

ADDENDUM #1
REQUEST FOR QUOTATIONS (RFQ) #21179
WV HIGHER EDUCATION POLICY COMMISSION
COVID-19 TESTING SERVICES FOR WV COLLEGE CAMPUSES
QUESTIONS AND ANSWERS

1. **Question:** Will a bid proposing the use of Rapid Antigen Testing be accepted for this RFQ?

Answer: No.

2. **Question:** If a sample collection method meets all criteria but is neither a nasopharyngeal nor oropharyngeal swab, will the vendor be considered? (We are able to provide PCR testing that has received an FDA EUA for unsupervised self-collection and is currently being used at a number of universities in the United States. The only criteria that this test does not meet or surpass is the collection method. These tests are saliva samples rather than nasopharyngeal or oropharyngeal swabs and utilize a VTM which allows for storage in ambient temperature for 5-7 days.)

Answer: All criteria for testing must be met to be met. If adequate residual in an acceptable medium for transport is available for positive tests, the proposal will be considered.

3. **Question:** Are you open to doing Rapid PCR onsite vs. sending to a lab? (There is a system that is being used widely now that with this volume can provide the rapid turnaround and the accuracy of PCR. It is CLIA waived so it wouldn't need a laboratory in West Virginia to process. They would be done at a location, i.e., school.)

Answer: All criteria for testing included in the RFQ, including vendor arrangements for provision of positive test residuals to WV labs who will do genetic sequencing, must be met regardless of the test system.

4. **Question:** We design and manufacture a smartphone-based, FDA authorized COVID rapid antigen test and also offer turnkey testing solutions. The RFQ makes explicit mention to PCR testing. Is PCR testing all you will consider?

Answer: Yes

5. **Question:** Could you please provide details on how you are currently conducting testing? Do students and employees self-administer their tests in the presence of your personnel? If no, could you please provide some details on your process?

Answer: Current process is that students self-administer tests in the presence of personnel.

6. **Question:** Are you open to having the selected vendor's personnel administer the tests?
Answer: Yes, if the vendor can manage all campuses who participate across the state of WV and accommodate testing schedules convenient to students and staff.
7. **Question:** Will you accept pricing for both self-administered tests and vendor-administered tests?
Answer: Yes, if above is met.
8. **Question:** Do we need to provide a WV Secretary of State Business Certificate with our proposal or just upon selection as a vendor.
Answer: The WV Secretary of State Business Certificate will be required upon award of the RFQ; it is not required to submit a proposal.
9. **Question:** What is the requirement for how the bid can be submitted?
Answer: Bids are received as paper copies which must be received prior to the date and time of the bid opening. We do request the bidder provide a copy of their bid on a thumb drive for ease of distribution and storage.
10. **Question:** How many PCR Tests overall do you anticipate needing?
Answer: If all colleges participate at a 10% weekly surveillance rate, the maximum will be up to 3500 tests weekly. However, that number will vary depending upon participation, local conditions, and vaccine rates.
11. **Question:** Are there any minors under 18 that will need to be tested?
Answer: It is possible that some students will be under 18 years of age. If so, and testing is needed, they will have a parent/guardian release.
12. **Question:** How many sites will need testing?
Answer: Up to 50 campus locations will need testing. However, this is the maximum and will be dependent on individual campus participation, local conditions, and vaccine rates.
13. **Question:** When do you need the testing to begin?
Answer: This will vary by campus; however, August 1 is our target date to have all testing processes and materials in place.
14. **Question:** What is the WV testing guidance? Are you planning to test on a weekly basis throughout the school year?
Answer: There is no updated guidance for Fall 2021, however current practice is weekly random sampling of 10% of the student population.
15. **Question:** Are you looking at testing students at home before they return to school?
Answer: This will vary by campus depending on local conditions and vaccination rates.

16. **Question:** Would you consider a model of students being tested at home before returning to campus?
Answer: If all parts of the RFQ are met, yes, this would be considered.
17. **Question:** Genetic sequencing. Would WV consider letting a vendor run the sequencing at their own CLIA CAP Accredited lab if they can demonstrate experience performing sequencing with another state?
Answer: This would depend on whether the vendor can meet all requirements of the RFQ.
18. **Question:** Why are vendors not allowed to ship samples in Hologic Aptima Buffer?
Answer: This is a requirement of the labs who will be doing the genetic sequencing.
19. **Question:** Is there a current vendor you are working with for testing? If so, please share the name of the vendor.
Answer: Vault Medical Services PA.
20. **Question:** Will athletes need to be tested more frequently?
Answer: Athletes are tested based on NCAA guidance. Frequent testing of athletes is not a consideration for this RFQ.
21. **Question:** Do you need vendors to complete any technical response as part of the RFQ or do you just want the price per test?
Answer: Vendors should indicate their ability to meet all requirements of the RFQ in addition to providing the price per test.
22. **Question:** Will the WV Higher Education Policy Commission accept and/or review a solution that comes at no cost to the organization with no out-of-pocket cost to the individual? One which the contractor seeks reimbursement through an individual's insurance carrier or third-party payor including the Health Resources Services Administration (HRSA) uninsured portal and commits to no balance billing to the individual and/or the organization?
Answer: Proposals must meet all requirements of the RFQ. If a solution such as suggested above meets all requirements of the RFQ, the proposal will be considered. However, the cost of the test the insurance carrier or 3rd party payor must be identified in the bid response.
23. **Question:** Is Mid-Turbinate or Anterior Nares swab collection acceptable?
Answer: Yes.
24. **Question:** Is a self-administered swab under non-medical supervision acceptable?
Answer: Yes.

25. **Question:** Are you planning on sequencing all positives? If yes to sequencing all positives, our lab partner has the largest CDC contract in the country and is able to provide sequencing of all positives for free.

Answer: Yes.

26. **Question:** Our saliva collection kit utilizes MTM and will be processed and sequenced at our lab partner, which reduces shipping costs (no cold transport needed) and is FDA Emergency Use Authorized for unsupervised collection. While samples will not be able to be processed using Hologic, you will have access to all results and sequencing data extremely quickly due to lab speed as well as there being no additional transport time to a WV state-run lab for sequencing. Is this desirable as an alternative?

Answer: If all requirements of the RFQ are met, the proposal will be considered.

27. **Question:** Is this a firm requirement to provide RLU value samples tested by Hologic Aptima (RLU>1100) or preferred? Providing this for positive samples is cost prohibitive as it requires an investment in equipment to run that Assay at many labs.

Answer: Yes.

28. **Question:** Your sequencing requirements state the following sample types: Nasopharyngeal (NP), nasal or oropharyngeal swabs. Would you accept saliva specimens? If you can't accept saliva, would you allow saliva if the lab was able to provide the genetic sequencing?

Answer: If there is adequate residual and the transport medium meets the requirements, the proposal will be considered.

29. **Question:** Would you accept a laboratory developed test (LDT) for pooled testing given FDA is not focused on pooling EUAs at this time?

Answer: No.

30. **Question:** Do you have a timeline on when you would expect an addendum addressing the questions you've received for this RFQ? We did not see that date on the original request.

Answer: The anticipated release date for the addendum is May 25, 2021.

31. **Question:** When formally responding to the RFQ, do you prefer live documents to be mailed to the bid delivery address, or would you prefer a PDF e-mailed to you instead? Or both? If just electronic delivery, will an e-signature suffice for all documents?

Answer: Paper bids must be delivered and received at the location included in the RFQ on June 2, 2021 by 3:00pm EDST. We do request the bidder provide a copy of their bid on a thumb drive for ease of distribution and storage. Electronic delivery of bids is not accepted.

32. **Question:** When ordering testing kits, will each order include a standard and/or minimum number of kits, or will each order vary by volume based on the needs of each ordering site?

Answer: Orders will vary by volume based on site.

33. **Question:** Is there a minimum number of kits you will need per order or per site?

Answer: No.

34. **Question:** When receiving testing kits, will the shipments(s) be directed to one location or will each shipment's end destination vary depending on which "Delivery/Authorized Personnel" placed that particular order of testing kits? Do you have a preferred method?

Answer: All kits will be shipped directly to the delivery/authorized personnel for that particular order.

35. **Question:** What is your preferred method of distribution of testing kits to the end-user (i.e., sample to be collected and tested)? Will there be a coordinator handing out collection containers to individuals or would you prefer each collection container be individually boxed so that you may leave for individuals to be tested to pick up from a central location?

Answer: A coordinator will hand out collection containers to individuals.

36. **Question:** When shipping samples to our lab, what would be the process for collection of kits and return shipment? Will they ship individually or batch shipments together? What is the minimum number of kits they will batch with their return shipment?

Answer: Current practice is batches of 25 are shipped to the lab via overnight shipping.

37. **Question:** In the RFQ, it requires the vendor to supply all positive samples to a "WV state approved laboratory" for genetic sequencing. Is this portion of the RFQ available to bid on as well?

Answer: No.

38. **Question:** Would you be interested in us (the supplying vendor) as your vendor to also sequence the positive samples, or has this been delegated already?

Answer: The current RFQ is only for collection of tests.

39. **Question:** Would you favor having an option for saliva based high-precision PCR test as are used at UCLA, Caltech, UC Santa Barbara, and Pepperdine? The saliva samples are easier to administer and less expensive to process, while maintaining gold standard PCR sensitivity and specificity.

Answer: If the option meets all other requirements of the RFQ, the proposal will be considered.

40. **Question:** Would you favor PCR testing over Pooled testing, all things equal?

Answer: PCR testing is preferred.