Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475664	05/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Choctaw Memorial Hospital	1405 E Kirk, Hugo, 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 05/26,27,28/2021. The laboratory was found out of compliance with the following CLIA regulations: 493.801; D2000: Enrollment and Testing of Samples 493.1447; D6109: Technical Supervisor The findings were reviewed with the director of laboratory services at the conclusion of the survey.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of records and interview with the director of laboratory services, the laboratory failed to enroll in a proficiency testing program for qualitative serum pregnancy testing. Findings include: (1) On 05/25/2021 the surveyor reviewed proficiency testing records for 2019 (second and third event), 2020 (first, second, and third events), and to date in 2021 (first event). There was no evidence the laboratory was enrolled in proficiency testing for serum qualitative pregnancy testing for the third 2019 event, first, second, and third 2020 events, and the first 2021 event; (2) The surveyor reviewed the records with the director of laboratory services who stated on 05/25/2021 at 09:50 am, the laboratory discontinued proficiency testing for serum qualitative pregnancy testing on 09/10/2019; (3) The following were examples of patient serum pregnancy testing performed when the laboratory was not enrolled in

	proficiency testing: (a) Patient #10178312 - testing performed on 05/17/2020 (b) Patient #10178614 - testing performed on 05/26/2020 (c) Patient #10178736 - testing performed on 05/28/2020 (d) Patient #10180996 - testing performed on 08/06/2020 (e) Patient #10181052 - testing performed on 08/07/2020 (f) Patient #10181298 - testing performed on 08/14/2020 (g) Patient #10181307 - testing performed on 08/15 /2020 (h) Patient #10181519 - testing performed on 08/21/2020 (i) Patient #10185958 - testing performed on 01/16/2021 (j) Patient #10186120 - testing performed on 01/21 /2021 (k) Patient #10186265 - testing performed on 01/27/2021 (l) Patient #10186320 - testing performed on 01/29/2021 (m) Patient #10187736 - testing performed on 03/24 /2021 (n) Patient #10187931 - testing performed on 03/30/2021 (o) Patient #10188190 - testing performed on 04/06/2021 (p) Patient #10188202 - testing performed on 04/06 /2021
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of laboratory services, the laboratory failed to maintain quality control records for at least 2 years. Findings include: (1) On 05/26/2021 at 09:30 am, the director of laboratory services stated to the surveyor CBC(Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On 05/27/2021, the surveyor requested QC (Quality Control) records, which consisted of L-J (Levey Jennings) graphs. The director of laboratory services stated to the surveyor on 05/27/2021 at 04:30 pm, the records were maintained in the analyzer and printouts were not maintained; (3) While searching in the analyzer's memory, the director of laboratory services stated to the surveyor on 05 /27/2021 at 04:45 that QC data could not be retrieved prior to 12/03/2019; (4) The surveyor explained to the director of laboratory services that all records must be maintained for at least 2 years.
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 director of laboratory services, the laboratory failed to follow the manufacturer's instructions for verifying flags obtained on the Hematology analyzer for 7 of 18 records and failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: VERIFYING HEMATOLOGY FLAGS (1) On 05/26/2021 at 09:40 am, the director of laboratory services stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On 05/27/2021 the surveyor reviewed the manufacturer's instructions for

verifying automated differential flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Microcytosis - "Verify RBC morphology on slide" (b) Leukocytopenia - "Review manual smear" (c) Immature Gran? - "Perform manual differential" (d) Left Shift? - "Perform manual differential" (e) Blasts? - "Perform manual differential" (f) Turbidity/HGB Interf? - "Check sample for interpering substnaces, i.e.,lipemia, icterus, cold agglutinin, and clotted sample" (3) The surveyor randomly reviewed 18 patient records which contained flags from CBC testing performed during May 2021. For 6 of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the 6 records were: (a) Record #1 - Testing was performed on 05/06/2021 at 03:59 am, with an Immature Gran? flag obtained; (b) Record #2 - Testing was performed on 05/13/2021 at 04:37 am, with a Leukocytopenia flag obtained; (c) Record #3 - Testing was performed on 05/13/2021 at 04:42 am, with an Immature Gran? flag obtained; (d) Record #4 - Testing was performed on 05/19/2021 at 05:04 am, with Immature Gran? and Left Shift? flags obtained; (e) Record #5 - Testing was performed on 05/24/2021 at 11:04 pm, with Blasts? and Immature Gran? flags obtained; (f) Record #6 - Testing was performed on 05/25/2021 at 04:18 am with a Turbidity/HGB Interf? flag obtained; (g) Record #7 - Testing was performed on 05/26/2021 at 11:13 pm with a Microcytosis flag obtained. (4) The surveyor reviewed the records with the director of laboratory services who stated on 05/27/2021 at 05:30 pm the flags obtained for the above 7 patients had not been verified. IMPLEMENTING COAGULATION REAGENTS (1) On 05/26/2021 at 09:20 am, the director of laboratory services stated to the surveyor the Sysmex CA-660 analyzer was used to perform PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (2) On 05/28/2021 at 11:00 am, the director of laboratory services stated to the surveyor the following reagents were put into use on 11/29/2020: (a) PT - Siemens Dade Innovin reagent, lot #549771 (b) PTT - Siemens Actin FSL reagent, lot #562637A (c) Siemens Ci-Trol control level 1, lot #564828A (d) Siemens Ci-Trol control level 3, lot #55654128 (3) On 05/04/2021, the surveyor reviewed the manufacturer's instructions for implementing new reagents, which stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (b) Section titled, "Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number reagents simultaneously or within 1 our of each other"; (v) "Calculate Linear Regression statistics". (c) Section titled, "Quality Control" (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTTN protocols"; (ii) Collect a minimum of 30 data points over multiple days and stability limits of control"; (iii) Calculate the mean, 2 SD and 3 SD range". (4) The surveyor reviewed the records for the changes with the following identified: (a) PT - Innovin reagent, lot #549771 (i) Although the laboratory performed the method correlation using 20 normal and 20 abnormal samples with the current and new lot number of reagents simultaneously, the comparison with the abnormal samples did not span the reportable range of 8.9-120. The specimens used by the laboratory ranged from 19.9-48.6. (b) PTT - Actin reagent, lot #562637A (i) Although the laboratory performed the method correlation using 20 normal and 20 abnormal samples with the current and new lot number of reagents simultaneously, the comparison with the abnormal samples did not span the reportable range of 17.8-150. The specimens used by the laboratory ranged from 35-75.9. (c) Siemens Ci-Trol

	control level 1 lot #564828A (i) The records showed the laboratory had assayed the new lot of quality control material using 20 data points instead of 30 data points as required. (d) Siemens Ci-Trol control level 3 lot #55654128 (i) The records showed the laboratory had assayed the new lot of quality control material using 20 data points instead of 30 data points as required. (4) The surveyor reviewed the records and the findings with the director of laboratory services. The director of laboratory services stated the following to the surveyor on 05/28/2021 at 11:40 am: (a) The laboratory did not span the reportable range for the method correlation for PT and PTT; (b) The laboratory had utilized 20 data points to assay the new lots of quality control materials for level 1 and level 3, instead of 30 data points; (c) The laboratory had not followed the manufacturer's instructions for implementing the coagulation reagents.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the director of laboratory services, the laboratory failed to ensure materials were being stored as required. Findings include: (1) On 05/27/2021 at 01:00 pm, the surveyor observed the outpatient phlebotomy room, located in a separate room. The following examples of collection tubes, used by the laboratory to collect patient blood specimens, were observed in the room, with the manufacturer's storage requirements: (a) BD Vacutainer 9 NC Coagulation Sodium Citrate 3.2% tubes - 25 tubes of lot #454334; storage requirement of 4-25 degrees Centigrade (C); (b) BD Vacutainer Serum tubes - 8 tubes of lot #1034950; storage requirement of 4-25 degrees C; (c) BD Vacutainer K2 EDTA tubes - 15 tubes of lot #454246; storage requirement of 4-25 degrees C. (2) On 05/28/2021 at 09:24 am, the surveyor asked the director of laboratory services if the temperature of the phlebotomy room was being monitored. The director of laboratory services stated on 05/28/2021 at 09:30 am, the laboratory was not monitoring the temperature of the outpatient phlebotomy room.
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 and interview with the director of laboratory services, the laboratory failed to follow their written protocol to ensure the blood bank centrifuge was functioning properly. Findings include: (1) On 05/26/2021 at 09:00 am, the director of laboratory services stated to the surveyor ABO/Rh, Antibody Screen and Compatibility testing were performed using the Ortho MTS gel system. The specimens were processed in the Ortho MTS Workstation centrifuge at a speed of 1027-1037 rpm (revolutions per minute) for 10 minutes; (2) On 05/27/2021, the surveyor reviewed the function check protocol titled, "Centrifuge Function Check Protocol" which required speed and timer checks be performed annually; (3) The surveyor reviewed the MTS Workstation centrifuge records for 2019 and 2020. Although the speed and timer checks had been performed on 10/15/2019 and 10/06 /2020, the checks had been documented as "OK" for the speed checks and "OK" for the timer checks. There was no documentation to show the speed and time obtained during the checks; (4) The surveyor reviewed the records with the director of laboratory services who stated on 05/27/2021 at 02:00 pm, the checks did not show the speed and time the centrifuge was checked.
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 director of laboratory services, the laboratory failed to ensure units of blood were stored under appropriate conditions for 8 of 29 refrigerator temperature charts and 8 of 29 freezer temperature charts. Findings include: (1) On 05/26/2021 at 09:10 am, the director of laboratory services stated the following to the surveyor: (a) The laboratory stored units of packed red blood cells in the blood bank refrigerator; (b) The laboratory stored units of FFP (Fresh Frozen Plasma) in the blood bank freezer; (c) The above units were to be used for patient transfusions. (2) On 05/27/2021 at 11:30 am, the surveyor observed the thermograph temperature recorders for the blood bank refrigerator and freezer. They had recorders connected to them for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees (C) Centigrade and units of FFP must be stored at -19 degrees C or colder). Each chart monitored the temperature for a 7 day period; (3) The surveyor reviewed 29 refrigerator charts and 29 freezer charts dated from 09/04/2020 through 05/18/2021. The review showed that 8 of 29 refrigerator charts and 8 of 29 freezer charts had not been changed by the 7th day of usage as follows: (a) Refrigerator (i) Chart #1 - The chart was put into use on 09/04/2020 and removed on 09/12/2020 (8 days); (ii) Chart #2 - The chart was put into use on 09/12/2020 and removed on 09/25/2020 (13 days); (iii) Chart #3 - The chart was put into use on 10/16/2020 and removed on 11/012020 (16 days); (iv) Chart #4 - The chart was put into use on 11/01/2020 and removed on 11 /17/2020 (16 days); (v) Chart #5 - The chart was put into use on 12/15/2020 and removed on 12/23/2020 (8 days); (vi) Chart #6 - The chart was put into use on 12/23 /2020 and removed on 01/12/2021 (20 days); (vii) Chart #7 - The chart was put into

	use on 04/13/2021 and removed on 04/27/2021 (14 days); (viii) Chart #8 - The chart was put into use on 05/04/2021 and removed on 05/18/2021 (14 days). (b) Freezer (i) Chart #1 - The chart was put into use on 09/04/2020 and removed on 09/12/2020 (8 days); (ii) Chart #2 - The chart was put into use on 09/12/2020 and removed on 09/25 /2020 (13 days); (iii) Chart #3 - The chart was put into use on 10/16/2020 and removed on 11/012020 (16 days); (iv) Chart #4 - The chart was put into use on 11/01 /2020 and removed on 11/17/2020 (16 days); (v) Chart #5 - The chart was put into use on 12/15/2020 and removed on 12/23/2020 (8 days); (vi) Chart #6 - The chart was put into use on 12/23/2020 and removed on 01/12/2021 (20 days); (vii) Chart #7 - The chart was put into use on 04/13/2021 and removed on 04/27/2021 (14 days); (viii) Chart #8 - The chart was put into use on 05/04/2021 and removed on 05/18/2021 (14 days). (4) The surveyor reviewed the charts with the director of laboratory services who stated on 05/27/2021 at 03:00 pm, the charts had not been changed by the 7th day as stated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the director of laboratory services, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers. Findings include: (1) On 05 /26/2021, the director of laboratory services stated to the surveyor Acetaminophen, Albumin, Alcohol, Alkaline Phosphatase, Amylase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), BUN (Blood Urea Nitrogen), Calcium, Carbamazepine, Cholesterol, Chloride, CK (Creatine Kinase), CKMB (CK Isoenzyme), CO2, Creatinine, Digoxin, Dilantin, Direct Bilirubin, Gentamicin, GGT (Gamma Glutamyl transferase), Glucose, HCG (Human Chorionic Gonadotropin), Hemoglobin A1c, HDL (High Density Lipoprotein), Lipase, Magnesium, Phenobarbital, Phosphorus, Potassium, Salicylate, Sodium, Tobramycin, Total Bilirubin, Theophylline, Total Protein, Triglyceride, TSH (Thyroid Stimulating Hormone), Free T4 (Thyroxin), Vancomycin, and Uric Acid testing were performed on two analyzers as follows: (a) The Dimension EXL analyzer, denoted by the laboratory as EXL 2 was the primary analyzer; (b) The Dimension EXL analyzer, denoted by the laboratory as EXL 1 was the back-up analyzer. (2) On 05/28/2021 the surveyor reviewed the comparison data for the analyzers for testing performed from January 2020 through 05/28/2021. There was no evidence the relationship between the analyzers had been evaluated twice in 2020 and to date in 2021. The relationship between the analyzers had been evaluated on 12/30/2020 (not prior to that date and after that date): (3) The surveyor reviewed the records with the director of laboratory services who stated on 05/28/2021 at 11:45 am, the relationship between the analyzers had not been evaluated prior to 12/30/2020 and to date in 2021.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447

	The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with technical the director of laboratory services, 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 director of laboratory services, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor, met the qualifications for 3 of 4 proficiency testing attestation forms. Findings include: (1) On 05/26/2021, the surveyor reviewed the Laboratory Personnel Report (Form CMS-209), that had been completed by the laboratory. The form listed the same individual as the laboratory director and the technical supervisor; (2) The surveyor then reviewed proficiency testing records for the following events: (a) Immunohematology - First 2020, second 2020, third 2020, and first 2021 (3) The documentation showed that the attestation statements for 3 of 4 events (first, second, and third 2020) had been signed by the director of laboratory services instead of the laboratory director/technical supervisor (the director of laboratory services had bachelor degree in science); (4) The findings were reviewed with the director of laboratory services who stated to the surveyor on 05/26/2021 at 10:00 am, the attestation statements for the above events had been signed by a person who did not qualify as a technical supervisor.