Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0476067	12/16/2020
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital	1401 W Locust St, Stilwell, OK	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 12/14,15,16/2020 The findings were reviewed with the technical consultant #1, technical consultant #2, and chief operating officer during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1447; D6108: Technical Supervisor
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to following the manufacturer's instructions for specimen transport and storage for one of 10 patient specimens. Findings include: (1) On 12/14/2020 at 11:30 am, technical consultant #1 stated the following to the surveyor: (a) The laboratory performed COVID-19 testing using the following instrument (i) Abbott ID Now - qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal swabs. (2) On 12/15/2020, the surveyor reviewed the manufacturer's product insert titled, "ID NOW COVID-19" which stated, "Direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, the nasal, throat or nasopharyngeal swab can be held in its original package (or placed in a conical tube and capped tightly) at room temperature (15-30C) for up to one (2) hours prior to testing. If a direct nasal, throat or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8C and tested within 24 hours from the time of sample collection."; (3) On 12/15/2020, the surveyor reviewed 10 test reports for patients tested from 11/05 /2020 through 12/14/2020 and identified the following: (a) Patient Report #5 -

	Specimen collection date and time (12/12/2020 at 06:05 am) and the result date and time (12/13/2020 at 07:26 pm), 37 hours and 21 minutes later. (4) The surveyor reviewed the records with technical consultant #1. Technical consultant #1 stated on 12/15/2020 at 03:30 pm the laboratory could not prove the results had been interpreted within one (2) hours after collection as indicated above or refrigerated and tested within 24 hours according to the manufacturer's instructions.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure attestation statements were signed by the laboratory director for one of 18 events. Findings include: (1) On 12/14/2020, the surveyor reviewed 2019 and 2020 proficiency testing records, with the following identified: (a) Second Immunohematology 2019 - The attestation statement had not been signed by the laboratory director. (2) The surveyor reviewed the records with technical consultant #1 who stated on 12/14/2020 at 04:35 pm, the attestation statement had not been signed by the laboratory director as indicated above.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to follow the manufacturer's instructions for test timing for Ammonia testing and Vitamin B12 testing for three of five test reports. Findings include: (1) On 12/14/2021 at 12:45 pm, technical consultant #1 state to the surveyor: (a) The laboratory performed Ammonia testing using the Integra 400; (b) The laboratory performed Vitamin B12 testing using the Cobas e411. (2) On 12/15/2020, the surveyor reviewed the manufacturer's instructions under the section titled, "Specimen collection and preparation" the following was identified: (a) Ammonia - "Place immediately on ice and centrifuge, preferably at 4C. Perform

	analysis within 20-30 minutes of venipuncture or freeze separated plasma immediately." (b) Vitamin B12 - "Due to possible evaporation effects, samples, calibrators and controls on the analyzers should be analyzed/measured within 2 hours.". (3) On 12/15/2021, the surveyor then reviewed patient testing records from 10 /06/2020 through 12/12/2020 and identified the following for three of five patient test reports: (a) Ammonia (i) Patient #109970 - The collection date and time was on 10/06 /2020 at 12:30 pm and the result date and time was on 10/06/2020 at 01:48 pm (one hour and 18 minutes later). (ii) Patient #21760 - The collection date and time was on 12/01/2020 at 01:50 pm and the result date and time was on 12/01/2020 at 04:06 pm (two hours and 16 minutes later). (b) Vitamin B12 (i) Patient #109419 -The collection date and time was on 12/08/2020 at 12:11 pm and the result date and time was on 12 /08/2020 at 02:54 pm (2 hours and 43 minutes later). (4) The surveyor reviewed the findings with technical consultant #1. Technical consultant #1 stated on 12/15/2021 at 04:15 pm, the laboratory could not prove the specimen was collected, tested, and resulted as required by the manufacturer.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to follow the manufacturer's instructions for implementing one of one coagulation reagent. Findings include: (1) On 12/14 /2020 at 12:40 pm, technical consultant #1 stated to the surveyor the ACL Elite analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio). The INR was calculated using the PT reference interval mean; (2) On 12/16 /2020 the surveyor reviewed the manufacturer's instructions contained in the "Hemostasis Performance Verification Manual" for implementing new reagents, which stated, "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, and perform a comparison study for all tests". In addition, the manufacturer required the following: (a) Section titled "Establishing a Normal Reference Interval" (i) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-does aspirin, etc."; (3) The surveyor reviewed the implementation records for Recombiplastin PT reagent lot #N0696619, with the following identified: (a) There was no evidence of the age and health status of the donors. (4) The surveyor reviewed the findings with technical consultant #1 who stated on 12/16/2020 at 02:55 pm, the manufacturer's instructions had not been followed for the reagent lot change as specified above.
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 a review of records and interview with technical consultant #1, the laboratory failed to ensure reagents had not exceeded their expiration date for one of nine days. Findings include: (1) On 12/14/2020 at 01:10 pm, technical consultant #1 stated to the surveyor Crossmatch testing was performed in the laboratory which included ABO Typing using Ortho MTS Gel system; (2) On 12/15/2020, the surveyor reviewed quality control and patient testing records for testing performed from 12/16 /2019 through 12/29/2019 and identified expired Ortho Confidence system (Ortho Confidence Cell 1, Ortho Confidence Cell 2, and Ortho Confidence Antibody) used to validate blood bank procedures had been used one of nine days of testing reviewed. The quality control and patient testing had been performed on 12/20/2019 using the following expired reagents: (a) Ortho Confidence System lot #CNF171, expiration date 12/19/2019. (3) The surveyor reviewed the records with technical consultant #1 who stated on 12/15/2020 at 04:10 pm new reagents were used but not documented on the Daily Blood Bank Quality Control log.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's reportable ranges, and interview with technical consultant #1, the laboratory failed to ensure the reportable ranges were utilized for two of two new test methods. Findings include: COBAS e411 (1) On 12/14 /2020 at 01:15 pm, technical consultant #1 stated to the surveyor, TSH (Thyroid Stimulating Hormone), Vitamin B12, and Vitamin D testing were performed using the Cobas e411 (Serial number 18R5-05) and available for patient use on 07/01/2020; (2) On 12/15/2020, the surveyor reviewed the performance specification records and identified the laboratory had demonstrated the following reportable ranges: (a) TSH - 0.09 - 92.91L (b) Vitamin B12 - 241.1 - 2000 pg/mL (c) Vitamin D - 5 - 96.9 g/mL (3) The surveyor then requested documentation to show the reportable ranges that were being utilized by the laboratory. The laboratory was using the following manufacturer's reportable ranges: (a) TSH - 0.005 - 100.0 L (b) Vitamin B12 - 50.0 - 2000 pg/mL (c) Vitamin D - 5 - 100.0 g/mL (4) The surveyor reviewed the findings with technical consultant #1, who stated on 12/15/2020 at 03:30 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above. GEM PREMIER 5000 (1) On 12/14/2020 at 01:25 pm, technical consultant #1 stated to the surveyor, Arterial Blood Gas testing was performed using the Gem Premier 5000 and available for patient use on 03/12/2020; (2) On 12/15 /2020, the surveyor reviewed the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) pH - 7.0 - 7.72 (b) pO2 - 32.0 - 551.0 mmHg (c) pCO2 - 19.0 - 124.0 mmHg (3) The surveyor then

	requested documentation to show the reportable ranges that were being utilized by the laboratory. The laboratory was using the following manufacturer's reportable ranges: (a) pH - 7.0 - 7.92 (b) pO2 - 6.0 - 690.0 mmHg (c) pCO2 -6.0 - 125.0 mmHg (4) The surveyor reviewed the findings with technical consultant #1, who stated on 12/15 /2020 at 04:30 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure units of blood were stored under appropriate conditions for one of nine refrigerator temperature charts. Findings include: (1) On 12/14/2020 at 01: 00 pm, technical consultant #1 stated the following to the surveyor: (a) The laboratory stored units of packed red blood cells in the blood bank refrigerator; (b) The units were to be used for patient transfusions. (2) On 12/14/2020 at 01:10 pm, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. It had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees (C) Centigrade). Each chart monitored the temperature for a seven day period; (3) On 12/16/2020, the surveyor reviewed nine refrigerator charts dated from 05/04/2020 through 07/07/2020. The review showed that one of nine charts had not been changed by the 7th day of usage as follows: (a) Chart #1 - The chart was put into use on 05/04/2020 and removed on 05/12/2020 (8 days). (4) The surveyor reviewed the findings with technical consultant #1 who stated on 12/16/2020 at 11:15 am, the chart had not been changed by the 7th day as stated above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient reports and interview with technical consultant #1, the laboratory failed to provide appropriate normal reference intervals for one of one test report for Beta HCG testing; one of one test report for ProBNP testing; one of one test report for Arterial Blood Gas testing; one of one test report for Ammonia testing; and one of one test report for Prothrombin Time testing. Findings include: BETA HCG, PROBNP, ARTERIAL BLOOD GAS, AMMONIA NORMAL REFERENCE RANGES (1) On 12/14/2020 at 11:25 am, technical consultant #1 stated the following to the surveyor: (a) Quantitative Beta HCG (Human Chorionic Gonadotropin) and

	ProBNP testing were performed on the Cobas e411analyzer; (b) Arterial Blood Gas (pH, pCO2, pO2) testing was performed on the GEM Premier 5000 analyzer; (c) Ammonia testing was performed on the Cobas 400 Plus analyzer. (2) The surveyor reviewed the following reports and identified the following: (a) Patient report on 12/14 /2020 at 02:33 pm did not include a normal reference range for Beta HCG testing; (b) Patient report on 11/30/2020 at 08:22 pm did not include a normal reference range for ProBNP testing; (c) Patient report on 11/21/2020 at 06:05 pm did not include normal reference rangeS for Arterial Blood Gas testing; (d) Patient report on 11/30/2020 at 03: 14 pm did not include a normal reference range for Ammonia testing. (3) The surveyor reviewed the reports with technical consultant #1, who stated on 12/15/2020 at 04:20 pm the above patient reports did not include normal reference ranges as indicated above. PROTHROMBIN TIME NORMAL REFERENCE RANGE (1) On 12/14/2020 at 11:35 am, technical consultant #1 stated the following to the surveyor (a) Technical consultant #1 stated to the surveyor the laboratory performed PT (Prothrombin Time) testing on the ACL Elite analyzer. In addition the following reagent was put into use on 03/04/2020: (a) Recombinplastin PT reagent lot #N0696619 (2) On 12/16/2020, the surveyor reviewed the PT reagent implementation records and identified the laboratory had verified a PT normal reference interval of 10.6 - 12.9 seconds; (3) On 12/16/2020, the surveyor then reviewed a patient PT report dated 11/24/2020 at 06:16 am with a normal reference range of 9.3 - 13.5 seconds; (4) The surveyor reviewed the findings with technical consultant #1. On 12 /16/2020 at 02:45 pm, technical consultant #1 stated that although the laboratory had established a PT normal reference interval with the PT reagent lot change, the laboratory had not implemented the change into the laboratory's computer information system.
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 a review of records and interview with technical consultant #1, the technical supervisor failed to provide technical supervision in accordance with 493.1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the educational qualifications. Refer to 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 a review of records and interview with technical consultant #1, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor, met the qualifications for two of six proficiency testing attestation forms. Findings include: (1) On 12/14/2020, the surveyor reviewed the Laboratory Personnel Report (Form CMS-209), that had been completed by the laboratory. The form listed the same individual as the laboratory director and the technical supervisor; (2) The surveyor then reviewed proficiency testing records for the following events: (a) Immunohematology - First 2019, second 2019, third 2019, first 2020, second 2020, and third 2020. (3) The documentation showed that the attestation statements for two of six events (first and third 2019) had been signed by technical consultant #1 instead of the laboratory director/technical supervisor (technical consultant #1 had a bachelor degree in science); (4) The findings were reviewed with technical consultant #1 who stated to the surveyor on 12/14/2020 at 04:30 pm, the attestation statements for the above events had been signed by a person who did not qualify as a technical supervisor.