Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472309	09/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Harmon Memorial Hospital	400 East Chestnut, Hollis, 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 09/06,07,08,09/2022. The laboratory was found out of compliance with the following CLIA Condition of Participation: 493.1447; D6108: Technical Supervisor The findings were reviewed with the laboratory director, hospital administrative director, general supervisor #1, general supervisor #2, and testing person #7 during an exit conference performed at the conclusion of the survey.
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 general supervisor #1 and general supervisor #2, the laboratory failed to ensure attestation statements were signed by the laboratory director for six of 16 events. Findings include: (1) On 09/07/2022, a review of proficiency testing records for 2021 and 2022 revealed the following: (a) First Chemistry Miscellaneous Event 2022 - The attestation statement had not been signed by the laboratory director; (b) First Microbiology Event 2022 - The attestation statement had not been signed by the laboratory director; (c) First Hematology Event 2022 - The attestation statement had not been signed by the laboratory director; (d)

	Second Microbiology Event 2022 - The attestation statement had not been signed by the laboratory director; (e) Second Hematology Event 2022 - The attestation statement had not been signed by the laboratory director; (f) Second Chemistry Core Event 2022 - The attestation statement had not been signed by the laboratory director. (2) The records were reviewed with general supervisor #1 and general supervisor #2. Both stated on 09/07/2022 at 01:30 pm, the attestation statements had not been signed by the the laboratory director as shown above.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and interview with testing person #7, general supervisor #1 and general supervisor #2, the laboratory failed to ensure one of three policies had been approved, signed, and dated by the laboratory director before use. Findings include: (1) On 09/06/2022 at 01:45 pm, testing person #7, general supervisor #1, and general supervisor #2 stated Urine Drug Screen Testing was performed using the Med Tox Scan Profile V test system; (2) Testing person #7, general supervisor #1 and general supervisor #2 confirmed during an interview on 09/08/2022 at 11:00 am that an IQCP (Individualized Quality Control Plan) had been developed for the test system; (3) A review of the IQCP revealed the QCP (Quality Control Plan) for the test system had not been approved, signed, and dated by the laboratory director; (4) The findings were reviewed with testing person #7, general supervisor #1, and general supervisor #2. All stated on 09/08/2022 at 02:00 pm, the QCP had not been approved, signed, and dated by the laboratory director.
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 and interview with general supervisor #1 and general supervisor #2, the laboratory failed to ensure the reportable range had been utilized for one of one new analyte. Findings include: (1) On 09/08/2022 at 01:00 pm, general supervisor #1 and general supervisor #2 stated the laboratory began performing Procalcitonin testing on the Vitros ECiQ analyzer in September 2020; (2) A review of the performance specification records for the new analyte revealed the laboratory had demonstrated a reportable range of 0.05-89.7; (3) General supervisor #1 provided the reportable range the laboratory was using from the LIS (Laboratory Information System), which confirmed the laboratory was using the manufacturer's reportable range of 0.03-100; (4) On 03/30/2022 at 02:00 pm, the findings were reviewed with

	general supervisor #1 and general supervisor #2. Both stated on 09/08/2022 at 02:50 pm, the laboratory was using the manufacturer's reportable range instead of the reportable range that had been demonstrated by the laboratory.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with testing person #7, general supervisor #1 and general supervisor #2, the laboratory failed to ensure the blood bank centrifuge was functioning properly for one of two function checks. Findings include: (1) On 09/06/2022 at 01:30 pm, testing person #7 stated the laboratory used the Ortho MTS centrifuge to process specimens for Antibody Screen and Compatibility testing; (2) On 09/07/2022 the following were reviewed: (a) The policy titled, "Centrifuge Policy" stated, "It is the policy of Harmon Memorial Hospital Laboratory Department that the centrifuges will be checked annually. This includes RPM and Timer Checks"; (b) The procedure titled, "Grading of Agglutination Reactions (MTS Gel Method)" stated, "Centrifuge the gel card at the preset conditions for 10 minutes". (3) A review of centrifuge speed and timer check records for 2021 through the current date revealed that, although the centrifuge speed and timer checks had been checked annually, for one of two checks the timer had not been checked at the time the centrifuge was used to process specimens: (a) 04/01 /2022 - The timer had been checked for five minutes instead of ten minutes (4) The records were reviewed with general supervisor #1 and general supervisor #2. Both stated on 09/07/2022 at 03:00 pm, the centrifuge timer had not been checked at the time specimens were processed.
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 a review of records and interview with general supervisor #1 and general supervisor #2, the laboratory failed to perform calibration verification procedures at least once every 6 months for two of two analytes. Findings include: (1) On 09/08 /2022 at 01:00 pm, general supervisor #1 and general supervisor #2 stated the laboratory performed Vitamin D testing using the Vitros ECiQ analyzer and Procalcitonin testing was added to the test menu in September 2020; (2) A review of 2022 calibration records revealed the calibration procedures for Vitamin D and Procalcitonin had been performed with two levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of records for 2020, 2021, and to date in 2022 revealed calibration verification had not been performed at least once every six months as follows: (a) Vitamin D - Not performed between 07/17/2021 and 04/12/2022; (b) Procalcitonin - Not performed between 09/15/2020 and 07/17/2021; and between 07/17/2021 and 04/12/2022; (4) The records were reviewed with general supervisor #1 and general supervisor #2. Both stated on 09/08/2022 at 02:55, calibration verification procedures had not been performed every six months.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, quality control package inserts, policies and procedures, phone conversation with the manufacturer's technical support representative, and interview with testing person #7, general supervisor #1, and general supervisor #2, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and that would detect immediate errors that would occur due to test system failure, adverse environmental conditions for two of two analytes reviewed. Findings include: (1) On 09/06/2022 at 01:15 pm, testing person #7 stated the following: (a) The Ortho Vitros 4600 analyzer was used to perform Glucose testing. Two levels of QC (Quality Control) materials were performed each day of patient testing and laboratory established ranges were used for determining

	acceptability of QC results; (b) The Ortho Vitros ECiQ analyzer was used to perform Troponin I testing. Two levels of QC materials were performed each day of patient testing and laboratory established ranges were used for determining acceptability of QC results. (2) On 09/09/2022, a review of the policy titled, "Quality Control & Statistics" referred to the Westgard Rules of quality control which defined systematic errors and based QC decisions on SD (Standard Deviations) stated, "Systematic Errors: Do not report any patient results until the problem is resolved." The following were examples of some of the guidelines: (a) "1.2S - One data point outside +/- 2SD from the mean" (b) "2.2S - Two consecutive data points outside +/-2SD from the mean" (3) A review of QC records (Levey-Jennings graphs and cumulative calculated data; and QC package inserts) for Glucose level one and level three; and Troponin I level three for August 2022 revealed the laboratory was using ranges as wide as the package insert guideline ranges instead of 2 SD ranges as referred to in the policy (note: the package insert ranges were to be used by the laboratory as a guide while establishing QC ranges) as follows: (a) Glucose - The laboratory was using MAS Omni-CORE Liquid Assayed Integrated Chemistry controls (i) Level one lot #OCR24061A - The laboratory was using a range of 46-70 which was as wide as the package insert guideline range of 47.7-71.5; (ii) Level three lot #OCR24063A - The laboratory was using a range of 281-421 which was as wide as the package insert guideline range of 278-418. (b) Troponin I - The laboratory was using MAS CardioImmune XL Liquid Assayed Cardiac Marker controls (i) Level one lot #CXL23063A - The laboratory was using a range of 27.39-41.11 which was a wide as the package insert guideline range of 26.2-39.4. (4) To clarify the package insert guideline ranges, a phone call was made to the manufacturer's technical support representative. The technical support representative stated on 09/09/2022 at 11:25 am, the published ranges in the package inserts for the MAS control materials above were intended for the laboratory to utlize as a guide while establishing their ranges and the listed ranges were a +/- 3SD or 20% of the mean (whichever was greater); (5) The findings were reviewed with testing person #7, general supervisor #1, and general supervisor #2. All stated on 09/09/2022 at 12:50 pm, ranges as wide as the manufacturer's guideline ranges had been used to evaluate QC results.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with testing person #7, general supervisor #1 and general supervisor #2, the laboratory failed to provide documentation the manufacturer's specifications had been followed for establishing quality control ranges for PT/INR testing for 2 of 2 lot numbers. Findings include: (1) On 09/06/2022 at 01:00 pm, testing person #7 stated: (a) The Hemochron Jr. Signature + analyzer was used to perform PT (Prothrombin Time)/ INR (International Normalized Ratio) testing using the Citrate PT cuvettes; (b) Normal and abnormal controls were tested on a weekly basis and with new lot numbers of cuvettes. (2) On 09/08/2022, a review of the manufacturer's instructions (package inserts) for the control materials stated, "Accriva recommends that each institution establish its own expected range of response based on the mean +/- 2 standard

	deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a coefficient of variation of approximately 14% or less for coagulation control tests"; (3) A review of quality control records for lot changes performed in 2021 and 2022 revealed the laboratory had not followed the manufacturer's instructions as follows: (a) Normal Control Lot #K1DNC008, put into use on 03/16/2022 - There was no evidence the laboratory had ensured the intra-laboratory variation in test results produced a coefficient of variation (CV) of 14% or less; (b) Abnormal Control Lot #H1DAC002, put into use on 11/30 /2021 - Although the laboratory had established their ranges, there was no evidence they had calculated a mean and +/- 2 standard deviations using at least 20 repeated results and ensured the intra-laboratory variation in results produced a CV of 14% or less. (4) The findings were discussed with testing person #7, general supervisor #1, and general supervisor #2. All stated on 09/08/2022 at 02:25 pm, the laboratory did not maintain documentation to prove the manufacturer's instructions had been followed.
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, policies and procedures, and interview with testing person #7, general supervisor #1 and general supervisor #2, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: (1) On 09/06/2022 at 01:30 pm, testing person #7 stated the laboratory stored units of packed red blood cells in the Helmer blood bank refrigerator. The units were to be used for patient transfusions; (2) On 09/08/2022, a review of the policy titled "Testing Refrigerator Alarms" stated, "The alarm on the refrigerator used to store blood is checked quarterly for proper functioning. The high and low temperatures of activation must be checked, and the results recorded."; (3) A review of alarm check records for 2021 and to date in 2022 revealed no evidence the alarm checks had been performed between 03/31/2022 and 09/08/2022; (4) The findings were reviewed with testing person #7, general supervisor #1, and general supervisor #2. All stated on 06/08/2022 there was no documentation to prove the alarm checks had been performed between 03 /31/2022 and 09/08/2022.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken

	to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 written policies and interview with testing person #7, general supervisor #1 and general supervisor #2, the laboratory failed to ensure transfusion reaction investigation records were complete for one of one record. Findings include: (1) On 09/06/2022 at 01:30 pm, testing person #7 stated the laboratory stored units of packed red blood cells in the Helmer blood bank refrigerator. The units were to be used for patient transfusions; (2) On 09/08/2022, a review of the policy titled, "Transfusion Reactions" outlined the testing that was to be performed by the laboratory when a possible transfusion reaction was suspected by nursing staff. The laboratory was required to complete a "Transfusion Reaction Investigation" form. The form included a space for the Pathologist to sign the form as reviewed and document comments and interpretation; (3) A review of blood bank records revealed a transfusion reaction investigation form had been completed for a patient transfused on 06/02/2022 at 04:24 pm. There was no documentation of the pathologist's interpretation and signature; (4) The record was reviewed with general supervisor #1 and general supervisor #2. Both stated on 09/08/2022 at 11:15 am, the pathologist's interpretation and signature had not been documented.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #7, general supervisor #1 and general supervisor #2, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP for three of three test systems. Findings include: (1) On 09/06/2022 at 01:45 pm, testing person #7, general supervisor #1, and general supervisor #2 stated the following: (a) Clostridium difficile testing was performed using the TechLab CDiff Quik Chek Complete test kit; (b) PT/INR (Prothrombin Time/International Normalized Ratio) testing were performed using the Hemochron Signature Elite analyzer; (c) Urine Drug Screen Testing was performed using the Med Tox Scan Profile V test system. (2) Testing person #7, general supervisor #1 and general supervisor #2 confirmed on 09/08/2022 at 11:00 am that IQCP's (Individualized Quality Control Plans) had been developed for the test systems; (3) A review of the IQCP's revealed that QA (Quality Assessment) reviews of the QCP's (Quality Control Plans) were to be performed on an annual basis; (4) A review of records for the test systems for 2020, 2021, and to date in 2022 revealed the following: (a) Clostridium difficile - The IQCP had been approved on 09/19/2016. There was no documentation QA reviews had been performed since 10/25/2020; (b) PT/INR - The IQCP had been approved on 01/01/2026. There was no documentation QA reviews had been performed since 10/25/2020; (c) Urine Drug Screen - The IQCP had been approved on 01/27/2016. There was no documentation QA reviews had been

	performed during the review period. (5) The records were reviewed with testing person #7, general supervisor #1, and general supervisor #2. All stated on 09/08/2022 at 02:00 pm, annual QA reviews had not been documented as performed 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 records and interview with testing person #7 and general supervisor #2, the laboratory failed to make appropriate reference ranges available for two of two patient Hematology reports. Findings include: (1) On 09/06/2022 at 10:25 am, testing person #7 stated the laboratory performed CBC (Complete Blood Count) testing using the Sysmex XN 550 analyzer; (2) On 09/07/2022, two patient CBC reports were reviewed - the first report was for an adult female patient with the testing performed on 07/19/2022 at 12:06 pm; the second report was for an adult male patient with the testing performed on 08/09/2022 at 12:48 pm. Both reports included the same reference intervals for the CBC parameters of RBC (Red Blood Cell), and Hemoglobin which were: (a) RBC - 4.0-5.2 10*3/uLl (b) Hemoglobin - 12.0-15.0 g /dL (3) The findings were reviewed with general supervisor #2 who stated on 09/07 /2022 the reports did not include gender specific reference ranges as shown above.
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 general supervisor #1 and general supervisor #2, 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 general supervisor #1 and general supervisor #2, the technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the qualifications to sign Immunohematology attestation statements for one of four proficiency testing events Findings include: (1) On 09/07/2022, a review of the Laboratory Personnel Report (Form CMS-209) listed the same individual as the laboratory director and technical supervisor; (2) A review of Immunohematology proficiency testing records for 2021 and 2022 revealed the attestation statement for the first 2022 event had been signed by an individual who did not meet the regulatory requirements of a technical supervisor; (3) The records were reviewed with general supervisor #1 and general supervisor #2. Both stated on 09/07/2022 at 01:20 pm, the attestation statement had not been signed by an individual meeting the regulatory qualifications of a technical supervisor for Immunohematology.