Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2201186	11/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hampton University Clinical Laboratory (Covid-19)	519 E Queens Street #214, Hampton University, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An unannounced CLIA complaint investigation (VA00053225) was conducted at Hampton University-COVID-19 Laboratory on 11/3/21-11/9/21 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Based on the tour of the testing site(s), review of documents and interviews, the allegations of the absence of lab technologists or qualified testing personnel, untrained staff performing sample collection, proper specimen collection, testing not conducted on-site and concerns of sample transportation off-site was unsubstantiated due to lack of evidence. The allegation of lack of test validity and supervision was substantiated. Specific deficiencies cited are as follows: The laboratory is not in compliance with the following 42 CFR Part 493 CLIA requirements: D5400 - 42 C.F.R. 493-1250 Condition: Analytic Systems, and D6076- 42 C.F.R. 493-1441 Condition: High Complexity Laboratory Director.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interviews, the lab failed to report SARS-CoV-2 (COVID-19) negative test results for 83 of 83 testing dates from 05/01/21 through 11/01/21.

	Findings include: 1. An interview and review of available COVID-19 daily testing log with the lab director, Vice President for Research and testing personnel (TP) A on 11 /09/21 at 1300 revealed the site performed Abbott BinaxNow COVID-19 Ag Card test method on 05/01/21 through 11/01/21. 2. 13,276 negative results were not reported as required during the period of review (83 testing dates). 3. The laboratory performed 13,298 COVID-19 tests during the period of review. 4. An exit interview with the lab director, Vice President for Research and testing personnel TP A on 11/09/21 at approximately 1300 confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), tour of the lab and remote testing site, manufacturer's instructions for use (IFU), policy and procedures (P&P), lack of documentation, patient testing data log, and interviews, the laboratory failed to: 1. have a written policy for reporting the Abbott BinaxNow COVID-19 Ag Card patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency from 05/01/21 and up to 11/03/21 (Refer to D5403), 2. monitor the room, refrigerator and freezer temperatures for 171 of 171 days and reporting 11,109 patients (Refer to D5413 part A), 3. document monitoring of temperatures to ensure storage and stability requirements for the Abbott BinaxNow COVID-19 AG cards/kits from 05/01/21 up to 11/02/21 while reporting 13,298 patient results (Refer to D5413 part B), 4. provide documentation of the initial verification of accuracy and precision for testing of patient samples using the new test methods (Refer to D5421) and 5. provide documentation the quality assessment (QA) mechanism defined in the written policy to identify and address analytic in the sub-specialty of virology for nine of nine months (Refer to D5791).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals

	(normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), policy and procedures (P&P), lack of documentation, and interviews, the laboratory failed to have a written policy for reporting the Abbott BinaxNow COVID-19 Ag Card patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency from 05/01/21 and up to 11/03/21. Findings include: 1. Review of the CMS 116 application and a tour of the COVID testing site on campus (Parking Lot 10) on 11/04/21 at approximately 10:35 AM revealed the laboratory performs COVID-19 testing with the Abbott BinaxNow COVID-19 Ag Card method. During an interview with nurse A on 11/04/21 at approximately 10:50 AM, the surveyor inquired about reporting the test results from the aforementioned test method to the health department. They stated, "I know that positive results are reported to administration and the health department but I'm unsure about the negative COVID-19 test results. I believe that the lab with the student health center reports those results." An interview with the primary TP at the Student Health Center (CLIA # 49D0230459) on 11/04/21 at approximately 11:15 AM revealed the research center lab took over patient testing with the Abbott BinaxNow COVID-19 Ag Card method at the on-campus testing site (Parking Lot 10) on 05/01/21. They stated, "I report my results tested in the health center and under my CLIA number to the health department via the VDH portal but I do not know if the research lab is reporting their results to the health department." 2. Review of the manufacturer's IFU's revealed the following statements: Abbott BinaxNow COVID-19 Ag Card (Antigen nasopharyngeal or nasal swab) - "Conditions of Authorization for Laboratory and Patient Care Setting", "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 3. Review of the P&P revealed lack of documentation of policy or procedure for reporting patient COVID- 19 positive and negative test results to the local health department. 4. An exit interview on 11/09/21 at approximately 1300 with the lab director, Vice President for Research and TP A confirmed the findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: A. Based on a tour of the lab, policy and procedure (P&P) review, manufacturer storage requirements, lack of documentation, patient testing data log, and interviews,

the lab failed to monitor the room, refrigerator and freezer temperatures for 171 of 171 days while reporting 11,109 patients. Dates of record review include 3/02/21 up to 11/04/21. Findings include: 1. A tour of the lab on 11/03/21 at approximately 1600 revealed one white refrigerator, three freezers, and reagents stored in a cabinet in the testing process area. An interview with testing personnel (TP) A on 11/03/21 at approximately 1620 revealed that patient samples are stored in the white refrigerator if they are processed with 72 hours and then frozen if the testing will occur greater than 72 hours. Processed samples and control buffer solution are stored in the >-10 to -30 degrees Celsius freezer and the Applied Biosystems Taqpath COVID-19 controls (positive and negative) stored in the >-70 degrees Celsius freezer. During the tour, the following reagents were observed in a cabinet in the testing process area: - MagMax Viral/Pathogen Wash Solution, - MagMax Viral/Pathogen Proteinase K, - MagMax Viral/Pathogen Binding Beads and - MagMax Viral/Pathogen Elution Buffer. The manufacturer storage temperatures located on the reagent bottles for the above-specified reagents is 15-25 degrees Celsius. The manufacturer storage temperatures from the package insert for the Applied Biosystems Taqpath COVID-19 control reagents is >-70 degrees Celsius. The tour confirmed patient samples stored in the white refrigerator and one freezer (freezer door digital readout at the date of tour -25 degrees Celsius) and the Applied Biosystems Taqpath COVID-19 controls (positive control lot #237426) in the >- 70 degrees Celsius freezer (door digital readout at the date of tour -73 degrees Celsius). 2. Review of the P&P revealed the following statements: "Inventory Control and Storage- 2. Storage: a. All supplies, materials, and items received will be stored according to the manufacturer's instructions." "Specimen Collection"- III. Testing Requirements: 6. Specimens should be stored at 2-8 degrees Celsius for up to 72 hours after collection. 7. If testing will be delayed or the specimens are to be transported to another facility, they should be stored at -70 degrees Celsius or below to maintain integrity." "Taqpath RNA Isolation and qRT-PCR- 4. Extraction Process, h. Store sample tube at 2-8 degrees Celsius in a sealed biohazard bag until results have been reported out. Positive samples should be stored at -80 degrees Celsius and negative samples should be discarded after 7 days." 3. The inspector requested to review documentation of temperature monitoring mechanism(s) for patient samples and reagents in an interview on 11/03/21 at approximately 1632 with TP A. They stated, "We are not taking temperatures." 4. Review of the Platform for Science (lab information system) patient testing data log confirmed 11,109 patients reported from 03/02/2021 up to 11/04/21. 5. In an exit interview on 11/09/21 at approximately 1300 with the lab director, Vice President for Research and TP A, the findings were confirmed. B. Based on the tour of the testing site, review of manufacturer's instruction for use (IFU), policy and procedures (P&P), lack of documentation, daily patient testing log, and interviews, the laboratory failed to document monitoring of temperatures to ensure storage and stability requirements for the Abbott BinaxNow COVID-19 AG cards/kits from 05/01/21 up to 11/02/21 while reporting 13,298 patient results. Findings include: 1. A tour of the remote testing site (Parking Lot 10) on 11/4/21 at approximately 10:00 AM revealed a designated outside tent (three of the four sides enclosed with canvas) with four tables and an outdoor space heater. The front table had approximately 12 Abbott BinaxNow COVID-19 AG patient test cards with identification forms. A large cardboard box located at the back table contained approximately 5 additional boxes of the Abbott BinaxNow COVID-19 AG cards. The tour of the blue trailer located behind the tent revealed that additional boxes of the Abbott BinaxNow COVID-19 AG cards/kits available for use. An observation by surveyor and an interview with testing personnel (TP) B at approximately 10:50 AM revealed that at the time of collection of patient samples, the cards are removed from the protective foil and placed on the table with timers for interpretation of results. The unused boxes of the Abbott BinaxNow COVID-19 AG

	cards/kits are stored in the blue trailer located behind the tent. The surveyor inquired about temperature monitoring during storage and use of the Abbott BinaxNow COVID-19 AG cards/boxes. TP A and TP B stated, "the temperatures are not monitored." 2. Review of the manufacturer's IFU revealed the following statement, "Storage and Stability, Store kit at 2-30C." 3. Review of the P&P revealed lack of documentation of a policy defining a temperature monitoring mechanism for storing and during the use of the Abbott BinaxNow COVID-19 AG cards/boxes. 4. Review of the daily patient testing log revealed 13,298 patients tested with the above-mentioned method from 05/01/21 up to 11/02/21. 5. In an exit interview on 11/09/21 at approximately 1300 with the lab director, Vice President for Research and TP A, the findings were confirmed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a tour of the lab, review of policy and procedures (P&P), lack of documentation, patient testing data log, and interviews, the lab failed to provide documentation of the initial verification of accuracy and precision for testing of patient samples using the new test methods, Taqpath COVID-19 RT-PCR Combo Kit on theThermo Fisher Scientific QuantStudio 5 Real-Time PCR instruments, prior to reporting patient results from 03/02/21 up to the date of survey on 11/03/21, reporting 11,109 patients. Findings include: 1. During a tour of the lab on 11/03/21 at approximately 1600 the surveyor observed two Thermo Fisher Scientific QuantStudio 5 Real-Time PCR instruments (serial numbers 272525077 and 272525079) and Thermo Fisher Scientific KingFisher Flex Purification System (serial number 711-82593) in use for testing patient samples for the presence or absence of SARs CoV-2 (COVID-19) via the Taqpath COVID-19 Combo Kit. The surveyor inquired when the instruments where installed and in use. Testing personnel (TP) A stated "they thought the installations were sometime in November 2020 and patient testing in March of 2021 but they would have to look back." 2. Review of the P&P revealed the following statements, "Process Validation and Verification, 3. Process: The following process will be carried out in order to verify and/or validate the Thermo-Fisher TaqPath COVID-19 protocol used in the HU Clinical laboratory. C. Collect and accession a mixture of twenty (20) samples (positive and negative) selected for process validation /verification using the Platform for Science protocol. i. Make sure that all samples have been either previously processed and have accompanying results or upon completion of processing, submit the samples and results to another source (i.e. reference laboratory) for result verification. Ii. Each sample should be run a minimum of three (3) times in order to verify accuracy, reproducibility, etc. d. Create two (2) plates (one per QuantStudio analyzer) and follow all procedural guidelines pertaining to the performance of the Thermo-Fisher TaqPath COVID-19 testing assay. e. Upon completion of tests run via the QuantStudion 5 RT-PCR instrument, print graphs and all test results coinciding with the run. This will be your verification/validation data. f.

	Provide data to lab manager for review. The lab manager will forward results of the verification/validation to the medical director for further review and approval. g. All data will be maintained on file as long as the HUCL has possession of the equipment and it is still operable. If the equipment should be disposed of, the records on file should be maintained for a period of two (2) years after disposal." The inspector requested to review the initial verification of performance records for the analyzers and COVID-19 test kit on 11/03/21 at approximately 1730. TP A replied, "I was not the supervisor at that time and that supervisor left a couple of months ago. I'm not sure where those documents are." 3. During a virtual interview with the lab director, Vice President for Research and TP A on 1/07/21 at approximately 1220, a document presented to the surveyor via email showed 69 samples were assayed on 2/24-25/21 for the presence or absence of COVID-19. The document did not include which test result(s) assayed on which analyzer (no serial number available for review). The inspector inquired about the printouts of the graphs and all test results as specified in the policy. TP A and the Vice President for Research stated they were unsure where the documents were located as the previous supervisor had left. 4. Review of the Platform for Science (lab information system) patient testing data log confirmed 11,109 patients reported from 03/02/2021 up to 11/04/21. 5. During an exit interview on 11/09/21 at approximately 1300 with the lab director, Vice President for Research and TP A, the installation documents for the two Thermo Fisher Scientific QuantStudio 5 Real-Time PCR instruments and Thermo Fisher Scientific KingFisher Flex Purification System were provided for review and verified that the installation date was 09/01/20. The initial verification of accuracy and precision records for the analyzers and COVID-19 test kit were not available for review and the findings confirmed.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), lack of documentation, and interviews, the lab failed to provide documentation the quality assessment (QA) mechanism defined in the written policy to identify and address analytic issues in the sub-specialty of virology for nine of nine months reviewed at the date of survey on 11 /03/21-11/09/21. Dates of record review include 3/02/21 up to 11/04/21. Findings include: 1. Review of the P&P "Quality Assessment Plan" revealed the following statements: "Specimen Criteria and Reporting- Corrective action policies and procedures must be available and followed to maintain laboratory operation for testing in a manner that ensures accurate and reliable student test results and reports. All corrective actions taken must be documented on the Incident Management Investigation Report Form located in the Hampton University Laboratory Quality Assurance Manual." "Quality Control", "Quality control must be performed and documented for each procedure as recommended by the manufacturer and described in the Hampton University Laboratory Procedure Manual. The laboratory technician will do a review and document all problems in the Hampton University Quality Assurance Manual when a test fails, internal and external controls are out of range, unsuccessful calibration, test results not reported in the correct time frame or results

	are unacceptable. The log sheets will be reviewed by the laboratory director and remedial action taken." 2. The surveyor requested to review documentation of corrective and remedial actions by the testing personnel (TP) and lab director as described within the policy from 3/02/21 up to 11/03/21-11/09/21 (nine months). The documents were not available for review. During a virtual interview on 11/07/21, the lab director and TP A stated that they do communicate via phone and email regarding the testing procedures. The surveyor requested documentation of the communications and outcomes of testing issues. The documentation was not available for review. 3. An exit interview on 11/09/21 at approximately 1300 with the lab director, Vice President for Research and TP A confirmed the findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the tour of the lab, manufacturer's instructions for use (IFU), policy and procedures (P&P), lack of documentation, patient testing data log, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, and interviews, the lab director failed to: 1. ensure the monitoring and documentation of the room, refrigerator and freezer temperatures for 171 of 171 days and reporting 11,109 patients (Refer to D6083), 2. provide documentation of the initial verification of accuracy and precision for testing of patient samples using the new test methods (Refer to D6086), 3. provide documentation the quality assessment (QA) mechanism defined in the written policy to identify and address analytic issues in the sub-specialty of virology for nine of nine months (Refer to D6094), and 4. review/evaluate the initial competency assessments for four of four TP prior to testing and reporting patient results with the new test methods (Refer to D6102).
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on a tour of the lab, policy and procedure (P&P) review, manufacturer storage requirements, lack of documentation, patient testing data log, and interviews, the lab director failed to ensure the monitoring and documentation of the room, refrigerator and freezer temperatures for 171 of 171 days and reporting 11,109 patients (Refer to D5413 part A).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on a tour of the lab, review of policy and procedures (P&P), lack of documentation, patient testing data log, and interviews, the lab director failed to provide documentation of the initial verification of accuracy and precision for testing of patient samples using the new test methods, Taqpath COVID-19 RT-PCR Combo Kit on the Thermo Fisher Scientific QuantStudio 5 Real-Time PCR instruments, prior to reporting patient results from 03/02/21 up to the date of survey on 11/03/21, reporting 11,109 patients (Refer to D5421).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), lack of documentation, and interviews, the lab director failed to provide documentation the quality assessment (QA) mechanism defined in the written policy to identify and address analytic issues in the sub-specialty of virology for nine of nine months reviewed at the date of survey on 11/03/21-11/09/21. (Refer to D5791).
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), available testing personnel (TP) files, lack of documentation, and interviews, the laboratory director (LD) failed to review/evaluate the initial competency assessments for four of four TP prior to testing and reporting patient results with the new test methods, Taqpath COVID-19 RT-PCR Combo Kit on the Thermo Fisher Scientific QuantStudio 5 Real-Time PCR instruments, prior to reporting patient results from 03/02/21 and up to 11/04/21, reporting 11,109 patients. Findings include: 1. Review of the laboratory's CLIA CMS-209 Form revealed four TP identified as performing COVID-19 patient testing using the above-mentioned methods from 03/02/21 and up to date of survey on 11/04/21. See Personnel Code attached. 2. Review of the available laboratory personnel records revealed lack of documentation of initial competency assessment(s) for TP A, B, C, and D prior to testing and releasing patients on 03/2/21. On 11/07/21, virtual review of TP documents revealed training took place on 11/19/20 and lacked signature or review by the lab director. The surveyor requested to review initial competency assessments for the specified TP. No records were available for review. 3. In an exit interview on 11/09/21 at

	approximately 1300 with the lab director, Vice President for Research and TP A the findings were confirmed.