Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1051792	12/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
O'Hare Clinical Labs	4909 W Division St Ste #302, Chicago, IL	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the laboratory's testing menu; procedures manual; laboratory records; and interview with the laboratory director (LD) the laboratory failed to be enrolled in HHS approved Proficiency Testing (PT) Program. Findings: 1. Review of the laboratory's testing menu revealed that the laboratory performs Real - Time (PCR) COVID- 19 Testing. 2. Review of the laboratory's procedure manual revealed that the laboratory had a policy titled, "Proficiency Testing Policy." it states, "a. The Laboratory will participate in Proficiency Testing (PT) Program available through a CMS approved provider. b. Each year and on introduction of new test, the Laboratory Director (LD) will review laboratory test menu to make sure that the laboratory is enrolled in a PT program that cover all in-house tests." 3. On December 30, 2020 at 12:00 PM, the surveyor requested PT records. The laboratory director told the surveyor that they had not enrolled in PT yet. 4. On December 30, 2020 at 12:15 PM, the LD confirmed the surveyor's 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 review of manufacturer's instrucitons, patients' test records, and interview with the Technical Supervisor (TS is the lab owner), the laboratory failed to report COVID-19 (SARS-CoV-2) test results to the Secretary during the Public Health Emergency. Findings: 1. Review of the Manufacturers 2. On December 30, 2020, at 2: 00 PM, the surveyor selected a total of 93 patients' test reports for COVID - 19 tests performed between December 2, 2020 through December 29, 2020, Five of 93 patients' tests reports were Positive for COVID -19 and 88 of 93 patients test reports were Negative for COVID-19. 3. On December 30, 2020 at 2:15 PM, the surveyor asked the Technical Supervisor to show her how results get reported to Public Health. The Technical Supervisor told the surveyor he gives the results to the " accountant" (lab adminstrator) to enter into a portal. The surveyor was told that this was not done at this location. 4. There was no documenation to show that COVID tests results were reported to Public Health for 93 of 93 test reports reviewed. 5. On December 30, 2020 at 2:20 PM, the TS confirmed the surveyor's findings.
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 observation and interview with the Laboratory Director (LD), safety procedures were not established and observed to ensure protection form physical chemical, biochemical, and electrical hazards, and biohazardous materials. Findings: 1. On December 30, 2020 at 1:00 AM, the surveyor was given a tour of the lab. The surveyor observed that that testing personnel entered the lab through an open doorway from a kitchen (clean area) or break area. The 1st area through the kitchen door is where extraction of patients' specimens is performed. There is a huge open window and another door leaving the extraction area that leads to the area where PCR amplification is performed. The surveyor observed that each phase of testing was performed in open areas with no doors. 2. On December 30, 2020 at 11:00 AM, the surveyor observed testing personnel wearing their masks, gloves, and lab coats in the kitchen of the laboratory. They would go back and forth from the lab to the kitchen and back again without removing their gloves, lab coats, and/or masks. 3. On December 30, 2020n at 11:15 AM, the LD confirmed the surveyor's findings.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208

	If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedures manual; verification records; quality control (QC) records; patients' test reports, and interview with the laboratory director (LD), the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299 for the subspecialty of General Immunology for its COVID-19 Real- Time PCR tests. Findings: 1. Review of the laboratory's procedure manual revealed, the laboratory lacked a comprehensive procedure manual that is approved by the current LD. See tags D5403 and D5407 2. There was a lack of documentation to show that the laboratory verified its Real - Time PCR test methods for the presence of COVID-19 prior to testing patients' specimens. See tag D5421 3. There was a lack of QC records. On December 30, 2020 at 2:30 PM, the surveyor requested that the lab show her just 10 QC records for patients tested from December 2, 2020 to December 29, 2020. Neither the LD nor the Technical Supervisor knew how to access QC records. See tag D5455 4. Review of 93 patients' test reports show that the incorrect address of the laboratory is recorded on 93 of 93 reports reviewed. See tag D5805.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and interview with laboratory director (LD), the laboratory did not provide testing personnel with a comprehensive procedures manual that was specific to O'Hare Clinical Laboratory Service. Findings: 1. Review of the laboratory's procedures manual revealed, the laboratory procedures manual is a generic procedure that is "shopped" around to numerous labs. It is verbatim to a procedure manual the surveyor reviewed 2 weeks ago in a different laboratory with different tests; and not specific to any one lab. These procedures

	manual did not include the following as it pertained to COVID-19 testing: (A) 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. (B) Step-by-step performance of the procedure, including test calculations and interpretation of results. (C) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (D) Calibration and calibration verification procedures. (E) The reportable range for test results for the test system as established or verified in 493.1253. (F) Control procedures. (G) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (H) Limitations in the test methodology, including interfering substances. (I) Reference intervals (normal values). (J) Imminently life-threatening test results, or panic or alert values. (K) Pertinent literature references. (L) 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. (M) Description of the course of action to take if a test system becomes inoperable. 2. On December 30, 2020 at 3:00 PM, the LD confirmed the surveyor's findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures manual and patients' test reports; observations; and interview with the laboratory director (LD), procedures were not approved, signed, and dated by the current laboratory director before use. Findings: 1. On December 30, 2020 at 11:30 AM, review of the laboratory's procedures manual revealed that the current laboratory director had not approved signed and dated the laboratory's procedure manual. 2. On December 30, 2020 at 2:00 PM, the surveyor reviewed a total of 93 patients' test reports for COVID -19 test results. There were COVID-19 test results documented on 93 of 93 test reports reviewed. 3. On December 30, 2020 at 2:00 PM, the surveyor observed the laboratory performing COVID-19 testing prior to the approval of the laboratory's procedure manual by the current LD. 4. On December 30, 2020 at 3:00 PM, the LD confirmed the surveyor's 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 review of the laboratory's application for CLIA Certification (Form 116); test menu; laboratory equipment; validation records; patients' test reports; and

	interview with laboratory director, the laboratory failed to be responsible for demonstrating that it can obtain performance specifications comparable to those established by the manufacturer: Findings: 1. Review of Form 116 revealed that the laboratory performed 15,000 COVID-19 TESTS using the following equipment: A. Thermo Fisher Scientific KingFisher Flex - automated Extraction instrument B. Thermo Fisher Scientific Quant Studio 5 Real Time PCR System C. Thermo Fisher Scientific Step One Plus Real Time PCR System D. Bio Rad CFX96 Touch Real-Time PCR Detection System 2. Review of the laboratory's test menu revealed that the laboratory only performs Real-Time PCR for the presence of COVID - 19. 3. On December 30, 2020 at 10:30 AM, the surveyor was given a tour of the laboratory. During the surveyor's tour of the laboratory, she observed the following instrumentation: A. Thermo Fisher Scientific KingFisher Flex - automated Extraction instrument B. Thermo Fisher Scientific Quant Studio 5 Real Time PCR System C. Thermo Fisher Scientific Step One Plus Real Time PCR System D. Bio Rad CFX96 Touch Real-Time PCR Detection System 4. On December 30, 2020 at 11:30 AM, the surveyor requested validation records. The surveyor was given a "Validation Report", dated 11/16/20 and signed by the former laboratory director (not the current director). The report reads, "Thirty patient samples were tested using PCR Step one plus1, PCr BioRad CFX, PCR Step one plus 2 utilizing Thermo-Fisher, and PCR Step one plus 1, PCR BioRad CFX, PCR One plus 2 utilizing Promega. The PCR results were compared generated from both extraction methods were compared." 5. There was no documentation to show that the required CDC validation specimens were used to show the performance characteristics of each of the following: A. Thermo Fisher Scientific KingFisher Flex - automated Extraction instrument B. Thermo Fisher Scientific Quant Studio 5 Real Time PCR System C. Thermo Fisher Scientific Step One Plus Real Time PCR System D. Bio Rad CFX96 Touch Real-Time PCR Detection System 6. On December 2020 at 2:00 PM, review of 93 patients' test reports revealed 93 of 93 patients' test results were reported before Real-Time PCR tests were validated. 7. On December 30, 2020 at 3:00 PM, the LD confirmed the surveyor's findings.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's testing menu; patients' test reports; and interview with the laboratory director (LD), the laboratory failed to test two control materials each day COVID- 19 tests were performed on patients' specimens. Findings: 1. Review of the laboratory's testing menu revealed the laboratory performs COVID- 19 Real - Time (RT) PCR testing. 2. On December 30, 2020 at 2:00 PM, the surveyor reviewed 97 patients' test reports for COVID - 19 Test results reported from December 2, 2020 through December 29, 2020. There were COVID - 19 Test results recorded on the Test report for 93 of 93 test results reported. 3. On December 30, 2020 at 2:30 PM, the surveyor requested corresponding Quality Control (QC) records

	for at least 10 of the days (December 2, 2020 to December 29, 2020) when patients specimens were analyzed; and results reported. Neither the LD nor Technical Supervisor knew how to retrieve QC records. One of the consultants from the consulting firm printed 1 QC record from the month of November 2020. The surveyor told the LD and TS that she did not ask for QC for the month of November. 4. There was no QC documentation made available to the surveyor for 10 of 10 days of QC requested by the surveyor. 5. On December 30, 2020 at 3:00 PM, the LD confirmed the surveyor's findings.
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 the CLIA application for Certification (CMS 116); COLA letter of confirmation; patients' test reports; and interview with the Technical Supervisor (owner) of the laboratory, the test report did not indicate the name and address of the laboratory location where the test was performed. 1. Review of the CMS 116 revealed that the laboratory's facility name is "O'Hare Clinical Laboratory, located at 4909 W Division St., Chicago, IL 60651. 2. On December 29, 2020 at 1:30 PM, the Technical Supervisor submitted a COLA confirmation letter, addressed to the previous laboratory director, dated December 29, 2020. The address on the letter was 4909 W Division St., Chicago, IL 60651. 3. On December 30, 2020 at 2:00 PM, the surveyor reviewed 97 patients' test reports. There was no documentation to show the laboratory's current location of 4909 W Division St., Chicago, IL for 93 of 93 patient's test reports reviewed. 4. On December 30, 2020 at 2;30 PM, the Technical Supervisor confirmed the surveyor's 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 review of laboratory procedures' manuals; personnel records; and interview with the laboratory director, the laboratory failed to have a director who meets the qualification requirements of 493.1443. Findings: 1. The laboratory did not have a qualified laboratory director. See tag D6078.
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443

The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies and procedures manual; Laboratory Personnel Report - CLIA (Form 209); Personnel records; and interview with the Laboratory Director (LD), the Laboratory Director failed to be certified by a board approved by HHS. Findings: 1. Review of the laboratory's policies and procedures manual revealed, in a section titled, "CLIA High Complexity Laboratory" under a section titled, "Laboratory Director," under # 5, Option 4, it states, "Doctor degree in a chemical, physical, biological or clinical laboratory science with board certification." 2. Review of Form 209 revealed, a new person is listed as LD of the laboratory. 3. Review of the LD's personnel records revealed the LD's foreign credentials were reviewed by Education International Evaluating Service. On May 14, 1992, Education International Evaluating Service indicated that the LD had the US equivalent of a PhD in Biochemistry. There was no documentation to show that the LD is Board Certified. 4. On December 30, 2020 at 11:00 AM, the surveyor asked the LD if he was Board Certified. The LD told the surveyor, that he is not Board Certified. Therefore, the surveyor asked him if he had every directed a lab before. The LD stated that he had never directed a lab before. 5. On December 30, 2020 at 11:15 AM, the LD confirmed the surveyor's findings.

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 review of Laboratory Personnel Report (Form 209); procedures manuals; personnel records; and interview with the technical supervisor (TS), the technical supervisor failed to be responsible for evaluating the competency of all testing personnel performing Real-Time PCR COVID Tests. Findings: 1. On December 30, 2020 at 10:30 AM, review of Form 209 revealed that there are a total of 3 testing personnel listed on Form 209. 2. Review of the laboratory's procedures manual revealed there is a form titled Laboratory Personnel Competency Assessment. 3. On December 30, 2020 at 10:30 AM, review of personnel records revealed that there was no documentation to show that testing personnel's competency was assessed for 3 of 3 testing personnel. 4. On December 30, 2020 at 11:00 AM, the technical supervisor confirmed the surveyor's findings.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory procedures' manuals; personnel records; and interview with the laboratory director, the laboratory failed to have a clinical consultant who meets the requirements of 493.1455. Findings: 1. The laboratory did not have a qualified clinical consultant. See tag D6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual; Laboratory Personnel Report-CLIA (Form 209) and personnel records, the Clinical Consultant failed to be qualified

	to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. Findings: 1. Review of the laboratory's procedures manual revealed that the laboratory performed Real -Time (RT) - PCR COVID- 19 Testing. 2. Review of Form 209 revealed that Person #1 (as listed on the 209) is listed as laboratory director, clinical consultant, and technical supervisor of the laboratory. 3. Review of personnel records revealed that Person #1 does not have credentials that qualify him to direct High Complexity Tests. See tag D6078. 4. Review of personnel records revealed that Person #1 does not have credentials that show He is a Doctor of Medicine licensed to practice medicine in the State of Illinois. 5. On December 30, 2020 at 11:30 AM, the LD confirmed the surveyor's 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 review of the laboratory's testing menu; application for CLIA Certification (Form 116) observation; Laboratory Personnel Report - CLIA (Form 209); personnel records; and interview with Testing Personnel (TP), there was an insufficient number of individuals who meets the qualifications required for the volume and complexity of tests performed. Findings: 1. Review of the laboratories testing menu revealed the laboratory performs COVID- 19 Real-Time (RT) PCR tests. 2. Review of the laboratory's application for CLIA Certification revealed that the laboratory's total test volume for COVID - 19 tests is 15,000 from November 2020 to December 2020. 3. On December 29, 2020 at 12:00 PM, during a State of Illinois Complaint Investigation, the surveyor observed 3 persons performing extraction of patients' specimens. TP #s 1, 3 and 4 (as listed on Form 209). TP # 2 (as listed on Form 209) arrived in the lab at 1:00 PM. TP #2 is the owner of the lab. TP #s 1, 3, and 4 told the surveyor that they only perform the extraction part of the test. And another person (who was not in the lab) performs the PCR part of the test. The person performing the PCR told the surveyor that he was from a consulting agency and was not part of the laboratory staff. 4. On December 30, 2020 at 10:30 AM, review of personnel records revealed there was no documentation to show the educational qualifications for 1o 3 persons performing COVID-19 RT PCR. None of which were performs the PCR amplification part of the testing process. See tag D6171 5 On December 30, 2020 at 11:00 AM, the LD confirmed the surveyor's findings.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60

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

This STANDARD is not met as evidenced by:
Based on review of the laboratory's test menu; Laboratory Personnel Report - CLIA (Form 209); personnel records; and interview with the laboratory director (LD), testing personnel (TP) failed to have documentation to show the highest US equivalent education achieved. Findings: 1. Review of the laboratory's test menu revealed the laboratory performed Real-Time PCR COVID - 19 tests. 2. Review of Form 209 revealed there are 3 persons (#2, #3, and #4 as listed on Form 209) listed as High Complexity Testing Persons. 3. There was no documentation to show the highest

	level of education achieved, equivalent to the US for 1 of 3 testing personnel (Person # 4 as listed on Form 209) performing High Complexity Tests. 3. On December 30, 2020 at 11:30 AM, the LD confirmed the surveyor's findings.