Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2190690	07/12/2022
Name of Provider or Supplier	**Street Address, City, State**	
Howard University Molecular Laboratory	520 W Street Nw Rooms 3031/32 & 3033/34, Washington, DC	

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
D2061	VIROLOGY CFR(s): 493.831(c) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, interview with the lab manager on July 7, 2022, and lab staff on July 12, 2022, the lab failed to return PT results to the PT agency within the time frame and resulted in a score of "0". Findings: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The lab failed to return the College of American Pathologist (CAP) 2021 CoV-2 2nd event results to the PT agency within the time frame. 3. The lab failed to perform an investigation into the failure and failed to perform the self evaluation with results obtained in the lab from unknown samples and the answers from the PT agency website. 4. The lab manager stated on July 7, 2022, at 1:30 PM that there was a delay in getting the PT performed and when she tried to submit the PT agency would not accept the results. 5. Lab personnel performed the PT investigation with a passing score on the self evaluation. The surveyor was presented with the documentation on July 12, 2022, at 1:00 PM.
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 review of patient SARS-CoV-2 test results and interview with the clinical consultant, the lab failed to prove that patient COVID-19 results were reported to local health department as required by the Public Health Emergency for the detection of COVID-19. Findings: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The lab failed to provide proof of reporting to the health department for positive and negative patient results received from 2020 to 2021. 3. The lab failed to provide documentation showing the health department received submitted patient results. 4. The clinical consultant stated on July 12, 2022 at 3:00 PM that he will get the information and forward to the surveyors. The documentation was not received.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of quality records (QC), error log records, and interview with laboratory staff, the laboratory failed to retain all QC records that are required for analytic review. Findings: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2.On April 27, 2022, the QC did not pass. The QC was repeated and passed. 3. The laboratory did not retain the failed QC results and only retained the passing QC. 4. The testing person and the general supervisor confirmed on July 12, 2022 at 2: 00 PM the all QC records were not retained as required for analytic reviews.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of written procedures and interview with staff, the laboratory written procedures did not include rejection criteria for patient specimens that were too old for testing (procedures did not define the acceptable period of time between

	collection, receipt and testing), and did not have rejection criteria for specimens collected in an unsuitable media or container. Findings: 1. The laboratory written procedure did not include rejection criteria for the age of the specimen and for specimens that were not collected in suitable collection media and tubes; and 2. This was confirmed on July 12, 2022 at 2:00 pm during interview with the general supervisor. 44487 II. Based on review of the written procedure manual and interview with laboratory staff, the lab failed to have written procedures for specimen collection, labeling, and transportation. Finding: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The lab did not have written procedures for specimen collection. 3. The clinical consultant stated that samples are self collected by the patients off site. Once collected a barcode label is added to the sample. The sample is bagged and transported to the lab by trained personnel. 4. The did not have a procedure for labelling the collected specimens with the barcode nor the patient identifiers that are required on the specimen. 4. Transportation of specimens and the disposition of the samples once received in the lab was not available. 5. The lab did not have the training included in the procedure for collection personnel. 6. The general supervisor confirmed on July 12, 2022 at 1:30 PM that a procedure was not available for the specimen collection, labeling, and transportation of patient samples.
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: Based on review of the written procedure manual, interview with the lab manager, and lab staff, the lab failed to have written procedures for monitoring lab temperatures in the event of power failure and surges. Findings: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. Observation of refrigerators and freezers on July 7, 2022 at 1:00 PM showed that temperatures were not monitored electronically in the event of problems. 3. The lab manager stated on July 7, 2022, at 1:00 PM that she has being trying to get the Information Technology department to work with her to set up an electronic online monitoring system. 4. The lab did not have written procedures for an alert identification system of lab personnel notified in the event of power and temperature failures. 5. The general supervisor confirmed on July 12, 2022, at 2:00 PM that written procedures for monitoring lab temperatures in the event of power failure and surges was not available.
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: I. Based on review of the validation of the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit, interview with the lab manager, and lab staff, the lab failed to maintain all required documentation and results of the validation. Findings: 1.The lab failed to maintain all documentation that was acquired during the validation process of the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit for SARS-COV-2 detection. 2. The lab did not maintain the data from samples received from the university hospital that were used in the validation process. 3.The lab did not establish the cut off or threshold values when testing samples to determine positive or negative results. 4. The lab did not maintain the data received in house when testing the samples to verify the manufacturers known statements. 5. The lab manager stated on July 7, 2022 at 2:20 PM that she was not aware that all data acquired during the validation needed to be maintained. 6. The lab staff updated the validation with the missing data and presented it to the surveyor on July 12, 2022. II. Based on record review and interview, the laboratory did not validate the use of saline (0.85%) as the patient specimen collection media used to collect and transport specimens. Findings: 1. The laboratory uses saline to collect specimens for testing, the package insert for the saline states that it is used for collection of baceteriology specimens, but does not state use for virology specimens and maintaing RNA suitability for testing. The FDA's information for use did not specify the use of Remel saline (0.85%) reagent for collectionb ut instead stated that "This test [Taq Path Covid-19 RNASE P Combo Kit 2.0] is also authorized for use with anterior nasal swab specimens that are collected using the Color COVID-19 Self-Swab Collection Kit with Saline when used consistent with its authorization".; 2. The laboratory did not perform validation studies to validate the Remel saline as an acceptable collection and transport media, and did not perform studies to establish suitable conditions for transporting specimens collected in Remel saline (such as time and temperature); and 3. This was confirmed during interview with the general supervisor the afternoon of July 12, 2022.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the written procedure manual, interview with the lab manager, and the general manager, the lab failed to perform preventative maintenance (PM) and function checks on all laboratory equipment and failed to have written procedures. Findings: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. Observation of pipettes and the ultraviolet (UV) hood on July 7, 2022, at 1:00 PM showed that PM procedures were not performed. 3. The lab manger stated on July 7, 2022, that the university purchasing department would not sign off on sending the pipettes out for calibration PM's. 4. The general supervisor stated on July12, 2022, at

	2:00 PM the PM procedures were not available for the UV hood and confirmed that PM procedures were not performed.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with lab staff, the lab failed to have written corrective action procedures. Findings: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The lab did not have written corrective action procedures for performing SARS-COV-2 detection with the Thermo Fisher TaqPath COVID-19 PCR test kit in the event when problems occurred. 3. The lab begin documenting laboratory quality control errors on April 27, 2022. 4. The general supervisor confirmed on July 12, 2022, at 1:00 PM that corrective procedure were not available.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of four patient final reports and interview with lab staff, the lab failed to establish the location where testing was performed for accurate determination and reporting of lab results. Findings: 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The patient final reports showed two addresses at the top of the page. Howard University 2041 George Ave NW, Washington DC 20060 and HWUFAC Howard Faculty 520 W St NW, Washington DC 20059. 3. The bottom of the patient final reports stated "performing lab information" HWU Howard University College of Medicine 2041 George Ave NW, Washington DC 20060. 4. The name of the lab surveyed on July 7th and 12th 2022 was Howard University 2041 Georgia Ave NW, Washington DC 20060. 5. The lab clinical consultant state on July 12, 2022, at 3: 00 PM that the address changed in the spring of 2021 to 520 W St NW, Washington DC 20059. 6. The lab clinical consultant confirmed on July 12, 2022, at 3:00 PM that the lab failed to establish the location on the patient final report where testing was performed for accurate determination and reporting of lab results.
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 record review and interview, the laboratory director failed to provide overall direction of the laboratory. The laboratory director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method See D6086);.The laboratory director failed to ensure the proficiency testing samples are tested as required under subpart H of this part (See D6089); The laboratory director failed to ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory (See D6092); The laboratory director failed to o assure the quality of laboratory services provided and to identify failures in quality as they occur (See D6094); The laboratory director failed to 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 (See D6102). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
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 record review, the laboratory director did not ensure that verification procedures were performed to ensure accurate and reliable SARS-CoV-2 test results. Findings: 1. The laboratory was using Remel saline for specimen transport media, but did not validate the use of the saline that was approved for bacterial and not viral specimen transport (see D5421 finding II for findings); and 2. The laboratory did not maintain records for the validation studies (See D5421 finding I for findings).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, interview with the lab manager on July 7, 2022, and lab staff on July 12, 2022, the lab director (LD) failed to ensure that PT results were return to the PT agency within the time frame. Findings: Refer to D2061 1. The lab performs SARS-COV-2 detection with the ThermoFisher

	TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The lab failed to return College of American Pathologist (CAP) 2021 COV-2 2nd event results to the PT agency within the time frame.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the proficiency testing (PT) records, interview with the lab manager on July 7, 2022, and lab staff on July 12, 2022, the lab director (LD) failed to ensure that an approved corrective action plan was established when PT results were unacceptable or unsatisfactory. Findings: Refer to D2061 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The lab failed to return College of American Pathologist (CAP) 2021 COV-2 2nd event results to the PT agency within the time frame and resulted in a score of "0"
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 record review and interview, the laboratory director did not establish quality assurance activities. Findings: 1. The quality control procedure states that quality assurance meetings are held monthly; 2. The laboratory had one documented staff meeting during the month of April 2022, laboratory testing began September 14, 2020; and 3. During interview with the general supervisor the afternoon of July 12, 2022, quality assurance meetings were described as taking place through email conversations; 4. There were no records showing the reporting of quality assurance indicators like specimen rejection rate, tracking of positivity rates, turn around times, problems and complaints. The laboratory written procedure did not state how indicators are selected to monitor, providing corrective actions for compalints and problems to ensure the reliability and accuracy of testing. 5. The extraction log had post it notes stuck to it, the post it note stuck to the February 2021 log stated that the acceptable range should be noted on the log, as of July 12, 2022 this change had not been made and the laboratory used post it notes to document quality assurance activities and these notes were never addressed in a quality assurance meeting to assign the task to a staff member and monitor.
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 record review and interview, the laboratory director did not have records showing that testing staff were credentialed, trained according to the laboratory's written procedure and had six month competency checks performed. Findings: 1. Credentialing records were requested, the laboratory did not have diplomas, certifications (if applicable) to show that staff had the appropriate education to perform high complexity testing; 2. The laboratory did not have six month competency check records for testing persons, general supervisor(s) and technical supervisor(s) 3. The laboratory written procedure stated that staff are trained and oriented over a ten day period. The training records did not include dates of training, who performed the training and the tasks the person was trained to perform to show what training occurred and that ten days were devoted to training; 4. This was confirmed with the general supervisor during the afternoon of July12, 2022.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the validation for the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit, interview with the lab manager, and lab staff, the lab manager failed to ensure that all required documentation and results acquired during validtion procedures were maintained. Findings: Refer to D5421 1.The lab failed to maintain all documentation that was acquired during the validation process of the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit for SARS-COV-2 detection. 2. The lab did not maintain the data from samples received from the university hospital that were used in the validation process. 3.The lab did not establish the cut off or threshold values when testing samples to determine positive or negative results. 4. The lab did not maintain the data received in house when testing the samples to verify the manufacturers known statements.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with lab staff, the lab manager failed to ensure that written corrective action procedures were available for accurate and reliable patient testing. Findings: Refer to D5779 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The lab did not have written corrective

	action procedures for performing SARS-COV-2 detection with the Thermo Fisher TaqPath COVID-19 PCR test kit in the event when problems occurred. 3. The lab begin documenting laboratory quality control errors on April 27, 2022.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of competency and training records, the technical supervisor did not perform and establish training and competency checks for testing staff. Findings: 1. The laboratory written procedure states that training must be performed for at least ten days for testing staff, but the training records for staff did not show the dates and the identity of the trainee and did not show training was performed over a ten day period; The ltechnical supervisor only had staff certificates to show as the training record; 2. The technical supervisor did not have six month competency checks documented for teting staff.
D6139	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1457(c) The clinical consultant must ensure that reports of test results include pertinent information required for specific patient interpretation. This STANDARD is not met as evidenced by: Based on review of four patient final reports and interview with lab staff, the clinical consultant failed to ensure that the location where testing was performed was established for accurate determination and reporting of lab results. Findings: Refer to D5805 1. The lab performs SARS-COV-2 detection with the ThermoFisher TaqPath Multiplex COVID-19 PCR test kit. Testing began September 14, 2020. 2. The patient final reports showed two addresses at the top of the page. Howard University 2041 George Ave NW, Washington DC 20060 and HWUFAC Howard Faculty 520 W St NW, Washington DC 20059. 3. The bottom of the patient final report stated "performing lab information" HWU Howard University College of Medicine 2041 George Ave NW, Washington DC 20060. 4. The name of the lab surveyed on July 7th and 12th 2022 was Howard University 2041 Georgia Ave NW, Washington DC 20060. 5. The lab clinical consultant state on July 12, 2022, at 3:00 PM that the address changed in the spring of 2021 to 520 W St NW, Washington DC 20059.