Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2191582	04/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Atc Testing And Screening Services Llc	4532 W Napoleon Ave, Suite 202, Metairie, LA	

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 Initial/Complaint (LA 00057518) survey was performed at ATC Testing and Screening Services, LLC-CLIA ID 19D2191582 on April 1, 2021. ATC Testing and Screening Services, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1205: CONDITION: Virology 42 CFR 493.1443 CONDITION: Laboratories Performing High Complexity Testing; Laboratory Director 42 CFR 493.1447 CONDITION: Laboratories Performing High Complexity Testing, Technical Supervisor 42 CFR 493.1453 CONDITION: Laboratories Performing High Complexity Testing; Clinical Consultant 42 CFR 493.1459 CONDITION: Laboratories Performing High Complexity Testing; General Supervisor 42 CFR 493.1487 CONDITION: Laboratories Performing High Complexity Testing; Testing Personnel
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, proficiency test records, and interview with personnel, the laboratory failed to maintain proficiency testing records for one (1) of one (1) event reviewed for COVID testing

	for two (2) years. Findings: 1. Observation by surveyors on April 1, 2021 at 9:42 am during the laboratory tour revealed the laboratory utilizes the GeneFinder COVID-19 Plus Real AmpKit for COVID testing. 2. Review of the laboratory's policies revealed the laboratory did not have a proficiency testing policy. 3. Review of the laboratory's 2020 College of American Pathologists (CAP) records revealed the following documents were not maintained: COV 2-B 2020 SARS-CoV-2 Molecular: a) Attestation statement signed by testing personnel and Laboratory Director or designee b) Report form and raw data c) Evaluation/Results record provided by CAP 4. In interview on April 1, 2021 at 1:47 pm, the Technical Supervisor stated he did not have the identified proficiency testing documents.
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 observation by surveyors, review of laboratory policies, and interview with personnel, the laboratory failed to establish and follow polices to minimize contamination during performance of the COVID testing procedure. Findings: 1. Observation by surveyors on April 1, 2021 at 9:42 am during the laboratory tour revealed the laboratory utilizes the GeneFinder COVID-19 Plus Real AmpKit for COVID testing. 2. Review of the GeneFinder's instructions for use under "Warnings and Precautions" and "Procedure"sections revealed the following: a) "Follow standard precautions. All patient specimens should be considered potentially infectious and handled accordingly." b) "All materials used in one area should remain in that area and should not be moved or used in other areas. After the assay procedures, the workbench and lab supplies should be cleaned and disinfected immediately." c) "All lab workbench and supplies should be cleaned and disinfected regularly using 75% Ethanol or UV light." d) "All pipette tips and centrifuge tubes in the assay should be DNase/RNase-free. The used centrifuge tubes and pipette tips should be discarded in waste bin with bleach and discarded after decontamination." e)" Clean and decontaminate all work surfaces, pipettes, centrifuges, and other equipment prior to use. Decontamination agents should be used including 10% bleach, 70% ethanol, and DNAZapTM solutions to minimize the risk of nucleic acid contamination." 3. In interview on April 1, 2021 at 9:42 am, the Technical Supervisor stated the laboratory previously used bleach to clean the workstation, however, it caused rusting of the metal tabletop. The Technical Supervisor stated the laboratory uses alcohol to clean the workstation. 4. Surveyors observed Testing Personnel 2 on April 1, 2021 at 10:00 am process two (2) patient samples for COVID testing without cleaning the workstation with alcohol prior to or after completion of patient testing. 5. Review of the laboratory's procedures revealed the laboratory did not include procedures including, but not limited to, agent used for cleaning/decontamination and frequency of performance.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous

	materials. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, manufacturer procedures, and interview with personnel, the laboratory failed to establish safety procedures for protection, handling, and disposal of biohazardous materials. Findings: 1. Observation by surveyors during the laboratory tour on April 1, 2021 at 9:42 am revealed the laboratory did not have any trash labeled biohazardous. Surveyors observed COVID patient samples labeled with patient name and date of birth in a large white plastic bucket on the floor. 2. In interview on April 1, 2021 at 9:42 am, the Technical Supervisor stated the samples observed in the bucket were old patient samples that needed to be discarded. The Technical Supervisor stated he opens the sample tubes and places them in a bucket located in his office that is filled with a 40 % bleach solution. The Technical Supervisor further stated he leaves the samples in the bleach solution for a few days then fishes them out and discards the patient sample tubes in the regular trash and the bleach solution down the drain. Surveyors observed uncapped samples and pipette tips in a bleach solution in a white plastic bucket with lid located in the Technical Supervisor's office. 3. Surveyors observed the laboratory receive two patient samples via FedEx Express on April 1, 2021 at 9:58 am. The samples were received in "Biohazard" bags inside of the FedEx package. Surveyors observed Testing Personnel 2 discard the empty "Biohazard" bags that contained the patient samples in a non-biohazard trash can and process the samples on open workstation. 4. In further interview on April 1, 2021 at 12:17 pm, the Technical Supervisor stated pipette tips used in the pre-lysis process are placed in bleach before being discarded into the regular trash. 5. Review of the GeneFinder's instructions for use under "Warnings and Precautions" section revealed the following: a) "Follow standard precautions. All patient specimens should be considered potentially infectious and handled accordingly." b) "Handle all specimens as if infectious using safe laboratory procedures. Refer to Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019-nCoV. Dispose of hazardous or biologically contaminated materials according to the practices of your institution." c) "Each step of operation, from specimen collection, storage and transportation, and laboratory testing, should be strictly conducted in line with relevant biosafety regulations and molecular laboratory management." d)" Following the amplification protocol, PCR plates should be placed into a sealable plastic bag for autoclaving and decontamination." 6. Review of the laboratory's procedures revealed the laboratory did not include safety procedures related to handling of biohazard materials to include, but not limited to personal protective equipment and safety equipment, spills and disposal of waste.
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: Based on observation by surveyors, review of laboratory's policies, patient test records, and interview with personnel, the laboratory failed to ensure the quality of testing in the specialty of Virology. Findings: 1. The laboratory failed to maintain

	proficiency testing records for one (1) of one (1) event reviewed for COVID testing for two (2) years. Refer to D2015. 2. The laboratory failed to establish and follow polices to minimize contamination during performance of the COVID testing procedure. Refer to D3003. 3. The laboratory failed to establish safety procedures for protection, handling and disposal of biohazardous materials. Refer to D3011. 4. The laboratory failed to have a system for handling complaints and problems reported to the laboratory. Refer to D5205. 5. The laboratory failed to have a system in place for identifying and documenting communication issues. Refer to D5207. 6. The laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Refer to D5209 I. 7. The laboratory failed to establish written policies and procedures to assess competency of the Technical Supervisor. Refer to D5209 II. 8. The laboratory failed to ensure test requisitions included information as required for random selection of four (4) of four (4) patients reviewed. Refer to D5305. 9. The laboratory failed to ensure nasopharyngeal specimens for COVID testing met manufacturer's storage and transport requirements. Refer to D5311 I. 10. The laboratory failed to ensure the collection dates were accurate. Refer to D5311 II. 11. The laboratory failed to document the time samples were received for COVID testing for ten (10) of ten (10) patients reviewed. Refer to D5313. 12. the laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Refer to D5317. 13. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 14. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 15. The laboratory failed to establish complete policies and procedures. Refer to D5403. 16. The laboratory failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements. Refer to D5413 I. 17. the laboratory failed to monitor the temperature of the laboratory's freezer where reagents are stored per manufacturer requirements. Refer to D5413 II. 18. The laboratory failed to properly store COVID reagents per manufacturer requirements. Refer to D5413 III. 19. The laboratory failed to label reagent aliquots with required information. Refer to D5415. 20. The laboratory failed to have complete performance verification studies for COVID testing approved by the Laboratory Director. Refer to D5421. 21. The laboratory failed to establish maintenance protocols for equipment utilized for COVID testing. Refer to D5433. 22. The laboratory failed to establish corrective action procedures to ensure patient test results. Refer to D5779. 23. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791. 24. The laboratory failed to include "Fact Sheets" to providers or patients for EUA COVID tests. Refer to D5809. 25. The laboratory failed to provide a copy of their client list to ensure the laboratory is in compliance with CLIA Regulations Part 493. Refer to D8103.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have a system for handling complaints and problems reported to the laboratory. Findings: 1. Review of the laboratory's policies revealed the laboratory

	did not have a written procedure for reporting complaints, including who is responsible for handling. 2. In interview on April 1, 2021 at 2:18 pm, the Technical Supervisor confirmed the laboratory did not have a written procedure for reporting /handling complaints.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, patient final test reports, and interview with personnel, the laboratory failed to have a system in place for identifying and documenting communication issues. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a written procedure for identifying and documenting communication issues. 2. Review of the laboratory's patient final test reports revealed the laboratory provided a phone number for their location. 3. In interview on April 1, 2021 at 2:18 pm the Technical Supervisor stated the phone number listed on the patient final reports is for the laboratory; however, the laboratory does not have a phone. The Technical Supervisor stated the patient should contact their doctor with questions and the doctors have his contact information if he needs to be reached.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Findings: 1. Review of the laboratory's polices revealed the laboratory did not have a written policy for assessing the competency of personnel performing laboratory testing that included frequency of performance and the following six (6) procedures as a minimal requirement: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on April 1, 2021, the Technical Supervisor stated the he trained the other testing personnel using the training forms from the manufacturer. II. Based on review of the laboratory's policies and interview with personnel, the laboratory failed to establish written policies and procedures to assess competency of the Technical Supervisor. Findings: 1. Review of the

	laboratory's CMS-209 form (Laboratory Personnel Report) form revealed one (1) Technical Supervisor. 2. Review of the laboratory's policies revealed the laboratory did not have procedures for assessing the competency of the Technical Supervisor. 3. Review of personnel records for the Technical Supervisor revealed the Laboratory Director did not perform a competency assessment on his duties as Technical Supervisor. 4. In interview on April 1, 2021, the Technical Supervisor confirmed the laboratory did not have documentation of Laboratory Director performing assessment of his Technical Supervisory duties.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's patient test requisitions and interview with personnel, the laboratory failed to ensure test requisitions included information as required for random selection of four (4) of four (4) patients reviewed. Findings: 1. Review of the laboratory's procedures revealed the laboratory did not establish a written policy for test requisition requirements. 2. Observation by surveyors at 9:53 am during the laboratory tour on April 1, 2021 revealed the laboratory accepts the following transport media: a) e-Swab b) Nest c) Labsero 3. Review of two (2) patient test requisitions (Patient 696 and Patient 697) labeled "Lab Requisition Form-COVID-19 Testing" from April 1, 2021 revealed the laboratory did not include the following information: a) Source of the specimen b) Date and time of specimen collection c) Contact information./identifier of authorized personnel ordering test d) Transport media submitted 4. Review of patient test requisitions from January 27, 2021 revealed the following two (2) patients' test requisitions did not include the identified information: Patient 1043 Patient 1044 5. In interview on April 1, 2021 at 1:04 pm, the Technical Supervisor stated clients receive the requisition forms from their company. The Technical Supervisor further stated clients do not receive the same type of requisition form. The Technical Supervisor confirmed the identified patient requisitions did not include the required information. Surveyors observed more than one (1) type of requisition form. 6. The laboratory did not provide surveyors a list of clients that are provided their laboratory services.
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 observation by surveyors, review of manufacturer's instructions, laboratory's procedures, test menu, and interview with personnel, the laboratory failed to ensure nasopharyngeal specimens for COVID testing met manufacturer's storage and transport requirements. Findings: 1. Surveyors observed the laboratory receive the following two (2) patient samples from a provider located in New Jersey at ambient temperature via FedEx Express on April 1, 2021 at 9:58 am: Patient 696 (Collection date and time were not documented on the requisition or sample) Patient 697 (Collection date and time were not documented on the requisition or sample) 2. Review of the GeneFinder's instructions for use under the "Procedure" section revealed the following: a)"Specimen Storage: The specimen may be tested immediately after collection, or it may be stored at 2-8 degrees C for up to 72 hours before testing. If a delay in testing or shipping is expected, the specimen may be stored at -18 degrees C for no longer than 1 week or at -70 degrees C for no longer than 6 months. b) "Transporting Specimens: Store specimens at 2-8 degrees C and ship overnight. If a specimen is frozen at -70 degrees C or lower, ship overnight on dry ice." 3. In interview on April 1, 2021 at 9:42 am, the Technical Supervisor stated the laboratory receives samples from mainly New Jersey, New York via FedEx, with a few local samples received by local courier. The Technical Supervisor stated samples are to be shipped on dry ice; however, FedEx samples are not received on dry ice. 4. Review of the laboratory's procedures revealed the laboratory did not have detailed written instructions for providers that included specimen handling, transport, and acceptability/rejection requirements. 5. The laboratory did not provide surveyors with an annual volume for COVID testing. The laboratory provided two (2) copies of the CLIA 116 application on April 12, 2021 that included the following two (2) differing annual volumes for COVID testing: 25,000 and 10,000. II. Based on observation by surveyors, review of the laboratory's policies, patient test requisitions, patient final reports, and interview with personnel, the laboratory failed to ensure the collection dates were accurate. Findings: 1. Review of the laboratory's procedures revealed the laboratory did not have detailed written instructions for providers that included specimen handling, transport, and acceptability/rejection requirements. 2. Review of random selection of patient test requisitions revealed the laboratory's patient test requisitions do not include date and time of collection. 3. Review of patient final test reports from December 28, 2020 revealed the following "collection, received and tested" dates for five (5) of ten (10) patients : "Collected: 12/28/2020" "Received: 12/27/2020" "Tested: 12/29/2020" a) Patient 523 b) Patient 524 c) Patient 525 d) Patient 526 e) Patient 527 4. In interview on April 1, 2021 at 1:17 pm, the Technical Supervisor confirmed the received date proceeded the date of collection for the identified five (5) patients. The Technical Supervisor stated the date of collection is entered remotely and samples are to be shipped overnight.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's patient test requisitions, test records, and interview with personnel, the laboratory failed to document the time samples were received for COVID testing for ten (10) of ten (10) patients reviewed. Findings: 1. Review of the laboratory's patient test requisitions and test records revealed the laboratory does not document the time the samples are received by the laboratory. 2. Review of the following ten (10) patient test records from December 28, 2021 revealed the receipt time was not documented : Patient 523 Patient 524 Patient 525 Patient 526 Patient 527 Patient 530 Patient 531 Patient 532 Patient 533 Patient 534 3. In interview on April 1, 2021 at 1:17 pm, the Technical Supervisor confirmed the receipt times of sample shipments are not documented.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, test menu, and interview with personnel, the laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Findings: 1. In interview on April 1, 2021 at 9:42 am, the Technical Supervisor stated the laboratory receives samples from mainly New Jersey, New York via FedEx, with a few local samples received by courier. 2. Review of the laboratory's "ATC Testing and Screening Services COVID Testing Process" revealed the laboratory did not include a) Specimen collection to include acceptable transport media b) Specimen storage and preservation. c) Conditions for specimen transportation. d) Specimen acceptability and rejection. e) Specimen referral, if applicable 3. The laboratory did not provide surveyors with an annual volume for COVID testing. The laboratory provided two (2) copies of the CLIA 116 application on April 12, 2021 that included the following two (2) differing annual volumes for COVID testing: 25,000 and 10,000.
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 observation by surveyors, review of laboratory policies, records, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Findings: 1. Review of the laboratory's procedures revealed the laboratory failed to have procedures to identify the following issues within the preanalytic system: 1. The laboratory failed to ensure test requisitions included information as required for random selection of four (4) of four (4) patients reviewed. Refer to D5305. 2. The laboratory failed to ensure nasopharyngeal specimens for COVID testing met

	manufacturer's storage and transport requirements. Refer to D5311 I. 3. The laboratory failed to ensure the collection date and time were accurate. Refer to D5311 II. 4. The laboratory failed to document the time samples were received for COVID testing for ten (10) of ten (10) patients reviewed. Refer to D5313. 5. The laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Refer to D5317.
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 review of the laboratory's procedures and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's "Standard Operating Procedure Training Program" procedure revealed the laboratory did not have written policies and procedures that included the following: a) Corrective action: to address failures that may occur in the preanalytic, analytic, and post analytic systems b) Maintenance: how often to perform, required function checks and frequency c) Retention of records requirements d) Twice a year verification for accuracy of COVID testing to include frequency, acceptability criteria, and corrective action plan e) Performance specification: detailed procedures for performing accuracy and precision (day-to-day, run-to-run, and within-run, as well as, operator variance), reportable and reference range studies, and actions to take when data from the studies fail to meet acceptability criteria f) Complaint Investigations g) Communication h) Reporting of SARS COV-2 test results to state public health agency i) Temperature monitoring: including corrective action for temperatures outside of acceptable range j) Corrected reports 2. In interview on April 1, 2021 at 1:30pm, the Technical Supervisor stated the laboratory used the manufacturer instructions for policies and that the manual needing work.
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 review of the laboratory's procedures and interview with personnel, the laboratory failed to establish complete policies and procedures. Findings: 1. Review of the laboratory's "Standard Operating Procedure Training Program" procedure revealed the laboratory did not have written policies and procedures that included the following: a) Detailed policies and procedures for patient preparation; specimen collection, specimen type, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493. 1242. b) Step-by-step performance of the procedure, including test calculations c) Preparation of solutions, controls, reagents, stains, and other materials used in testing d) Quality Control to include, but not limited to: What quality control is required, frequency of performance; who is to monitor and corrective actions for unacceptable results e) Reportable range for test results for the test system as established or verified f) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability g) Limitations in the test methodology; including interfering substances h) Reference intervals (normal values) i) Imminently life-threatening test results, or panic or alert values j) Pertinent literature references k) Laboratory's system for entering results in the patient record and reporting patient test results l) Course of action if test system becomes inoperable 2. In interview on April 1, 2021 at 1:30pm, the Technical Supervisor stated the laboratory used the manufacturer instructions for policies and that the manual needing work.
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: I. Based on observation by surveyors, review of manufacturer's temperature requirements, and interview with personnel, the laboratory failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements. Findings: 1. Observation by surveyors during the laboratory tour on April 1, 2021 at 10:00 am revealed the laboratory did not monitor the room temperature of the laboratory where the following reagents were stored: a) Qiagen Buffer AVL Viral Lysis Buffer, 31 mL b) Qiagen Buffer AVL Viral Lysis Buffer, 155 mL c) Qiagen Buffer AW1 Wash Buffer 1 d) Qiagen Buffer AW2 Wash Buffer 2 e) Qiagen Buffer AVE f) QI Amp Viral RNA mini Kit g) Qiagen Vac Connectors 2. Review of the manufacturer's storage requirements for the identified Qiagen reagents revealed the following: 15-25 degrees Celsius. 3. In interview on April 1, 2021 at 10:05 am, the Technical Supervisor confirmed the laboratory did not monitor the room temperature of the laboratory. II. Based on observation by surveyors, review of manufacturer's temperature requirements, and interview with personnel, the laboratory failed to

	monitor the temperature of the laboratory's freezer where reagents are stored per manufacturer requirements. Findings: 1. Observation by surveyors during the laboratory tour on April 1, 2021 at 10:00 am revealed the laboratory did not monitor the Samsung freezer temperature where the following reagents were stored: a) GeneFinder COVID 19 Plus Real Amp Kit, Lot 2004-R45-37 and Lot 2004-R45-43 b) CFX Qualification Plate 2. Review of the manufacturers' storage requirements for the identified reagents revealed the following: -20 degrees Celsius 3. In interview on April 1, 2021 at 10:23 am, the Technical Supervisor stated the refrigerator/freezer were monitored electronically. Surveyors did not observe a thermometer sensor. The Technical Supervisor was unable to show surveyors a thermometer sensor or temperature logs. III. Based on observation by surveyors, review of manufacturer's temperature requirements, and interview with personnel, the laboratory failed to properly store COVID reagents per manufacturer requirements. Findings: 1. Observation by surveyors during the laboratory tour on April 1, 2021 at 10:00 am revealed the following reagent was stored in the laboratory's Samsung refrigerator: Qiagen Carrier RNA , Lot 166039691, Quantity: ten (10) tubes 2. Further observation by surveyors revealed the refrigerator did not have a temperature monitoring device. 3. Review of the manufacturer's storage requirements revealed the following: "Store at room temperature 15-25 degrees Celsius" 4. In interview on April 1, 2021 at 10:30 am, the Technical Supervisor stated he thought the identified reagent could be stored in the refrigerator.
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 observation by surveyors and interview with personnel, the laboratory failed to label reagent aliquots with required information. Findings: 1. Observation by surveyors during laboratory tour on April 1, 2021 at 10:00 am revealed reagents in unidentified aliquot tubes located in the laboratory's Samsung freezer inside a styrofoam cooler. The aliquot tubes were labeled "I" and "II." 2. Further observation by surveyors revealed the laboratory did not include the identity, storage requirements or expiration dates of the contents of the aliquot tubes. 3. In interview on April 1, 2021 at 10:40 am, the Technical Supervisor stated the identified aliquot tubes are RNA elutes. The Technical Supervisor confirmed the laboratory did not include the required information for the aliquot tubes.
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 observation by surveyors, review of the laboratory's procedures, validation studies, and interview with personnel, the laboratory failed to have complete performance verification studies for COVID testing approved by the Laboratory Director. Findings: 1. Observation by surveyors on April 1, 2021 at 9:42 am during the laboratory tour revealed the laboratory utilizes the GeneFinder COVID-19 Plus Real AmpKit for COVID testing. 2. Review of the laboratory's procedures revealed the laboratory did not have written policies and procedures for verifying the performance specifications. 3. Review of the laboratory's validation studies revealed the following information was not included: a) Laboratory Director approval/signature b) Inclusion of positive patients with the patient samples. 4. In interview on April 1, 2021 at 11:02 am, the Technical Supervisor confirmed the approval by the Laboratory Director was not documented.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the laboratory failed to establish maintenance protocols for equipment utilized for COVID testing. Findings: 1. Observation by surveyors on April 1, 2021 at 9:42 am during the laboratory tour revealed the laboratory utilizes the GeneFinder COVID-19 Plus Real AmpKit for COVID testing. 2. Review of the laboratory's policies revealed the laboratory did not have written procedures for maintenance for equipment utilized for COVID testing to include, but not limited to, pipettes and centrifuges. 3. In interview on April 1, 2021 at 2:45pm, the Technical Supervisor stated the laboratory follows manufacturer instructions but did not have a policy for maintenance protocols throughout the laboratory.
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 laboratory's policies and interview with personnel, the laboratory failed to establish corrective action procedures to ensure patient test results. Findings: 1. Review of the laboratory's policies revealed the laboratory did not include

	corrective action procedures to address problems that may occur that includes, but not limited to, the test system, equipment, quality controls and test records. 2. In interview on April 1, 2021 at 1:17 pm, the Technical Supervisor stated errors on reports that results in corrected reports are not logged. The Technical Supervisor stated at 2:30 pm, in November the power was out in the building. The Technical Supervisor stated at 2:41 pm the laboratory's centrifuge was broken and clinics were notified, however, did not provide surveyors the date of the incident. The Technical Supervisor did not provide surveyors with documentation of the incidents and corrective actions performed.
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 observation by surveyors, record review, and interview with personnel, the laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Findings: 1.The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403. 3. The laboratory failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements. Refer to D5413 I. 4. the laboratory failed to monitor the temperature of the laboratory's freezer where reagents are stored per manufacturer requirements. Refer to D5413 II. 5. The laboratory failed to properly store COVID reagents per manufacturer requirements. Refer to D5413 III. 6. The laboratory failed to label reagent aliquots with required information. Refer to D5415. 7. The laboratory failed to have complete performance verification studies for COVID testing approved by the Laboratory Director. Refer to D5421. 8. The laboratory failed to establish maintenance protocols for equipment utilized for COVID testing. Refer to D5433. 9. The laboratory failed to establish corrective action procedures to ensure patient test results. Refer to D5779.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the United States Food and Drug Administration (FDA) Emergency Use Authorization (EUA) instructions, and interview with personnel, the laboratory failed to include "Fact Sheets" to providers or

	patients for EUA COVID tests. Findings: 1. Observation by surveyors on April 1, 2021 at 9:42 am during the laboratory tour revealed the laboratory utilizes the GeneFinder COVID-19 Plus Real AmpKit for COVID testing. 2. Review of the FDA EUA letter for the GeneFinder COVID test revealed the following statement: "Your product is authorized to be accompanied by the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients: Fact Sheet for Healthcare Providers: GeneFinder COVID-19 Plus RealAmp Kit Fact Sheet for Patients: GeneFinder COVID-19 Plus RealAmp Kit" 3. In interview on April 1, 2021 at 11:05 am, the Technical Supervisor stated he did not know if fact sheets were provided to patients or providers.
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 observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction. Findings: 1. The Laboratory Director failed to ensure personnel filled the Clinical Consultant position. Refer to D6079. 2. The Laboratory Director failed to ensure the laboratory established safety procedures for protection, handling and disposal of biohazardous materials. Refer to D6084. 3. The Laboratory Director failed to establish complete performance specifications for COVID testing. Refer to D6086. 4. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6087. 5. the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6094. 6. The Laboratory Director failed to ensure the laboratory established maintenance protocols for equipment utilized for COVID testing. Refer to D6095. 7. The Laboratory Director failed to ensure final reports included required pertinent information. Refer to D6098. 8. The Laboratory Director failed to ensure the position of General Supervisor was filled to provide on-site supervision of high complexity test performance by testing personnel. Refer to D6100. 9. The Laboratory Director failed to ensure two (2) of two (2) Testing Personnel had training and/or approval to perform COVID 19 testing prior to patient testing. Refer to D6102 I. 10. The Laboratory Director failed to ensure one (1) of two (2) personnel met the state of Louisiana licensure requirement. Refer to D6102 II. 11. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were complete. Refer to D6103. 12. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Refer to D6106.
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 review of the laboratory's CMS-209 form, the Laboratory Director failed to ensure personnel filled the Clinical Consultant position. Refer to D6134.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, manufacturer procedures, and interview with personnel, the Laboratory Director failed to ensure the laboratory established safety procedures for protection, handling and disposal of biohazardous materials. Refer to D3011.
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 observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to establish complete performance specifications for COVID testing. Refer to D5421.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of policies, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to maintain proficiency testing records for one (1) of one (1) event reviewed for COVID testing for two (2) years. Refer to D2015. 2. The laboratory failed to establish and follow polices to minimize contamination during COVID testing procedure. Refer to D3003. 3. The laboratory failed to have a system for handling complaints and problems reported to the

	laboratory. Refer to D5205. 4. The laboratory failed to have a system in place for identifying and documenting communication issues. Refer to D5207. 5. The laboratory failed to ensure test requisitions included information as required for random selection of four (4) of four (4) patients reviewed. Refer to D5305. 6. The laboratory failed to ensure nasopharyngeal specimens for COVID testing met manufacturer's storage and transport requirements. Refer to D5311 I. 7. The laboratory failed to ensure the collection dates were accurate. Refer to D5311 II. 8. The laboratory failed to document the time samples were received for COVID testing for ten (10) of ten (10) patients reviewed. Refer to D5313. 9. The laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Refer to D5317. 10. The laboratory failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements. Refer to D5413 I. 11. The laboratory failed to monitor the temperature of the laboratory's freezer where reagents are stored per manufacturer requirements. Refer to D5413 II. 12. The laboratory failed to properly store COVID reagents per manufacturer requirements. Refer to D5413 III. 13. The laboratory failed to label reagent aliquots with required information. Refer to D5415.
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 observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the preanalytic system. Refer to D5391. 2. The laboratory failed to establish procedures to monitor, assess, and correct problems, identified with the analytic system. Refer to D5791.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of the laboratory's policies, and interview with personnel, the Laboratory Director failed to ensure the laboratory established maintenance protocols for equipment utilized for COVID testing. Refer to D5433.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) The laboratory director must ensure that reports of test results include pertinent information required for interpretation.

	This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure final reports included required pertinent information. Refer to D5809.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4). This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the position of General Supervisor was filled to provide on-site supervision of high complexity test performance by testing personnel. Refer to D6141.
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: I . Based on review of the laboratory's CMS-209 personnel form, training records and interview with personnel, the Laboratory Director failed to ensure two (2) of two (2) Testing Personnel had training and/or approval to perform COVID 19 testing prior to patient testing. Findings: 1. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records the following testing personnel did not have documentation of training for the GeneFinder COVID testing and/or documentation of the Laboratory Director's approval/signature for patient testing: Testing Personnel 1: Training did not include interpretation/reporting of results and no approval/signature of the Laboratory Director Testing Personnel 2: No documentation of training 2. In interview on April 1, 2021 at 2:00 pm, the Technical Supervisor confirmed his training documents did not include interpretation of results or approval/signature by the Laboratory Director. Testing Personnel 1 also confirmed the laboratory did not have documentation of training for Testing Personnel 2. II. Based on review of the laboratory's CMS-209 personnel form, personnel records, and interview with personnel, the Laboratory Director failed to ensure one (1) of two (2) personnel met the state of Louisiana licensure requirement. Findings: 1. The laboratory failed to ensure the Technical Supervisor met the state of Louisiana licensure requirement. Refer to D6111. 2. The laboratory failed to ensure the General Supervisor met State of Louisiana licensure requirement. Refer to D6143. 3. The laboratory failed to ensure one (1) of two (2) testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Refer to D6170.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were complete. Findings: 1. The laboratory failed to establish written policies and procedures to assess competency assessment policies for testing personnel. Refer D5209 I. 2. The laboratory failed to establish written policies and procedures to assess competency of the Technical Supervisor. Refer D5209 II.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures. Refer to D5403.
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 observation by surveyors, record review, and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Findings: 1. The laboratory failed to ensure the Technical Supervisor met the state of Louisiana licensure requirement. Refer to D6111. 2. The Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Refer to D6112. 3. The Technical Supervisor failed to ensure the laboratory established complete performance specifications for COVID testing. Refer to D6115. 4. The Technical Supervisor failed to have documentation of initial training/orientation for Testing Personnel 2. Refer to D6120.
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 review of personnel records and interview with personnel, the laboratory failed to ensure the Technical Supervisor met the state of Louisiana licensure requirement. Findings: 1. Review of personnel records for the Technical Supervisor revealed no documentation of a Louisiana State Board of Medical Examiners (LSBME) license for laboratory testing. 2. In interview on April 1, 2021 at 1:45 pm, the Technical Supervisor confirmed he is not licensed by LSBME.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. The laboratory failed to establish and follow polices to minimize contamination during COVID testing procedure. Refer to D3003. 2. The laboratory failed to ensure nasopharyngeal specimens for COVID testing met manufacturer's storage and transport requirements. Refer to D5311 I. 3. The laboratory failed to ensure the collection dates were accurate. Refer to D5311 II. 4. The laboratory failed to document the time samples were received for COVID testing for ten (10) of ten (10) patients reviewed. Refer to D5313. 5. The laboratory failed to ensure detailed written instructions for providers to maintain integrity of samples were established. Refer to D5317. 6. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 7. The laboratory failed to establish complete policies and procedures. Refer to D5403. 8. The laboratory failed to monitor the room temperature where reagents and supplies are stored per manufacturer requirements.

	Refer to D5413 I. 9. The laboratory failed to monitor the temperature of the laboratory's freezer where reagents are stored per manufacturer requirements. Refer to D5413 II. 10. The laboratory failed to properly store COVID reagents per manufacturer requirements. Refer to D5413 III. 11. The laboratory failed to label reagent aliquots with required information. Refer to D5415. 12. The laboratory failed to establish maintenance protocols for equipment utilized for COVID testing. Refer to D5433. 13. The laboratory failed to establish corrective action procedures to ensure patient test results. Refer to D5779. 14. The laboratory failed to include "Fact Sheets" to providers or patients for EUA COVID tests. Refer to D5809.
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 observation to surveyors, record review, and interview with personnel, the Technical Supervisor failed to ensure the laboratory established complete performance specifications for COVID testing. Refer to D5421.
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 and interview with personnel, the Technical Supervisor failed to have documentation of initial training/orientation for Testing Personnel 2. Refer to D6102 I.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's CMS-209 Personnel form the laboratory failed to ensure the position of Clinical Consultant was filled. Findings: 1. Surveyors requested the CMS-209 (Laboratory Personnel Report) form from the laboratory on the following three (3) occasions: a) Surveyors provided paperwork to Testing Personnel 1 at April 1, 2021 at 9:35 am b) Surveyors left "Return Document Request:" form and

	paperwork with Testing Personnel 1 on April 1, 2021 with a the indicated due date of April 6, 2021 by 5:00 pm c) Surveyor emailed laboratory on April 9, 2021 at 11:21 am requesting document with a due date of April 12, 2021 by 5:00 pm 2. The laboratory provided surveyors with their CMS-209 form via email on April 12, 2021 at 4:41 pm. 3. Review of the laboratory's CMS-209 form submitted via email revealed the laboratory submitted duplicate forms signed by the Laboratory Director on April 12, 2021. 4. Further review of the laboratory's CMS-209 forms revealed the laboratory did not indicate who serves as the Clinical Consultant.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's CMS-209 Personnel form the laboratory failed to ensure the position of General Supervisor was filled. Findings: 1. Surveyors requested the CMS-209 (Laboratory Personnel Report) form from the laboratory on the following three (3) occasions: a) Surveyors provided paperwork to Testing Personnel 1 at April 1, 2021 at 9:35 am b) Surveyors left "Return Document Request:" form and paperwork with Testing Personnel 1 on April 1, 2021 with a the indicated due date of April 6, 2021 by 5:00 pm c) Surveyor emailed laboratory on April 9, 2021 at 11:21 am requesting document with a due date of April 12, 2021 by 5:00 pm 2. The laboratory provided surveyors with their CMS-209 form via email on April 12, 2021 at 4:41 pm. 3. Review of the laboratory's CMS-209 form submitted via email revealed the laboratory submitted duplicate forms signed by the Laboratory Director on April 12, 2021. 4. Further review of the laboratory's CMS-209 forms revealed the laboratory did not indicate who serves as the General Supervisor.
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 review of the laboratory's CMS-209 form, personnel records, and interview with personnel, the laboratory failed to ensure Testing Personnel met state licensure requirements for high complexity testing. Refer to D6170.
D6170	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(a) Each individual performing high complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by:

	Based on review of personnel records, laboratory's CMS-209 form, and interview with personnel, the laboratory failed to ensure one (1) of two (2) testing personnel met the state of Louisiana licensure requirement to perform high complexity testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Record) form submitted to surveyors on April 12, 2021 revealed the Technical Supervisor was not indicated as a Testing Personnel. 2. In interview on April 1, 2021 at 9:53 am, the Technical Supervisor stated he and Testing Personnel 2 are both trained to do all steps of testing including interpretation. 3. Review of the Technical Supervisor's personnel records revealed training documents for COVID testing completed on October 5, 2020. 4. Review of personnel records for the Technical Supervisor revealed no documentation of a Louisiana State Board of Medical Examiners (LSBME) license for laboratory testing. 5. In interview on April 1, 2021 at 1:45 pm, the Technical Supervisor confirmed he is not licensed by LSBME.
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on interview with personnel and email correspondence, the laboratory failed to provide a copy of their client list to ensure the laboratory is in compliance with CLIA Regulations Part 493. Findings: 1. On April 1, 2021 at 1:34 pm, surveyors requested a list of clients/providers the laboratory provides laboratory services to. 2. On April 1, 2021 at 4:47 pm, surveyors emailed "19D2191582 Document Request Form" to the Technical Supervisor that requested a copy of the client list be submitted via email by 5:00 pm on April 6, 2021. 3. On April 9, 2021 at 11:22 am, surveyor emailed the Technical Supervisor requesting documents that were not received, which included the laboratory's client list. 4. Surveyors did not receive the laboratory's client list by the requested due date of April 12, 2021 by 5:00 pm.