Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1078862	09/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Alpha Medical Llc	8635 Lemont Rd, Downers Grove, 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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor review of the laboratory records, proficiency testing (PT) reports, and interview with the laboratory director (LD); the laboratory failed to properly manage and evaluate the overall quality of testing. The laboratory must meet the requirements in 493.1231 through 493.1236. Findings include: 1. The laboratory failed to verify the accuracy of the Semen Analysis tests it performs in the laboratory. See D5213. 2. The laboratory failed to verify the accuracy bi-annually for semen analysis, microscopic urinalysis, lupus anticoagulants, antiphospholipid antibody ELISA assays, and reproductive immuno phenotype testing performed. See D5217.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on record review, proficiency testing (PT) reports, and an interview with the

	laboratory director (LD), the laboratory failed to verify the accuracy of the Semen Analysis tests it performs in the laboratory. Findings include: 1. The American Association of Bio analysts (AAB) and American Proficiency Institute (API) PT programs' report, quality control (QC) logs, procedures manual, and patients' final reports were reviewed for the year 2018, 2019, and 2020 for Semen Motility and General Immunology. 2. The PT programs results for Semen Analysis revealed the following: *AAB 2018 Event #2 - Semen Analysis - scored "50%"; *AAB 2019 Event #1 - Sperm Count - score "Not Graded"; *AAB 2019 Event #2 - No documentation provided by LD, no evidence of participation; *API 2020 Event #1 - Sperm Count - scored "100%" 3. The laboratory failed to follow its PT policy to evaluate all PT failures and "no scores". 4. Sperm analysis were performed and reported on 65 patients during the period of 08/25/18 thru 02/25/2020, when the accuracy of it's testing had not been verified. 5. On a Recertification survey 09/02 /2020 at 5:45 PM, the LD 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 record review, proficiency testing (PT) reports, and an interview with the laboratory director (LD), the laboratory failed to verify the accuracy twice annually for semen analysis, microscopic urinalysis, lupus anticoagulants, antiphospholipid antibody ELISA assays, and reproductive immuno phenotype testing performed. Findings include: 1. The American Association of Bio analysts (AAB) and American Proficiency Institute (API) PT, and Medical Laboratory Evaluation (MLE) PT programs' reports, split sample PT reports, quality control (QC) logs, procedures manual, and patients' final reports were reviewed for 2018, 2019, and 2020. Semen Analysis: 2. The final reports of 5 patients selected for review revealed the following results: *Total Count (Sperm) *Total Motility *Prog. (Progressive) Motility *NonProg (Non-Progressive) Motility *Immotile, *Total Motile Count, and *Morphology 3. The AAB and API PT program reports reviewed for 2018, 2019, and 2020 showed the laboratory participated in Total Sperm count and Sperm morphology only. 4. Further review of PT documentation found no bi-annual method to verify accuracy was performed by the laboratory in 2018, 2019 and 2020 for Sperm motility analysis. 5. Sperm motility analysis were performed and reported on 65 patients during the period of 08/25/18 thru 02/25/2020, when the accuracy of it's testing had not been verified. 6. Interview with the LD on 09/02/2020 at 10:30 am confirmed the above findings. Microscopic Urinalysis: 7. Review of MLE PT for 2018, 2019, and 2020 identified the laboratory failed to enroll in microscopic urinalysis PT in 2020. 8. Further review of PT documentation found no bi-annual method accuracy was performed by the laboratory in 2020 for microscopic urinalysis. 9. Interview with the LD on 9-2-2020 at 3:20pm confirmed the laboratory failed to enroll in PT for microscopic urinalysis testing in 2020 with MLE and no alternative arrangements were made to verify the accuracy of this test. 10. Microscopic urinalysis was performed and reported for 148 patients from September of 2019 to August 31, 2020. Lupus Anticoagulant (Lupus Screen): 11. Review of PT documentation found no record of bi-annual method accuracy of lupus anticoagulant testing performed on the ACL 1000 analyzer. 12. Interview with the LD on 9-2-2020 at 3:20pm confirmed the laboratory failed to verify the accuracy of lupus anticoagulant testing in 2018, 2019,

	and 2020. 13. Lupus Screen testing was performed and reported for 25 patients from September of 2019 to August 31, 2020. Antiphospholipid Antibody (APA) ELISA assays: 14. Review of split sample proficiency documentation for APA testing revealed the laboratory failed to perform bi-annual evaluations in 2018 and 2019. 2019 - 1 Review was completed 4-9-2019. 2018 - No reviews documented. 15. APA testing was performed and reported for 216 patients from September of 2019 to August 31, 2020. Reproductive ImmnoPhenotype (RIPh) testing: 16. Review of split sample proficiency documentation for RIPh testing revealed the laboratory failed to perform bi-annual evaluations in 2019. 2019 - 1 Review was completed 5-29-2019. 17. RIPh testing was performed and reported for 338 patients from September of 2019 to August 31, 2020. 18. On a Recertification survey conducted on 09/02/2020 at 5:45 PM, the LD 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 direct observation, record and manual review, manufacturer's instructions, and an interview with the laboratory director (LD), the laboratory failed to meet the applicable analytic systems requirements in 493.1251 through 493.1283 for performing General Immunology, Semen Analysis, and Hematology testing in the laboratory. Findings Include: 1. The laboratory failed to meet the following analytic systems requirements: *Failed to have written procedures for all assays and tests. D5401. *Failed to ensure all test and assay meet procedures requirements specified in 493.1251(b)(1) - (14). D5403. *Failed to monitor and document manufacturer's required conditions essential for proper storage of test kits. D5413. *Failed to ensure expired supplies are not to be used. See. D5417. *Failed to establish the performance specifications for the laboratory developed tests (LDT) in Flow Cytometry. D5423. *Failed to establish and follow maintenance protocols that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. D5433. *Failed to perform bi-annual calibration procedures. See D5439.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory director (LD); the laboratory failed to have written procedures for Prothrombin Time (PT),

	activated partial thromboplastin (PTT), and lupus anticoagulant testing performed in the specialty of hematology. Findings Include: 1. The laboratory's coagulation procedure manual was reviewed. 2. Review of the coagulation manual found no written procedures for PT, PTT, and lupus anticoagulant testing performed on the ACL 1000 analyzer. 3. On survey date 9-02-2020, at 6:00 pm, the LD confirmed no individual written procedure were available for each coagulation test performed on the ACL 1000.
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 record review and an interview with the laboratory director (LD), the laboratory's procedure manual failed to include all the applicable requirements specified in 493.1251(b)(1) - (14) for all tests, assays, and examinations performed by the laboratory for Sperm DNA Fragmentation (SDF), Reproductive Immuno Phenotype (RIPh), and Natural Killer Cell Activation w/Suppression (NKa) testing. Findings Include: 1. The laboratory's procedure manual and patient test records were reviewed. 2. The laboratory tested patients with the following Flow Cytometry Assays: Sperm DNA Fragmentation (SDF), Reproductive Immuno Phenotype (RIPh), and Natural Killer Cell Activation w/Suppression (NKa). 3. The procedures manual failed to include the following written policies and procedures: * The Control procedures for the SDF, RIPh, and NKa assays. * Corrective action to take when control results fail to meet the laboratory's criteria for acceptability * Limitations in the test methodology, including interfering substances. * Reference intervals (normal values). * Imminently life-threatening test results, or panic or alert values, if applicable * 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; and * Description of the course of action to take if a test system becomes inoperable. 4. The laboratory performed 1,295 patient tests for SDF, RIPh, and NKa from September 1, 2019 to August 31, 2020. 5. On a Recertification survey conducted on 09/02/2020 at 6:00 PM, the LD 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 direct observation, record review, and an interview with the laboratory director (LD); the laboratory failed to monitor and document manufacturer's required conditions essential for proper storage of test kits to ensure accurate and reliable test system operations. Findings include: 1. On 09/02/2020 at 2:10 PM during a tour of the laboratory, the surveyors observed 2 (two) refrigerators with no thermometers to measure the internal temperature: Sanyo Mini Refrigerator - SN#-07010018 and Hall Refrigerator #1. 2. The laboratory's standard operating procedures (SOP) and monthly temperature logs from October 2018 through May 2019 and September 2020 were reviewed. 3. Each monthly temperature chart listed these refrigerators/freezers: 1 refrigerators (5) and 1 freezer (-25) in the Hematology laboratory 1 refrigerator in room Chemistry E 1 refrigerator in the Hallway 1 refrigerator in the Molecular Immunology 1 refrigerator in the Molecular Diagnostics laboratory; and 1 refrigerator in the Flow Cytometry laboratory 4. Review of 9 out of 9 monthly temperature charts revealed the following: *The word "OK" was written instead of temperatures. *The charts did not include temperature ranges *Charts were not review by technical supervisor or LD during these months. 5. The SOP failed to include a policy and procedure that ensured actual temperatures were documented and monitor for the reagents, kits, controls, and patient specimens are stored in them for accurate and reliable testing. 6. On a Recertification survey 09/02/2020 at 6:15 PM, the LD confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, record review, and an interview with the laboratory director (LD), the laboratory failed to ensure reagents, kits, and supplies are not used when they have exceeded their expiration date. Findings: 1. On 09/02/2020 at 2:10 PM during a tour of the laboratory, the surveyors observed the following: Expired reagents, *Acridin Orange Solution - Lot#MKCF7037; received 04/19/2018; opened 04/23/2018; expired 07/2019; *Acridine Orange Hydrocloride hydrate - Lot#37596PH; expired 09/2019; *Dimethyl Sulphoxide (DMSO) - Lot#RNBD914, expired 07/2017; *HSA-Solution - Human Serum Albumin - Lot#030583, expired 06 /10/2019 Expired kits Anti-PR3-hn-hr (IgG) - Lot #E190403BV; expired 04/02/2020 Anti-Sm (IgG) - Lot #E190715DB; expired 07/14/2020 Anti-SS-B (IgG) - Lot

	#E190806BE; expired 08/05/2020 Anti-Histones (IgG) - Lot #E190718AU; expired 07 /17/2020 Anti-SSA(IgG) - Lot #E190715CY; expired 07/14/2020 Anti-Scl-70 (IgG) - Lot #E190701AV; expired 06/30/2020 Anti-nRNP/Sm (IgG) - Lot #E190129AM; expired 01/28/2020 2. The laboratory's policies and procedures manual was reviewed. 3. The laboratory failed to establish policies and procedures to ensure supplies are not used past the expiration dates. 4. On a Recertification survey conducted on 09/02 /2020 at 6:00 PM, the LD 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 direct observation, review of laboratory records, and interviews with testing personnel #4 (TP#4) and the laboratory director (LD); the laboratory failed to establish the performance specifications for the laboratory developed tests (LDT) Sperm DNA Fragmentation (SDF), Reproductive Immuno Phenotype (RIPh), and Natural Killer Cell Activation w/Suppression (NKa) testing on two new Accuri C6 flow cytometers. Findings Include: 1. During tour of the laboratory facility on 9-2-2020, at 2:10 pm, the surveyor observed two Accuri C6 flow cytometers used for LDTs. a. Accuri C6 - Instrument #1, Serial Number: 3325 b. Accuri C6 - Instrument #2, Serial Number: 1251 2. Interview with the TP#4, at 2:15 pm, on 9-02-2020 confirmed the test menu for each flow cytometer. a. Instrument #1 - RIPh testing only. b. Instrument #2 - NKa and SDF testing. 3. Laboratory documentation for the new Accuri C6 flow cytometry analyzers was reviewed. 4. The document titled, "Equipment Failure FACSCAN", stated the FACSCAN analyzer was replaced by two Accuri C6 flow cytometers and was signed and dated by the laboratory director on 6-4-2020. 5. Review of Accuri C6 Flow cytometer verification of performance documentation revealed the laboratory failed to perform complete verification of performance studies for Sperm DNA Fragmentation (SDF), Reproductive Immuno Phenotype (RIPh), and Natural Killer Cell Activation w/Suppression (NKa) testing prior to patient testing. The laboratory failed to address the following characteristics of a verification of performance study for each LDT: a. Accuracy. b. Precision. c. Analytical sensitivity. d. Analytical specificity to include interfering substances. e. Reportable range of test results for the test system. f. Reference intervals (normal values). g. Any other performance characteristic required for test performance. 6. Review of laboratory testing records found 338 patient tests were reported for RIPh, 686 for Nka, and 271 for SDF from August 31, 2019 to September 1, 2020. 7. Interview with the LD on 9-2-2020, at 6:00pm, confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)

	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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and an interview with the laboratory director (LD), the laboratory failed to establish maintenance protocol for centrifuges and ensure maintenance protocols were followed for pipettes, refrigerator /freezers, and incubators to ensure accurate and reliable testing. Findings: 1. On 09/02 /2020 at 9:45am, during a tour of the Semen Analysis laboratory, the surveyor observed equipment and instruments used for testing in the laboratory: Nikon Diaphot 300 microscope Nikon Eclipse TE300 microscope Labconco Biological Hood Stay-Clean Hood 2. On 09/02/2020 at 2:10 PM, during a tour of the laboratory, the surveyors observed several rooms of equipment and instruments used for testing in the laboratory: (2) Megafuge 2.0 Heraeus Centrifuges Eppendorf Pipette SN #T56953A - 200ul Eppendorf Pipette SN #011647 - Adjustable Eppendorf Pipette SN #A9364 - 0-10ul Eppendorf Pipette SN #P-4348 - 2-20ul Eppendorf Pipette SN #N-1024 - 2-20ul Eppendorf Pipette SN #012390 - Adjustable - 100-1000ul Eppendorf Pipette SN #Q-7126 Eppendorf Pipette SN #Q-7120 Eppendorf Pipette SN #Q-7119 Eppendorf Pipette SN #A9354 Incubator SN #36805-1830 3. The laboratory's general policy manual and maintenance logs were reviewed. 4. The laboratory failed to have a maintenance policy for the above mentioned centrifuges, microscopes and hoods in use by the laboratory and no preventative maintenance, tachometer checks, filter changes, air flow checks, or timer verifications were documented. 5. Review of page 23 of the "General Policy" for the laboratory indicated the following under the "Regular maintenance" heading: "Pipettes will be calibrated every year, either in house using accepted methods by weighing water against the volume on a working, certified scale and adjusting for water density and room temperature or using an external service provider in alternative years. Both calibration documents will be maintained in the QA binder." 6. Review of maintenance logs revealed the laboratory failed to document yearly calibrations in 2018, 2019, and 2020 for all pipettes used in the laboratory. 7. Review of page 9 of the "General Policy" for the laboratory indicated the following: "2.1 Incubators should be monitored daily for appropriate temperature and weekly for media pH. Temperature and pH log form will be used. Calibrated thermometer and pH should be used for recording." Additionally, on page 23 the "General Policy" stated, Incubators and refrigerators will be inspected and certified annually by qualified service technicians." 8. The laboratory failed to document daily, weekly, and annual maintenance as indicated in the laboratory's general policy for the Incubator, SN#36805-1830 and the 8 refrigerators/freezers identified on the preventative maintenance log "Refrigerator STA" in 2018, 2019, and 2020. 9. Interview with the LD on 9-2-2020, at 6:00pm, confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification

	procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on record review, manufacturer's instructions, and an interview with the laboratory director (LD), the laboratory failed to follow the manufacturer's instructions to perform calibrations every 6 months on the analyzer used for Complete Blood Count (CBC) testing, during the years 2018, 2019, and 2020. Findings Include: 1. The CBC analyzer's manual and calibration records were reviewed. 2. The CBC analyzer's manual stated the following on page 6-4: "Scheduled calibration...should conform to the guideline established by regulatory agencies." and "Calibration is recommended following the replacement of any major instrument component ... Calibration should also be confirmed by running the same samples used to calibrate the instrument to test the accuracy of the reported results." 3. The calibration records revealed calibrations were performed on 02/20/2018 and 05/28/2019. The laboratory repeatedly failed to perform calibrations every 6 (six) months to verify the CBC analyzer's reportable ranges as required by the manufacturer. 4. On a Recertification survey conducted on 09/02/2020 at 6:00 PM, the LD confirmed the above findings.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory personnel records, the laboratory personnel report (CMS-209), and interview with the laboratory director (LD); the laboratory failed to have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. Findings include: 1. The laboratory's technical supervisor #3, as identified on the CMS-209, failed to meet the qualification and experience requirements. See D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is 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)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(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 (c)(1)(ii) Be certified in clinical pathology 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 (c)(2)(i) 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; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(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 (d)(1)(ii) Be certified in clinical pathology 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 (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or

both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(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 (e)(1)(ii) Be certified in clinical pathology 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 (e)(2)(i) 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; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology 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 (f)(2)(i) 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; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or

experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(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 (g)(1)(ii) Be certified in clinical pathology 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 (g)(2)(i) 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; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology 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 (h)(2)(i) 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; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have

earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(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 (i)(1)(ii) Be certified in clinical pathology 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 (i)(2)(i) 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; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology 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 (j)(2)(i) 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; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of

medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology 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 (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology 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; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) 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-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology 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 (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) 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-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology 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 (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology 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 (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology 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 (n)(2)(i) 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; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) 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; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) 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; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the

	specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology 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 (q)(2)(i) 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; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, CMS-209 (Laboratory Personnel Report), and interview with the laboratory director (LD); the laboratory failed to have foreign equivalency documentation and 4 years of documented experience in high complexity testing for technical supervisor #3 (TS#3), as identified on the laboratory personnel report (CMS-209). Findings Include: 1. Review of the CMS-209, Laboratory Personnel Reoprt, identified TS#3 for the specialty of diagnostic immunology. 2. Review of Educational Credential Evaluators (ECE) documentation revealed TS#3 had "completion of five years of study in a medicine program." The ECE documentation failed to indicate if a bachelors degree had been earned and the major of study. 3. No documentation was provided to verify 4 years of high complexity testing experience in a CLIA certified laboratory. 4. Interview with the LD at 6:00 pm, on 09-02-2020, 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 review of the laboratory personnel records, CMS-209 (Laboratory Personnel Report), and interview with the laboratory director (LD); the laboratory failed to have 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. Findings Include: 1. The laboratory failed to ensure testing personnel #4, as listed on the CMS-209, was qualified for high complexity testing. 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 review of laboratory personnel records, CMS-209 (Laboratory Personnel Report), and interview with the laboratory director (LD); the laboratory failed to have foreign equivalency documentation for testing personnel #4 (TP#4), as identified on the laboratory personnel report (CMS-209). Findings Include: 1. Review of the CMS-209 identified TP#4. 2. Review of Educational Credential Evaluators (ECE) documentation for TP#4 revealed TP#4 had the "completion of five years of study in a medicine program." The ECE documentation failed to indicate a qualifying degree had been earned and the major of study. 3. Interview with the LD at 6:00 pm, on 09-02-2020, confirmed the above findings.