Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D2097807	07/06/2020
Name of Provider or Supplier	**Street Address, City, State**	
Precision Clinical Laboratory	11275 E Mississippi Ave, Ste 2wi, Aurora, CO	

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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Enrollment and Testing of Proficiency Testing Samples was not met. The laboratory failed to test proficiency testing samples in the same manner as it tests patient specimens (see D2006), and test proficiency testing samples the same number of times that it routinely tests patient samples (see D2010).
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.

	This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, instrument test records, Standard Operating Procedures (SOP), patient test results and laboratory staff interview, the laboratory failed to test American Proficiency Institute (API), the laboratory's PT provider, PT samples in the same manner as its patient specimens for the second and third proficiency testing events of 2019 in the subspecialty of routine chemistry. The findings include: a. The laboratory tested its API routine chemistry PT samples for the second proficiency testing event of 2019 on June 3, 2019. b. For the second proficiency testing event of 2019, the laboratory reported to API five analytes, direct bilirubin, total iron, LDL cholesterol (calculated), sodium, and thyroid stimulating hormone (TSH), as "suspended." c. For the second proficiency testing event of 2019, API scored the laboratory's reported PT test results as 100% for the analytes the laboratory reported as "suspended." d. However, on June 3, 2019, the laboratory tested and reported two patient specimens for sodium (lab accession numbers 62052 and 62115), and tested and reported one patient specimen for TSH (lab accession number 62115) indicating that the laboratory had not "suspended" patient testing for sodium and TSH. e. The laboratory tested its API routine chemistry PT samples for the third proficiency event of 2019 on September 5, 2019 and again on September 6, 2019. The tests on both days were performed by the same testing person. f. The laboratory's proficiency testing results from both days were reviewed by the Technical Supervisor on September 6, 2019. g. The Technical Supervisor averaged test results obtained from the September 5 and 6, 2019 test runs to obtain the final proficiency test results reported to API. h. For the third proficiency testing event of 2019, the laboratory reported to API six analytes, direct bilirubin, total iron, LDL cholesterol (calculated), HDL cholesterol, total cholesterol, and phosphorus, as "suspended." i. However, on September 5, 2019, the laboratory tested and reported one patient specimen (lab accession number 69423) for total cholesterol, LDL cholesterol (calculated), and HDL cholesterol, and on September 6, 2019, the laboratory tested and reported one patient specimen (lab accession number 69539) for total cholesterol, LDL cholesterol (calculated), and HDL cholesterol indicating that the laboratory had not "suspended" patient testing for total cholesterol, LDL cholesterol (calculated), and HDL cholesterol. j. The laboratories PT SOP states: - No Inter-Laboratory Comparison will occur. - All PT samples will be run the same as patients. - PT samples will be run by all testing personnel. - PT samples will only be run once. k. On May 21, 2019 at approximately 4:00 pm, the laboratory Technical Supervisor confirmed that sodium, TSH, total cholesterol, LDL cholesterol (calculated), and HDL cholesterol were reported to API for the second and third PT events of 2019 as "suspended" even though the laboratory continued to test and report these test results for patient specimens, and also confirmed that PT samples for the second and third proficiency testing events of 2019 were not tested in the same manner consistent with the established SOP and in the same manner as the laboratory tests patient specimens.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records, instrument test records, Standard

	Operating Procedures (SOP), patient test results and laboratory staff interview, the laboratory failed to test American Proficiency Institute (API), the laboratory's PT provider, PT samples the same number of times that it routinely tests patient samples. The findings include: a. On September 5 and 6, 2019, the laboratory tested its API routine chemistry PT samples for the third proficiency event of 2019. The Technical Supervisor averaged test results obtained from the September 5 and 6, 2019 test runs to obtain the final proficiency test results reported to API. b. On May 21, 2019 at approximately 4:00 pm, the Technical Supervisor confirmed that PT samples for the second and third proficiency testing events of 2019 were not tested in the same manner consistent with the established SOP and in the same manner as the laboratory tests patient specimens. (See D2006).
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiency cited herein, the Condition: Successful Participation in Proficiency Testing was not met. The laboratory failed to achieve satisfactory proficiency testing scores in two of three 2019 proficiency testing events for the analyte chloride resulting in unsuccessful chloride proficiency testing performance (see D2096).
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API), the laboratory's proficiency testing provider, proficiency testing reports and Technical Supervisor interview, the laboratory failed to achieve satisfactory performance for chloride in two consecutive proficiency testing events or two out of three consecutive proficiency testing events in

	2019 resulting in unsuccessful chloride proficiency testing performance. The findings include: a. A review of the laboratory's proficiency testing records indicated that for the first proficiency testing event of 2019, the laboratory received an unsatisfactory chloride proficiency testing score of 40%. In addition, for the second proficiency testing event of 2019, the laboratory received an unsatisfactory chloride proficiency testing score of 20% constituting unsuccessful chloride proficiency testing performance. b. On May 18, 2020 at 4:00 pm, the Technical Supervisor stated that the unsatisfactory proficiency testing score for the first proficiency testing event of 2019 was due to clerical error, and the unsatisfactory proficiency testing score for the second proficiency testing event of 2019 was due to lack of reagents to perform chloride testing.
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 here in, the Condition: Facility Administration was not met. The laboratory failed to be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process (see D3001), be constructed, arranged, and maintained to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized (see D3003), be constructed, arranged, and maintained to ensure molecular amplification procedures that are not contained in closed systems have a uni-directional workflow to include separate areas for specimen preparation, amplification, product detection, and reagent preparation (see D3005), retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years (see D3027), and retain quality control and patient test records, including instrument printouts, for at least 2 years (see D3031).
D3001	FACILITIES CFR(s): 493.1101(a)(1) The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process. This STANDARD is not met as evidenced by: Based on patient test record review, direct observation, and Technical Supervisor interview, the laboratory failed to be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of patient COVID-19 Polymerase Chain Reaction (PCR) testing. The findings include: a. The

	Standard Operating Procedure (SOP) for the laboratory's COVID-19 (Coronavirus) PCR test procedure stated: "6. In the clean reagent preparation room prepare the master mix," "10. Before moving the plate to the nucleic acid handling area. . .," and "11. In the nucleic acid extraction room. . ." b. No separate areas, rooms, or hood existed as suggested in the laboratory's SOP above. One single "AirScience" laminar airflow hood was noted in the one room the laboratory used for nucleic acid extraction, master mix preparation, and PCR plate setup. c. According to laboratory records, the laboratory performed and reported approximately 40 patients COVID-19 test results from April 13, 2020 to May 19, 2020. d. On May 21, 2020 at approximately 3:00 pm, the Technical Supervisor confirmed that the room the laboratory utilized for its patient COVID-19 testing was not consistent with the laboratory's SOP.
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 BGI Genomics manufacturers documentation and Technical Supervisor interview, the laboratory failed to have constructed, arranged and maintained the COVID-19 laboratory in such a manner to ensure contamination of patient specimens, equipment, instruments, reagents, materials, and supplies is minimized when performing patient testing. The findings include: a. One single "AirScience" laminar airflow hood is used for storing equipment, reagents and other supplies for use in the nucleic acid extraction process, master mix preparation and PCR plate setup for COVID-19 testing. b. The BGI Genomics manufacturer's instructions states "clean and decontaminate all work surfaces, pipettes, centrifuges and other equipment prior to use. Decontamination agents should be used including 10% bleach, 70% ethanol, and DNAzap or RNase Away to minimize the risk of nucleic acid contamination." 3. c. Laboratory personnel decontaminate the work area by using "Cloroxwipes 4. d.Approximately 40 patients have been tested for COVID-19 since April 13, 2020. 5. e. The Technical Supervisor confirmed on May 21, 2020 at approximately 3:00 pm that the decontamination process utilized by the lab personnel is not consistent with the manufacturer's instructions.
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 and Technical Supervisor interview, the laboratory failed to be constructed, arranged, and maintained in such a manner to ensure that molecular amplification procedures for the laboratory's patient COVID-19 test, that was not contained in closed systems, had a uni-directional workflow to include separate areas for specimen preparation, amplification, product detection, and reagent preparation.

	The findings include: a. For its patient COVID-19 Polymerase Chain Reaction (PCR) test, the laboratory had a room that contained the Applied Bioscience 7500 Real Time PCR System for molecular amplification, and another room that contained the "AirScience" laminar airflow hood used by the laboratory for reagent preparation, nucleic acid extraction, master mix preparation, and PCR plate set up. b. According to laboratory records, the laboratory performed and reported approximately 40 patient COVID-19 test results from April 13, 2020 to May 19, 2020. c. On May 21, 2020 at approximately 3:00 pm, the Technical Supervisor confirmed that the areas utilized for its patient COVID-19 PCR testing was not contained in a closed system and did not have a uni-directional workflow.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on patient record review and Technical Supervisor interview, the laboratory failed to retain patient test requisitions and test authorizations for its patient COVID-19 testing for approximately 40 patients tested from April 13, 2020 to May 19, 2020 for at least 2 years. The findings include: a. The laboratory maintained no records of test requisitions or laboratory patient reports for its patient COVID-19 testing performed from April 13, 2020 to May 19, 2020. b. On May 19, 2020 at approximately 3:00 pm, the Technical Supervisor confirmed that no test requisitions or laboratory patient reports were available and that the laboratory only provided verbal patient COVID-19 test results.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: 1. Based on review of the laboratory's Vitek 2 instrument test printouts, and patient microbiology test reports, Technical Supervisor and Testing Personnel interview, the laboratory failed to retain instrument test printouts documenting the testing of two patient urine microbiology identification and susceptibility results reported between May 1, 2020 and May 4, 2020. The findings include: a. The laboratory used the Vitek 2 instrument to perform patient urine microbiology identification and susceptibility testing. b. Records of patient test results from the Vitek 2 were stored in the Vitek 2 instrument for retrieval and reporting. c. Patient test results obtained from the Vitek 2 instrument were manually entered into the laboratory's information system by the testing person. d. One patient urine sample, (lab accession number 83196) which had been collected on April 23, 2020, test result was performed using the Vitek 2 instrument and reported on May 4, 2020 as Proteus mirabilis including susceptibility results. e. One patient urine sample, (lab accession number 83080) which had been collected on April 21, 2020, test result was performed using the Vitek 2 instrument

	and reported on May 1, 2020 as Escherichia coli including susceptibility results. f. Both patient test results were manually entered into the laboratory's information system by the Technical Supervisor on the reporting dates indicated. g. The Vitek 2 instrument did not have any record of either patient being tested and of the test results the laboratory reported. h. On May 21, 2020 at approximately 2:00 pm, Testing Personnel #1 confirmed that no Vitek instrument testing records existed for either patient, that all records of tests performed on the Vitek 2 instrument were retained in the instrument, and that both patient Vitek 2 instrument test results indicated above were manually entered by the Technical Supervisor in the laboratory's information system for reporting. The laboratory could not authenticate the test results reported. 2. Based on review of patient COVID-19 test records, direct observation, and Technical Supervisor interview, the laboratory failed to retain quality control (QC) and patient test records, that included instrument printouts, for approximately 40 patient COVID-19 specimens tested from April 13, 2020 to May 19, 2020. The findings include: a. The laboratory maintained no records pertaining to QC and patient specimen testing results for its patient COVID-19 testing performed and reported from April 13, 2020 to May 19, 2020. b. On May 21, 2020 at approximately 4:00 pm, the Technical Supervisor confirmed that the laboratory was unable to provide any COVID-19 QC and patient test records due to the fact the laboratory's information system for its COVID-19 testing was in the process of being developed.
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Bacteriology was not met. The laboratory failed to have an adequate manual system in place to ensure patient bacteriology test results were accurately and reliably sent from the point of data entry to final report destination (see D5801), and follow written policies and procedures for an ongoing mechanism to monitor, and assess, when indicated, correct problems identified in the bacteriology postanalytic systems (see D5891).
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Virology was not met. The laboratory failed to have a written COVID-19 procedure manual that included specimen collection, labeling, storage, preservation, transportation, and criteria for specimen acceptability and rejection, step-by-step performance of the procedure, corrective action to take when calibration or quality control results fail to meet the laboratory's criteria for acceptability, and a description

	of the course of action to take if the test system becomes inoperable (see D5403), have a COVID-19 written procedure that was approved and signed by the laboratory director before use (see D5407), follow manufacturer's COVID-19 instructions (see D5411), verify COVID-19 test performance specifications prior to reporting patient test results (see D5421), document quality control procedures performed for the extraction phase of the laboratory's COVID-19 testing (see D5453), document quality control procedures performed for the molecular amplification phase of the laboratory's COVID-19 testing (see D5455), document any corrective actions taken when quality control materials were not used during COVID-19 extraction and molecular amplification phases of testing (see D5783), retain records of patient COVID-19 testing (see D5789), and follow established procedures to monitor and assess the laboratory's patient COVID-19 testing (see D5791).
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Hematology was not met. The laboratory failed to follow a written hematology procedure manual (see D5401), follow the manufacturer's instructions for the laboratory's hematology analyzer (see D5411), properly label hematology quality control materials (see D5415), include two quality control materials for the laboratory's hematology testing prior to reporting patient test results (see D5447), document any corrective actions when test results of hematology quality control materials did not meet the laboratory's criteria for acceptability (see D5783), and follow established procedures to monitor and assess the laboratory's patient hematology testing (see D5791).
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 review of the laboratory's proficiency testing (PT) records, quality assessment (QA) procedure, instrument test records, patient test results, and Technical Supervisor interview, the laboratory failed to follow established QA policies and procedures to identify and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236 related to PT results. The findings include: a. The laboratory's QA procedure stated that all PT samples are to be performed in the same manner as patient testing. Routine chemistry PT samples tested in the second and third proficiency events of 2019 were not performed in the same manner as patient testing. (See D2006) b. The laboratory's QA procedure #530 stated that records are maintained for at least two years. Test records for two patient

	urine microbiology specimens from April/May 2020 were not maintained by the laboratory. (See D3031) c. On May 21, 2020 at approximately 4:00 pm, the Technical Supervisor confirmed that the laboratory failed to follow their established QA procedure for proficiency testing and maintaining test records for at least two years.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Analytic Systems was not met. The laboratory failed to follow established written procedures manual (see D5401), have a comprehensive written procedures manual (see D5403), have procedures that were approved and signed by the laboratory director before use (see D5407), follow manufacturer's instructions (see D5411), have properly labeled quality control materials (see D5415), verify test performance specifications before reporting patient test results (see D5421), include at least two quality control materials of different concentrations at least once a day patient specimens are assayed (see D5447), include two quality control materials for a test system that has an extraction phase at least once a day patient specimens are assayed (see D5453), include two quality control materials for a test system that has a molecular amplification procedure at least once a day patient specimens are assayed (see D5455), document corrective actions when quality control test results did not meet the laboratory's established criteria for acceptability or were not tested (see D5783), retain records of patient testing (see D5789), and follow established procedures to monitor and assess the laboratory's patient COVID-19 and hematology testing (see D5791).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records, Standard Operating Procedure (SOP), patient test results, and Technical Supervisor interview, the laboratory failed to follow the laboratory's established SOP for patient testing performed using the Beckman Coulter LH750 by not testing three quality control materials each day of patient testing for 54 days between July 2019 through March 2020. The findings include: a. The laboratory performed patient complete blood counts (CBC) testing using the Beckman Coulter LH750 test system. The laboratory's SOP for the Beckman Coulter LH750 stated that three levels of quality control

	materials must be tested each 8 hours of patient testing. In addition, the SOP stated that quality control materials must be tested and results must be within acceptable limits before analyzing and reporting patient CBC samples. b. Nine patient test records from CBC tests performed between September 9, 2019 and March 19, 2020 reviewed showed that the laboratory only tested two levels of quality control materials, and not three as required, prior to reporting these patient CBC test results: 9.9.2019 - 1 patient sample reported without testing the abnormal level 2 QC material. (Lab #69629) 11.6.2019 - 1 patient sample reported without testing the abnormal level 1 QC material. (Lab #73526) 12.30.2019 - 1 patient sample reported without testing the normal Level QC material. (Lab #76855) 3.3.2020 - 5 patient samples reported without testing the abnormal Level 2 QC material. (Lab #80946, 80975, 80997,80940, 80976) 3.19.2020 - 1 patient sample reported without testing the abnormal level 1 QC material. (Lab #81918) c. Hematology QC records for the Beckman Coulter LH750 reviewed showed a total of 54 days between July 2019 and March 2020 where only two levels, not the three as required, of QC materials were tested. These dates include: July 2019 4, 5, 10, 23, and 24 (only one level of QC material was tested on 7.24.2019) August 2019 7, 14, 15, 27, and 29 September 2019 9 October 2019 11, 22, and 24 November 2019 6, 8, 13, 21, 27, and 29 December 2019 2, 3, 4, 5, 9, 10, 11, 12, and 13 January 2020 1, 2, 3, 6, 8, 13, 17, 23, 24, and 30 February 2020 4, 5, 7, 14, 17, 20, and 21 (only one level of QC material was tested on 2.17.2020) March 2020 2, 3, 6, 9, 10, 12, and 20 d. Laboratory records indicate that the laboratory director reviewed and signed every QC record on the dates listed above. e. The Technical Supervisor stated that QC materials were not available at the laboratory on the dates listed above. f. On 5.21.2020 at approximately 4:00 pm, the Technical Supervisor confirmed that only two, not the three required, levels of hematology QC materials were tested on the dates listed above which was not consistent with the laboratory's established SOP.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's COVID-19 Standard Operating Procedure (SOP) and Technical Supervisor interview, the laboratory failed to include in its written procedure manual the following applicable requirements: specimen collection,

	labeling, storage, preservation, transportation and criteria for specimen acceptability and rejection; step-by-step performance of the procedure; corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; and description of the course of action to take if a test system becomes inoperable for the laboratory's COVID-19 procedure. The findings include: a. The laboratory's written COVID-19 SOP did not include instructions for specimen collection, labeling, storage, preservation, transportation, and criteria for specimen acceptability and rejection. The laboratory's written COVID-19 SOP stated that the patient specimen types to be tested include "throat swabs or broncho-alveolar lavage fluid (BALF)." However, the Technical Supervisor stated that the patient specimen types received are "nasopharyngeal (NP) swabs in a transport media." b. The laboratory's written COVID-19 SOP did not include step-by-step instructions for the extraction phase of the COVID-19 testing. c. The laboratory's written COVID-19 SOP did not include information related to corrective actions to take if the test system becomes inoperable. d. According to laboratory records, the laboratory performed and reported approximately 40 patient COVID-19 test results from April 13, 2020 to May 19, 2020. e. On May 19, 2020 at approximately 2:00 pm, the Technical Supervisor confirmed that the laboratory's written COVID-19 SOP did not include all of the applicable information indicated above.
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 review of the laboratory's COVID-19 Standard Operating Procedure (SOP) and Technical Supervisor interview, the laboratory failed to ensure that the laboratory director had approved and signed the laboratory's written COVID-19 SOP prior to testing approximately 40 patient COVID-19 samples. The findings include: a. The laboratory maintained documentation to indicate that its written COVID-19 SOP was in effect on 4/13/2020. However, laboratory documentation also indicated that the laboratory director did not sign and approve the written COVID-19 SOP until 4.27.2020. b. Laboratory records indicate that approximately 40 patient specimens were tested and reported using the laboratory's COVID-19 test protocol prior to the laboratory director's approval on 4.27.2020. c. On May 19, 2020 at approximately 2: 00 pm, the Technical Supervisor confirmed that patient samples were tested and reported prior to the laboratory's COVID-19 SOP being signed and approved by the laboratory director.
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: 1. Based on review of the manufacturer's instructions and the laboratory's Standard

	Operating Procedures (SOP), direct observation, and Technical Supervisor interview, the laboratory failed to follow the manufacturer's instructions for the Sysmex XNL-550 hematology analyzer used by the laboratory to test patient complete blood count (CBC) specimens. The findings include: a. The laboratory used the Sysmex XNL-550 hematology analyzer to test and report patient complete blood counts (CBCs). According to the Sysmex XNL-550 hematology analyzer instructions, patient specimens are not to be continuously "rocked" prior to testing. b. Six patient CBC specimens were directly observed being continuously "rocked" from 10:00 am until 4: 30 pm on May 18, 2020 prior to testing using the Sysmex XNL-550 hematology analyzer. c. Sysmex XNL-550 hematology analyzer instructions and the laboratory's current SOP stated that patient specimens not to be continuously "rocked" prior to testing. d. On May 18, 2020 at approximately 4:30 pm, the Technical Supervisor confirmed that six patient CBC specimens were being continuously "rocked," and stated that patient CBC specimens were tested towards the end of the day all at once. 2. Based on review of the manufacturer's instructions and Technical Supervisor interview, the laboratory failed to follow the BGI Genomics manufacturer's instructions for patient specimen sample requirements. The findings include: a. According to laboratory records, the laboratory performed and reported approximately 40 patient COVID-19 test results from April 13, 2020 to May 19, 2020 using BGI Genomics test system. BGI Genomics' instructions stated that acceptable patient specimen types are either a throat swab or a broncho-alveolar lavage fluid (BALF) for COVID-19 testing. b. The Technical Supervisor stated that he was unaware of BGI Genomics' patient specimen requirements, and thought that a nasopharyngeal swab provided in a transport media was adequate. c. On May 19, 2020 at approximately 4: 30 pm, the Technical Supervisor confirmed that the patient specimens received by the laboratory for COVID-19 testing were nasopharyngeal swabs in a transport media and not consistent with the manufacturer's patient specimen requirements.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the laboratory's written hematology Standard Operating Procedure (SOP), direct observation, and Technical Supervisor interview, the laboratory failed to properly label hematology quality control materials for use on the Sysmex XNL-550 with preparation and expiration dates as specified in the laboratory's SOP. The findings include: a. The written hematology SOP for the Sysmex XNL-550, which was used to test and report patient complete blood counts (CBC) specimens, stated that quality control (QC) material vials were stable for 15 days after the vial caps were pierced when refrigerated, and that each vial must be labeled with the expiration date after opening or cap piercing. b. Numerous Sysmex XNL-550 QC material vials were observed packaged in a plastic container. Laboratory records indicated that this plastic container had been opened on 3.24.2020. c. On May 18, 2020 at approximately 11:30 am, it was directly observed that three Sysmex XNL-550 QC vials in the plastic container had not been properly labeled with the expiration date after the vials were opened or pierced. d. The Technical Supervisor stated that he knew when the vials

	were opened and verified that testing personnel did not label the vials with expiration dates as specified in the laboratory's SOP.
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 test performance specifications documents and Technical Supervisor interview, the laboratory failed to verify the performance of the laboratory's COVID-19 PCR test manufactured by BGI Genomics to include accuracy, precision, analytical sensitivity, and analytical specificity to interfering substances prior to reporting patient COVID-19 test results on approximately 40 patient samples from April 13, 2020 to May 19, 2020. The findings include: a. The laboratory maintained no documentation to indicate that the laboratory had verified test performance specifications for the laboratory's COVID-19 test system that was manufactured by BGI Genomics prior to reporting patient COVID-19 results. These test performance specifications included accuracy, precision, analytical sensitivity, and analytical specificity to interfering substances. b. When the laboratory's COVID-19 BGI Genomics verification documentation was requested, the laboratory provided a document that included the testing of approximately 40 specimens. This document included no analysis of the data from the testing of the 40 specimens to indicate that the laboratory had verified accuracy, precision, analytical sensitivity, and analytical specificity to interfering substances for the laboratory's COVID-19 BGI Genomics test system. c. The Technical Supervisor stated that he thought the presented document was sufficient to indicate that the laboratory has verified BGI Genomics test performance specifications. d. On May 21, 2020 at approximately 3:00 pm, the Technical Supervisor confirmed that verification data beyond the testing of the 40 specimens, did not exist.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's written hematology Standard Operting Procedure (SOP), direct observation and Technical supervisor interview, the laboratory failed to test three levels of Quality Control (QC) material each 8 hours of operation and verify that QC results were within acceptable limits before reporting patient Complete Blood

	Count (CBC) results as specified in the laboratory's SOP. The findings include: a. The laboratory's written hematology SOP for the Beckman Coulter LH750 stated that three levels of QC materials must be tested each 8 hours of operation, and that the test results of these quality control materials must be within acceptable limits before testing and reporting patient CBC results. b. The laboratory maintained no QC records for the following dates when patient CBC specimens were tested and reported using the Beckman Coulter LH750 hematology analyzer: 10.29.2020 - 1 patient tested and results reported. 11.19.2019 - 1 patient tested and results reported. 12.15.2019 - 1 patient tested and results reported. 2.28.2020 - 1 patient tested and results reported. 3.11.2020 - 1 patient tested and results reported. 3.17.2020 - 2 patients tested and results reported. 3.18.2020 - 4 patients tested and results reported. 3.25.2020 - 2 patients tested and results reported. c. On 5.21.2020 at approximately 4:00 pm, the Technical Supervisor confirmed that QC materials were not tested on the Beckman Coulter LH750 on the dates listed above prior to reporting patient CBC test results.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation and Technical Supervisor interview, the laboratory failed to document quality control procedures performed during the extraction phase for the laboratory's COVID-19 Polymerase Chain Reaction (PCR) testing. The findings include: a. When requested, the laboratory provided no documentation regarding QC performed during the extraction phase for its COVID-19 PCR testing. b. According to laboratory records, the laboratory performed and reported approximately 40 patients COVID-19 patient test results from April 13, 2020 to May 19, 2020. c. On May 21, 2020 at approximately 3:00 pm, the Technical Supervisor confirmed that the laboratory was unable to provide QC records for the extraction phase of its COVID-19 PCR patient testing.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control (QC) documentation and Technical Supervisor interview, the laboratory failed to document control procedures for the molecular

	amplification phase for the laboratory's COVID-19 Polymerase Chain Reaction (PCR) testing. The findings include: a. When requested, the laboratory provided no documentation regarding QC performed during the molecular amplification phase for its COVID-19 PCR testing. b. According to laboratory records, the laboratory performed and reported approximately 40 patients COVID-19 test results from April 13, 2020 to May 19, 2020. c. On May 21, 2020 at approximately 3:00 pm, the Technical Supervisor confirmed that the laboratory was unable to provide QC records for the molecular amplification phase of its COVID-19 PCR patient testing.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, Standard Operating Procedures (SOP), and patient test results, and Technical Supervisor interview, the laboratory failed to document corrective actions that were taken when QC materials tested on the Beckman Coulter LH750 hematology analyzer did not meet the established criteria for acceptability as defined in the laboratory's hematology SOP for 54 days of patient testing between July 2019 and March 2020, and failed to document any corrective actions were taken when QC material was not tested during the laboratory's COVID-19 extraction and amplification phases of testing on April 13, 2020. The findings include: a. The laboratory's hematology SOP stated that the "Quality Control Action Log and the Corrective Action Form - LIS Instrumentation and QC" will be completed for any quality control problems. b. The laboratory's quality control SOP stated that any troubleshooting of QC must be documented on the "Corrective Action Form" and submitted to the laboratory director for review. c. The laboratory's quality assessment SOP stated: "QC performance according to written policies and procedures," "QC is performed at the proper frequency," "Corrective actions documented for any out-of-range results," "Verify patient results are held until QC is within expected ranges," and "Verify Laboratory Director has reviewed and signed QC charts monthly." d. The laboratory maintained no documentation of corrective actions taken when no QC materials were tested prior to reporting 13 patient complete blood count (CBC) specimen test results using the Beckman Coulter LH750 hematology analyzer. (See D5447) e. The laboratory maintained no documentation of corrective actions taken when only two, not three as required by the laboratory's SOP, levels of QC materials was tested prior to reporting patient complete blood count (CBC) specimen test results using the Beckman Coulter LH750 for 54 days between July 2019 and March 2020. (See D5401) f. The laboratory maintained no documentation of any corrective actions taken when no QC materials were included in the COVID-19 extraction phase for testing performed on April 13, 2020 when approximately 40 patient COVID-19 specimens were tested and reported. (See D5453) g. The laboratory maintained no documentation of any corrective actions taken when no QC materials were included in the COVID-19 molecular amplification phase for testing performed on April 13, 2020 when approximately 40 patient COVID-

	19 specimens were tested and reported. (See D5455) h. On May 21, 2020 at approximately 4:00 pm, the Technical Supervisor confirmed that no corrective actions were documented as required by the laboratory's SOP for the QC failures described above.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on review of patient test records and instrument data, and Technical Supervisor interview, the laboratory failed to retain records of patient COVID-19 testing that included instrument printouts. The findings include: a. For its COVID-19 Polymerase Chain Reaction (PCR) test, the laboratory used the Applied Bioscience 7500 Real Time PCR system. It was noted that there was no printer attached to the laboratory's Applied Bioscience 7500 Real Time PCR system. b. The laboratory provided no documentation regarding patient testing, position of patient specimens on PCR plates, and test run result curves and associated numerical value of those curves for its patient COVID-19 test. c. A review of patient COVID-19 PCR test runs on a computer screen indicated no documentation of patient sample or quality control material position on the PCR plates. d. According to laboratory records, the laboratory performed and reported approximately 40 patients COVID-19 test results from April 13, 2020 to May 19, 2020. e. On May 21, 2020 at approximately 3:00 pm, the Technical Supervisor confirmed that the laboratory was unable to provide any patient COVID-19 test records to include patient test results, and patient specimen and quality control material positions on the PCR plates.
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 review of patient test records, Standard Operating Procedures (SOP's), quality control (QC) records, corrective action documentation, and Technical Supervisor interview, the laboratory failed to follow established procedures to monitor and assess the analytical phase of testing and to correct problems identified in the specialties of hematology and microbiology between July 2019 and May 2020. The findings include: a. The laboratory failed to ensure that three levels of QC material tested on the Beckman Coulter LH750 prior to testing and reporting patient complete blood counts (CBC) specimens. (See D5401) b. The laboratory failed to assess its COVID-19 SOP to ensure the SOP included all of applicable requirements prior to use and testing patient specimens. (See D5403) c. The laboratory failed to ensure that its COVID-19 SOP was signed and approved by the laboratory director before testing patient samples. (See D5407) d. The laboratory failed to ensure that the manufacturer instructions and established SOP for patient specimens tested on the Sysmex XNL-

	550 were followed. (See D5411) e. The laboratory failed to assess patient COVID-19 specimen requirements as specified by the test system manufacturer prior to receipt and testing of patient samples. (See D5411) f. The laboratory failed to monitor the proper labeling of QC materials used on the Sysmex XNL-550 as specified in the laboratory's SOP. (See D5415) g. The laboratory failed to ensure that test performance specification for the laboratory's COVID-19 test method were verified prior to reporting patient test results. (See D5421) h. The laboratory failed to correct ongoing QC failures prior to reporting patient test results. (See D5447, D5453, and D5455) i. The laboratory failed to follow written policies and procedures to document corrective actions. (See D5783) j. The laboratory failed to ensure that patient COVID-19 test records and quality control documentation were retained. (See D5789)
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7) that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the number and severity of the deficiencies cited herein, the Condition: Postanalytic Systems was not met. The laboratory failed to have an adequate manual system to ensure patient test results were accurately entered into the laboratory's information system for reporting (See D5801), and follow the establish procedure to monitor and assess the accuracy of the reporting of patient test results. (See D5891)
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's Vitek 2 instrument records and patient test results, and Technical Supervisor and testing personnel interview, the laboratory failed to ensure that a patient urine culture identification and susceptibility test results, that was reported on May 4, 2020, manually entered from the Vitek 2 instrument was accurately entered into the laboratory's information system. The finding include: a. Laboratory records indicated that one patient collected and submitted three separate urine specimens (4.21.2020, 4.27.2020 and 4.28.2020). Each urine specimen was submitted to the laboratory for culture and susceptibility testing. b. Culture test results for the first two urine specimens collected on 4.21.2020 and 4.27.2020 were reported

	by the laboratory on May 1, 2020 as "multiple bacteria, morphotypes present,." c. Culture test results for the third urine specimen collected on 4.28.2020 was tested on the laboratory's Vitek 2 instrument. Records from the Vitek 2 instrument indicated that this urine specimen had test results that indicated culture results, with a 95% probability, of Francisella tularensis, and included the analysis message "Confirm by serological tests, highly pathogenic organism." It was noted that the laboratory does not perform serological confirmations on microbiological organisms. d. Laboratory records indicate that the final culture test result reported by the laboratory on 5.4.2020 for the third urine specimen collected on 4.28.2020 was Escherichia coli along with the susceptibility testing results. Laboratory records also indicated that this test result was manually entered into the laboratory's information system by the Technical Supervisor on May 4, 2020 at 8:45 am. e. On May 21, 2020 at approximately 2:00 pm, laboratory Testing Personnel # 1 confirmed that the results reported for the patient urine specimen collected on 4.28.2020 was not what had been identified by the laboratory's Vitek 2 instrument, and that those results were manually entered by the Technical Supervisor on May 4, 2020 at 8:45 am.
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 patient test records and quality assessment (QA) Procedure #530 and Technical Supervisor interview, the laboratory failed to follow the established QA procedure to monitor and assess the accuracy of urine microbiology test results reported for three patients in May 2020. The findings include: a. The laboratory's QA procedure stated in the Post-Analytic Section that laboratory records and final test results on patient's chart are the same. b. Two patient urine microbiology test results reported by the laboratory did not have supporting test records from the laboratory's Vitek 2 instrument. (See D3031) c. One patient urine microbiology test result reported differed from the test result recorded by the laboratory's Vitek 2 instrument. (See D5801) d. On May 21, 2020 at approximately 4:00 pm, the Technical Supervisor confirmed that the QA review of patient test records was not consistent with the established QA procedure.
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 laboratory director failed to ensure that testing systems used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance (See D6082), verification procedures used to are adequate to determine

	the accuracy, precision, and other pertinent performance characteristics of the method (See D6086), testing personnel were performing the test methods as required for accurate and reliable results (See D6087), routine chemistry proficiency testing samples provided by American Proficiency Institute (API) were tested as required under subpart H of this part (See D6089), quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (See D6093) quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur (See D6094), remedial actions were taken and documented when deviations from the laboratory's established performance characteristics are identified (See D6096), and approved procedure was available to all personnel responsible for any aspect of the COVID-19 testing process (See D6106).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of patient test results and quality control (QC) records, and staff interview, the laboratory director failed to ensure that testing systems used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanaltyic, analytic, and post analytic phases of testing. The findings include: a. The laboratory failed to meet the applicable requirements under 493.1101 through 493.1105 for facility administration. (See D3000) b. The laboratory failed meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299 for the Bacteriology subspecialty. (See D5002) c. The laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493.1281 through 493.1299 for the Virology subspecialty. (See D5010) d. The laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493.1281 through 493.1299 for the Hematology specialty. (See D5024)
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 verification test data, quality control (QC) records and Technical Supervisor interview, the laboratory director failed to ensure that the verification procedures used to validate the BGI Genomics COVID-19 Polymerase Chain Reaction (PCR) test method were adequate to determine performance characteristics of the method prior to testing patient specimens. The findings include: a. The laboratory maintained no documentation to indicate that the laboratory had verified

	test performance specifications for the laboratory's COVID-19 test system prior to starting patient testing. (See D5421)
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of patient test results, quality control (QC) records and Standard Operating Procedures (SOP's), and Technical Supervisor interview, the laboratory director failed to ensure that the testing personnel were performing the test methods as required for accurate and reliable results for hematology and microbiology tests. The findings include: a. The laboratory failed to follow the laboratory's established SOP for patient testing performed using the Beckman Coulter LH750 by not testing three quality control materials each day of patient testing. (See D5401) b. The laboratory failed to include in its written procedure manual the following applicable requirements: specimen collection, labeling, storage, preservation, transportation and criteria for specimen acceptability and rejection; step-by-step performance of the procedure; corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; and description of the course of action to take if a test system becomes inoperable for the laboratory's COVID-19. (See D5403) c. The laboratory failed to follow the manufacturer's instructions for the Sysmex XNL-550 hematology analyzer used by the laboratory to test patient Complete Blood Count (CBC) specimens. (See D5411) d. The laboratory failed to properly label hematology quality control materials for use on the Sysmex XNL-550 with preparation and expiration dates as specified in the laboratory's SOP. (See D5415) e. The laboratory failed to include two quality control materials using the Beckman Coulter LH750 hematology analyzer. (See D5447) f. The laboratory failed to document quality control procedures performed during the extraction phase for COVID-19 testing. (See D5453) g. The laboratory failed to document quality control procedures for the molecular amplification phase for COVID-19 testing. (See D5455)
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and Technical Consultant interview, the laboratory director failed to ensure that the routine chemistry samples provided by American Proficiency Institute (API) were tested as required under subpart H. The findings include: a. The laboratory failed to meet the Condition: Enrollment and Testing of [Proficiency Testing] Sample. (See D2000) b. The laboratory failed to examine the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimen. (See D2006) c. The laboratory failed to test proficiency testing samples the same number of times that it routinely test patient samples. (See D2010) d. The laboratory failed to successfully participate in proficiency testing. (See D2016)

D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 review of patient test results, quality control (QC) records, and Technical Supervisor interview, the laboratory director failed to ensure that a QC program was established for the COVID-19 test method and failed to ensure that the established QC program for the hematology testing was maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. The findings include: a. The laboratory failed to include two quality control materials when using the hematology analyzer Beckman Coulter LH750. (See D5477) b. The laboratory failed to include two quality control materials when performing the extraction phase for its COVID-19 testing. (See D5453) c. The laboratory failed to include two quality control materials when performing the amplification process for its COVID-19 testing. (See D5455)
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 review of patient test results, quality control (QC) records, quality assessment (QA) records, and Standard Operating Procedures (SOP's), and Technical Supervisor interview, the laboratory director failed to ensure that an effective QA program was established and maintained to identify failures in quality as they occur for test performed in the specialties of chemistry, microbiology and hematology. The findings include: a. The laboratory failed to establish and maintain 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 related to proficiency testing results. (See D5291) b. The laboratory failed to follow established and maintain quality assessment procedures to monitor and assess the analytical phase of testing and to correct problems identified in the specialties of hematology and microbiology. (See D5791) c. The laboratory failed to follow established and maintain quality assessment procedures to monitor and assess the post analytic system and to correct problems identified in the specialty of microbiology. (See D5891)
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

	This STANDARD is not met as evidenced by: Based on review of patient test results, quality control (QC) records, quality assessment (QA) records, Standard Operating Procedures (SOP's) and Technical Supervisor interview, the laboratory director failed to ensure that necessary remedial actions were taken and documented when deviations occurred as specified in established laboratory policies and procedures to address QC failures and patient reporting errors in the specialties of hematology and microbiology. The findings include: a. The laboratory failed to document corrective actions that were taken when QC materials tested on the Beckman Coulter LH750 hematology analyzer did not meet the established criteria for acceptability as defined in the laboratory's hematology SOP, and failed to document any corrective actions were taken when QC material was not tested during the laboratory's COVID-19 extraction and amplification phases of testing. (See D5783)
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the laboratory's COVID-19 procedure, and Technical Supervisor interview, the laboratory director failed to ensure that an approved procedure was available to all personnel responsible for any aspect of the COVID-19 testing process. The findings include: a. The laboratory director failed to approve and sign the laboratory's COVID-19 Standard Operating Procedure (SOP) prior to starting patient testing. (See D5407)