Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2258440	10/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cire Labs Llc	513 Baylor Court Suite B, Chesapeake, VA	

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 announced CLIA initial survey was conducted on-site at Cire Labs, LLC on October 18-19, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The onsite inspection also included a virtual exit interview with the laboratory director, administrative business manager, technical supervisor, and managing member on 10/20/22. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and was in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CRC part 493 CLIA Requirements. Specific deficiencies cited are as follows and includes three Conditions under 42 CRC part 493 CLIA Regulation: D5400 -42 CRC. 493.1250 Analytic Systems D6076 -42 CRC. 493.1441 Laboratory Director D6168 -42 CRC. 493.1487 Condition Testing Personnel
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 tour, review of procedures, manufacturer's package inserts, daily temperature/environment logs, result data logs, lack of documentation, and interviews the laboratory failed to: 1. ensure that two (2) of 2 patient Seasun Biomaterials TOP viral specimens for COVID-19 testing were stored at 2-8 degrees Celsius (C) per the approved procedure as observed during the inspection on October 18, 2022; 2. monitor daily room relative humidity (%) levels to ensure manufacturer's requirements were followed for the Seasun Biomaterials SmartAmp Gene

	Amplificator analyzer for the timeframe of the test validation steps in April 2022 to the date of the inspection on October 18-19, 2022; 3. evaluate, verify/validate the performance specifications for the high complexity AQ-TOP COVID-19 reverse transcriptase Real-Time Loop Mediated Isothermal Amplification (RT-LAMP) assay on the Seasun Biomaterials SmartAmp Gene Amplificator instrument for patient COVID-19 testing prior to reporting eighty patient results during the timeframe of August 2, 2022 up to the inspection on October 18-19, 2022; 4. document relative centrifugal force verification for the microplate centrifuge utilized in patient sample processing for RT-LAMP COVID-19 assays during the timeframe of the test validation steps in April 2022 and up to the date of the inspection on October 18-19, 2022. See D5401, D5413, D5421, D5435.
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 a tour, review of procedures, manufacturer's package inserts, and interviews, the laboratory failed to ensure that two (2) of 2 patient Seasun Biomaterials TOP viral specimens for COVID-19 testing were stored at 2-8 degrees Celsius (C) per their approved procedure as observed during the inspection on October 18, 2022. Findings include: 1. During a tour on 10/18/22 at approximately 1 PM, the inspector noted the laboratory's freezer temperature recorded as -20.78 degrees Celsius (C) on the attached Delta Trac digital thermometer. A review of the freezer contents revealed Seasun Biomaterials test reagents and the following patient Seasun Biomaterials TOP viral collection tube specimens labeled with accompanying requisitions for Cire Labs, LLC PCR COVID-19 testing stored for future batch testing: ID #8791 collected on 10 /17/22 at 5 PM, ID #1625 collected on 10/18/22 at 12:29 PM 2. Review of the laboratory's policy manual revealed a procedure (titled: COVID-19 PCR Testing) that stated under Specimen Collection, Storage and Handling: "Specimens may be stored at 2-8 degrees Celsius for up to 72 hours". 3. Review of the Seasun Biomaterials TOP Virus Collection Kit for COVID-19 manufacturer's package insert revealed the following instructions: Warnings and Limitations: "Freezing of samples should be avoided" 4. The inspector inquired regarding a description of the laboratory's routine specimen storage protocols. The administrative business manager stated on 10/18/22 at approximately 2:30 PM, "The samples are routinely placed with the requisitions in the freezer because we batch them before we make a run." 5. The inspector inquired regarding the observed lack of refrigerator unit in the laboratory as it pertained to the policy and manufacturer's instructions for the COVID-19 PCR samples to be store at refrigerated 2-8 C. The laboratory's managing member stated on 10/18/22 at approximately 3:00 PM, "We do not have a refrigerator for the laboratory. I will get one ordered today." 6. A virtual exit interview with the lab director, administrative business manager, lab technical supervisor, and managing member on 10/20/22 at approximately 4:00 PM, confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of procedures, manufacturer's user manual, daily temperature /environment logs, patient test logs, lack of documentation, and interviews, the laboratory failed to monitor daily room relative humidity (%) levels to ensure manufacturer's requirements were followed for the Seasun Biomaterials SmartAmp Gene Amplificator analyzer for the timeframe of the test validation steps in April 2022 to the date of the inspection on October 18-19, 2022. Findings include: 1. Review of the facility's laboratory procedure manual revealed a Seasun Real-Time Gene Amplificator User Manual that stated, "Section 4.4 Storage and Use Conditions: Relative Humidity limit of 15-95 % ". The inspector noted that the procedure manual included a validation correlation was conducted for the Seasun Gene Amplificator in April 2022. 2. Review of the available temperature/environment log records from April 2022 to 10/18/22 revealed no laboratory room humidity monitoring. 3. Review of the Seasun Real-Time Gene Amplificator patient test logs revealed the following dates that patient COVID-19 results were reported: 8/2/22, 8/4/22, 8/9/22, 8/16/22, 8 /17/22, 8/19/22, 8/23/22, 8/25/22, 8/26/22, 8/30/22, 9/9/22, 9/14/22, 9/16/22, 9/21/22, 9/22/22, 9/23/22, 9/28/22, 10/4/22, 10/5/22, 10/6/22, 10/11/22, 10/13/22, 10/14/22. 4. The inspector requested to review corrective action for lack of humidity monitoring according to the manufacturer's specification for the dates of the correlation study in April 2022 and for the dates of patient testing outlined above. No records were available for review. 5. A virtual exit interview with the lab director, administrative business manager, lab technical supervisor, and managing member on 10/20/22 at approximately 4:00 PM, confirmed the above findings.
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 a tour of the lab, review of procedures, result data logs, lack of documentation, and interviews, the laboratory failed to evaluate, verify/validate the performance specifications for the high complexity AQ-TOP COVID-19 reverse transcriptase Real-Time Loop Mediated Isothermal Amplification (RT-LAMP) assay on the Seasun Biomaterials SmartAmp Gene Amplificator instrument for patient SARS-CoV-2 (COVID-19) prior to reporting eighty (80) patient results during the timeframe of an initial test validation activity in April 2022 to the date of the

	inspection on October 18-19, 2022. Findings include: 1. During a tour of the laboratory on 10/18/22 at approximately 1 PM, the inspector noted one Seasun SmartAMP Real-time Gene Amplificator and Seasun Biomaterials RT-LAMP assay in use for COVID-19 PCR testing. 2. Review of the laboratory procedures revealed a record (titled: Validation Studies of AQ-TOP Covid Detection Kit and Seasun Fluorescence) signed by the lab director dated 04/05/22. The document included a chart that recorded twenty (20) correlation samples with a reference laboratory. The chart indicated that Cire Labs, LLC resulted nineteen (19) negative results that correlated with the reference laboratory's negative PCR results. The chart also indicated that Cire Labs, LLC resulted one (1) positive result that did not correlate with a negative PCR resulted from the reference laboratory. 3. The inspector requested to review additional validation study findings that included verification of precision prior to patient testing and inquired regarding additional split sample results for a comparison of positive results. No additional performance specification /validation results were available for review. 4. Review of the SmartAmp Gene Amplificator instrument test test logs from 08/01/22 to 10/13/22 revealed the following patient results were reported: Forty (40) negative; Twenty-eight (28) positive; Twelve (12) inconclusive; A total of 80 test patients assayed and resulted. 5. A virtual exit interview with the lab director, administrative business manager, lab technical supervisor, and managing member on 10/20/22 at approximately 4:00 PM, confirmed the above findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, manufacturer's package inserts, lack of documentation, and interviews, the laboratory failed to document relative centrifugal force (RCF g force) verification for the microplate centrifuge utilized in patient sample processing for reverse transcriptase Real-Time Loop Mediated Isothermal Amplification (RT-LAMP) COVID-19 assays during the timeframe of the test validation steps in April 2022 to the date of the inspection on October 18-19, 2022. Findings include: 1. During a lab tour with the laboratory's administrative business manager on 10/18/22 at approximately 1 PM, the inspector noted a Southwest Science Microplate Centrifuge (Model SC20-Plate) in use for COVID-19 RT-LAMP specimen elution/processing. 2. Review of the laboratory procedures and manufacturer's package inserts revealed the following stated instructions: Covid PCR Testing Procedure - "Limitations of method: The specimens to be tested must be processed in accordance with the conditions specified in the instructions. Inappropriate specimen preparation and operation may lead to inaccurate results. Extraction of nucleic acid from samples must be performed according to the specified methods. Other extraction approaches have not been evaluated". Seasun Biomaterials Extraction Kit - "Items prepared by users: Equipment, Centrifuge with speed >7,500

	g" Seasun AQ-TOP Covid-19 Rapid Detection Kit Procedure Workflow Instruction Sheet - "For Wash and Elution Centrifuge at >7,500 g for 1 min" Southwest Science Microplate Centrifuge Model SC20-Plate Package Insert: "Specifications: Max speed is 2550 RPM, Max RCF is 600 g". 3. The inspector requested to review documentation of the centrifuge RCF verification for the required >7,500 g setting according to the procedures/manufacturer's instructions outlined above. No RCF calibration or verification documentation for the Southwest Science Model SC20-Plate was available on the date of the survey 10/18/22. 4. A virtual exit interview with the lab director, administrative business manager, lab technical supervisor, and managing member on 10/20/22 at approximately 4:00 PM, confirmed the above findings.
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 a review of the laboratory procedure manual, lack of documentation, and interviews, the laboratory failed to establish/follow a written policy to identify and address analytic issues in order to monitor, assess and correct problems in the sub speciality of virology for the timeframe from April 2022 up to the initial inspection on October 18-19, 2022. Findings include: 1. Review of the laboratory's AQ-TOP COVID-19 reverse transcriptase Real-Time Loop Mediated Isothermal Amplification (RT-LAMP) assay and Seasun Biomaterials SmartAmp Gene Amplificator instrument procedures revealed no quality assurance (QA) plan to monitor, assess and correct problems with the virology test procedures. 2. The inspector requested to review laboratory QA protocols for specimen and reagent storage conditions, equipment /instrument/test/system maintenance and function checks, establishment and verification of method performance specifications, calibration and calibration verification, comparison of test results, review of quality controls, and corrective /remedial action plans. No QA plan or review records were available for review upon request. 3. A virtual exit interview with the lab director, administrative business manager, lab technical supervisor, and managing member on 10/20/22 at approximately 4:00 PM, confirmed the above findings.
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 a tour, review of manufacturer's user manual, test logs, analyzer online test records, lack of documentation, and interviews, the laboratory failed to maintain a mechanism to ensure the accuracy of manually transcribed patient SARS-CoV-2 (COVID-19) results reported from the Seasun Biomaterials SmartAmp Gene

	Amplificator analyzer during the timeframe of August 2022 to the date of the survey October 18-19, 2022. Findings include: 1. During a tour of the laboratory on 10/18/22 at approximately 1 PM, the inspector noted a Seasun SmartAMP Real-time Gene Amplificator and Seasun Biomaterials RT-LAMP assay in use for COVID-19 testing. A conversation with the administrative business manager at approximately 1:30 PM, revealed that the patient results are manually transcribed onto the laboratory's COVID-19 test report and then are scanned by the nursing staff into the electronic medical record. 2. Review of the SmartAmp Gene Amplificator analyzer user guide revealed instructions for entering patient identification numbers for each microplate sample well utilized on the assay run that stated, "Select Sample ID, select positive control, negative control, enter each of the sample ID's in the SAMPLE ID A1-A8/B1-B8 window, each run allows a set up of 16 samples, the positive and negative control can be selected with the 16". 3. The inspector requested to review the test logs for the timeframe of August 2022 to 10/19/22. The following dates of testing and patient ID number results were reviewed: August 2022: 8/02 - ID 9272, 12507, 12454, 11624, 12241; 8/04 - ID 11984, 12549, 10245, 9454; 8/09 - ID 12529, 12258, 12677, 12660; 8 /16 - ID 11887, 8775, 12567; 8/17 - ID 12416; 8/19 - ID 1527, 12763; 8/23 - ID 8874, 11780, 12464, 1417, 7587, 1727 8/25 - ID 8361, 1993, 11036; 8/26 - ID 1442; 8/30 - ID 12166; 30 patients resulted in August 2022. September 2022 9/09 - ID 11894, 11665; 9/14 - ID 5658, 5514, 12508, 10918, 9402, 12002, 7636, 9790, 6666, 12020, 6226, 8975, 10627; 9/16 - ID 11533, 11431, 12262, 9402, 1592; 9/21 - ID 10605, 12455, 12189; 9/22 - ID 11456, 12615; 9/23 - ID 11373, 10923, 4879, 11429; 9/28 - ID 12877, 7696, 9769, 4953; 33 patients resulted in August 2022. October 2022 10/04 - ID 9963, 12884, 12753, 12886, 12227, 9732, 11615, 10239; 10/05 - ID 12580; 10/06 - ID 12463, 12572; 10/11 - ID 12634, 3924, 5088; 10/13 - ID 11688, 11393; 10/14 - ID 11776 17 patients resulted in October 2022 up to 10/14/22. 4. The inspector requested to review the SmartAmp Gene Amplificator analyzer's data records that correlated with the timeframe of the test log results outlined above. The review of the analyzer's results revealed no patient ID's were entered for the test wells on the assay runs dated 08/02/22 to 10/11/22. The inspector inquired regarding the lack of patient identifiers on the SmartAMP PCR amplification microplate well assignments on the assay runs prior to 10/13/22. The administrative business manager stated on 10/19/22 at approximately 12 noon, "We did not enter the patient ID into the SmartAMP prior to last week. We just started to enter the patient ID's. The techs ran the samples in order based on the order of the test requisitions log." 5. Review of the procedure manual revealed no quality assurance policy for monitoring/evaluating the accuracy of the laboratory's COVID-19 PCR manually entered test reports. The inspector requested to review documentation of accuracy reviews of manually transcribed patient COVID-19 results. No chart review/periodic quality audits were available for review for the timeframe of patient testing outlined above. 6. A virtual exit interview with the lab director, administrative business manager, lab technical supervisor, and managing member on 10/20/22 at approximately 4:00 PM, confirmed the above findings.
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 tour of the lab, review of procedures, manufacturer's user manual, test result logs, analyzer online test records, lack of documentation, and interviews, the laboratory director failed to: 1. ensure that the performance specifications for the high complexity Seasun Biomaterials SmartAmp Gene Amplificator instrument was evaluated to determine accuracy and precision prior to reporting eighty patient results during the timeframe of an initial test validation activity in April 2022 to the date of the inspection on October 18-19, 2022; 2. ensure quality assessment mechanisms were defined to identify and address analytic issues in the sub speciality of virology from the timeframe of initial validation steps in April 2022 up to the date of the inspection, October 18-19, 2022; See D6086, D6094.
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 tour of the lab, review of procedures, patient test logs, lack of documentation, and interviews, the laboratory director failed to ensure that the performance specifications for the high complexity AQ-TOP COVID-19 reverse transcriptase Real-Time Loop Mediated Isothermal Amplification assay utilized on the Seasun Biomaterials SmartAmp Gene Amplificator instrument was evaluated to determine accuracy and precision prior to reporting eighty patient results during the timeframe of an initial test validation activity in April 2022 to the date of the inspection on October 18-19, 2022. Cross Reference D5421.
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 a tour, the review of procedures, manufacturer's user manual, test logs, analyzer online test records, lack of documentation, and interviews, the lab director failed to ensure that documentation of written/approved quality assessment mechanisms were defined to identify and address analytic issues in the sub speciality of virology from the timeframe of initial start up in April 2022 up to the date of the inspection, October 18-19, 2022. Cross Reference D5791, D5891
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

	This STANDARD is not met as evidenced by: Based on a tour, review of procedures, manufacturer's package inserts, test logs, and interviews, the technical supervisor (TS) failed to ensure that patient viral specimens for high complexity COVID-19 testing were maintained/stored at 2-8 degrees Celsius (C) per procedure/manufacturer's package instructions prior to processing/reporting eighty (80) test results during the timeframe of August 2022 to the inspection of October 18-19, 2022. Cross Reference D5401. Findings include: 1. During a tour of the laboratory on 10/18/22 at approximately 1 PM, the inspector noted the freezer temperature recorded as -20.78 degrees Celsius (C) on the attached Delta Trac digital thermometer. A review of the freezer contents revealed the following patient Seasun Biomaterials TOP viral specimens labeled with accompanying requisitions for Cire Labs, LLC PCR COVID-19 testing stored for future batch testing: ID #8791 collected on 10/17/22 at 5 PM, ID #1625 collected on 10/18/22 at 12:29 PM 2. Review of the laboratory's policy manual revealed the following statements: COVID-19 PCR Testing Procedure - "Specimen Collection, Storage and Handling: Specimens may be stored at 2-8 degrees Celsius for up to 72 hours"; Seasun Biomaterials TOP Virus Collection Kit for COVID-19 manufacturer's package insert - "Warnings and Limitations: Freezing of samples should be avoided". 3. The inspector inquired regarding the laboratory's routine specimen storage protocols. The administrative business manager stated on 10/18/22 at approximately 2:30 PM, "The samples are placed with the requisitions in the freezer because we batch them before we make a run." 4. The inspector inquired regarding the observed lack of refrigerator unit in the laboratory as it pertained to the policy and manufacturer's instructions for the COVID-19 PCR samples to be store at refrigerated 2-8 C. The laboratory's managing member stated on 10/18/22 at approximately 3:00 PM, "We do not have one but I will get a refrigerator for the laboratory." 5. Review of the rapid RT-LAMP COVID-19 test test logs from 08/01/22 to 10/13/22 revealed a total of 80 test patients were assayed /reported on batched runs while no refrigerator temperatures were documented. 6. A virtual exit interview with the lab director, administrative business manager, TS, and managing member on 10/20/22 at approximately 4:00 PM, 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 CLIA Laboratory Personnel Report Form, available testing personnel (TP) files, lack of documentation, and an interview, the laboratory failed to ensure that three of seven TP qualified to perform high complexity testing as observed on the date of the initial inspection October 18-19, 2022. See D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy,

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

This STANDARD is not met as evidenced by:
Based on a review of the CLIA Laboratory Personnel Report Form (CMS-209 Form),

	available testing personnel (TP) files, lack of documentation, and interviews, the laboratory failed to retain education records to ensure documentation that three (3) of seven (7) TP were qualified to perform high complexity testing during the review timeframe of August 2022 and up to the date of the initial CLIA inspection on October 18-19, 2022. Findings include: 1. Review of the laboratory's CMS 209 form revealed that the lab director identified 7 TP as responsible for performing high complexity AQ-TOP COVID-19 reverse transcriptase Real-Time Loop Mediated Isothermal Amplification (RT-LAMP) and operating the Seasun Biomaterials SmartAmp Gene Amplificator instrument for patient COVID-19 testing. 2. Review of the available laboratory personnel records revealed no education documentation for TP 1-3 (See Personnel Code Sheet attached). The inspector requested to review education documentation for the TP outlined above. No records were available for review. The inspector noted: TP 1 - initial training recorded on 08/01/22 by the technical supervisor, TP 2 - initial training in process, TP 3 - initial training in process. 3. A virtual exit interview with the lab director, administrative business manager, lab technical supervisor, and managing member on 10/20/22 at approximately 4:00 PM, confirmed the above findings.