Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D1099562	02/12/2021
Name of Provider or Supplier	**Street Address, City, State**	
Genesis Diagnostics	900 Towne Center Drive, Langhorne, PA	

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 complaint investigation was conducted on site with 42 CFR regulations through February 11-12. The complaint was substantiated in regards to COVID-19 testing. The laboratory was surveyed and failed to meet the following condition of the CLIA regulations found at CFR 42 493.1 through 493.1780 resulting in the following IMMEDIATELY JEOPARDY finding: D5200 - 493.1230 - General laboratory systems D5300 - 493.1240 - Preanalytic systems D5400- 493.1250 Condition: Analytic systems D6168 - 493.1487 - Laboratories performing high complexity testing; testing personnel In addition, the laboratory also had the following CONDITION LEVEL finding: D3000 - 42 C.F.R. 493.1100 Condition: Facility Administration D5010 - 42 C.F.R. 493.1205 Condition: Virology; D5800 - 42 C.F.R. 493.1290 Condition: Postanalytic systems; D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor;
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: 1. The laboratory failed to maintain an environment where contamination was

	minimized (Refer to D3003). 2. The laboratory failed to maintain a unidirectional workflow for molecular testing (Refer to D3005).
D3003	FACILITIES CFR(s): 493.1101(a)(2) The laboratory must be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. This STANDARD is not met as evidenced by: Based on observations, interviews, and review of procedures the laboratory failed to maintain an environment where contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. 1. A tour of the accessioning area took place on 2/11/2021 at 9:45 am where several accessioning staff were not wearing gloves or laboratory coats. No hand sanitizer or sink was available for hand washing upon entry or exit of the accessioning room. Food and drink were on counters in the accessioning area, including but not limited to: a paper coffee cup, bottles of water, a container of food with silverware, and honey packets kept in storage containers next to laboratory supplies. 2. A tour of the extraction room on 2/11 /2021 at 10:15 am showed no staff wearing laboratory coats. Only one box of gloves in one size was immediately available. No hand sanitizer or sink was available for hand washing upon entry or exit of the extraction room. 3. The laboratory's VP of R&D stated that laboratory personnel did not need to wear laboratory coats if they were wearing scrubs. 4. Testing personnel (TP) #5 was chewing gum while manually extracting specimens during observation of COVID standard operating procedure on 2 /11/2021 around 10:30 am. 5. TP#1 stated during an interview on 2/11/2021 at 12:30 pm that lab coats were "normally worn but I don't know where they are right now." 6. The laboratory's standard operating procedure (SOP) "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) on Bio-Rad CFX384" states "Do not eat, smoke, apply cosmetics, or handle contact lenses in areas where reagents and human specimens are handled" and "Use personal protective equipment such as (but not limited to) gloves, eye protection, masks, and lab coats when handling kit reagents while performing this assay and handling materials including samples, reagents, pipettes, and other equipment and reagents."
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on observation and record review the laboratory failed to have a uni-directional workflow for molecular amplification systems. 1. The laboratory's standard operating procedure (SOP) "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) on Bio-Rad CFX384" states "workflow in the laboratory should proceed in a unidirectional manner" and "wear a clean lab coat and powder free disposable gloves (not previously worn) when setting up assay." The laboratory's SOP states "Between extractions and/or handling DNA/RNA, use 70% ethanol to clean gloves and wait for

	it to evaporate before proceeding with work." 2. Testing personnel moved freely from extraction room to amplification room and back with no decontamination process in between rooms during observation of COVID standard operating procedure on 2/11 /2021 around 10:30 am and around 12:30pm. 3. The laboratories 2020 internal audit observed "overcrowding conditions in the molecular preparatory room providing opportunities for method and run contamination." There was no corrective action for the observation.
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 lack of documentation laboratory failed to retain quality control records, maintenance records, and PCR plate records. The surveyors requested documentation on 2/11/2021 at 9:30, 12:00 pm and 2:00pm and on 2/12/2021 at 10:45am. The laboratory failed to provide documentation prior to the end of the survey of 2/12/2021 at 2:00pm.
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: 1. The laboratory failed to establish performance specifications (refer to D5421). 2. The laboratory failed to provide evidence it was performing quality control in accordance with regulations (D5449). 3. The laboratory failed to have a procedure manual that was available to and followed by all testing personnel (D5401).
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: 1. The laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control (Refer to

	D5201). 2. The laboratory failed to ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results (Refer to D5203).
D5201	CONFIDENTIALITY OF PATIENT INFORMATION CFR(s): 493.1231 The laboratory must ensure confidentiality of patient information throughout all phases of the total testing process that are under the laboratory's control. This STANDARD is not met as evidenced by: Based on observation, interview, lack of documentation, and review of standard operating procedure the laboratory failed to ensure confidentiality of patient information throughout all phases of the total testing process. 1. During an interview on 2/11/2021 at approximately 1:45pm testing personnel (not listed on the 209 but states they perform COVID testing) stated they do not perform result reporting on COVID specimens. Results are reported from a team in India. When asked how the laboratory handles problems with result reporting, testing personnel stated that they communicate through a WhatsApp chat. 2. On 2/11/2021 at approximately 1:45 pm a WhatsApp chatroom was enlarged on a television in the extraction room, several different phone numbers were in the chat. Patient names as well as images of lists of patient names and images of potential patient reports were in the chat. 3. The surveyor requests documentation of the chat as well as any compliance records regarding the use of WhatsApp at approximately 2pm and 3pm on 2/11/2021. The records were not provided to the surveyors prior to the end of survey at 2pm on 2/12/2021. 4. The laboratory's standard operating procedure (SOP) "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) in Bio-Rad CFX384" does not mention the use of WhatsApp to aide in result reporting or laboratory issues.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on observations, record review and lack of documentation the laboratory failed to establish and follow written policies and procedures to ensure identity and integrity of patient specimens. 1. The laboratory's standard operating procedure (SOP) "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) in Bio-Rad CFX384" states "Label the vial with the patient's name, DOB, specimen type, and date collected." 2. During a tour of the specimen accessioning area at 9:45 am on 2/11 /2021, several specimens were observed in the specimen accessioning area with labels only containing the patient's name, and an accessioning number from another system that the laboratory does not use. Some specimens only had a patient name. 3. Laboratory personnel label specimens with a label that contains barcode, name, date of birth, collection date, and accession number, etc. upon arrival to the specimen accessioning area. There is no collection time on the specimen label. 4. During an interview on 2/11/2021 at 12:00pm, the laboratory's IT manager states that the

	collection date "is the date the first laboratory receives the specimens" since the facility is a reference laboratory. This may or may not be the date the patient specimen collected. 5. During an interview with testing personnel on 2/11/2021 at 10: 30 am TP #5 indicated they would use the collection date on the specimen tube to determine if they would test the sample, and that could not exceed 3 days. 6. The laboratory's SOP "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) in Bio-Rad CFX384" does not addressed how to maintain specimen identification through the scanning, extraction, amplification, and reporting process or what to do if a mislabeled specimen is identified or suspected.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: 1. The laboratory failed to have a written or electronic request for patient testing from an authorized person (refer to D5301). 2. The laboratory failed to follow written policies and procedures to ensure specimens are properly stored (refer to D5311). 3. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems (refer to D5391).
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on the laboratory's standard operating procedure and record review the laboratory failed to have a written or electronic request for patient testing from an authorized person. 1. The laboratory's standard operating procedure "General Laboratory Policy" page 5 lists a table "Persons Authorized to Order Tests and Receive Directly the Results of Clinical Laboratory Testing of Specimens." 2. Five of 79 patient records reviewed did not indicate an authorized provider/individual who ordered testing: a. Test requisition and report patient ID #39582282 reported on 2/10 /2021 b. Test requisition and report patient ID #8937972 reported on 2/10/2021 c. Test requisition and report patient ID #25792952 reported on 2/9/2021 d. Test requisition and report patient ID #56620804 reported on 2/10/2021 e. Test requisition and report patient ID #485611190 reported on 2/08/2021
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: Based on record review and observation the laboratory failed to follow written policies and procedures to ensure specimens are properly stored. 1. During a laboratory tour on 2/11/2021 at 9:45 am, a refrigerator labeled refrigerator #7 was missing documentation of monitoring from 1/21/2021-1/31/2021 and 2/9/2021-2/10 /2021. Documentation prior to 2021 was unavailable. The refrigerator calibration date was 8/5/2014. The temperature wheel on the refrigerator was dated 2014. The thermometer inside the refrigerator was marked with a due date for calibration of 5/5 /2020. The refrigerator contained hundreds of specimens stored. During a laboratory tour on 2/12/2021 the dates missing documentation of temperature monitoring had been filled in with no documentation of corrective action. 2. During a laboratory tour on 2/11/2021 at 11:00 am, a refrigerator in the amplification room labeled refrigerator #3 was missing temperature monitoring from the following dates of 2021: a. January 1, 2, 3, 5, 6, 7, 10, 11, 17, 24, 27, 28, 31 b. February 8, 11 3. During a laboratory tour on 2/11/2021 at 1:00 pm, a freezer labeled freezer #7 in the hallway storing specimens was missing temperature monitoring from the following dates: a. January 1, 3, 23, 24, 29, 30 b. February 1, 4, 5, 6, 7, 8, 9, 10 4. The documentation does not indicate the year being monitored and documented. The acceptable range of temperature is (-20C) - (-30C). The recorded temperatures are outside of the acceptable range on the following dates: a. January 2, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 31 b. February 2, 3 5. On 2/12/2021 during a laboratory tour a new temperature monitoring log for freezer #7 was on the freezer with different temperatures and different signatures from the original log observed on 2/11/2021 (for example 1/12/2021 on 2/11/2021 was recorded as -15 by RC and on 2/12/2021 was recorded as -8 by hh). All temperatures for 1/1/2021-2/12/2021 were filled in on the log. All temperatures documented were outside of the acceptable range of (-20C) - (-30C). No corrective action was documented on any temperature monitoring log. 6. The laboratory's standard operating procedure (SOP) "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) in Bio-Rad CFX384" states "Storing specimens - Specimens can be stored at 2-8C for up to 72 hours after collection. If a delay in extraction is expected, store specimens at -70C or lower. Extracted nucleic acid should be stored at -70C or lower." There was no -70C freezer on site.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to establish and follow policies and procedures to monitor, assess, and correct problems identified in preanalytics. 1. Based on record review "Problem Log" preanalytic issues were documented from 9/18/2020 until 11/10/2020. There were no records from 11/11

	/2020 until 1/16/2020. 2. The laboratory did not provide any written policies or procedures defining use of the "Problem Log."
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: 1. The laboratory failed to have a procedure manual available to and followed by testing personnel (refer to D5401). 2. The laboratory failed to meet regulation requirements of the procedure manual (refer to D5403). 3. The laboratory failed to monitor and document temperature and humidity for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting (refer to D5413). 4. The laboratory failed to establish and verify performance specifications (refer to D5421). 5. The laboratory failed to perform maintenance (refer to D5429). 6. The laboratory failed to meet quality control regulations (refer to D5449).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observations and interview the laboratory failed to provide a written procedure manual for all tests, assays, and examinations performed by the laboratory. 1. During a tour of laboratory on 2/11/2021 at 10:15am the surveyors looked for standard operating procedures (SOPs) in the extraction room. Management of the laboratory indicated they would get SOPs "soon." The surveyors obtained the SOP for COVID testing "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) on Bio-Rad CFX384" around 12:15pm. 2. During an interview with testing personnel on 2/11/2021 at 10:30 am, TP #5 states "if the sample is low in volume, I'll add PBS (phosphate-buffered saline)" when asked how much TP #5 states, "as much as I need to get 40 microliters to test the sample." The laboratory's SOP does not indicate to add buffer. 3 .During an interview with TP#1 on 2/11/2021 at 12:30pm, testing personnel states "I don't know where procedure manuals are." 4. During an interview on 2/11/2021 at 1:37pm, TS#3 states "there's usually one in the lab and one online but we got a new server" and indicates they cannot currently access the COVID SOP. Testing personnel not listed on the CMS 209 indicated during the same interview they have not seen an SOP.
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 document review and interview the laboratory failed to meet requirement 3, 13, and 14 regarding Standard Operating Procedure: 1. During an interview on 2/11 /2021 at 1:37pm TS#3 indicates that results are not reported directly by the laboratory. "The results are reported in India." When asked how the laboratory communicates with those reporting results another TP not listed on the CMS 209 indicates there is a WhatsApp chat to communicate regarding problem samples with testing personnel in India. 2. The laboratory's SOP "Rapid Real-time PCR-based Screening for SARS-COV-2 (COVID-19) on Bio-Rad CFX384" does not indicate use of this communication in regards to reporting COVID 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 lack of documentation and record review the laboratory failed to monitor temperature and humidity for reagents, specimens, and test system. 1. Temperature and humidity monitoring records were requested on 2/11/2021 at 9:30 am, and again throughout the day at 10 am, 11 am, 12pm, and 2 pm. The surveyor requests records upon entry on 2/12/2021 at 10:30 am. The laboratory could not provide for temperature and humidity monitoring of the laboratories or storage rooms where reagents were stored. 2. Based on record review and the laboratory's standard operating procedure the laboratory failed to follow EUA requirements regarding storing specimens. Requirements include: Specimens can be stored at 2-8C for up to

	72 hours after collection. If a delay in extraction is expected, store specimens at -70C or lower. There was no -70C freezer for specimen storage on site shown to surveys during 2/11/2021 or 2/12/2021. 3. In a review of patient test result reports 25 of 79 reports released outside of stability from collection date until time of result reported: 1. Patient ID 485611190 collected on 1/28/2021 at 12:00am reported on 2/08/2021 at 8:32pm. 2. Patient ID 069440026 collected on 2/4/2021 at 12:00am reported on 2/10 /2021 at 9:22am. 3. Patient ID 984092801 collected on 1/29/2021 at 8:45am reported on 2/04/2021 at 11:52am. 4. Patient ID 658396864 collected on 1/30/2021 at 6:47am reported on 2/03/2021 at 04:07pm. 5. Patient ID 929398784 collected on 1/30/2021 at 7:04am reported on 2/04/2021 at 5:35am. 6. Patient ID 844207680 collected on 1/30 /2021 at 6:42am reported on 2/03/2021 at 04:07pm. 7. Patient ID 427679212 collected on 1/30/2021 at 6:40am reported on 2/03/2021 at 04:07pm. 8. Patient ID 036995352 collected on 1/27/2021 at 12:00am reported on 2/04/2021 at 05:36am. 9. Patient ID 716800381 collected on 2/01/2021 at 12:00am reported on 2/04/2021 at 12:53pm. 10. Patient ID 650879386 collected on 1/29/2021 at 4:21pm reported on 2/04/2021 at 12: 53pm. 11. Patient ID 797807050 collected on 2/01/2021 at 12:00am reported on 2/04 /2021 at 11:52am. 12. Patient ID 97814229 collected on 1/28/2021 at 2:48pm reported on 2/04/2021 at 12:53pm. 13. Patient ID 114469957 collected on 1/28/2021 at 12: 00am reported on 2/04/2021 at 02:31pm. 14. Patient ID 45467997 collected on 12/24 /2020 at 5:47pm reported on 12/31/2020 at 05:23pm. 15. Patient ID 85915822 collected on 12/27/2020 at 3:59pm reported on 1/03/2021 at 06:22 am. 16. Patient ID 551780016 collected on 12/27/2020 at 12:00am reported on 12/31/2020 at 03:08am. 17. Patient ID 34325769 collected on 12/24/2020 at 5:44PM reported on 12/31/2020 at 05:23pm. 18. Patient ID 103483048 collected on 12/28/2020 at 12:00am reported on 12/31/2020 at 03:08am. 19. Patient ID 240600368 collected on 12/28/2020 at 12: 00am reported on 12/31/2020 at 03:08am. 20. Patient ID 977769250 collected on 12 /28/2020 at 12:00am reported on 12/31/2020 at 03:08am. 21. Patient ID 430305995 collected on 12/28/2020 at 12:00am reported on 12/31/2020 at 03:08am. 22. Patient ID 37779399 collected on 01/02/2021 at 12:00am reported on 01/07/2021 at 07:59pm. 23. Patient ID 594093785 collected on 1/03/2021 at 12:00 am reported on 1/06/2021 at 01:34pm. 24. Patient ID 174873281 collected on 1/02/2021 at 4:48pm reported on 01/06/2021 at 07:04pm. 25. Patient ID 75486244 collected on 01/04/2021 at 12:00pm reported on 01/07/2021 at 07:38pm.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observations and laboratory's standard operating procedure the laboratory failed to properly label reagents, material and supplies with proper preparation and expiration dates. 1. During a laboratory tour on 2/11/2021 at 10:30 am reagents in the extraction area labels read: "H20 2/10" "COVID BEAD 2/8/21" "NGS BEADS CDNA 2/10/2021" AND "TE BUFFER", this writing was only on the lid of the reagent and not on the container. Any dates on the lids do not indicate a preparation date or expiration date. 2. Expiration dates for QuickExtract DNA Extraction Soln, NEST 0.1ml 96 well PCR plate, 2019-nCoV CDC EUA kit, 219-nCoV_N_Positive

	Control, Hs_RPP30 Positive Control, ThermoFisher reagent reservoirs, and Applied Biosystems MicroAmp Optical 384 well reaction plates do not have expiration dates defined in the standard operating procedure.
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 record review, lack of documentation and interview with Laboratory Director the laboratory failed to verify performance specifications of COVID testing. 1. The surveyors requested documentation of verification of performance specifications on 2/11/2021 at 9:30 am, 11:00 am, 11:30am, 12:00 pm, and 2:00 pm and on 2/12/2021 at 10:45 am, 11:30 am, and 12:00 pm. At around 12:00pm on 2/12/2021 the laboratory director states: "I'm going to be honest with you, I don't have it." 2. The Internal Audit for 2020 states "observed: missing validations" for the molecular laboratory. There is no corrective action in this document.
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 observation, interview and review of documentations the laboratory failed to maintain calibration and maintenance up to date for below instruments: 1. A tour of the laboratory on 2/11/2021 at 11 AM, where the surveyors found below instruments out of date for calibration and maintenance: a. Thermo Scientific Sonal ST* Centrifuge; Due: 15-May-2020 b. Integria 12.5 micro litter Pipette; Due: 15-May-2020 c. Eppendorf Centrifuge 5417C #1694; No sticker, nor was last calibration documentation received. d. Clean Room centrifuge LMC 300; Due: 15-May-2020 e. Olympus CX41 Microscope; Due: February 2020 f. Pipette Serial No (Extraction room): 142731117; Due: 4/14/17 g. Pipette ID No: 242790039 (Extraction room); Due: May 2020 2. ECS Metrology LLC maintenance work order for pipettes presented by the lab and above pipettes were not listed. 3. The laboratory's standard operating procedure (SOP) "General Laboratory Policy" on "equipment maintenance" states "equipment maintenance is done as required and properly documented in the equipment maintenance log located in the lab." 4. During an interview on 2/11/2021 at approximately 2 PM, the laboratory's VP of R&D stated that some of these instruments are not in use. There was nothing to distinguish which instruments were or were not in use in the laboratory. 42356

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview, the laboratory failed to meet quality control requirements. 1. The surveyors requested all quality control documentation related to COVID testing on 2/11/2021 at 9:30, 12:00 pm and 2:00pm and on 2/12 /2021 at 10:45am and 12:00 pm. The laboratory failed to provide any documentation regarding quality control prior to the end of the survey of 2/12/2021 at 2:00pm. 2. Testing personnel did indicate that QC was performed with each extraction during interviews on 2/11/2021. When asked for quality control failures or a rejected run log on 2/11/2021 the Laboratory Director replied "I haven't seen that yet" and no documentation was provided to surveyors.
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 record review and lack of documentation the laboratory failed to establish and follow written policies and procedures. 1. The laboratory did provide evidence of a quality assessment policy. The only QA activity provided was internal audits from 2019 and 2020. 2. The 2019 internal audit stated corrective actions but evidence was not provided. 3. The 2020 internal audit did not have corrective action performed.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination (refer to D5801).

D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on lack of documentation and observation the laboratory failed to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry to final report destination. 1. The laboratory had outsourced result reporting to India, therefore it could not be observed. 2. The laboratory failed to provide documentation of the post-analytic process. The documentation was requested on 2/11/2021 at 2pm and was not provided by 2/12/2021 at 2 pm.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review of personnel file and interview with lab director, the laboratory failed to make sure the 4 of 6 technical consultants were qualified under CLIA requirement for COVID-19 testing. (See D6035).
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical

	technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on record review of personnel file and interview with lab director, the laboratory failed to make sure the 4 of 6 technical consultants were qualified under CLIA requirement. 1. The personnel form CMS-209 filled out by the laboratory at the time of survey listed 6 TC technical consultants for COVID-19 testing. 2. Technical consultant #2 (TC#2), the lab could not provide a copy of his US equivalency diploma and clinical experience. Patient results are reported by TC#2 in India who operate 24 /7 as the laboratory does. The surveyor was not able to determine if he is qualified or not because of lack of evidence. 3. Review of Technical consultant #3 (TC#3) Laboratory Technical Personnel Folder revealed, hiring date: 3/25/2019; she had proper education but did not have 2 years' experience to be qualified for technical consultant. 4. Review of Technical consultant #4 (TC#4) Laboratory Technical Personnel Folder revealed, hiring date: 7/20/2020; she had proper education but did not have 2 years' experience to be qualified for technical consultant. 5. Technical consultant #5 (TC#5), the lab could not provide a copy of his US equivalency diploma and clinical experience. Patient results are reported by TC#5 in India who operate 24 /7 as the laboratory does. The surveyor was not able to determine if he is qualified or not because of lack of evidence. 6. During an interview on 2/12/2021 at approximately 1 PM, the laboratory's director stated that he is not able to provide a copy of TC#2 and TC#5 US equivalency diploma and clinical experience.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

	This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, there was no delegation letter to clinical consultant (CC), technical consultant (TC), technical supervisor (TS) or general supervisor (GS) to perform responsibilities based on their qualification. 1. Laboratory technical personnel folder reviewed and there was no indication or evidence of delegation assignment to CC, TC, TS or GS available. 2. The personnel form CMS-209 listed 2 clinical consultants, 6 technical consultants, 4 technical supervisors and 1 general supervisor. 3. Personnel files showed the competency and training of the testing personnel was performed by TS#3. 4. In an interview with lab director on 2/11/21 at 12:30 PM he confirmed that there were not delegation letter available and just verbally he assigned TS#3 to do training and competency on testing personnel for COVID-19 testing.
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 failed to ensure that the quality assessment programs are established and maintained. 1. Record review of Annual Internal Audit 2019 & 2020 conducted onsite. Those audits did not cover all aspects of quality assessment activities throughout of the lab. 2. During an interview on 2/11/2021 at approximately 1:30 PM, the laboratory's director confirmed that those audits are the only QA assessment activity lab performed.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, there was no written policy by the laboratory director for the lab personnel' duites. The findings include: 1. The personnel form CMS-209 filled out by the laboratory at the time of survey listed Clinical Consultant (CC), Technical Consultants (TC), Technical Supervisors (TS), General Supervisor (GS) and testing personnel (TP). 2. Personnel files showed the competency and training of the testing personnel was performed by TS#3. 3. The Personnel file documents were all signed by the same person who indicated as Technical Supervisor TS#3 in personnel form CMS-209 but not qualified to be TS. 4. In an interview with lab director on 2/11/21 at 1:30 PM he confirmed that there were not duties policy available for personnel working in laboratory.

D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review of personnel file and interview with lab director, the laboratory failed to make sure the 3 of 4 technical supervisors were qualified under CLIA requirement for COVID-19 testing. (See D6111).
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and

the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of

this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of

this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or

hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or

(l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)

(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:
Based on record review of personnel file and interview with lab director, the laboratory failed to make sure the 3 of 4 technical supervisors were qualified under CLIA requirement. 1. The personnel form CMS-209 filled out by the laboratory at the time of survey listed 4 TS technical supervisors for COVID-19 testing. 2. Review of Technical supervisor #1 (TS#1) Laboratory Technical Personnel Folder revealed, hiring date: 3/25/2019; she had proper education but did not have 4 years' experience to be qualified for technical supervisor. 3. Review of Technical Supervisor #3 (TS#3) Laboratory Technical Personnel Folder revealed, hiring date: 7/20/2020; she had proper education but did not have 4 years' experience to be qualified for technical supervisor. Personnel files showed the competency and training of the testing personnel was performed by TS#3. 4. Technical Supervisor #4 (TS#4), the lab could not provide a copy of his US equivalency diploma and clinical experience. Patient results are reported by TS#4 in India who operate 24/7 as the laboratory does. The surveyor was not able to determine if he is qualified or not because of lack of evidence. 5. During an interview on 2/12/2021 at approximately 1 PM, the laboratory's director stated that he is not able to provide a copy of TS#4 US equivalency diploma and clinical experience.

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 record review of personnel file and interview with lab director, the laboratory failed to make sure the 3 of 11 testing personnel's (TP) were completed their evaluation of competencies. A. The personnel form CMS-209 filled out by the laboratory at the time of survey listed 11 TP testing personnel's for COVID-19 testing. B. Review of Testing personnel #1 (TP#1), Laboratory Technical Personnel Folder revealed, hiring date: 3/25/2019; no competencies available at the time of survey. C. Review of Testing Personnel #2 (TP#2), Laboratory Technical Personnel Folder revealed, hiring date: 1/18/2018; missing competencies for 2019, 2020 and 2021 for both molecular and COVID testing. D. Review of Testing personnel #3 (TP#3) Laboratory Technical Personnel Folder revealed, hiring date: 7/20/2020; no 6 months competency available at the time of survey. Review of in-service training dated 12/18 /2020 did not include 6 criteria assessment for CLIA requirement. E. The laboratory' standard operating procedure (SOP) "Laboratory Technical Personnel Folder" states, "Six-month performance evaluation- from date of hire and annual performance evaluation thereafter." F. In an interview with lab director on 2/11/21, at approximately 2 PM, he was not able to provide more evidence related to competency of testing personals.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on record review of personnel file and interview, the laboratory failed to make sure the 1 of 11 testing personnel was qualified under CLIA requirement for COVID-19 testing. (See D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that

specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on record review of personnel file and interview with lab direcotr, the laboratory failed to make sure the 1 of 11 testing personnel was qualified under CLIA requirement. 1. The personnel form CMS-209 filled out by the laboratory at the time of survey listed 11 testing personnel for COVID-19. 2. Review of Testing person #6 (TP#6) lab technical personnel folder revealed, hiring date: 8/18/2020. Review of her educational transcript, she did not complete 24 credit hours of science for her

	education to be met testing personnel' requirement under CLIA. At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either 24 semester hours of medical laboratory technology courses; or 24 semester hours of science courses that include Six semester hours of chemistry; Six semester hours of biology; and Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination. 3. The laboratory' standard operating procedure (SOP) "Laboratory Technical Personnel Folder" on "Transcript" states, "Identifying the courses relevant to the sciences covered and passed by the individual." 4. In an interview with lab director on 2/11/21, at approximately 1:30 PM, he was not able to provide more evidence related to TP#6 education qualification.