Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0471986	**(X3) Date Survey Completed** 01/27/2021
Name of Provider or Supplier Mercy Hospital Love County	**Street Address, City, State** 300 Wanda Street, Marietta, 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 01/25,26,27/2021 The findings were reviewed with laboratory director, laboratory manager, technical consultant #3, general supervisor #5, chief of staff, quality director nurse manager, and the hospital administrator during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1447; D6108: Technical Supervisor
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory failed to have a written technical consultant and general supervisor competency policy based on the position responsibilities as listed in Subpart M. Findings include: (1) On 01/25/2021 the surveyor reviewed the competency assessment policy. It did not include guidance for assessing the competency of the technical consultant and general supervisor; (2) The surveyor then reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence of competencies performed for the technical consultant #2, technical consultant #3, general supervisor #1, general supervisor #2, general supervisor #3, general supervisor #4, and general supervisor #5 based on their job responsibilities; (3) The surveyor asked the laboratory manager if a written policy to evaluate the technical consultant and general supervisor based on job responsibilities was available. The laboratory manager stated on 01/25/2021 at 01:25 pm a policy had not been written and the above competencies had not been performed.

D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for two of 28 events. Findings include: (1) On 01/25/2021, the surveyor reviewed 2019 and 2020 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third Chemistry Core Event (i) Total Cholesterol - 5 of 5 results exhibited a negative bias (aa) Sample CH-11 - SDI of -2.3 (bb) Sample CH-12 - SDI of -2.3 (cc) Sample CH-13 - SDI of -2.7 (dd) Sample CH-14 - SDI of -2.2 (ee) Sample CH-15 - SDI of -2.5 (ii) BNP - 3 of 5 results exhibited a negative bias (aa) Sample CH-12 - SDI of -3.0 (bb) Sample CH-13 - SDI of -2.1 (cc) Sample CH-15 - SDI of -2.4 (iii) Albumin - 3 of 5 results exhibited a negative bias (aa) Sample CH-11 - SDI of -2.8 (bb) Sample CH-12 - SDI of -2.2 (cc) Sample CH-14 - SDI of -2.3 (b) First 2020 Chemistry Core Event (i) Total Cholesterol - 3 of 5 results exhibited a negative bias (aa) Sample CH-02 - SDI of -2.6 (bb) Sample CH-04 - SDI of -2.5 (cc) Sample CH-05 - SDI of -2.0 (ii) Troponin - 3 of 5 results exhibited a positive bias (aa) Sample CM-01 - SDI of 2.6 (bb) Sample CM-03 - SDI of 2.7 (cc) Sample CM-04 - SDI of 2.2 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 01/25/2021 at 06:00 pm the biases had not been addressed.
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 the laboratory manager, the laboratory failed to follow the manufacturer's instructions for test timing for a blood gas cartridge for one of four test reports. Findings include: (1) On 01/25/2021 at 11:25 am, the laboratory manager stated to the surveyor: (a) The laboratory performed pH, pCO2,and pO2 using the CG4+ cartridge with the Abbott iSTAT 1 Analyzer; (2) On 01/27/2021, the surveyor reviewed the manufacturer's instructions under the section titled, "Mixing and Test Timing (time from collection to cartridge fill) for Chemistry and Blood Gas Cartridge". For test timing, the instructions stated, "Samples for pH, PCO2, PO2, TCO3 and ionized calcium should be tested within 10 minutes."; (3) On 01/27/2021, the surveyor reviewed patient testing records on 1/26/2020, 11/10/2020, 12/02/2020, 12/17/2020, and 12/18/2020 and identified the following for one of four patient test reports: (a) Patient Report

	#20LC-300G0001- The specimen collection date and time was on 10/26/2020 and the result time was on 10/26/2020 at 10:46 am (18 minutes later). (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated on 01/27/2021 at 02:26 pm, the laboratory could not prove the specimen was collected and tested within 10 minutes as required by the manufacturer.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to follow manual differential procedures for one of 18 patient reports. Findings include: (1) On 01/25/2021 at 11:30 am, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex 1000i analyzer; (2) On 01/27/2021, the surveyor reviewed the laboratory's written procedure titled, "HEMATOLOGY CRITERIA FOR MANUAL DIFFERENTIAL" under the section titled, "General Description" stated: (a) "8. When MCHC is > 36 (look for Spherocytes) also look for lipemia or icteric plasma and consider Cold Agglutinens as a possibility.". (3) On 01/27/2021, the surveyor reviewed patient records on 12/03/2020, 12/05/2020, and 12/06/2020 and identified the following: (a) Patient E1504057622 - Tested on 12/03/2020 at 12:47 pm with a MCHC (Mean Corpuscular Hemoglobin Concentration) result of 36.5 g/dL. (4) The surveyor reviewed the record with the laboratory manager and asked if the laboratory had followed their written procedure for MCHC results greater than 36 g/dL. The laboratory manager stated on 01/27/2021 at 10:05 am, the procedure had not been followed as indicated above.
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 the laboratory manager, the laboratory failed to follow the manufacturer's instructions for verifying morphology flags for four of 18 patient reports. Findings include: (1) On 01 /25/2021 at 11:30 am, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex 1000i analyzer; (2) 01/27/2021, the surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Anemia - "Verify RBC morphology on slide" (b) Blasts? - "Perform manual differential" (c) WBC ABN Scattergram - "Perform manual differential" (3) The surveyor randomly reviewed 18 patient records which

	contained morphology flags from CBC testing performed on 12/03/2020, 12/05/2020, and 12/06/2020. For four of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the four records were: (a) Testing was performed on 12/05/2020 at 02:57 am, with an WBC Abn Scattergram flag obtained; (b) Testing was performed on 12/05/2020 at 08:44 pm, with an Anemia flag obtained; (c) Testing was performed on 12/06/2020 at 12:19 am, with an Anemia flag obtained; (c) Testing was performed on 12/06/2020 at 08:09 am, with a Blasts? flag obtained. (4) The surveyor reviewed the records with the laboratory manager, who stated on 01/27/2020 at 03:41 pm that the flags obtained for the above four patients had not been verified.
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 the laboratory manager, the laboratory failed to ensure control materials were not used beyond the manufacturer's open vial stability for one of one lot number for Erythrocyte Sedimentation Rate; and failed to ensure control materials were not used beyond the manufacturer's expiration date for two of two days. Findings include: ERYTHROCYTE SEDIMENTATION RATE QUALITY CONTROL (1) On 01/25/2021 at 11:00 am, the laboratory manager stated the following to the surveyor: (a) The laboratory performed ESR (erythrocyte sedimentation rate) was performed using the Mini-Cube analyzer; (b) Two levels of ESR-Chex Plus quality control materials were performed each day of patient testing. (2) On 01/26/2021, the surveyor reviewed the manufacturer's information sheet for the control materials. Under the section, "Open-vial stability" the manufacturer stated once opened the controls were stable for "7 days"; (3) The survey reviewed quality control records for one lot number of quality control materials used from 01/03/2021 through the second day of the survey (01/26/2021). It was identified controls had been used beyond the manufacturer's open vial stability date for one of one lot number reviewed as follows: (a) Level 1 (L1) - Lot# 611 had an open date of 01/03/2021 (written on the bottle and observed by the surveyor on 01/25/2021 at 11:10 am); (1) The quality control material was available for use beyond the manufacturer's open vial stability of 01/10/2021; (b) Level 2 (L2) - Lot# 611 had an open date 01/03/2021 (written on the bottle and observed by the surveyor at 11:10 am); (1) The quality control material was available for use beyond the manufacturer's open vial stability of 01/10/2021. (4) The surveyor reviewed the records with the laboratory manager. The laboratory manager stated on 01/25/2021 at 04:10 pm, the quality control materials were available for use beyond the manufacturer's stability date. BLOOD BANK QUALITY CONTROL (1) On 01/25/2021 at 10:10 am, the laboratory manager stated to the surveyor Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method; (2) On 01/26/2021, the surveyor reviewed quality control for testing performed from 08/14/2019 through 09/07/2019 and identified expired Confidence (Cell 1, Cell 2, Antibody used to validate blood bank procedures) had been used two of three days of quality control testing reviewed. The quality control had been performed on 09/03/2019 and 09/07/2019 using the expired following reagents: (a) Confidence lot# CNF-160, expiration date 08/27/2019. (3) The surveyor reviewed the records with the laboratory manager

	who stated on 01/26/2021 at 04:15 pm the blood bank reagents had been changed but not documented on the Blood Bank MTS QC Records.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance procedures on the hematology analyzer for two and seven months; and failed to follow manufacturer's instructions for performing weekly maintenance procedures on the MTS Dispenser for 10 of 22 months. Findings include: SYSMEX 1000i (1) On 01/25/2021 at 11:30 am, the laboratory manager stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On 01/26/2021, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log. The weekly requirement was as follows: (a) Power Down IPU (3) On 01/26/2020, the surveyor reviewed maintenance records from April 2020 through October 2020. The weekly maintenance had not been documented as performed between: (a) 04/22/2020 and 05/07/2020 (b) 10/07/2020 and 10/21/2020 (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated on 01/26/2021 at 04:00 pm the weekly maintenance had not been documented as performed as identified above. MTS DISPENSER (1) On 01/25/20201 at 11:45 am, the laboratory manager stated to the surveyor the laboratory preformed blood bank testing using the Ortho MTS gel system; (2) On 01/26/2020, the surveyor reviewed the manufacture's maintenance requirements as stated on the manufacturer's maintenance log. The weekly requirements were a follows: (a) Clean with 70% isopropyl Alcohol and rinse with deionized or distilled water (3) On 01/26/2021, the surveyor reviewed maintenance records from January 2019 through October 2020. The weekly documented had not been documented as performed between: (a) 02/15/2019 - 03/16/2019 (b) 03/16/2019 - 04/19/2019 (c) 08/11/2019 - 08/14/2019 (d) 08/14/2019 - 09/26/2019 (e) 02/14/2020 - 03/13/2020 (f) 05/13/2020 - 05/26/2020 (g) 09/22/2020 - 10/16/2020 (4) The surveyor reviewed the findings with the laboratory manager. The laboratory manager stated on 01/26/2021 at 04:10 pm the weekly maintenance had not been documented as performed as identified 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 the laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions for five of 13 refrigerator temperature charts. Findings include: (1) On 01/25/2021 at 10: 10 am, the laboratory manager stated the following to the surveyor: (a) The laboratory stored units of packed red blood cells in the blood bank refrigerator; (b) The above units were to be used for patient transfusions. (2) On 01/25/2021 at 10:15 am, 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 7 day period; (3) On 01/26/2021, the surveyor reviewed 13 refrigerator charts from 08/23/2020 through 11/25/2020. The review showed that five of 13 charts had not been changed by the 7th day of usage as follows: (a) Chart #3 - The chart was put into use on 09/05/2020 and removed on 09/13/2020 (9 days); (b) Chart #6 - The chart was put into use on 09/26 /2020 and removed on 10/04/2020 (9 days); (c) Chart #7 - The chart was put into use on 10/04/2020 and removed on 10/17/2020 (13 days); (d) Chart #8 - The chart was put into use on 10/17/2020 and removed on 10/25/2020 (8 days); (e) Chart #11 - The chart was put into use on 11/07/2020 and removed on 11/15/2020 (9 days); (4) The surveyor reviewed the charts with the laboratory manager who stated on 01/26/2021 at 03:00 pm, the charts had not been changed by the 7th day as stated above.
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 laboratory manager, the laboratory failed to ensure that written policies provided safety for individuals being transfused for two of seven units of packed red blood cells. Findings include: (1) On 05/12/2021 at 10:05 am, technical consultant #2 stated to the surveyor the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) using the tube method; (2) The surveyor reviewed the hospital policy regarding transfusion reactions. The policy titled, "BLOOD PRODUCT ADMINISTRATION" under the section titled, "DOCUMENTATION", stated: (a) "8. Vital signs are to be recorded prior to starting the blood product, every five minutes for the first fifteen minutes, every thirty minutes times one, and then hourly until the infusion is complete." (3) The surveyor then reviewed records for seven units of PRBCs (Packed Red Blood Cells) that had been transfused on 11/18/2019, 10/28/2020, 12/22/2020, 04 /14/2021, and 04/26/2021 for five patients, and identified the following: (a) Every five minutes for the first fifteen minutes after the transfusion started (i) Patient # V00000883835 - Transfused with 1 unit PRBCs (unit # W091020455662) on 12/22

	/2020. The transfusion started at 09:05 pm and the first vital was documented at 10:50 pm (1 hour 45 minutes later). (b) Vitals signs every 30 minutes after the first 15 minutes of the transfusion (i) Patient #J00000623009 - Transfused with 1 unit PRBCs (unit #W091020388888) on 10/28/2020. The transfusion started at 07:25 pm and vitals were document at 07:30 pm, 07:35 pm and 08:05 pm (25 minutes later); (4) The surveyor reviewed the findings with technical consultant #2 and general supervisor #3, both stated on 05/13/2021 at 04:00 pm the written policy and procedure for blood administration had not been followed as indicated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for five of 28 events. Findings include: (1) On 01/25/2021, the surveyor reviewed 2019 and 2020 proficiency testing events. For five of 28 events, the attestation statements had been signed approximately one to four months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2019 Chemistry Core Event - The sample testing had been completed on 02/04 /2019, and the attestation statement had not been signed by the laboratory director /designee until 06/20/2019; (b) Second 2019 Microbiology Event - The sample testing had been completed on 07/08/2019, and the attestation statement had not been signed by the laboratory director/designee until 08/20/2019; (c) Third 2019 Microbiology Event - The sample testing had been completed on 10/22/2019, and the attestation statement had not been signed by the laboratory director/designee until 12/17/2019; (d) Second 2020 Chemistry Core Event - The sample testing had been completed on 06/09/2020, and the attestation statement had not been signed by the laboratory director/designee until 7/14/2020; (e) Second 2020 Hematology/Coagulation Event - The sample testing had been completed on 07/22/2020, and the attestation statement had not been signed by the laboratory director/designee until 10/20/2020. (2) The surveyor reviewed the findings with the laboratory manager who stated on 01/25 /20201 at 04:45 pm the attestations had been signed approximately one to four months after the proficiency samples had been tested. The surveyor explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.
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 laboratory manager, 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 the laboratory manager, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor met the qualifications for one of one of semiannual competency assessments. Findings include: (1) On 01/25/2021, the surveyor reviewed records for one testing person who had been hired to perform high complexity testing (ABO/Rh, Antibody Screen and Compatibility testing) since the previous recertification survey performed. The records indicated the semi-annual evaluation for the testing person had been performed by an individual who did not meet the regulatory qualification requirements of the technical supervisor: (a) Testing Person #4 - The 10/21/2019 semi-annual evaluation had been performed by the laboratory manager (this person had earned a bachelor degree in applied science). (2) The surveyor explained to the laboratory manager that all components of the semi-annual competency evaluations must be performed by a person who qualifies as a technical supervisor (493.1449 (q) an individual with an MD or DO with a current medical license in state of laboratory's location and certified in anatomic pathology by ABP or AOBP or equivalent qualifications or resident in a program leading to ABP or AOBP certification in anatomic and clinical pathology who performs duties delegated by the technical supervisor for histopathology). On 01/25/2021 at 02:20 pm, the laboratory manager stated to the surveyor the semi-annual evaluation had not been performed by someone who met the qualifications of a technical supervisor as indicated above. NOTE: The regulations only allow for an individual qualifying as a

	general supervisor to perform initial training and annual competency evaluations as stated at 493.1463 "Standard; General supervisor responsibilities: (b)(3) Providing orientation to all testing personnel; and (b)(4) Annually evaluating and documenting the performance of all testing personnel"