Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2120905	06/12/2020
Name of Provider or Supplier	**Street Address, City, State**	
Nova Labs, Llc	1050 Las Tablas Rd Ste 14, Templeton, CA	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Facility Administration was not met. The findings include: 1. The laboratory failed to be arranged and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized See D3003. 2. The laboratory failed to have a uni-directional workflow for specimen preparation, extraction and amplification detection, and reagent preparation for the procedures not contained in a closed system. See D3005. 3. The laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials See D3011.
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 review of the laboratory written procedures, and interview with the technical supervisor (TS-1) and laboratory assistant on June 11, 2020, the laboratory failed to establish policies and procedures to ensure that contamination of patient specimens, equipment, instruments, reagents, materials, and supplies for the laboratory's COVID-19 Polymerase Chain Reaction (PCR) testing processes were minimized as evidenced by: Contamination Program: a. In review of the laboratory's written procedures for its COVID-19 PCR test processes, the laboratory failed to have written protocols for a detection program to ensure that patient specimens, equipment, instruments, reagents, materials, and supplies were not contaminated. b. The laboratory could not provide documentation to show it had performed any environmental testing to ensure that its COVID-19 PCR test processes were not contaminated. c. In an interview with the technical supervisor on 6-11-2020 @ 10:00 a.m., when asked if the laboratory conducted any COVID-19 PCR contamination detection protocols, the technical supervisor stated: "It has only been two weeks since we opened; we have not done swab [contamination] testing." 35533 Physical Lab Processes: d. The laboratory performs SARS CoV-2 (COVID-19) RT-PCR diagnostic testing. During a tour of the laboratory's molecular testing processes on June 10-11, 2020, three areas where potential contamination of patient specimens, equipment, instruments, and supplies were identified: (A) the biosafety level-2 laboratory (BSL-2) laboratory (RM-1), (B) the biosafety level-1 (BSL-1) laboratory's (RM-3's) reagents; and (C) the laboratory's contaminated pipette washing area located in a reagent storage room (RM-2). e. In RM-1, patient specimens are received (through the laboratory's front door where all packages are received). Just inside, to the left of the front receiving doorway, is located the BSL-2 fume hood where patient specimens are uncapped and deswabbed under the BSL-2 hood, and placed on a specimen media tube rack. The specimen media tube rack is then carried, uncovered, past the Elution (E171) and qPCR Hamilton Starlab (assay tray) automated pipette aliquot stations (E164 or D400) to the specimen sample aliquot station (E178 or E179). f. After the patient samples are pipetted into either the laboratory's laboratory development test (LDT) testing trays or the Centers for Disease Control and Prevention (CDC) Emergency Use Authorization (EUA) testing trays (E178 or E179), the sample trays are walked, uncovered, to the next automated pipette station for elution/extraction (E171). After the elution /extraction process is complete, the new sample trays are walked, uncovered, to the qPCR probes and primer loading stations (either E164 or D400) which are located across from the elution/extraction pipette station (E171) or across from the aliquot stations (E178 or E179). g. Once the qPCR process is complete, the samples are then removed from the pipette stations (D400 or E164), covered, and walked to the QuantStudio amplification and detection room (past the elution/extraction station (E171)), and the patient specimen aliquot stations (E178 or E179). h. During the onsite tour of the laboratory process on June 11, 2020 at 11:44 a.m., it was observed by demonstration and interview with the technical supervisor (TS-1) that the uncovered assay trays were moved from each of the pipette stations to the next pipette station in a multidirectional flow pattern, allowing for the possible introduction of contaminants during each phase of the testing process. i. The laboratory's coat rack for used laboratory coats and used goggles is located in RM-2 where contaminated pipettes are rinsed and placed in automated pipette washers, where the laboratory's glassware is washed, where the quality control materials (master mix) are prepared, and where room temperature reagents are stored. There is an open doorway between the specimen processing room (RM-1) and this room (RM-2). j. The laboratory procedures, for each of the laboratory processing steps references the CDC Interim

	Guidelines located at: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html for the staff to follow for "Safe laboratory procedures". This link does not provide testing personnel and those engaged in preanalytic, and analytic processes, as to what the "safe laboratory procedures" are, (which the procedures refer to), for each of the tasks being performed. k. According to the CDC COVID-19 EUA, the personnel are to "Wear a clean lab coat and powder-free disposable gloves (not previously worn) when setting up assays". During the laboratory tour of the COVID-19 testing process demonstration on June 11, 2020, the technical supervisor (TS-1) at 11:44 a.m. stated: "I do not get a new lab coat between the assay steps; I change my gloves, but hang up my lab coat unless it is visibly soiled or I believe I have contaminated it." l. It was observed during the three days of onsite survey (June 10 - 12, 2020), each person (conducting specimen preparation and testing for COVID-19), reused their same laboratory coat or no laboratory coat when performing tasks in the BSL-2 laboratory (RM-1). m. The TS-1 confirmed by interview on June 11, 2020 at approximately 11:44 a.m. the reuse of laboratory coats for herself and other laboratory personnel used during COVID-19 preanalytic and analytic assay procedures. n. The laboratory's written procedure "Labware Cleaning (SOP #C5 - C7)" established the laboratory's glassware and used pipette cleaning procedures. SOP #C7 states: "Deep well plates and buffer plates can be cleaned in the lab sink." o. The laboratory's sink is located in RM-2 where room temperature reagents are stored, used pipettes are rinsed and placed in the automatic pipette washers, used deep well and buffer plates are cleaned and stored, and where the coat rack for reused laboratory coats and used googles, is located. p. TS-1 confirmed on June 11, 2020 at approximately 11:44 a.m. that the room temperature reagents storage area and cleaning procedures are performed in the same room (RM-2) where the used laboratory coats are stored. q. The laboratory's BSL-1 laboratory (RM-3) contained the refrigerated reagents for the laboratory's COVID-19 RT-PCR testing, as well as a sink used for the laboratory's histopathology testing. r. During a tour of RM-3 on June 11, 2020 at 09:30 a.m., the federal surveyor directly observed one of the laboratory's staff drinking one of two beverages located on a preparation table while using a laptop . s. The laboratory policies and procedures all state: "Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled." t. The RM-3 also contained a three- gallon water dispenser. When interviewed on June 11, 2020 at 09:30 am, a laboratory assistant stated: ". . . that's for the histopathology department; it's not for drinking." The water dispenser was not labeled as to the use for the water. u. The laboratory does not have a procedure/policy for labeling of reagents. v. According to laboratory records, the laboratory reports performing approximately 15,893 patient COVID-19 assays from May 22, 2020 to June 12, 2020.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: Based on direct observation of the laboratory's COVID-19 Polymerase Chain Reaction (PCR) testing, and interviews with the technical supervisor (TS-1) and laboratory staff on June 10, 2020, for its molecular amplification procedure, which is not contained in a closed system, the laboratory failed to have a uni-directional workflow for specimen preparation, extraction and amplification detection, and

	reagent preparation. The findings include: a. During an onsite tour of the laboratory processes, it was noted that, (for the laboratory's COVID-19 PCR testing), patient samples trays were moved, uncovered, from various locations within the laboratory, in a multidirectional workflow pattern, allowing for the possible introduction of contaminants during each phase of the testing process. See D3003. b. The laboratory's molecular COVID-19 PCR testing is set up in one room with two adjoining rooms. Patient specimen receipt and deswabbing of patient specimens are performed under a hood in the back of the main laboratory (RM-1). The patient specimens are then placed in a sample rack and moved to the next station , across the laboratory (approximately five (5) feet), past the elution station and the two PCR stations to the patient specimen pipette station. See D3003. c. The laboratory's molecular COVID-19 PCR testing is not set up in a unidirectional workflow, but crisscrosses between various locations within the laboratory. See D3003. d. TS-1 confirmed by interview on June 11, 2020 at approximately 11:44 a.m. that the laboratory's molecular COVID-19 PCR testing was not set up in a unidirectional flow. e. Based on laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient tests from May 22, 2020 through June 12, 2020.
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 direct observation, interview with the TS-1 and review of the CDC EUA protocol on June 11, 2020, the laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. The findings include: a. The laboratory performs molecular testing for SARS CoV-2. In the biosafety laboratory one (BSL-1) room of the laboratory, the refrigerated reagents for SARS CoV-2 testing and histopathology reagents are stored. b. During a tour of the BSL-1 (room RM-3 of the laboratory) June 11, 2020 at 09:20 a.m., with a laboratory assistant, the surveyor directly observed another laboratory staff with two beverages at the preparation table where the other staff was working on a laptop. c. The laboratory's policies and procedures all state: "Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled." d. The BSL-1 (RM-3) also contained a three gallon water dispenser located inside the room. When interviewed, the laboratory assistant stated on June 11, 2020 at approximately 09:20 a.m.:". . .that's for the histopathology department, it's not for drinking." The water dispenser was not labeled regarding how the water was to be used. e. The laboratory does not have a policy or procedure regarding labeling of reagents. See D5407. f. The laboratory's technical supervisor (TS-1) and laboratory assistant confirmed by interview on June 11, 2020 at approximately 09:20 a.m. that laboratory staff were not following the laboratory's policy regarding eating and drinking in the laboratory, and she confirmed the laboratory did not maintain a policy for labeling of reagents in the BSL-1 laboratory. g. The laboratory coat rack for used laboratory coats and goggles is located in room RM-2 of the laboratory. In this same room, used, contaminated pipettes are rinsed and placed in automated pipette washers, and the laboratory's glassware and quality control materials (mastermix) is prepared. There is also an open doorway between the specimen processing room (RM-1) and this room (RM-2). h. According to the Centers for Disease Control and Prevention

	(CDC) Emergency Use Authorization (EUA) laboratory personnel are to "wear a clean lab coat and powder-free disposable gloves (not previously worn) when setting up assays." During a tour of the laboratory, the laboratory technical supervisor (TS-1) stated on June 11, 2020 at 11:00 a.m.: "I do not get a new lab coat between the assay steps; I change my gloves but hang up my lab coat unless it is visibly soiled or I believe I have contaminated it." i. It was observed during the three days of onsite survey, that each person conducting various phases of COVID-19 patient specimen processing and assay preparation wore the same laboratory coat or no laboratory coat. j. The laboratory staff did not follow their policy's and procedures as listed in the CDC-EUA protocols that the laboratory had implemented. See D3003 k. TS-1 confirmed by interview on June 11, 2020 at approximately 11:45 a.m. the reuse of laboratory coats by testing personnel and other laboratory personnel while conducting COVID-19 preanalytic and analytic assay procedures. l. According to laboratory records, the laboratory performed and reported 15,893 patient COVID-19 assays from May 22, 2020 to June 12, 2020.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on records review and interview with the laboratory technical supervisor (TS-1) on June 11, 2020, the laboratory failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 42 C.F.R. 493.1239 for the high complexity molecular testing performed. The findings include: 1. The laboratory failed to establish and follow written policies and procedures that ensure optimum integrity of patient specimens from the time of collection to the receipt of the specimen through completion of testing and reporting of results. (See D5203) 2. The laboratory failed to establish written policies and procedures to assess employee and consultant competency. (See D5209) 3. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements specified at 42 C.F.R.493.1231 through 493.1236. (See D5291)
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's nine (9) signed policies and procedures for SARS nCOV-2 molecular testing and interview with the laboratory's technical supervisor

	(TS-1) on June 10, 2020, the laboratory failed to establish and follow written policies and procedures to ensure optimum integrity of a patient's specimen from the time of collection, to the receipt by the laboratory of the specimen, to the completion of testing and reporting of patient results. The findings include: a. The laboratory's FDA CDC EUA approved COVID-19 methodology, and it's non-FDA approved LDT protocols specify that patient specimens must be maintained at 2 - 8 degree C, and tested within 72 hours of collection, or frozen at -70 degree C. b. The laboratory records indicate that the laboratory received and tested 188 patient COVID-19 specimens on May 29, 2020 which had been collected on May 25, 2020. The laboratory did not have documentation as to time and temperatures for the patient samples received, (if the specimens were frozen at -70 C). c. The laboratory's established policies and procedures did not include a patient specimen assessment criteria component for documentation for acceptability in regards to time and temperature of patient specimens upon receipt, in accordance with the CDC protocols or the LDT protocols used in the laboratory for optimum integrity. d. The laboratory did not have a client services testing procedure manual, describing specimen collection specifications, specimen transportation (including packaging, time and temperature requirements) for acceptable specimen submission. See D-5317. e. The laboratory's policies and procedures did not include processes for identification of acceptable or unacceptable specimens or a process for documenting rejection processes. See D-5403 f. The laboratory TS-1 confirmed by interview on June 11, 2020 at approximately 12:44 p.m. that the laboratory had not established written policies or procedures for identification and documenting the integrity of patient's specimens from the time of collection through the receipt of the samples, or identification criteria for rejection of patient specimens. See D-5391 and D-5491. g. According to laboratory records, the laboratory performed and reported approximately 15,893 SARS CoV-2 patient samples from May 22, 2020 through June 12, 2020.
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: Based on review of the laboratory's most recently completed Form CMS-209, Laboratory Personnel Report (CLIA) and the laboratory's written delegation of responsibility policy, and interview with the laboratory technical supervisor (TS-1), who was listed on the most recently completed Form CMS-209, on June 10, 2020, the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency. The findings include: a. The laboratory performs molecular Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) testing for the detection of SARS nCoV-2 (COVID-19) virus in patient specimens. b. The laboratory's most recently completed Form CMS-209 lists five (5) testing personnel and six (6) laboratory personnel who are engaged in preanalytic testing processes. c. The laboratory did not have documentation of competency assessment for the (5) testing personnel listed on the most recently completed Form CMS-209 or for the (6) laboratory personnel who are engaged in preanalytic testing processes. d. During the onsite survey, a technical supervisor referred to as a "Scientific Consultant", not listed on the most recently completed Form CMS-209, but provided technical information on the COVID-19 testing the laboratory performed related the

	laboratory's selection and establishment and verification of test performance specifications, validations and verifications studies for the laboratory's LDT and CDC EUA platforms. e. The technical supervisor (TS-2) stated on June 10, 2020 that he had selected the testing methods implemented for the laboratory's COVID-19 testing and had established the verification of test methodology correlation studies for the two COVID-19 testing platform selected. f. The laboratory maintained no documentation that TS-2 had a competency evaluation for the testing performed. g. TS-1 confirmed by interview on June 10, 2020 at approximately 12:44 p.m. that the laboratory had not established written competency policies or procedures to assess employee or consultant competency. h. According to laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient specimens from May 22, 2020 to June 12, 2020.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on interview with the TS-1 and review of the laboratory's (9) written policies and procedures (P&P) for COVID-19 patient testing on June 11, 2020, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. The findings include: a. The laboratory's P&P did not include an ongoing mechanism to perform or document quality issues regarding specimen acceptability, and tracking or correction of problems regarding patient specimens submitted for testing. b. The laboratory's technical supervisor (TS-1) stated that there were two (2) instances regarding acceptable patient specimen submissions potentially affecting patient testing results. The laboratory had documented one of these instances on the laboratory's corrective action form report, but had not completed or documented any assessment and/or corrective actions taken . c. On May 26, 2020 the laboratory received patient samples in media tube types that did not fit the Hamiltion specimen aliquoting parameters validated by the laboratory. d. On June 12, 2020 the laboratory received patient samples in medial tube types that did not fit the Hamilton specimen aliquoting parameters validated by the laboratory. e. The laboratory did not document the second instance (submitted patient specimen was collected and received in an unacceptable collection tube), and had not completed any assessment and/or corrective actions. As a result of these events, the laboratory did not change or correct policies or procedures that would address any problems that may have been identified. f. TS-1 confirmed by interview on June 11, 2020 at approximately 11:00 a.m. that the laboratory did not have quality assessment written policies or procedures for general laboratory systems. g. According to laboratory records, the laboratory performed and reported 15,893 COVID-19 patient tests between May 22, 2020 to June 12, 2020
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic

	system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedures, laboratory's testing documentation, direct observations, interviews, and manufacturer's instructions, the laboratory failed to monitor and evaluate the overall quality of the preanalytic system and correctly identify problems as evidenced by: 1. The laboratory failed to establish written policies and procedures for patient specimen storage, conditions for patient specimen transportation, and patient specimen rejection to ensure that patient specimens were maintained and received by the laboratory at an acceptable condition (2 - 8 degrees C or -70 degrees C) while being transported to the laboratory (See D5311-1). 2. The laboratory failed to have a rejection criteria to ensure specimens did not exceed the 72 hour time frame when COVID-19 specimens were shipped at 2-8 degrees C or document if the specimens came in on dry ice and frozen at -70 degrees past the 72 hours (See D5311-2). 3.The laboratory failed to document the time that it receives COVID-19 specimens (See D5313). 4. The laboratory, which accepts referal specimens, failed to make available written instructions for additional viral transport media that the laboratory does not provide, the conditions of specimen transportation for their client's COVID-19 specimens with both the CDC's FDA approved EUA (COVID-19), and the laboratory's laboratory developed tests (Bioneer, COVID-19) (See D5317). 5. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems (See D5391).
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: 1. Based on review of the laboratory's procedure Cornonavirus testing manual, direct observations of the laboratory's equipment in the laboratory, manufacturer's EUA instructions, laboratory's documentation , and interview with the technical supervisor (TS-1), the laboratory failed to establish written policies and procedures for patient specimen storage, conditions for patient specimen transportation, and patient specimen rejection to ensure that patient specimens were maintained and received by the laboratory at an acceptable condition (2 - 8 degrees C or -70 degrees C) while being transported to the laboratory during the time period of May 22,2020 to June 12, 2020 for COVID-19 testing. The findings include: a. In review of the laboratory's procedure manual titled "2019-Novel Cornonavirus Receiving protocol", the laboratory did not state in the written procedure the acceptable conditions for patient specimens transportation for processing. b. The laboratory's Centers for Disease

Control and Prevention (CDC) COVID-19 test system, approved by the Federal Drug Administration (FDA) under Emergency Use Authorization (EUA) protocol, stated under the section titled "Transporting Specimens:" Store specimens at 2 - 8 degrees C and ship overnight to CDC on ice pack. If a specimen is frozen at -70 degrees C, ship overnight to CDC on dry ice..specimens can be stored at 2-8 degrees for up to 72 hours after collection" The laboratory adopted this CDC protocol as their own. c. The laboratory's laboratory developed (LDT) test system, Bioneer, protocol stated: "In addition, transport it at 4 degrees C and it is recommended to keep at -70 degrees C if it is not possible to transport it within 48 hours..." d. In interview with Technical supervisor (TS-1) on 6-11-2020 @0828 "We don't take the temperature when the [patient]samples come in the laboratory." e. In direct observation on 6-11-2020 @1325, the laboratory did not have a -70 degree freezer to ensure specimen storage integrity after 72 hours. f. In direct observation on 6-11-2020 @0834 of laboratory supplies, the laboratory did not have a mechanism to monitor temperature in patient specimen transport containers, or have a mechanism to ensure patient specimens where at the proper transport condition upon receipt by the laboratory. g. Review of eleven (11) patient records, the following patients collected on 5/25/2020 and received on 5/29/2020, did not have the condition of the samples documented when they where received in the laboratory on either the laboratory test reports or other testing documentation: patient ID 156078 patient ID 156075 patient ID 156072 patient ID 156064 patient ID 156062 patient ID 156054 patient ID 156053 patient ID 155401 patient ID 155292 patient ID 153982 patient ID 152435 h. There were 188 patients recorded as collected on May 25, 2020 which were received and tested on May 29, 2020. 2. Based on review of the laboratory's COVID-19 procedure manual , manufacturer's CDC EUA instructions, laboratory patient test reports, and interview with the Technical Supervisor (TS-1), the laboratory failed to have a rejection criteria to ensure specimens did not exceed the 72 hour time frame when COVID-19 specimens were shipped at 2-8 degrees C or document if the specimens came in on dry ice and frozen at -70 degrees past the 72 hours, for 23 of 29 patient records reviewed for both CDC and Bioneer Assays as evidenced by: a. In review of the laboratory's procedure manual under "2019-Novel Cornonavirus Receiving" protocol states, "Verify specimens have not spilled in individual biohazard bags. If a specimen has been spilled in a biohazard bag, do not open, place in the designated reject area to be properly documented. Issues consist of receiving specimen vial without barcode label, receiving with multiple labels with different patient information, receiving spilled/leaking in individual specimen biohazard bags, receiving without swab in specimen vial. Verify specimens have proper identifiers, first and last name, date of birth, date of collection and barcode. All specimens that have not spilled in transit and have the proper identifiers, place is designated run area to be de-swabbed." b. In review of the laboratory's procedure for Nasopharyneal Sample receiving stated: "Photograph rejected samples to the client" The laboratory maintained no written policy and procedure that detailed the criteria for rejection of patient nasopharyneal specimens. c. In review of the CDC-FDA approved EUA protocol state under the section transporting specimens, " Store specimens at 2-8 degrees C and ship overnight to CDC on ice pack. If a specimen is frozen at -70 degrees C, ship overnight to CDC on dry ice..specimens can be stored at 2-8 degrees for up to 72 hours after collection" d. In review of (23) patient test reports, the laboratory's patient COVID-19 test records indicated that the following patient specimens, collected on May 25, 2020, and received by the laboratory on May 29, 2020, were tested by the laboratory even though these patient specimens were outside the laboratory's criteria for acceptability: patient 154329 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154335 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154337 received in lab on 5/29/2020, collected on 5

	/25/2020, 1 day past 72 hour threshold patient 154347 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154348 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154404 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154409 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154413 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154425 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154430 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154440 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154446 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154463 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154465 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154467 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154469 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154484 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154485 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154492 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154500 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154504 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154507 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold patient 154513 received in lab on 5/29/2020, collected on 5/25/2020, 1 day past 72 hour threshold e. In direct observation on 6-11-2020 @1325, the laboratory did not have a -70 degree freezer to ensure specimen storage integrity after 72 hours. f. In interview on 6-11-2020 with the Technical Supervisor @0926 stated, "I don't recall if I have received anything on dry ice on May 29th. I will check my emails to make sure." The laboratory couldn't produce documents to show any specimens were on dry ice and which were received by the laboratory. g. In interview on 6-10-2020 @1318 the Technical Supervisor stated, "The CDC method was used for the nursing home patients in Texas received and tested on 5/29/2020," which had the recorded collection dates of May 25, 2020.
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 patient COVID-19 testing records and interview, the laboratory failed to document the time that it received 20 of 20 patient COVID-19 specimens. The findings include: a. In review of patient testing records for patient specimens received on May 29, 2020, the laboratory failed to document the time it received patient specimens for COVID-19 testing: specimen ID # 176128 received on 5/29/2020, no time documented specimen ID # 176130 received on 5/29/2020, no time documented specimen ID # 176142 received on 5/29/2020, no time documented specimen ID # 176153 received on 5/29/2020, no time documented specimen ID # 176154 received on 5/29/2020, no time documented specimen ID # 176176 received on 5/29/2020, no time documented specimen ID # 176183 received on 5/29/2020, no time documented specimen ID # 154329 received on 5/29/2020, no time documented specimen ID # 154335 received on 5/29/2020, no time documented specimen ID #154337 received on 5/29/2020, no time documented specimen ID #154348 received

	on 5/29/2020, no time documented specimen ID #154404 received on 5/29/2020, no time documented specimen ID #154409 received on 5/29/2020, no time documented specimen ID #154413 received on 5/29/2020, no time documented specimen ID #154425 received on 5/29/2020, no time documented specimen ID #154430 received on 5/29/2020, no time documented specimen ID # 15440 received on 5/29/2020, no time documented specimen ID # 15444 received on 5/29/2020, no time documented specimen ID # 15446 received on 5/29/2020, no time documented b. In an interview with the Technical supervisor on 6-11-2020 @ 1500 she confirmed that the laboratory did not collect and document the time of receipt of patient specimens in the laboratory.
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 client service manual posted on their website, and interview with the laboratory technical supervisor (TS-1), the laboratory, which accepts referal specimens, failed to make available written instructions for additional viral transport media that the laboratory does not provide, the conditions of specimen transportation for their client's COVID-19 specimens with both the CDC's FDA approved EUA (COVID-19), and the laboratory's laboratory developed tests (Bioneer, COVID-19) as evidenced by: a. On June 10, 2019 @ 1234,the technical supervisor stated when asked if the laboratory provided written instructions to its clients as to how to send patient specimens to the laboratory: "No, we didn't send them [the laboratory's clients] a manual on what specimens we can take (i.e. viral media)." b. In review of the laboratory's client service manual that was printed from the customer service laboratory website states, "B. Storage in preservation buffer. 1. Samples can be transported and stored at room temperature at (25 degree C) or up to 1 week without significant loss of RNA quality (2 Weeks for DNA)." c. In interview with the Technical Supervisor (TS-1) on 6-11-2020 @1420, she stated that the laboratory client service manual that was printed from the website was only for their proprietary collection kits. Due to a shortage of their proprietary collection kits, they had not sent out to their collection kits to clients. She also stated, that she was unaware if that information in the printed online manual was even sent out to clients. d. The laboratory's "Management Services Agreement" with other laboratories provides no information as to the conditions of patient specimen transportation. Only instructions of some supplies needed are included. e. The laboratory could not provide any documentation of sending written instructions of specimen handling requirements to other laboratories for both COVID-19 assays for other media types. The laboratory did not have written instructions for specimen handling with other types of transport media. f. According to laboratory records, the laboratory performed and reported 15,893 COVID-19 patient tests between May 22, 2020 to June 12, 2020.
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 interview with the technical supervisor (TS-1) June 11, 2020 at 11:44 a.m. and review of the laboratory's written policies and procedures (P&P) on June 11, 2020, the laboratory failed to establish 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. The findings include: a. The laboratory's P&P did not include an ongoing mechanism to perform or document quality issues regarding specimen acceptability, tracking or correction of problems regarding patient specimens submitted for testing. See D5311 and D5317. b. The laboratory technical supervisor (TS-1) confirmed by interview on June 11, 2020 at approximately 11:00 a.m. that the laboratory did not have quality assessment policies and procedures. c. Based on laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient tests between May 22, 2020 to June 12, 2020.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the the laboratory's testing records, manufacturer's instructions, interviews, direct observations, and review of the laboratory's procedures, the laboratory failed to monitor and evaluate the overall quality of the analytic system and correct problems as evidenced by: 1. The laboratory failed to ensure a complete written procedure manual was available for the COVID-19 CDC approved EUA, and Bioneer LDT test (See 5403). 2. The laboratory failed to have a policies and procedures approved, signed and dated by the current laboratory director for all aspects of the testing performed (See D5407). 3. The laboratory failed to follow the CDC's time and temperature instructions for the thermocycler parameters used for COVID-19 testing. (See D5411). 4. The laboratory failed to demonstrate that it can obtain performance specifications established by the CDC's FDA-approved EUA (COVID-19) for precision (See 5421). 5. The laboratory failed to demonstrate that they had established test performance specifications for their COVID-19 laboratory developed test (LDT) that was manufactured by Bioneer for precision and other performance characteristic required for test performance (patient specimen temperature transportation stability studies) prior to reporting patient test results. (See D5423). 6. The laboratory failed to establish P&P for an ongoing mechanism to monitor , assess, and when indicated, correct problems identified in the analytic systems (See D5791).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b)

	The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, and interview with the Technical supervisor (TS-1), and testing person #4, the laboratory failed to ensure a complete written procedure manual was available for the COVID-19 CDC approved EUA, and Bioneer LDT test as evidenced by: a. The laboratory's written procedure did not include the following as it relates to the laboratory's adopted COVID-19 Centers for Disease Control and Prevention (CDC) Food and Drug Administration (FDA) Emergency Use Authorization (EUA) approved test, and the laboratory's laboratory developed test (LDT) manufactured by Bioneer: b. Requirements for specimen collection, storage, preservation, transportation, and criteria for specimen acceptability and rejection as described in 493.1242 for saliva, and nasopharyneal samples for both of the laboratory's testing platforms. Quality control procedures which included frequency of use and procedures on, how to prepare the quality control materials; Corrective action to take when test results of quality control materials fail to meet the laboratory's criteria for acceptability; Description of the course of action to take if a test system becomes inoperable; and Step by step performance of the procedures, including interpretation of test results. c. The laboratory technical supervisor TS-1 confirmed on June 10, 2020 that the laboratory did not have policy's or procedures that included items listed above. d. According to laboratory records, the laboratory performed and reported 15,893 COVID-19 patient tests since May 22, 2020 to June 12, 2020.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on COVID-19 test policy and procedure record review and interview with the laboratory technical supervisor (TS-1) on June 10, 2020, the laboratory failed to have written policies and procedures that were dated by the current laboratory director for all aspects of the testing performed. The findings include: a. The following nine (9)

	written policies/procedures for COVID-19 testing that had been signed by the laboratory director but not dated: Receiving Protocol (effective April 17, 2020, no date of signature); Swab Removal Protocol (effective April 17, 2020, no date of signature); Aliquoting Protocol (effective April 17, 2020, no date of signature); Extraction Protocol (effective April 17, 2020, no date of signature); Loading Probes and Primer for qPCR Prep Plate Protocol (effective April 17, 2020, no date); Master Mix Protocol (effective April 17, 2020, no date of signature) Bioneer COVID-19 Plate Lot Verification (effective April 17, 2020, no date of signature) Laboratory Cleaning Protocol (effective April 17, 2020, no date of signature) Delegation of Duties (1220) Policy (signed and dated June 10, 2020 by laboratory director). b. The laboratory implemented COVID-19 patient testing and reporting on May 22, 2020. c. Eight (8) of the nine (9) policies/procedures listed above did not include a date of approval with the laboratory director's signature. d. On the initial date of survey (June 10, 2020) the laboratory staff were writing policy's and procedures for performing SARS nCOV-2 (COVID-19) molecular testing. e. The BSL-1 (RM-3) also contained a three gallon water dispenser. When interviewed, the laboratory assistant stated at approximately 09:20 a.m.:". . .that's for the histopathology department, it's not for drinking." The water dispenser was not labeled regarding how the water was to be used. f. The laboratory did not have a policy or procedure for labeling reagents. g. The laboratory TS-1 confirmed by interview on June 11, 2020 at approximately 11:44 a.m., that the laboratory did not have policies or procedures for all aspects of the laboratory COVID-19 testing signed and dated prior to performing and resulting patient testing. h. According to laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient tests from May 22, 2020 through June 12, 2020.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the laboratory's adopted Centers for Disease Control and Prevention (CDC) Food and Drug Administration (FDA) Emergency Use Authorization (EUA) approved COVID-19 test protocol, and laboratory COVID-19 testing documentation, and interview with Techincal supervisor (TS-1) and Technical supervisor (TS-2 not listed on the CMS-209) , the laboratory failed to follow the CDC's time and temperature instructions for the thermocycler parameters used for COVID-19 testing. The findings include: a. The laboratory's adopted COVID-19 CDC FDA EUA approved written protocol states that the thermocycler parameters must be set as follows: Stage 1 set to 15 minutes at 45 degrees C Stage 2 set to 2 minutes at 95 degrees C Stage 3 step 1 set to 3 secs at 95 degrees C Stage 3 step 2 set to 30 secs at 55 degrees C In stage 3, reps should be set at 45. b. Review of the laboratory's thermocycler parameter settings on 6-11-2020 @1314 indicated the following: Stage 1: 20 minutes at 45 degrees C Stage 2: 3 minutes at 95 degrees C Stage 3 step 1: 3 secs at 95 degrees C Stage 3 step 2: 45 secs at 60 degrees C. c. In review of the laboratory's on board perimeters on their Quantstudio instrument for the Bioneer LDT test and their CDC FDA approved tests, their was no difference between the two instrument thermocycler settings. The laboratory's setting on the their thermocycler were for both tests: Stage 1: 20 minutes at 45 degrees C Stage 2: 3 minutes at 95

	degrees C Stage 3 step 1: 3 secs at 95 degrees C Stage 3 step 2: 45 secs at 60 degrees C. The only difference was on how they were labeled "NOVA_IDT and NOVA_". d. In interview with the Technical supervisor (TS-1) and the Technical supervisor (TS-2) (not listed on the CMS-209, referred to as the scientific consultant), on 6-11-2020 @1317, stated, "We got the cycling parameters from a professor in Florida, a pathology stat lab" Both the technical and scientific consultant on 6-11-2020 @1331also stated that the setting perimeters for the thermocycler for the adopted COVID-19 CDC test and the laboratory's COVID-19 laboratory developed test (LDT) on both test "had been setup like this [from] day one of testing." e. The laboratory reports performing 15,893 COVID-19 patient tests since May 22, 2020 to June 12, 2020.
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 review of the laboratory's COVID-19 verification studies document review, and interview with the technical supervisor (TS-1), the laboratory failed to demonstrate that it can obtain test performance specifications established by the manufacturer of the test for the laboratory's adopted Centers for Disease Control and Prevention (CDC) Food and Drug Administration (FDA) Emergency Use Authorization (EUA)-approved COVID-19 test for precision. The findings included: Precision: a. In review of the laboratory's verification studies document, "Accelerated emergency use authorization (EUA) Summary Bioneer and CDC IDT EUA COVID-19 (SARS-COV-2) Real Time RT-PCT TEST (NOVA A DX), the laboratory's document detailing the laboratory's verification of test performance for their adopted CDC FDA EUA approved COVID-19 test system did not indicate that precision of the test system had been verified by the laboratory prior to reporting patient test results. b. On June 11, 2020 @ 1109, TS-1 and technical supervisor #2 (TS-2), who was not listed on the Form CMS-209, Laboratory Personnel Report (CLIA), stated that they had not compiled the data for precision studies for their CDC assay. c. The laboratory maintained no documentation to indicate that the laboratory had completed precision studies for the CDC FDA EUA approved COVID-19 test system prior to reporting patient test results. d. The laboratory reports performing and resulting 15,893 patient COVID-19 specimens from May 22, 2020 to June 12, 2020.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the

	performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's COVID-19 establishment studies document review, and manufacturer's instructions, and by interview with both technical consultants , the laboratory failed to demonstrate that they had established test performance specifications for their COVID-19 laboratory developed test (LDT) that was manufactured by Bioneer for precision and other performance characteristic required for test performance (patient specimen temperature transportation stability studies) prior to reporting patient test results. The findings include: Precision: a. In review of the document, Accelerated emergency use authorization (EUA) Summary Bioneer and CDC IDT EUA COVID-19 (SARS-COV-2) Real Time RT-PCT TEST (NOVA A DX), detailing the laboratory's establishment of test performance for their COVID-19 LDT test system did not indicate that precision of the test system had been established by the laboratory prior to reporting patient test results. b. In interview with both the Technical supervisor and Technical supervisor #2 (not listed on the CMS-209, scientific consultant) on 6-11-2020 @1109 stated that they had not compiled the data for precision studies for their COVID-19 LDT assay. c. The laboratory maintained no documentation to indicate that the laboratory had completed precision studies for their COVID-19 LDT assay prior to reporting patient test results. Specimen Temperature Transportation Studies: d. In review of the document, "Accelerated emergency use authorization (EUA) Summary Bioneer and CDC IDT EUA COVID-19 (SARS-COV-2) Real Time RT-PCT TEST (NOVA A DX)," The laboratory's document detailing the laboratory's establishment of test performance for their COVID-19 LDT test system did not indicate that patient specimen temperature stability for the test system had been established by the laboratory prior to reporting patient test results. e. In review of Accupower Bioneer Real-time PCR kit the manufacturer's instruction states, "In addition, transport it at 4 degrees C and it is recommended to keep at -70 degree C if it is not possible to transport it within 48 hours..." f. In interview with both the Technical supervisor (TS-1) and "scientific consultant" (TS-2, not listed on the CMS-209), on 6-11-2020@1110, both stated that they have not performed a specimen stability study. g. The laboratory maintained no documentation to indicate the laboratory established a temperature range for transportation of patient specimens for accurate and reliable testing for their COVID-19 LDT assay prior to reporting patient test results. h. The laboratory reports performing 15,893 patient COVID-19 tests since May 22, 2020 to June 12, 2020.
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 interviews with the laboratory staff and review of the laboratory's quality

	policies and procedures (P&P) on June 11, 2020, the laboratory failed to establish P&P for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. The findings include: a. The laboratory did not have policies or procedures for monitoring, assessing or correcting problems identified in the analytic system. See D5403 and D5407. b. The laboratory TS-1 confirmed by interview on June 11, 2020 at approximately 3:46 p.m., that the laboratory did not establish quality assessment policies and procedures for molecular COVID-19 testing. c. According to laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient tests from May 22, 2020 through June 12, 2020.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: 1. Based on review of patient test reports, and interview , for 10 of 10 randomly selected patient COVID-19 test reports, the laboratory failed to indicate on the test reports which of two COVID-19 tests the laboratory had performed to report the patient COVID-19 test result. The findings include: a. In review of the CDC FDA-approved EUA method, the method targets N1 and N2 nucleocapsid protein of Covid-19. b. In review of the FDA-not approved laboratory development test methodology from bioneer, the method targets the E gene and rdRp gene of COVID-19. c. For the following 10 of 10 randomly selected patient COVID-19 test reports, the laboratory did not indicate on the test report which COVID-19 assay the laboratory had performed to report the patient COVID-19 test result: patient rec # 169503, no documentation of test method used on patient report. patient rec # 74660, no documentation of test method used on patient report. patient rec # 73935, no documentation of test method used on patient report. patient rec # 72712, no documentation of test method used on patient report. patient rec # 74660, no documentation of test method used on patient report. patient rec # 180800, no documentation of test method used on patient report. patient rec# 176139, no documentation of test method used on patient report. patient rec# 176128, no documentation of test method used on patient report. patient rec # 176176, no documentation of test method used on patient report. patient rec # 176154, no documentation of test method used on patient report. d. In interview with technical supervisor (TS-1) and technical supervisor #2 (TS-2) (not listed on the CMS-209, scientific advisor) on 6-10-2020 @1330 confirmed that they couldn't distinguish the two methods on the test reports, the test method could only be identified if they looked at the testing records held by the laboratory. 2. Based on review of the CDC's FDA-approved testing method's EUA and patient testing reports, the laboratory failed to follow the CDC's instructions on how to report patient COVID-19 testing results for (8) of (8) patient test reports reviewed, as evidenced by: a. In review of the CDC's FDA-approved COVID-19 testing method, the instructions state that "under the

	Diagnostic panel results", (under the interpretation section), states that positive patient results should be reported as, "positive 2019-nCov" b. In review of the following patient test reports, (with a received date of 5/29/2020) that were positive, the laboratory recorded the patient results as "Detected" rather than "positive 2019-nCov". patient accession #154337, result = detected patient accession #154440, result = detected patient accession #154484, result = detected patient accession #154492, results = detected patient accession # 154507, results = detected patient accession # 154513, results = detected patient accession # 154532, results = detected patient accession #159611, results = detected c. In interview with the technical supervisor #1 and Technical supervisor #2 (not listed on the 209, scientific advisor) on 6-10-2020 @1345 p.m., stated that they were not aware that the CDC EUA had specific requirement for reporting the test results. They stated that "Detected" was the usual microbiological way to report patient test results. d. In interview with the Technical supervisor on 6-10-2020 @1318 she confirmed that the CDC method was used for these patients. 3. Based on review of the Bioneer manufacturer's instructions, and patient test reports, the laboratory failed to to follow Bioneer's instructions (as the laboratory adapted on its own) on how to report patient COVID-19 testing results 1 of 1 reviewed as evidenced by: a. In review of the manufacturer's instructions for Bioneer LDT method, states under Data Analysis, "it is determined to be positive, ..it is determined to be negative" b. In review of the the following patients, the laboratory documented "Not Detected" rather than "Negative" on patient test reports: patient accession #72712, results not detected c. The laboratory reports performing 15,893 patient COVID-19 tests since May 22, 2020.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures (P&P) and interview with the laboratory technical supervisor (TS-1) on June 11, 2020 at 11:44 a.m., the laboratory failed to establish P&P for monitoring, assessing and correcting problems identified in postanalytic testing. The findings include: a. The laboratory performs two (2) COVID-19 testing platforms, one of the platforms is a CDC FDA EUA approved methodology, the other is a laboratory developed test (LDT). b. The laboratory had received one complaint regarding patient COVID-19 testing results which had been ran on media tube types they had not validated. The laboratory did not have documentation of corrective actions taken. c. By interview with the TS-1 June 11, 2020 at 11:44 a.m., the laboratory had to stop using their LDT testing platform due to inability to obtain reagents. The laboratory did not document the corrective actions taken to the change in testing algorithm due to lack of reagent availability. d. By interview with the TS-1 on June 12, 2020 at 09:00 a.m. (regarding discordant sample submission temperatures between the testing platforms used and the client service manual on the laboratory's website), the laboratory was unable to implement their own use of test kits media due to lack of reagents. The laboratory did not correct the websites client service manual regarding acceptable shipping requirements. e. The laboratory technical supervisor related during the laboratory overview of COVID-19 testing, that they were adjusting the automated aliquot pipette system to respond to media tube types being submitted that the laboratory had not initially validated for

	their testing platform. The laboratory did not have documentation of actions taken to correct the problem identified. f. The laboratory technical supervisor (TS-1) confirmed by interview on June 11, 2020 at 11:44 a.m. that the laboratory had not established policies or procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified. g. According to laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient tests between May 22, 2020 to June 12, 2020.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing; Laboratory Director was not met. The findings include: 1. The laboratory director failed to ensure that the physical plan and environmental conditions of the laboratory are appropriate for the testing performed (see D6083). 2. The laboratory director failed to ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the testing methods used (see D6086). 3. The laboratory director failed to ensure that reports of test results include pertinent information required for interpretation (see D6098). 4. The laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform test and report test results in accordance with the personnel responsibilities (see D6101).
D6083	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. This STANDARD is not met as evidenced by: Based on direct observations of the laboratory's COVID-19 testing processes and interview with the technical supervisor (TS-1) on June 11, 2020, the laboratory director failed to ensure that the physical plant and environmental conditions of the laboratory are appropriate for the testing performed. The findings include: a. The laboratory failed to be arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized. See D3003. b. The laboratory failed to have for its molecular amplification procedures that were not contained in closed systems, a uni-directional workflow for specimen preparation, amplification and product detection, and reagent preparation. See D3005. c. The laboratory failed to observe safety procedures to ensure protection from physical, chemical, biochemical, and biohazardous materials. See 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 review of the laboratory's verification and establishment of test performance specifications records for the two COVID-19 assays used by the laboratory and by interviews with the laboratory's technical supervisors (TS-1) and "Scientific Consultant" (TS-2) on June 11, 2020, the laboratory director failed to ensure that verification procedures used are adequate to determine the precision and other pertinent performance characteristics of the methods. The findings include: a. The laboratory failed to demonstrate that it can obtain test performance specifications established by the manufacturer of the test for the laboratory's adopted Centers for Disease Control and Prevention (CDC) Food and Drug Administration (FDA) Emergency Use Authorization (EUA)-approved COVID-19 test for precision. See D5421. b. The laboratory failed to demonstrate that they had established test performance specifications for their COVID-19 laboratory developed test (LDT) that was manufactured by Bioneer for precision and another performance characteristic required for test performance (patient specimen temperature transportation stability studies) prior to reporting patient test results. See D5423. c. The laboratory technical supervisor (TS-1) confirmed by interview on June 11, 2020 at approximately 10:39 a. m., that the laboratory director had not signed the instrument verification records. d. According to laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient tests from May 22, 2020 through June 12, 2020.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review of the laboratory's policy and procedures manuals signed by the laboratory director and interview with the laboratory technical supervisor (TS-1), on June 10, 2020, the laboratory director failed to ensure, that for the FDA approved CDC-EUA SARS nCoV-2 (COVID-19) testing protocol and the laboratory's developed testing (LDT, Bioneer protocol, Covid- 19) that quality assessment policies and procedures were established for monitoring all aspects of test performance for preanalytic, analytic and postanalytic phases of testing. The findings include: a. The laboratory director failed to monitor and evaluate the overall quality of the general laboratory systems and correct identified problems for the high complexity molecular testing performed. (See D5203, D5209, D5291). b. The laboratory director failed to establish written policies and procedures for an ongoing quality assessment mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic, analytic and postanalytic systems. (See D5291, D5311, D5411, D5791, D5891).
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 review of patient recorded test reports, and interview with the laboratory technical supervisor (TS-1) on June 11, 2020, the laboratory director failed to ensure that reports of test results include pertinent information required for interpretation. The findings include: a. The laboratory failed to indicate on the test reports which of two COVID-19 tests the laboratory had performed to report patient COVID-19 test results. See D5805. b. The laboratory reports performing 15,893 patient COVID-19 tests from May 22, 2020 to June 12, 2020.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records and the most recently completed Form CMS-209, Laboratory Personnel Report (CLIA), and interview with the technical supervisor (TS-1), the laboratory director failed to employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities. The findings include: a. The individual the laboratory identified as "scientific consultant" was performing the duties of technical supervisor. These duties included the selection of test methodologies the laboratory performed, and the development of test validation and verification studies. The laboratory maintained no documentation to indicate this individual met the technical supervisor qualification requirements at 42 C.F.R. 493.1449. See D6108. b. For three (3) of three (3) laboratory personnel identified on the laboratory's "Delegation of Duties" form as testing personnel (form 1220), the laboratory maintained no documentation to indicate that these three individuals were qualified as testing personnel as specified in 42 C.F.R. 493.1489. c. On June 10, 2020 at approximately 11:44 a.m., TS-1 confirmed by interview on June 10, 2020 at approximately 11:44 a.m. that the laboratory did not have qualifications documentation of the individuals identified above. d. The laboratory reports performing 15,893 patient COVID-19 tests from May 22, 2020 to June 12, 2020.
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 review of the laboratory's CMS-209 personnel form, the laboratory's testing records and interview with the laboratory technical supervisor (TS-1) listed on the CMS-209 on June 11,2020, the individual referred to as a "Scientific Consultant" (not listed on the CMS-209), was performing as a technical supervisor (TS-2) for the laboratory's selection, development of validation and verification studies, and did not meet the qualification requirements of 42 C.F.R. 493.1449 to provide technical supervision. The findings include: 1. The laboratory does not have documentation of training and education for the TS-2 personnel. (See D6111) 2. The laboratory does not have documentation of delegation of authority for the TS-2 personnel. (See D6111) 3. The laboratory technical supervisor failed to ensure that each individual performing tests received training and education appropriate for SARS nCoV-2 (COVID-19) molecular testing, and failed to evaluate the competency of the personnel to assure that the staff maintain their competency to perform testing procedures and report test results. (See D6120) 4. The laboratory technical supervisor listed on the CMS-209 personnel report (TS-1) on June 11, 2020, the laboratory failed to follow the manufacturers instructions for evaluating acceptable analytic performance from initial receipt of the specimen, through sample analysis and reporting of test results. (See D6117)
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 interview with the laboratory technical supervisor (TS-1) listed on the most recently completed Form CMS-209, Laboratory Personnel Report (CLIA), and interview with the individual the laboratory referred to as the "Scientific Consultant" (TS-2) (who was not listed on the Form CMS-209, and review of the laboratory's personnel records on June 10, 2020, the laboratory failed to maintain documentation to indicate that the individual the laboratory referred to as the "Scientific Consultant" (TS-2) was qualified as a technical supervisor. The findings included: a. During an interview on June 10, 2020 at approximately 11:00 a.m. with the TS-1 and the "Scientific Consultant" (TS-2) regarding the laboratory's validation and verification processes for the laboratory's two COVID-19 testing platforms, the "Scientific Consultant" (TS-2) indicated that he had assisted in the selection, performance, and

	consolidation of the laboratory's correlation studies for the two COVID- 19 test platforms which the laboratory implemented in April 2020. b. Requested laboratory data and documents were provided by the "Scientific Consultant" and not by TS-1, who did not have access to this information. The data and documents provided indicated that the "Scientific Consultant" (TS-2) was directly involved with the selection and performance of the laboratory's validation and verification studies for the laboratory's two COVID-19 testing platforms. c. The "Scientific Consultant" confirmed that he had set up the temperatures and cycle times for the amplification processes for the COVID-19 tests. d. The "Scientific Consultant" confirmed that he was the one who selected the data and prepared the reports for correlation studies between the two COVID-19 test methodologies. e. Based on the above activities described above, the "Scientific Consultant" was performing the duties and activities of a technical supervisor pursuant to 42 C.F.R. 493.1463. f. The "Scientific Consultant" was not listed on the laboratory's most recently completed Form CMS-209 as a technical supervisor. g. The laboratory maintained no documentation to indicate that the "Scientific Consultant" was qualified as a technical supervisor pursuant to 42 C.F.R. 493.1449. h. On June 12, 2020 at approximately 09:15 a.m., TS-1 confirmed that the "Scientific Consultant" was not listed on the most recently completed Form CMS- 209 or on the laboratory's "Delegation of Duties" form. i. According to laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 patient tests from May 22, 2020 through June 12, 2020.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's control procedures and interview with the laboratory technical supervisor (TS-1) listed on the CMS-209 personnel report (TS-1) on June 11, 2020, the laboratory failed to follow the manufacturer's instructions for evaluating acceptable analytic performance from initial receipt of the specimen, through sample analysis and reporting of test results. The findings include: a. Upon review of the laboratory's quality control procedures for the FDA EUA approved CDC-SARS nCoV-2 (COVID-19) methodology, the CDC EUA specifies that each patient specimen result must be reviewed for "acceptable florescence growth curve in the RNase P gene"(RP) prior to approving and releasing patients test results. IF the RP is negative for the clinical specimen and all 2019-n-CoV markers are negative, the extraction process and test should be repeated. b. By interview with the TS-1 on June 11, 2020 at 12:00 p.m. regarding the laboratory's quality control process and process review of random patient sampling results performed on May 29, 2020, the laboratory did not review patient specimen RP curve results prior to releasing patient test results. Date PT ID Test Methodology 05/29 74660 CDC-EUA 05/29 164641 CDC-EUA 05 /29 169503 CDC-EUA 05/29 180800 CDC-EUA c. The laboratory's technical supervisor (TS-1) verified by interview and demonstration on June 11, 2020 at 12:00 p.m., that the laboratory only reviews the quality control numerical results for

	acceptability, and does not review the patients "RP" curves prior to releasing patient test results. d. According to laboratory records, the laboratory performed and reported 188 COVID-19 patient tests on May 29, 2020.
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 laboratory personnel record review and interview with the technical supervisor on June 10, 2020, the technical supervisor (TS-1) failed to ensure that each individual performing tests received training and education appropriate for SARS CoV-2 (COVID-19) molecular testing, and failed to evaluate the competency of the testing personnel to assure that the staff maintain their competency to perform these testing procedures and report test results. The finding include: a. The technical supervisor, acting as testing personnel, was performing the high complexity COVID-19 PCR testing. The laboratory maintained no documentation to indicate that the technical supervisor had been trained or was competent to perform the COVID-19 testing that was being performed. b. The laboratory's most recently completed Form CMS-209, Laboratory Personnel Report (CLIA) and the laboratory's "Delegation of Duties" policy (form 1220), identified three (3) individuals who performed aliquoting and extractions procedures for the laboratory's COVID-19 tests. The laboratory maintained no documentation to indicate that these individuals were trained and were competent to perform the duties they were assigned. c. Preanalytical procedures for the laboratory's COVID-19 tests were being performed by six (6) individuals. The laboratory maintained no documentation to indicate that these individuals were trained and were competent to perform the duties they were assigned. d. On June 10, 2020 at approximately 10:00 a.m. the technical supervisor confirmed that the laboratory had not established policies or procedures for documentation of staff training and competency and that there was no documentation of training or competency for the above described individuals. e. According to laboratory records, the laboratory performed and reported approximately 15,893 COVID-19 tests between May 22, 2020 to June 12, 2020.
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 the number and severity of the deficiencies cited herein, the Condition: Laboratories Performing High Complexity Testing; Testing Personnel was not met. The findings include: 1. The laboratory failed to ensure that the personnel involved

	with testing of patient samples met the educational and training requirements as required to perform high complexity testing (see D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have

	earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing personnel records, the laboratory's 1220 "Delegation of Functions" form, the laboratory's most recently completed Form CMS-209, Laboratory Personnel Report (CLIA), and interview with the technical supervisor (TS-1) on June 10, 2020, the laboratory failed to ensure that the personnel involved with testing of patient samples met the educational and training requirements as required to perform high complexity testing. The findings included: a. The laboratory performs Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) diagnostic molecular testing for the detection of SARS nCoV-2 (COVID-19) in patient specimens. b. The laboratory's "Delegation of Functions" form (signed by the laboratory director and TS-1 on June 10, 2020) list three individuals (LT-1, LT-2, and LT-3) as testing personnel who performed aliqouting and extraction procedures for high complexity molecular COVID-19 tests. c. The laboratory maintained no documentation to indicate that these three (3) individuals possess the education and training to perform high complexity molecular extraction procedures. d. For LT-1, the laboratory maintained no documentation of education and laboratory training or competency to indicate that TL-1 was qualified to perform high complexity testing. e. For LT-2 , the laboratory maintained no documentation to indicate that LT-2 possessed the education to be as a certified phlebotomist, and no documentation of laboratory training or competency to indicate that LT-2 was qualified to perform high complexity testing. f. For LT-3 , the laboratory maintained no documentation of a graduate degree in biochemistry, and no documentation of laboratory training, competency to perform high complexity testing. g. On June 10, 2020 at approximately 10:44 a.m. TS-1 confirmed that the laboratory did not have documentation to indicate that LT-1, LT-2, and LT-3 were qualified to perform high complexity molecular testing. h. According to laboratory records, the laboratory performed and reported approximately 15,893 high complexity COVID-19 patient tests from May 22, 2020 through June 12, 2020.