Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0959698	08/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Clear Lake Pediatric Clinic, Pa	16 Professional Park Dr, Webster, TX	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An onsite recertification survey was performed on 8/27/21. The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780 resulting in the following IMMEDIATELY JEOPARDY findings: D5400 493.1250 Analytic Systems The immediate jeopardy conditions were abated as evidenced by a letter signed by the laboratory director on 8 /27/21. See the attached letter. and the following CONDITION LEVEL findings: D6076 493.1441 Condition: Laboratories performing high complexity testing; laboratory director D6168 493.1487 Condition: Laboratories performing high complexity testing; testing personnel The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
D2127	HEMATOLOGY CFR(s): 493.851(d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing records for 2019 and staff interview, it was revealed that the laboratory failed to return its proficiency testing results to API within the time frame specified by the program for 1 out of 3 testing events in 2019, resulting in unsatisfactory performance for all analytes in the specialty of Hematology. Findings include: 1. A review of the laboratory's API proficiency testing records revealed the laboratory received the following unsatisfactory scores for 2019 Hematology /Coagulation third event: White Blood Cell Differential. - score 0% Erythrocyte Count - score 0% Hematocrit - score 0% Hemoglobin - score 0% Leukocyte Count - score 0% Platelet Count - score 0% 2. Further review of the laboratory's API records for the

	2019 Hematology/Coagulation third event revealed the following notation: "I mailed the Hematology/Coagulation test on the late date, due to looking at the wrong dates due." 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 8 /27/21 at 1:40 p.m. in the patient exam room, after review of the records, confirmed the above findings.
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 a review of the laboratory's test records, a review of the laboratory's policies, and staff interview, it was revealed that the laboratory failed to report a total of 322 SARS-CoV-2 antigen patient test results, that contained both negative and positive antigen test results, as required by 400.200 for 86 of 86 days from November 17, 2020 to August 27, 2021. Findings include: 1. A review of the laboratory's test records from 2020 to 2021 revealed the laboratory started SARS-CoV-2 antigen patient testing using the RapiGEN Biocredit COVID-19 antigen test on November 17, 2020. 2. A review of the laboratory's policies revealed no documentation of a policy /procedure related to SARS-CoV-2 test reporting. 3. A review of the laboratory's SARS-CoV-2 antigen patient test records from November 17, 2020 to August 27, 2021, revealed the laboratory failed to have documentation of reporting 282 negative and 40 positive test records for 86 of 86 days of testing. 4. An interview with the laboratory director on 8/27/21 at 2:00 p.m. in the patient exam room, after review of the records, confirmed the above findings.
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 a review of the laboratory's records from November 2020 to August 2021 and staff interview, it was revealed that the laboratory failed to have documentation of 2 of 2 accuracy assessments in 2020 for SARS-CoV-2 antigen testing using the RapiGEN Biocredit COVID-19 Antigen test. Findings include: 1. A review of the laboratory's test records revealed the laboratory started SARS-CoV-2 antigen testing using the RapiGEN Biocredit COVID-19 Antigen test in November 2020. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of the twice annual accuracy assessments in 2020 for SARS-CoV-2 antigen testing using the RapiGEN Biocredit COVID-19 Antigen test. 3. An interview

	with the laboratory director on 8/27/21 at 2:00 p.m. in the patient exam room, after review of the records, confirmed the above findings.
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 a review of the laboratory's policies, a review of the laboratory's records, a review of patient test records, and staff interview, it was revealed that the laboratory failed to meet the requirements of the analytic systems as evidenced by: 1. The laboratory failed to make available a written procedure for the laboratory personnel to follow for SARS-CoV-2 antigen testing using the RapiGEN Biocredit COVID-19 Antigen test. (Refer to D5403) 2. The laboratory failed to have documentation of establishing the performance specifications for the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. (Refer to D5423) 3. The laboratory failed to have documentation of verifying the calibration by running quality controls for 3 of 3 calibrations performed on the Beckman Coulter Act Diff 2 hematology analyzer in 2020 and 2021. (Refer to D5437) 4. The laboratory failed to have documentation of running a negative and positive quality control each day of patient testing on the RapiGEN Biocredit COVID-19 Antigen test. (Refer to D5449)
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 a review of the laboratory's test records, a review of the laboratory's

	policies, a review of patient test records, and staff interview, it was revealed that the laboratory failed to have a written procedure for the laboratory personnel to follow for SARS-CoV-2 antigen testing using the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. Findings include: 1. A review of the laboratory's test records revealed the laboratory started using the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test in November 2020. 2. A review of the laboratory's policies revealed the laboratory failed to have a written procedure for for SARS-CoV-2 antigen testing using the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test that includes: a. Requirements for patient preparation; specimen collection, labeling, storage, processing, and criteria for specimen acceptability and rejection b. Step-by-step performance of the procedure, including interpretation of results. c. Control procedures. d. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability e. Limitations in the test methodology, including interfering substances. f. Reference intervals (normal values). g. 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. 3. A review of patient test records from November 2020 to August 2021 revealed the laboratory reported 322 patient tests using the RapiGEN Biocredit COVID-19 Antigen test. 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/27/21 at 2:00 p.m. in the laboratory, after review of the records, confirmed the above findings.
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 review of the laboratory's policies, laboratory's test records, a review of the FDA website, patient test records from November 2020 to August 2021, and staff interview, it was revealed that the laboratory failed to have documentation of establishing the performance specifications (preanalytical studies, accuracy, precision, analytical sensitivity, analytical specificity- to include interfering substances) for the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. Findings include: 1. A review of the laboratory policy titled 'Verification of Performance for New Equipment' revealed the following: "When the laboratory introduces a new CLIA non-waived system it must establish that the new system meets criteria to be clinically useful." 2. A review of the laboratory's test records revealed the laboratory started using the RapiGEN Biocredit COVID-19 Antigen test in November 2020. 3. A review of the FDA website revealed no documentation of an EUA (emergency use authorization) approval for the RapiGEN Biocredit COVID-19 Antigen test. ***Since the FDA had not approved this test for an EUA, the test system is a lab developed test. The laboratory must establish preanalytical studies, precision, analytical sensitivity,

	analytical specificity, and reportable range for this test. 4. Further review of the laboratory's records revealed the laboratory failed to have documentation of the establishment studies for the RapiGEN Biocredit COVID-19 Antigen test that includes the following: - preanalytical studies - accuracy - precision - analytical sensitivity - analytical specificity (to include interfering substances) 5. A review of patient test records from November 2020 to August 2021 revealed the laboratory reported 322 patient tests using the RapiGEN Biocredit COVID-19 Antigen test. 6. An interview with the laboratory director on 8/27/21 at 2:00 p.m. hours in the patient exam room, after review of the records, was not aware that this test kit was not EUA approved.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the Operator's guide for the Beckman Coulter Act Diff 2 hematology analyzer, the laboratory's calibration records from 2020 to 2021, review of the laboratory's quality control records, and staff interview, it was revealed that the laboratory failed to have documentation of verifying the calibration by running quality controls for 3 of 3 calibrations performed on the Beckman Coulter Act Diff 2 hematology analyzer in 2020 and 2021. Findings include: 1. A review of the Operator's Guide for the Beckman Coulter Act Diff 2 hematology analyzer (Product number: 4237495B, 6/2003)reveals the last step in the calibration procedure: "Verify calibration by running 4C PLUS cell control." 2. A review of the laboratory's calibration records for the Beckman Coulter Act Diff 2 hematology analyzer revealed the analyzer was calibrated on the following 3 dates: 1/3/20 7/8/20 4/20/21 3. A review of the laboratory's quality control records revealed no documentation of the 4C PLUS cell controls being run after the analyzer was calibrated. 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/27/21 at 1:40 p.m. in the patient exam room, after review of the records, confirmed the above findings. NOTE: This is a repeat deficiency from the survey conducted on 7/9/19.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's quality control records from November 2020 to August 2021, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running a negative and positive quality control each day of patient testing for 86 of 86 days from November 2020 to August 2021 on the RapiGEN Biocredit COVID-19 Antigen test. Findings include: 1. A review of the laboratory's policy titled 'Quality Assessment Plan' revealed the following: "It is the responsibility of every technologist to ensure that the required controls have been performed and satisfactory performance has been obtained prior to the release of any patient results." 2. A review of the laboratory's quality control records from November 2020 to August 2021 revealed the laboratory failed to have documentation of running a negative and positive control each day of patient testing from November 2020 to August 2021 on the RapiGEN Biocredit COVID-19 Antigen test. 3. A random review of patient test records revealed the following 18 patients were resulted when a positive and negative quality control was not run: Date: 12/4/20 Patient ID: 082317 Date: 12/24/20 Patient ID: 111618 Date: 1/5/21 Patient ID: 050816 Date: 1/12/21 Patient ID: 072709 Patient ID: 111215 Patient ID: 042303 Date: 2/23/21 Patient ID: 051302 Patient ID: 052605 Date: 3/23/21 Patient ID: 022107 Patient ID: 082703 Date: 4/21/21 Patient ID: 051010 Patient ID: 111509 Date: 7/31/21 Patient ID: 042297 Date: 8/18/21 Patient ID: 100113 Patient ID: 072906 Patient ID: 050701 Patient ID: 082702 Patient ID: 102519 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 8/27/21 at 2:00 p.m. in the patient exam room, after review of the records, revealed the kit did not come with quality control material, so the laboratory did not run any. This confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's test records, a review of patient test records and staff interview, it was revealed that the laboratory failed to have an effective QA (quality assessment) in place to identify and correct problems for the analytical phase of testing. Findings include: 1. A review of the laboratory's policy titled 'Quality Assessment Plan' revealed the following: "The laboratory has an ongoing Quality Assessment Program that is designed to monitor, evaluate and improve the quality of the laboratory performance and ensures the reliability of test data, and to evaluate the competency of the laboratory staff. The laboratory will identify and resolve any problems that may affect lab performance and thus patient care." 2. The laboratory failed to make available a written procedure for the laboratory personnel to follow for SARS-CoV-2 antigen testing using the RapiGEN Biocredit COVID-19 Antigen test. (Refer to D5403) 3. The laboratory failed to have documentation of establishing the performance specifications for the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. (Refer to D5423) 4. The laboratory failed to have documentation of verifying the calibration by running

	quality controls for 3 of 3 calibrations performed on the Beckman Coulter Act Diff 2 hematology analyzer in 2020 and 2021. (Refer to D5437) 5. The laboratory failed to have documentation of running a negative and positive quality control each day of patient testing on the RapiGEN Biocredit COVID-19 Antigen test. (Refer to D5449)
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 a review of the laboratory's records and staff interview, it was revealed that the laboratory director failed to provide overall management and direction for the laboratory. Findings include: 1. The laboratory director failed to ensure the laboratory provided quality laboratory services for all aspects of test performance. (Refer to D6093) 2. The laboratory director failed to ensure the laboratory performed establishment studies for its test systems before reporting patient test results. (Refer to D6086) 3. The laboratory director failed to ensure 2 of 2 testing personnel had documentation of training prior to performing patient's SARS-Cov-2 testing on the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. (Refer to D6102)
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 a review of the laboratory's test records and staff interview, it was revealed that the laboratory director failed to ensure the laboratory performed establishment studies for its test systems before reporting patient test results. (Refer to D5423)
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 a review of laboratory's analytic systems and staff interview, it was revealed that the laboratory director failed to ensure the laboratory provided quality laboratory services for all aspects of test performance. (Refer to D5449)
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)

	The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the laboratory's test records, a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, a review of patient test records from November 2020 to August 2021, and staff interview, it was revealed that the laboratory director failed to ensure 2 of 2 testing personnel had documentation of training prior to performing patient's SARS-Cov-2 testing on the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. Findings include: 1. A review of the laboratory's policy titled 'Quality Assurance Plan' revealed the following: "Each employee must be trained on new procedures or new equipment. The training must be documented and signed by the employee and the trainer. These records are kept in the employee's personnel file and should be available for inspection." 2. A review of the laboratory's test records revealed the laboratory started using the RapiGEN Biocredit COVID-19 Antigen test in November 2020. 3. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 8/25/21) revealed the laboratory identified 2 testing personnel performing SARS-Cov-2 testing on the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. 4. A review of the laboratory's personnel records revealed testing person #1 and testing person #2 failed to have documentation of training for performing SARS-Cov-2 testing on the non-EUA approved RapiGEN Biocredit COVID-19 Antigen test. 5. A review of patient test records from November 2020 to August 2021 revealed the laboratory reported 322 patient tests using the RapiGEN Biocredit COVID-19 Antigen test. 6. An interview with testing person #1 on 8/27/21 at 2:00 p.m. in the laboratory, after review of the records, confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of education to qualify 2 of 2 testing personnel to perform high complexity testing. (Refer to D6171).
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory

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

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's submitted CMS 209 form, a review of the FDA website, a review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to ensure 2 of 2 testing personnel met the

	requirements to perform high complexity testing (SARS-CoV-2 antigen testing using the RapiGEN Biocredit COVID-19 Antigen test). Findings include: 1. A review of the laboratory's submitted CMS-209 form listed 2 testing personnel performing patient testing. 2. A review of the FDA website revealed no documentation of an EUA (emergency use authorization) approval for the RapiGEN Biocredit COVID-19 Antigen test. ***Since the FDA had not approved this test for an EUA, the test system is a lab developed test (high complexity testing). 3. A review of the laboratory's personnel records for testing person #1 and testing person #2 revealed both testing personnel had documentation of a high school diploma, which does not qualify them to perform high complexity testing. 4. An interview with testing person #1 on 8/27/21 at 2:00 p.m. in the laboratory, after review of the records, confirmed the above findings.