Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2189543	11/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
P23 Labs, Llc	1101 Chatham Parkway Suite A6, Savannah, GA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Clinical Laboratory Improvement Amendments (CLIA) complaint investigation and an inital certification survey were completed on November 4, 2020. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 surveyor observation and an interview with the Chief Operations Officer (COO), the laboratory failed to provide a shower station and eyewash for immediate emergency use within the laboratory area. The findings include: 1. The laboratory failed to have a shower station and eyewash available in the laboratory to ensure safety measures of any person's eyes or body that may be exposed to injurious corrosive materials, for quick drenching or flushing for immediate emergency use. A tour of the laboratory confirmed a shower station and eye wash was absent from the laboratory area. 2. The COO confirmed on 11/3/2020, at 11:30 AM, in the laboratory, that a shower station and eye wash has been absent from the laboratory since August 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 P23 Labs, Quality Manual, Testing Personnel (TP) Training Checklist and interview with Chief Operating Officer (COO), the laboratory failed to list all mandatory competency assessment criteria on training checklist for TP assessment. The finding includes: 1. The laboratory started COVID-19 testing on September 21, 2020 and only had initial competency records available for review. Review of the P23 Labs, Quality Manual on November 3, 2020, revealed the laboratory failed to include language that addressed the semi-annual competency assessment requirement and testing evaluation process. The policy stated that personnel competency assessment is evaluated annually,but did not mention semi-annual evaluation. The manual did not include a copy of the training checklist or how to use. 2. A review of the TP competency assessment training checklist found the laboratory failed to include all 6 competency assessment criteria such as specimen handling, record reporting, proficiency testing, problem solving and a system for complaints. 3. A review found the laboratory failed to document the name of the person who performed the initial competency training on the checklist. The laboratory had a space for documenting the trainer's name on form that was left blank for all TP. The laboratory director failed to sign the initial competency assessment checklist for 3 of 3 TP. 4. An interview with the COO on November 3, 2020 at 11:00 AM confirmed the laboratory did not include all of the 6 competency assessment criteria on the training checklist or semi-annual competency assessment.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency test (PT) records and interview with the COO, the laboratory failed to ensure that at least twice annually the laboratory verified the accuracy of QuantStudio 5 Taq-Path COVID-19 assay and unregulated analytes. The findings include: 1. Review of the laboratory's records revealed that there was no documentation of peer review or internal proficiency testing (PT) performed twice annually for the QuantStudio 5 Taq-Path COVID-19 assay or unregulated analytes. 2. The laboratory does not have a policy indicating how PT for unregulated analytes is assessed. 3. The COO confirmed on 11/3/2020, at 1:30 PM, in the conference room, that the laboratory has not performed PT twice annually for the QuantStudio 5 Taq-Path COVID-19 assay or unregulated analytes.
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 surveyor review of Quality Manual and interview with the COO, the laboratory failed to perform and document the quality assessment monitors for the laboratory. The findings include: 1. A review of the Quality Manual and laboratory procedure on page 1 of 29, revealed the laboratory did not provide specific guidance or instructions for P23 labs staff to follow for monitoring, assessing and correcting problems in the laboratory. 2. A review revealed the laboratory did not perform or list the names of monitors for their laboratory testing or laboratory information system. 4. An interview with the COO on November 3, 2020 at 2:00 PM confirmed the laboratory did not complete any quality assessment monitors for laboratory processes performed.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual (SOP), quality assurance (QA) records, and interview with the testing personnel the laboratory failed to ensure and verify an ongoing assessment to evaluate, monitor, and when indicated, correct problems identified in the laboratory. The findings include: 1. Review of QA records revealed that the laboratory's current QA policy does not indicate the necessary steps to be taken to identify and correct problems, nor efforts to prevent recurrences and necessary procedures to prevent reoccurrence of problems in the laboratory. 2. There is no evidence or documentation that corrective actions are being performed in the laboratory. 3. The COO confirmed on 11/3/2020, at 12:30 PM, in the conference room, that the laboratory is performing corrective actions but not documenting them. The COO also confirmed that the QA policy does not adequately assess and identify problems in the laboratory.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor review of laboratory records and an interview with the Chief Operating Officer (COO), the laboratory failed to have a written procedure for specimen rejection and the labeling of specimens. The findings include: 1. A review of the laboratory procedure manual and interview with the COO, the laboratory failed to have a written procedure for the criteria of specimen rejection for all test performed in the laboratory from August 2020 through November 2020. 2. An interview with the

	COO, in the conference room, on 11/3/2020 at 2:30 PM, confirmed that the laboratory did not have a written procedure for specimen rejection or labeling of specimens. 41221 Based on record review, observation, and interview the laboratory failed to ensure specimen integrity by analyzing saliva specimens received beyond the established stability time frame. Findings: 1) Review of the Emergency Use Authorization (EUA) issued October 20, 2020 by Food and Drug Administration (FDA) under "Sample Collection and Transport", saliva specimens must be tested within 72 hours of collection. 2) Review of the Laboratory Daily Log Report for date range from 10/21/20 -11/04/20 showed approximately 3,340 tests that were run. Of the 3,340 tests approximately 1,930 were saliva specimens. 179 saliva specimens were identified as being tested beyond the 72 hour stability as outlined in the EUA. 3) Random sampling of the 179 saliva specimens: Sample ID Collection Date Test Date 2010220003 10/16/20 10/22/20 2010220005 10/16/20 10/22/20 2010220006 10/16/20 10/22/20 2010220007 10/16/20 10/22/20 2010220008 10/16/20 10/22/20 2010220009 10/16/20 10/22/20 2010220010 10/16/20 10/22/20 2010220011 10/16/20 10/22/20 2010220012 10/16/20 10/22/20 2010220013 10/16/20 10/22/20 2010220014 10/16/20 10/22/20 2010220015 10/16/20 10/22/20 2010220016 10/16/20 10/22/20 2010270287 10/23/20 10/27/20 2010270288 10/23/20 10/27/20 2010270289 10/23/20 10/27/20 2010270290 10/23/20 10/27/20 2010270291 10/23/20 10/27/20 2010270292 10/20/20 10/27/20 2010270293 10/20/20 10/27/20 2010270294 10/20/20 10/27/20 2010280284 10/23/20 10/28/20 2010280285 10/23/20 10/28/20 2010280286 10/23/20 10/28/20 2010280287 10/22/20 10/28/20 2010280288 10/22/20 10/28/20 2010280289 10/22/20 10/28/20 2010280290 10/23/20 10/28/20 2010280291 10/23/20 10/28/20 2010280292 10/23/20 10/28/20 2010280292 10/22/20 10/28/20 2010280293 10/23/20 10/28/20 2010280294 10/22/20 10/28/20 2010280295 10/22/20 10/28/20 2010280296 10/22/20 10/28/20 2010280297 10/22/20 10/28/20 2010280298 10/22/20 10/28/20 2010280299 10/22/20 10/28/20 2010280300 10/22/20 10/28/20 2010280301 10/22/20 10/28/20 2010280302 10/22/20 10/28/20 2010280303 10/22/20 10/28/20 2010280304 10/22/20 10/28/20 2010280305 10/22/20 10/28/20 2010280306 10/22/20 10/28/20 2010280307 10/22/20 10/28/20 2010280308 10/22/20 10/28/20 2011030078 10/30/20 11/03/20 2011030079 10/30/20 11/03/20 2011030080 10/30/20 11/03/20 2011030081 10/30/20 11/03/20 2011030082 10/30/20 11/03/20 2011030083 10/30/20 11/03/20 2011030084 10/30/20 11/03/20 4) In interview with the Chief Operational Officer in her office on 11/4/20 at 1607 hours confirmation was given that all listed specimens were saliva samples and were accepted for testing. 5) Observation of receipt and accessioning of approximately 400 samples on 11/4/20 at 1020 hours demonstrated that all specimens received were saliva samples. Based on record review and interview the laboratory failed to ensure the integrity of frozen, extracted specimens. Findings: 1) The Chief Operational Officer 11/3/20 at 1045 hours in the conference room stated that the Little Rock lab location ceased testing on 8/27/20. Samples received in Little Rock, AR were extracted and shipped frozen in dry ice, same- day by FedEx to Savannah, GA for analysis. 2) The surveyor requested documentation of stability studies for extracted specimens on 11/4/20 at 1144 hours in the conference room. The COO stated that the laboratory did not have documented stability studies. 3) Review of an email sent from COO to the surveyor dated 11/4/20 at 1326 hours states that 2383 samples were extracted in Little Rock and shipped to Savannah.
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 surveyor review of the laboratory procedure manual and interview with the COO, the laboratory failed to establish a client services manual with written instructions to each client that sends specimens/test requests to the laboratory. The findings include: 1. The laboratory does not have a written policy and procedure manual to instruct their clientele how to send patient specimens and request test from the laboratory from August 2020 through November 2020. 2. The instructions should contain information on specimen handling (e.g., collection, preservation, storage, transport, testing schedule times and how to obtain additional assistance for unusual circumstances). 3. The COO confirmed on 11/3/2020 at 12:30 PM in the conference room, that the laboratory does not have a written policy and procedure manual to instruct their clientele how to send patient specimens and request test from the laboratory.
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: The laboratory failed to monitor and evaluate the overall quality of the analytic systems regarding the procedure manual, maintenance and function checks, calibration verification, and control procedures for all instrumentation present in the laboratory. (Refer to D5401, D5421, and D5441)
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 surveyor review of the laboratory's procedure manual and interview, the laboratory failed to have a written procedure for all tests, assays, and examinations performed in the laboratory. The findings include: 1. The laboratory did not have an established written procedure manual for all tests, examinations, and assays performed in the laboratory. 2. The laboratory does not have procedures for specimen labeling, handling, storage, and reportable ranges for patient test results, validations, quality assurance or patient reporting. 3. The laboratory did not have a procedure for their QuantStudio 5 Taq-Path COVID-19 assay. 4. The procedure manual was not reviewed

	and signed by LD. 5. The COO confirmed on 11/3/2020 at 12:30 PM in the conference room, that the laboratory did not have a procedure manual for all test performed in the laboratory.
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 laboratory records and interview with the COO, it was determined that the laboratory failed to meet analytic system requirements for their QuantStudio 5 Taq-Path COVID-19 assay from August 2020 through November 2020. The findings include: 1. The laboratory verification process failed to provide a written description that documents all actions required to validate their QuantStudio 5 Taq-Path COVID-19 assay with CLIA requirements. The laboratory must describe how each test is validated with statistically significant verification for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference ranges. 2. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for their allergen assay. The laboratory had no records for the validation or correlation data for their QuantStudio 5 Taq-Path COVID-19 assay. 3. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for QuantStudio 5 Taq-Path COVID-19 assay. 4. The laboratory limits of detection are not supported by the data provided by the laboratory and failed to establish lower and upper limits of detection for their QuantStudio 5 Taq-Path COVID-19 assay. 5. An interview with the COO, on 11/3/2020 at 1:00 PM, in the conference room, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference interval (normal range) for their QuantStudio 5 Taq-Path COVID-19 assay from August 2020 through November 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 a lack of documentation and interview the laboratory failed to document a validation of the Portal LIMS (Laboratory Information Management System) created for one client. The findings include: 1. A review of documents available at the time of the survey revealed no documentation of a validation for a Portal LIMS created for a single client which was in use August 14 - 17, 2020. The portal reported results to 21 patients prior to their samples arriving at the laboratory. 2. An interview of the COO (Chief Operating Officer) on 11/04/2020 at 10:47 AM confirmed that no documentation was available for a validation of the Portal LIMS in question.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and interview with the COO, the laboratory failed to monitor the QC failures, corrective actions, accuracy and precision of test performance for their QuantStudio 5 Taq-Path COVID-19 assay. The findings include: 1. Review of QC records revealed no evidence that quality control pass or fail records are reviewed by the Technical Supervisor (TS) or Laboratory Director (LD) prior to reporting patient results. The laboratory does not have a method or policy for reviewing quality control values to determine shifts or trends for their QuantStudio 5 Taq-Path COVID-19 assay. 2. An interview with the COO, on 11/3/2020 at 2:30 PM, in the conference room, confirmed that the laboratory is performing QC but does not have any supporting documentation that QC records were being reviewed by the TS or LD prior to reporting patient results from August 2020 through November 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: Based on review of patient test reports and interview with the COO, the laboratory failed to include units of measure, reference ranges, normal values, and type of specimen kit used for testing on patient test reports. The findings include: 1. A review of 2 patient reports failed to include reference ranges or the specimen (nasopharyngeal swabs or saliva) kit used for testing their QuantStudio 5 Taq-Path COVID-19 assay. 2. An interview with the COO, in the conference room, on 11/3/2020 at 2:30 PM, confirmed that the laboratory's test reports failed to include and identify include units of measure, reference ranges, normal values, or specimen kit type from August 2020 through November 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 surveyor record review and interview it was determined the Laboratory Director failed to ensure adequate validation and verification of test methods that were used to establish their COVID-19 assay. The Laboratory Director failed to ensure that the quality control (QC) and quality assessment (QA) programs were maintained appropriately. (Refer to D6082, D6093, D6094 and 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 surveyor review of laboratory records and an interview with testing personnel (TP), The Laboratory Director (LD) failed to provide statistical data that validated the accuracy, precision, analytical specificity, and analytical sensitivity of their QuantStudio 5 Taq-Path COVID-19 assay. The findings include: 1. The laboratory verification process failed to provide a written description that documents all actions required to validate their QuantStudio 5 Taq-Path COVID-19 assay with CLIA requirements. The laboratory must describe how each test is validated with statistically significant verification for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference ranges. 2. The laboratory failed to provide statistically significant data that validated the accuracy, precision, analytical specificity, and analytical sensitivity for their COVID-19. The laboratory had no records for the validation or correlation data for their QuantStudio 5 Taq-Path COVID-19 assay. 3. The laboratory failed to provide validation and linearity records for their own reportable ranges and reference ranges for QuantStudio 5 Taq-Path COVID-19 assay. 4. The laboratory limits of detection are not supported by the data provided by the laboratory and failed to establish lower and upper limits of detection for their QuantStudio 5 Taq-Path COVID-19 assay. 5. The LD failed to verify and

	establish validation and quality control data for their QuantStudio 5 Taq-Path COVID-19 assay prior to performing patient testing. 6. An interview with the COO, on 11/3 /2020 at 1:00 PM, in the conference room, confirmed that the laboratory failed to meet specifications for accuracy, precision, analytical specificity, analytical sensitivity, reportable range, and reference interval (normal range) for their QuantStudio 5 Taq-Path COVID-19 assay.
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 the laboratory's quality control (QC) records and interview with the COO, the laboratory director (LD) failed to monitor the QC failures, corrective actions, accuracy and precision of test performance for their QuantStudio 5 Taq-Path COVID-19 assay . The findings include: 1. Review of QC records revealed no evidence that quality control pass or fail records are reviewed by the Technical Supervisor (TS) or Laboratory Director (LD) prior to submitting patient results. The LD does not have a method or policy for reviewing quality control values to determine shifts or trends for their QuantStudio 5 Taq-Path COVID-19 assay . 2. An interview with the COO, on 11/3/2020 at 2:30 PM, in the conference room, confirmed that the laboratory is performing QC but does not have any supporting documentation that QC records were being reviewed by the TS or LD prior to submitting patient reports from August 2020 through November 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 surveyor review of laboratory records and interview with the COO, the laboratory director failed to establish a written quality assessment (QA) to monitor, assess, and correct problems in the general laboratory system for quality assessment. The findings include: 1. The laboratory did not have a written quality assessment policy that encompasses all facets of the laboratory's technical and non-technical functions. 2. The laboratory failed to have a QA to assess patient confidentially, specimen integrity and identification, complaint, corrective actions, proficiency test performance, and personnel competency. 3. An interview with the COO, on 11/3/2020 at 1:00 PM, in the conference room, confirmed that the laboratory failed to have a written and established QA policy.
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 surveyor review of the laboratory's procedure manual and interview, the laboratory director failed to establish and have a written procedure for all tests, assays, and examinations performed in the laboratory. The findings include: 1. The laboratory did not have an established written procedure manual for all tests, examinations, and assays performed in the laboratory. 2. The laboratory did not have procedures for specimen labeling, handling, storage, reportable ranges for patient test results, validations, quality assurance or patient reporting. 3. The laboratory did not have a procedure for their QuantStudio 5 Taq-Path COVID-19 assay. 4. The procedure manual was not reviewed and signed by LD. 5. The COO confirmed on 11/3/2020 at 12:30 PM in the conference room, that the laboratory did not have a procedure manual for all test performed in the laboratory from August 2020 through November 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 surveyor review of personnel records and interview with the Laboratory Director (LD), the Technical Supervisor failed to assess the six competency assessment criteria for testing personnel for the specialty of General Immunology. The findings include: 1. A review of testing personnel records revealed that a competency assessment was performed for laboratory procedures and skills evaluation, but the assessment did not address the six competency assessment criteria for their QuantStudio 5 Taq-Path COVID-19 assay procedure. 2. An interview with the COO in the conference room, on 09/09/20 at 11:30 AM, confirmed that annual competencies did not contain the six competency assessment criteria for testing personnel for the specialty of General Immunology from August 2020 through November 2020.
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 college transcript and interview with the COO, the laboratory failed to ensure testing personnel qualified to perform high complexity testing. The findings include: 1. A review of college transcript revealed laboratory allowed person with BS in Medical Science in Engineering to perform high complexity testing. Review of the college transcripts found TP#2 completed two organic chemistry classes and no clinical biological science classes. 2. An interview with the COO on November 3, 2020 at 3:00 PM confirmed the TP #2 did not qualify to perform high complexity testing.