s) for the additional one year shall not exceed the contract price(s) of the original contract increased/decreased by no more than the percentage increase/decrease of the other services category of the CPI-W section of the Consumer Price Index of the United States Bureau of Labor Statistics for the latest twelve months for which statistics are available.
 2. If during any subsequent renewal periods, the Commonwealth elects to exercise the option to renew the contract, the contract price(s) for the subsequent renewal period shall not exceed the contract price(s) of the previous renewal period increased/decreased by more than the percentage increase/decrease of the other services category of the CPI-W section of the Consumer Price Index of the United States Bureau of Labor Statistics for the latest twelve months for which statistics are available.
- G. **SUBMISSION OF INVOICES:** All invoices shall be submitted within sixty days of contract term expiration for the initial contract period as well as for each subsequent contract renewal period. Any invoices submitted after the sixty day period will not be processed for payment.
- H. **OPERATING VEHICLES ON JAMES MADISON UNIVERSITY CAMPUS:** Operating vehicles on sidewalks, plazas, and areas heavily used by pedestrians is prohibited. In the unlikely event a driver should find it necessary to drive on James Madison University sidewalks, plazas, and areas

heavily used by pedestrians, the driver must yield to pedestrians. For a complete list of parking regulations, please go to www.jmu.edu/parking; or to acquire a service representative parking permit, contact Parking Services at 540.568.3300. The safety of our students, faculty and staff is of paramount importance to us. Accordingly, violators may be charged.

- I. COOPERATIVE PURCHASING / USE OF AGREEMENT BY THIRD PARTIES: It is the intent of this solicitation and resulting contract(s) to allow for cooperative procurement. Accordingly, any public body, (to include government/state agencies, political subdivisions, etc.), cooperative purchasing organizations, public or private health or educational institutions or any University related foundation and affiliated corporations may access any resulting contract if authorized by the Contractor.

Participation in this cooperative procurement is strictly voluntary. If authorized by the Contractor(s), the resultant contract(s) will be extended to the entities indicated above to purchase goods and services in accordance with contract terms. As a separate contractual relationship, the participating entity will place its own orders directly with the Contractor(s) and shall fully and independently administer its use of the contract(s) to include contractual disputes, invoicing and payments without direct administration from the University. No modification of this contract or execution of a separate agreement is required to participate; however, the participating entity and the Contractor may modify the terms and conditions of this contract to accommodate specific governing laws, regulations, policies, and business goals required by the participating entity. Any such modification will apply solely between the participating entity and the Contractor.

The Contractor will notify the University in writing of any such entities accessing this contract. The Contractor will provide semi-annual usage reports for all entities accessing the contract. The University shall not be held liable for any costs or damages incurred by any other participating entity as a result of any authorization by the Contractor to extend the contract. It is understood and agreed that the University is not responsible for the acts or omissions of any entity and will not be considered in default of the contract no matter the circumstances.

Use of this contract(s) does not preclude any participating entity from using other contracts or competitive processes as needed.

- J. SMALL BUSINESS SUBCONTRACTING AND EVIDENCE OF COMPLIANCE:

1. It is the goal of the Commonwealth that 42% of its purchases are made from small businesses. This includes discretionary spending in prime contracts and subcontracts. All potential offerors are required to submit a Small Business Subcontracting Plan. Unless the offeror is registered as a Department of Small Business and Supplier Diversity (SBSD)-certified small business and where it is practicable for any portion of the awarded contract to be subcontracted to other suppliers, the contractor is encouraged to offer such subcontracting opportunities to SBSD-certified small businesses. This shall not exclude SBSD-certified women-owned and minority-owned businesses when they have received SBSD small business certification. No offeror or subcontractor shall be considered a Small Business, a Women-Owned Business or a Minority-Owned Business unless certified as such by the Department of Small Business and Supplier Diversity (SBSD) by the due date for receipt of proposals. If small business subcontractors are used, the prime contractor agrees to report the use of small business subcontractors by providing the purchasing office at a minimum the following information: name of small business with the SBSD certification number or FEIN, phone number, total dollar amount subcontracted, category type (small, women-owned, or minority-owned), and type of product/service provided.

This information shall be submitted to: JMU Office of Procurement Services, Attn: SWAM Subcontracting Compliance, MSC 5720, Harrisonburg, VA 22807.

2. Each prime contractor who wins an award in which provision of a small business subcontracting plan is a condition of the award, shall deliver to the contracting agency or institution with every request for payment, evidence of compliance (subject only to insubstantial shortfalls and to shortfalls arising from subcontractor default) with the small business subcontracting plan. **This information shall be submitted to: JMU Office of Procurement Services, SWAM Subcontracting Compliance, MSC 5720, Harrisonburg, VA 22807.** When such business has been subcontracted to these firms and upon completion of the contract, the contractor agrees to furnish the purchasing office at a minimum the following information: name of firm with the Department of Small Business and Supplier Diversity (SBSD) certification number or FEIN number, phone number, total dollar amount subcontracted, category type (small, women-owned, or minority-owned), and type of product or service provided. Payment(s) may be withheld until compliance with the plan is received and confirmed by the agency or institution. The agency or institution reserves the right to pursue other appropriate remedies to include, but not be limited to, termination for default.
 3. Each prime contractor who wins an award valued over \$200,000 shall deliver to the contracting agency or institution with every request for payment, information on use of subcontractors that are not Department of Small Business and Supplier Diversity (SBSD)-certified small businesses. When such business has been subcontracted to these firms and upon completion of the contract, the contractor agrees to furnish the purchasing office at a minimum the following information: name of firm, phone number, FEIN number, total dollar amount subcontracted, and type of product or service provided. **This information shall be submitted to: JMU Office of Procurement Services, Attn: SWAM Subcontracting Compliance, MSC 5720, Harrisonburg, VA 22807.**
- K. AUTHORIZATION TO CONDUCT BUSINESS IN THE COMMONWEALTH: A contractor organized as a stock or nonstock corporation, limited liability company, business trust, or limited partnership or registered as a registered limited liability partnership shall be authorized to transact business in the Commonwealth as a domestic or foreign business entity if so required by Title 13.1 or Title 50 of the Code of Virginia or as otherwise required by law. Any business entity described above that enters into a contract with a public body shall not allow its existence to lapse or its certificate of authority or registration to transact business in the Commonwealth, if so required under Title 13.1 or Title 50, to be revoked or cancelled at any time during the term of the contract. A public body may void any contract with a business entity if the business entity fails to remain in compliance with the provisions of this section.
- L. PUBLIC POSTING OF COOPERATIVE CONTRACTS: James Madison University maintains a web-based contracts database with a public gateway access. Any resulting cooperative contract/s to this solicitation will be posted to the publicly accessible website. Contents identified as proprietary information will not be made public.
- M. CRIMINAL BACKGROUND CHECKS OF PERSONNEL ASSIGNED BY CONTRACTOR TO PERFORM WORK ON JMU PROPERTY: The Contractor shall obtain criminal background checks on all of their contracted employees who will be assigned to perform services on James Madison University property. The results of the background checks will be directed solely to the Contractor. The Contractor bears responsibility for confirming to the University contract administrator that the background checks have been completed prior to work being performed by their employees or subcontractors. The Contractor shall only assign to work on the University campus those individuals whom it deems qualified and permissible based on the results of completed background checks.

Notwithstanding any other provision herein, and to ensure the safety of students, faculty, staff and facilities, James Madison University reserves the right to approve or disapprove any contract employee that will work on JMU property. Disapproval by the University will solely apply to JMU property and should have no bearing on the Contractor's employment of an individual outside of James Madison University.

- N. INDEMNIFICATION: Contractor agrees to indemnify, defend and hold harmless the Commonwealth of Virginia, its officers, agents, and employees from any claims, damages and actions of any kind or nature, whether at law or in equity, arising from or caused by the use of any materials, goods, or equipment of any kind or nature furnished by the contractor/any services of any kind or nature furnished by the contractor, provided that such liability is not attributable to the sole negligence of the using agency or to failure of the using agency to use the materials, goods, or equipment in the manner already and permanently described by the contractor on the materials, goods or equipment delivered.
- O. ADDITIONAL GOODS AND SERVICES: The University may acquire other goods or services that the supplier provides than those specifically solicited. The University reserves the right, subject to mutual agreement, for the Contractor to provide additional goods and/or services under the same pricing, terms, and conditions and to make modifications or enhancements to the existing goods and services. Such additional goods and services may include other products, components, accessories, subsystems, or related services that are newly introduced during the term of this Agreement. Such additional goods and services will be provided to the University at favored nations pricing, terms, and conditions.
- P. ADVERTISING: In the event a contract is awarded for supplies, equipment, or services resulting from this proposal, no indication of such sales or services to James Madison University will be used in product literature or advertising without the express written consent of the University. The contractor shall not state in any of its advertising or product literature that James Madison University has purchased or uses any of its products or services, and the contractor shall not include James Madison University in any client list in advertising and promotional materials without the express written consent of the University.
- Q. ELECTRICAL EQUIPMENT STANDARDS: All equipment/material shall conform to the latest issue of all applicable standards as established by National Electrical Manufacturer's Association (NEMA), American National Standards Institute (ANSI), and Occupational Safety & Health Administration (OSHA). All equipment and material, for which there are OSHA standards, shall bear an appropriate label of approval for use intended from a Nationally Recognized Testing Laboratory (NRTL).
- R. RIGHTS AND LICENSE IN AND TO UNIVERSITY DATA: The parties agree that as between them, all rights including all intellectual property rights in and to University Data shall remain the exclusive property of the University, and Contractor has a limited, nonexclusive license to use the data as provided in the Agreement solely for the purpose of performing its obligations hereunder. The Agreement does not give a party any rights, implied or otherwise, to the other's data, content, or intellectual property.
- S. DATA PRIVACY AND SUBCONTRACTORS: Contractor will use University Data only for the purpose of fulfilling its duties under the Agreement and will not share such data with or disclose it to any third party without the prior written consent of the University, except as required by law. University Data will not be stored outside the United States without prior written consent from the University. Contractor will provide access to University Data only to its employees and subcontractors who need to access the data to fulfill obligations under the Agreement. The Contractor shall be responsible and liable for the acts and omissions of its subcontractors, including

but not limited to third-party cloud hosting providers, and shall assure compliance with the requirements of the Agreement.

- T. DATA SECURITY: Contractor will store and process University Data in accordance with commercial best practices, including appropriate administrative, physical, and technical safeguards, to secure such data from unauthorized access, disclosure, alteration, and use. Such measures will be no less protective than those used to secure Contractor's own data of a similar type, and in no event less than reasonable in view of the type and nature of the data involved.
- U. SECURITY BREACH RESPONSE: Immediately (within one day) upon becoming aware of a Security Breach, or of circumstances that could have resulted in unauthorized access to or disclosure or use of University Data, Contractor will notify the University, fully investigate the incident, and cooperate fully with the University's investigation of and response to the incident. Except as otherwise required by law, Contractor will not provide notice of the incident directly to individuals whose Personally Identifiable Information was involved, regulatory agencies, or other entities, without prior written permission from the University.
- V. DATA TRANSFER UPON TERMINATION OR EXPIRATION: Upon termination or expiration of the Agreement, Contractor will ensure that all University Data are securely transferred, returned or destroyed as directed by the University in its sole discretion within 60 days of termination of the Agreement. Contractor shall ensure that such transfer uses facilities, methods, and data formats that are accessible and compatible with the relevant systems of the University. In the event that the University requests destruction of its data, Contractor agrees to securely destroy all data in its possession and in the possession of any subcontractors or agents to which Contractor might have transferred University data. Contractor agrees to provide documentation of data destruction to the University.
- W. CIVILITY IN STATE WORKPLACES: The contractor shall take all reasonable steps to ensure that no individual, while performing work on behalf of the contractor or any subcontractor in connection with this agreement (each, a "Contract Worker"), shall engage in 1) harassment (including sexual harassment), bullying, cyber-bullying, or threatening or violent conduct, or 2) discriminatory behavior on the basis of race, sex, color, national origin, religious belief, sexual orientation, gender identity or expression, age, political affiliation, veteran status, or disability.

The contractor shall provide each Contract Worker with a copy of this Section and will require Contract Workers to participate in training on civility in the State workplace. Upon request, the contractor shall provide documentation that each Contract Worker has received such training.

For purposes of this Section, "State workplace" includes any location, permanent or temporary, where a

Commonwealth employee performs any work-related duty or is representing his or her agency, as well as surrounding perimeters, parking lots, outside meeting locations, and means of travel to and from these locations. Communications are deemed to occur in a State workplace if the Contract Worker reasonably should know that the phone number, email, or other method of communication is associated with a State workplace or is associated with a person who is a State employee.

The Commonwealth of Virginia may require, at its sole discretion, the removal and replacement of any Contract Worker who the Commonwealth reasonably believes to have violated this Section.

This Section creates obligations solely on the part of the contractor. Employees or other third parties may benefit incidentally from this Section and from training materials or other communications distributed on this topic, but the Parties to this agreement intend this Section to be enforceable solely by the Commonwealth and not by employees or other third parties.

- X. **HIPAA – CONFIDENTIALITY AND RECORDS:** The Contractor assures that information, data and records obtained during the performance of this contract, to include personal facts and circumstances related to patients, shall be considered confidential during and following the terms of this contract and will be stored and maintained in strict compliance with applicable state and federal laws, and, further, shall not be divulged without JMU's written consent and then only in strict accordance with said applicable laws. The Contractor shall hold all information provided by JMU as proprietary and confidential and shall make no unauthorized reproduction or distribution of such material. Upon termination of this contract and/or within thirty (30) days of receipt of final payment for services, all materials, data, and information in the possession of the Contractor, provided to or obtained by the Contractor during the performance of this contract and to satisfy the requirements of the contract, shall be provided to JMU in hard copy and/or electronic form. Except where law allows, the Contractor shall not retain hard copies of the material, data, and information and all electronically stored material, data, and information shall be expunged from equipment and systems retained by the Contractor.

IX. METHOD OF PAYMENT

The contractor will be paid on the basis of invoices submitted in accordance with the solicitation and any negotiations. James Madison University recognizes the importance of expediting the payment process for our vendors and suppliers; however, vendor enrollment for E-Payments has temporarily been suspended as we transition to a new bank. Once we are operational with our new bank, we will ask that our vendors and suppliers enroll in our bank's single use Commercial Card Number process or electronic deposit (ACH) to your bank account so that future payments are made electronically. Contractors signed up for the single use Commercial Card Number process will receive the benefit of being paid in Net 15 days. Additional information is available online at: <http://www.jmu.edu/financeoffice/accounting-operations-disbursements/cash-investments/vendor-payment-methods.shtml>

X. PRICING SCHEDULE

The offeror shall provide pricing for all products and services included in proposal indicating one-time and on-going costs. The resulting contract will be cooperative and pricing shall be inclusive for the attached Zone Map, of which JMU falls within Zone 2.

Specify any associated charge card processing fees, if applicable, to be billed to the university. Vendors shall provide their VISA registration number when indicating charge card processing fees. Any vendor requiring information on VISA registration may refer to <https://usa.visa.com/support/small-business/regulations-fees.html> and for questions <https://usa.visa.com/dam/VCOM/global/support-legal/documents/merchant-surcharging-qa-for-web.pdf>.

XI. ATTACHMENTS

Attachment A: Offeror Data Sheet
Attachment B: Small, Women, and Minority-owned Business (SWaM) Utilization Plan
Attachment C: Standard Contract Sample
Attachment D: Zone Map

ATTACHMENT A

OFFEROR DATA SHEET

TO BE COMPLETED BY OFFEROR

1. **QUALIFICATIONS OF OFFEROR:** Offerors must have the capability and capacity in all respects to fully satisfy the contractual requirements.
2. **YEARS IN BUSINESS:** Indicate the length of time you have been in business providing these types of goods and services.

Years _____ Months _____

3. **REFERENCES:** Indicate below a listing of at least five (5) organizations, either commercial or governmental/educational, that your agency is servicing. Include the name and address of the person the purchasing agency has your permission to contact.

CLIENT	LENGTH OF SERVICE	ADDRESS	CONTACT PERSON/PHONE #
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4. List full names and addresses of Offeror and any branch offices which may be responsible for administering the contract.

5. **RELATIONSHIP WITH THE COMMONWEALTH OF VIRGINIA:** Is any member of the firm an employee of the Commonwealth of Virginia who has a personal interest in this contract pursuant to the [CODE OF VIRGINIA](#), SECTION 2.2-3100 – 3131?

[] YES [] NO

IF YES, EXPLAIN: _____

ATTACHMENT B

Small, Women and Minority-owned Businesses (SWaM) Utilization Plan

Offeror Name: _____ **Preparer Name:** _____

Date: _____

Is your firm a **Small Business Enterprise** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes _____ No _____

If yes, certification number: _____ Certification date: _____

Is your firm a **Woman-owned Business Enterprise** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes _____ No _____

If yes, certification number: _____ Certification date: _____

Is your firm a **Minority-Owned Business Enterprise** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes _____ No _____

If yes, certification number: _____ Certification date: _____

Is your firm a **Micro Business** certified by the Department of Small Business and Supplier Diversity (SBSD)? Yes _____ No _____

If yes, certification number: _____ Certification date: _____

Instructions: *Populate the table below to show your firm's plans for utilization of small, women-owned and minority-owned business enterprises in the performance of the contract. Describe plans to utilize SWAMs businesses as part of joint ventures, partnerships, subcontractors, suppliers, etc.*

Small Business: "Small business " means a business, independently owned or operated by one or more persons who are citizens of the United States or non-citizens who are in full compliance with United States immigration law, which, together with affiliates, has 250 or fewer employees, or average annual gross receipts of \$10 million or less averaged over the previous three years.

Woman-Owned Business Enterprise: A business concern which is at least 51 percent owned by one or more women who are U.S. citizens or legal resident aliens, or in the case of a corporation, partnership or limited liability company or other entity, at least 51 percent of the equity ownership interest in which is owned by one or more women, and whose management and daily business operations are controlled by one or more of such individuals. **For purposes of the SWAM Program, all certified women-owned businesses are also a small business enterprise.**

Minority-Owned Business Enterprise: A business concern which is at least 51 percent owned by one or more minorities or in the case of a corporation, partnership or limited liability company or other entity, at least 51 percent of the equity ownership interest in which is owned by one or more minorities and whose management and daily business operations are controlled by one or more of such individuals. **For purposes of the SWAM Program, all certified minority-owned businesses are also a small business enterprise.**

Micro Business is a certified Small Business under the SWaM Program and has no more than twenty-five (25) employees **AND** no more than \$3 million in average annual revenue over the three-year period prior to their certification.

All small, women, and minority owned businesses must be certified by the Commonwealth of Virginia Department of Small Business and Supplier Diversity (SBSD) to be counted in the SWAM program. Certification applications are available through SBSD at 800-223-0671 in Virginia, 804-786-6585 outside Virginia, or online at <http://www.sbsd.virginia.gov/> (Customer Service).

RETURN OF THIS PAGE IS REQUIRED

ATTACHMENT B (CNT'D)
Small, Women and Minority-owned Businesses (SWaM) Utilization Plan

Procurement Name and Number: _____

Date Form Completed: _____

Listing of Sub-Contractors, to include, Small, Woman Owned and Minority Owned Businesses
for this Proposal and Subsequent Contract

Offeror / Proposer:

Firm

Address

Contact Person/No.

Sub-Contractor's Name and Address	Contact Person & Phone Number	SBSD Certification Number	Services or Materials Provided	Total Subcontractor Contract Amount (to include change orders)	Total Dollars Paid Subcontractor to date (to be submitted with request for payment from JMU)

(Form shall be submitted with proposal and if awarded, again with submission of each request for payment)

RETURN OF THIS PAGE IS REQUIRED

ATTACHMENT C



**COMMONWEALTH OF VIRGINIA
STANDARD CONTRACT**

Contract No. _____

This contract entered into this _____ day of _____, 20____, by _____ hereinafter called the "Contractor" and Commonwealth of Virginia, James Madison University called the "Purchasing Agency".

WITNESSETH that the Contractor and the Purchasing Agency, in consideration of the mutual covenants, promises and agreements herein contained, agree as follows:

SCOPE OF CONTRACT: The Contractor shall provide the services to the Purchasing Agency as set forth in the Contract Documents.

PERIOD OF PERFORMANCE: From _____ through _____

The contract documents shall consist of:

- (1) This signed form;
- (2) The following portions of the Request for Proposals dated _____:
 - (a) The Statement of Needs,
 - (b) The General Terms and Conditions,
 - (c) The Special Terms and Conditions together with any negotiated modifications of those Special Conditions;
 - (d) List each addendum that may be issued
- (3) The Contractor's Proposal dated _____ and the following negotiated modification to the Proposal, all of which documents are incorporated herein.
 - (a) Negotiations summary dated _____.

IN WITNESS WHEREOF, the parties have caused this Contract to be duly executed intending to be bound thereby.

CONTRACTOR:

PURCHASING AGENCY:

By: _____
(Signature)

By: _____
(Signature)

(Printed Name)

(Printed Name)

Title: _____

Title: _____

ATTACHMENT D

Zone Map



Virginia Association of State College & University Purchasing Professionals (VASCUPP)

List of member institutions by zones

<u>Zone 1</u> George Mason University (Fairfax)	<u>Zone 2</u> James Madison University (Harrisonburg)	<u>Zone 3</u> University of Virginia (Charlottesville)
<u>Zone 4</u> University of Mary Washington (Fredericksburg)	<u>Zone 5</u> College of William and Mary (Williamsburg) Old Dominion University (Norfolk)	<u>Zone 6</u> Virginia Commonwealth University (Richmond)
<u>Zone 7</u> Longwood University (Farmville)	<u>Zone 8</u> Virginia Military Institute (Lexington) Virginia Tech (Blacksburg) Radford University (Radford)	<u>Zone 9</u> University of Virginia - Wise (Wise)



January 5, 2021

ADDENDUM NO.: One

TO ALL OFFERORS:

REFERENCE: Request for Proposal No: **RFP# FDC-1101**
Dated: December 11, 2020
Commodity: Clinical Staffing and Services for COVID Testing/Vaccinations Clinics
RFP Closing On: **January 12, 2021 @ 2:00pm**

Please note the clarifications and/or changes made on this proposal program:

1. Section VI., B – Award is now changed to read as follows:

AWARD TO MULTIPLE OFFERORS: Selection shall be made of two or more offerors deemed to be fully qualified and best suited among those submitting proposals on the basis of the evaluation factors included in the Request for Proposals, including price, if so stated in the Request for Proposals. Negotiations shall be conducted with the offerors so selected. Price shall be considered, but need not be the sole determining factor. After negotiations have been conducted with each offeror so selected, the agency shall select the offeror which, in its opinion, has made the best proposal, and shall award the contract to that offeror. The Commonwealth reserves the right to make multiple awards as a result of this solicitation. The Commonwealth may cancel this Request for Proposals or reject proposals at any time prior to an award, and is not required to furnish a statement of the reasons why a particular proposal was not deemed to be the most advantageous. Should the Commonwealth determine in writing and in its sole discretion that only one offeror is fully qualified, or that one offeror is clearly more highly qualified than the others under consideration, a contract may be negotiated and awarded to that offeror. The award document will be a contract incorporating by reference all the requirements, terms and conditions of the solicitation and the contractor's proposal as negotiated.

2. Question: Is there an incumbent on the contract? If yes, could you please share any estimate on spending done so far?

Answer: There is no incumbent as this is a new request for this type of service.

3. Question: Could you please let us know if the vendors which are not SWaM certified are eligible to submit proposal?

Answer: All vendors are able to submit a proposal. If your firm is SWaM certified, please include the necessary certification information with your proposal submission – see Attachment B in the RFP document.

4. Question: What is the total number of resources who are currently working on this project? Please let us know their position name and hourly rate?

Answer: There is not a current contract for these services. There are not persons currently in these positions.

5. Question: Is the budget allocated for this contract? If yes, can you please let us know the same?

Answer: As this is a new request, there is no budget information available.

6. Question: What's the tentative award/execution date for this contract?

Answer: The evaluation process will be conducted quickly and thoroughly once the RFP closes. Award will be made as soon as possible. The tentative award will be made in late January or early February. However, this is an estimation. The number of proposals received and the time it takes to thoroughly evaluate them may impact the estimate award timeline.

7. Question: Does customer anticipate any future need of clinics to administer COVID-19 vaccinations linked with this contract?

Answer: JMU will need the contract as long as there is a need to administer COVID-19 vaccines. It is possible that this will last through fall of 2021, but JMU has no way of knowing that at this time.

8. Question: Is there any estimate on total count needed along with position title that client prefer in completing the scope of services? Also, could you please share the job description of position needed?

Answer: The count of each position will be dependent on the number of tests/vaccines the company can perform in a day/shift. For testing and vaccines there will need to be administrative staff and staff to perform testing (these staff do not need to have a medical license). For vaccines we will need administrative staff and RN to give the injections. The number of staff depends on how many the company does in a day.

9. Question: Could you please explain the role of (SWaM) Utilization Plan? Also, Is there any minimum mandatory small business goal requirement that customer encourage to meet? If yes please specify the total percentage of goal that vendor need to meet?

Answer: There is no minimum requirement; JMU is encouraged to work with SWaM vendors for purchases whenever possible and has university goals related to purchases. This is in accordance with initiatives mandated by the Governor of the Commonwealth of Virginia. The Commonwealth of Virginia has a 42% goal related to the use of SWaM businesses.

10. Question: How many vendors are expected to be awarded for this contract?

Answer: This is a multi-award RFP. The resulting contracts will be cooperatively awarded so that any other state agency could potentially utilize the contract. The number of awards/contracts will depend on the responses received.

11. Question: Do vendors need to propose pricing inclusive for the attached Zone Map, of which JMU falls within Zone?

Answer: This will be a cooperatively awarded contract. Therefore, pricing for all zones will need to be provided.

12. Question: Are hourly rate range acceptable for proposed personnel including key?

Answer: Yes.

13. Question: Are there any specific expectations that customer is looking in shortlisting vendors on this contract?

Answer: Vendors are asked to respond to all questions in the RFP as thoroughly as possible so that JMU can use the information to evaluate vendors for potential award.

14. Question: RFP Stated that Specify at least three (3) clients, preferably from a higher education institution, for similar staffing and services related to testing and/or vaccination clinics, and so considering COVID-19 is recent pandemic virus is this mandatory to submit all three clients experience having similar experience of testing and or vaccination clinics related to COVID-19?

Answer: Understanding that specific COVID-19 experience may not exist, please provide references that relate as closely as possible to the services request in the RFP.

15. Question: Could you please confirm if total of 5 references with similar services are needed at a firm level to qualify the past performance requirements other than above three client references?

Answer: The three client references can be included with the request for five references of similar services.

16. Question: Do the services needs to be delivered onsite or is there a possibility for remote operations and performance?

Answer: These services must be delivered through onsite operations and performance.

17. Question: How many clinics across Harrisonburg do you want?

Answer: For JMU, all clinics will be on the JMU campus. The number of clinics will depend on the number of tests/vaccine available.

18. Question: Have you identified areas or specific sites for those clinics?

Answer: We have multiple locations available for potential clinics. These sites include gyms, outside locations, and a convocation center.

19. Question: Will JMU provide clinic space or is that the vendors responsibility?

Answer: See the answer to question 18. JMU will provide necessary access to these spaces.

20. Question: Confirm JMU will procure testing units and test cartridges/ kits?

Answer: JMU is currently working to procure testing when/as it is available.

21. Question: Confirm JMU will procure vaccinations when made available?

Answer: JMU has applied to the CDC to become a vaccination site.

22. Question: Confirm what should be included in our pricing, any or all of the following?

Answer: Staffing and PPE should be included in the pricing.

23. Question: What is the current testing process? How many tests have been performed to date?

Answer: JMU has not yet completed a clinic with the BinaxNow Cards. JMU has performed up to several hundred test per week on campus using a reference lab for PCR testing and in-house antigen and PCR testing. The Virginia Department of Health also performed multiple testing events on our campus.

24. Question: Is there a strategy or process to determine when participants will get tested (i.e. scheduled cadence, mass testing, symptomatic testing, etc.)?

Answer: JMU is mostly looking at entry and exit testing at this time. It is possible that this could increase to weekly testing if/when we get BinaxNow cards. The plan is for this testing to be asymptomatic.

25. Question: Who will be tested, employees, students, etc.?

Answer: At this time JMU is only planning to test students at these large events. This may change with the addition of BinaxNow card availability.

26. Question: Is there a preferred staffing model and hours of operation per clinic?

Answer: As long as there is adequate staff to meet the requirements, there is not preferred staffing model. JMU can be flexible with clinics hours. Some evening and weekend hours may be necessary to meet the needs of students.

27. Question: Has JMU held conversations with any vendors to this point around the scope of this RFP?

Answer: No. The only vendor related is for our weekly PCR testing which is an end-to-end service.

28. Question: Is JMU looking for dedicated COVID-19 testing and vaccine clinics or integrated into existing clinics offering other medical services?

Answer: JMU is looking for dedicated COVID-19 testing/vaccine clinics that will be operated outside of our normal medical clinics.

29. Question: Is there willingness to consider additional testing strategies and devices beyond the BinaxNow device?

Answer: If the price is similar to the BinaxNow tests, JMU would be willing to consider other/additional testing strategies and devices. However, this RFP is specifically seeking firms that can provide staffing to run clinics with JMU purchased testing and vaccines; with the current plan to be utilization of the BinaxNow tests.

30. Question: Given COVID-19 is a new phenomenon that provides very little opportunity for experience and 3 Client References, is JMU willing to consider references for employer-sponsored medical services that includes COVID-19 response?

Answer: Understanding that specific COVID-19 experience may not exist, please provide references that relate as closely as possible to the services request in the RFP.

31. Question: How many FTE will you be looking for?

Answer: This depends on the number of tests/vaccines per clinic. The vendor needs to specify how many tests/vaccines they can appropriately process per clinic.

32. Question: Are you only interested in RNS? Or could you utilize admins/LPNS?

Answer: Admins will be needed for both testing and vaccine clinics. LPNs are acceptable.

33. Question: How many hours a week do you anticipate utilizing the caregivers?

Answer: This will depend on the number and length of clinics, which is still to be determined.

34. Question: Will a vendor be considered if they can only provide personnel?

Answer: JMU is not looking for just temporary staff. We are looking for a vendor who can supply the necessary staffing and testing site infrastructure.

35. Question: Is there an opportunity for these positions to assist with COVID-19 testing during Sporting events?

Answer: At this time there is not a need for testing during sporting events. If that changes, then this contract will be evaluated for use.

36. Question: Will James Madison University provide medical oversight for the testing? Medical oversight includes writing the prescription for the 6k COVID-19 tests and having our clinical staff who administers the test work under the prescribing physician's license. This is typically not an issue if you have an on-campus clinic staffed by a doctor.

Answer: This should not be an issue as JMU has an on-campus clinic staffed by a doctor. JMU will provide medical oversight.

37. Question: What are the most frequently used job categories in the subject matter RFP?

Answer: The question unclear. If you are asking what positions are needed, JMU needs admins, persons to perform testing, and nurses.

38. Question: What is the average length of the assignment?

Answer: JMU does not have a set limit at this time. An estimate would be 6-12 months. Many items related to COVID-19 are unknown, the provider will need to be flexible in understanding that the number of length of clinics will be determined by ongoing COVID-19 crisis and the availability of tests and vaccines to hold clinics.

39. Question: Is there any benefit for local vendor?

Answer: All vendors will be evaluated based on the criteria included in the RFP.

40. Question: Is it mandatory to take a sub-contractor?

Answer: It is not required. However, if you do utilize a sub-contractor as part of your proposed solution, please include the necessary information about the sub-contractor so that they evaluated properly – See Attachment B of the RFP document.

41. Question: Kindly change the mode of submission to email only due to COVID-19.

Answer: Electronic proposal submissions will not be accepted. Only sealed proposals will be accepted. JMU routinely receives parcels from UPS, FedEx, DHL, and USPS.

42. Question: Kindly provide specific format for the technical proposal.

Answer: The intent of the question is unclear, however, review section V of the RFP document for proposal submission requirements.

43. Question: Kindly provide specific format for Cost.

Answer: The intent of the question is unclear, however, review section V of the RFP document for proposal submission requirements.

44. Question: How has JMU managed COVID-19 testing prior to this RFP?

Answer: Symptomatic testing in our medical clinics, weekly PCR testing with end-to-end services from a vendor, and a large amount of support/testing from VDH.

45. Question: Is JMU looking for an end-to-end solution?

Answer: JMU is looking for a turnkey solution for testing and vaccination clinics. JMU currently plans to provide the BinaxNow testing and vaccines, when available, for the clinics.

46. Question: What laboratory service does JMU utilize for current testing?

Answer: LabCorp and in-house testing are currently utilized. The BinaxNow test is anticipated as the testing for the clinics referenced in this RFP.

47. Question: Will JMU offer laboratory services under this RFP?

Answer: JMU will be using BinaxNOW cards.

48. Question: Is JMU open to alternative COVID-19 test kits?

Answer: BinaxNOW cards will be expected unless the price for the other antigen tests are similar to these tests. JMU is not seeking testing via this RFP. Should any awarded vendor for our clinics additionally have testing options available we may consider them as additional goods and services, but actual use of any testing would require additional negotiation and documentation to meet the university's requirements.

49. Question: Will JMU and other locations provide physical testing space with basic furnishing and utilities for testing/vaccination?

Answer: See questions 18 and 19.

50. Question: Is PCR with 48 hours TAT an accepted testing modality?

Answer: Yes, but JMU is expecting to use BinaxNow cards for these testing events. JMU will not consider PCR testing unless the cost is similar to the BinaxNOW cards. At this time the price difference is too great.

51. Question: As testing begins, are you expecting to initially staff the clinics with licensed individuals who are able to administer vaccines? Or would there be additional licensed staff members brought on to do vaccination when the vaccine becomes available?

Answer: Staff performing testing does not need to be licensed. Staff performing vaccinations will need to be licensed.

52. Question: Will the vendor be responsible for materials related to vaccine administration? Or only test administration?

Answer: JMU's understanding is that the vaccine comes with the supplies at this time. JMU will need to reevaluate when/if that changes.

53. Question: How many students and/or employees are expected to be tested and at what frequency?

Answer: This is mainly for entry and exit testing. JMU expects to do approximately 1,500 tests per day for multiple days in the row at the start and end of school.

54. Question: How many students and/or employees are expected to be vaccinated?

Answer: JMU has approximately 25,000 in our community. We do not expect these to all be vaccinated at the same time. We expect to have vaccine allotted to us in smaller quantities. Again, we have not yet been notified what this will look like.

55. Question: Does this work require insurance collection and registration?

Answer: No. At this time there is not insurance collection. This will change if the vaccine is not provided by VDH/CDC.

56. Question: How many clinic locations are you anticipating?

Answer: That is unknown at this time. It will depend on the number of tests/vaccines to be performed.

57. Question: What will be standard operating hours and days for the clinics?

Answer: JMU can be flexible with clinic times. Evenings/weekends may be necessary to meet student needs.

58. Question: Will client allow for a HIPAA-compliant software solution to be used for test ordering and resulting or is an existing system to be used?

Answer: JMU is open to either of these options. Any additional software solution would require risk assessment by our IT team and would require additional documentation (SOC II) and a JMU IT Addendum to be signed. The BinaxNow test has an incorporated APP for results and the BinaxNow test is our current expected test for these clinics.

59. Question: Is the solicitation for Clinical Staffing only or does the contractor must be a testing facility?

Answer: The vendor is not required to be a reference lab. BinaxNOW cards are administered onsite. This solicitation is for clinical staffing.

60. Question: Is the solicitation a year-round engagement or just during the regular school and summer only?

Answer: This is for the regular school year only.

61. Question: Will there be any Pre-Bid Virtual Conference regarding the solicitation?

Answer: No pre-proposal conference is scheduled for this RFP.

Signify receipt of this addendum by initialing “*Addendum #1*_____” on the signature page of your proposal.

Sincerely,

Doug Chester
Buyer Senior
Phone: (540-568-4272)