

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0476048	(X3) Date Survey Completed 12/18/2020
Name of Provider or Supplier Northeastern Health System-Sequoyah	Street Address, City, State 213 East Redwood Ave, Sallisaw, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 12/17/2020 and 12/18/2020. The findings were reviewed with technical consultant #1, technical consultant #2, cardiopulmonary director, director of nursing, and hospital administrator at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1447; D6108: Technical Supervisor
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee for 3 of 18 events. Findings include: (1) On 12/17/2020, the surveyor reviewed 2019 and 2020 proficiency testing records, with the following identified: (a) First 2020 Chemistry Core Event - The attestation statement had not been signed by the laboratory director or designee; (b) First 2020 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director or designee; (c) Second 2020 Immunohematology Event - The attestation statement had not been signed by the laboratory director or designee. (2) The surveyor</p>

reviewed the records with technical consultant #1, who stated on 12/17/2020 at 01:15 pm the attestation statements had not been signed by the laboratory director as indicated above.

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 technical consultant #1, the laboratory failed to review and evaluate proficiency testing results for 2 of 18 events. Findings include: BIAS (1) On 12/17/2020, 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) First 2019 Hematology Event (i) MCV (Mean Corpuscular Volume) - 5 of 5 results exhibited a negative bias (aa) Sample XE-01 - SDI of -2.1 (bb) Sample XE-02 - SDI of -2.0 (cc) Sample XE-03 - SDI of -2.1 (dd) Sample XE-04 - SDI of -2.5 (ee) Sample XE-05 - SDI of -2.1 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with technical consultant #1. Technical consultant #1 stated on 12/17/2020 at 01:10 pm the biases had not been addressed. FAILURES (1) On 12/17/2020, the surveyor reviewed 2019 and 2020 proficiency testing records and identified the following failure: (a) Second 2020 Chemistry Core Event (i) Cholesterol - The laboratory failed the result for 1 of 5 samples (CH-08). (2) The surveyor could not locate evidence in the records proving the failure had been addressed; (3) The surveyor reviewed the records with technical consultant #1, and asked if corrective action had been taken and documented for the failure. Technical consultant #1 stated on 12/17/2020 at 01:03 pm corrective action had not been taken.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing Ammonia testing for 1 of 5 patient samples; and failed to follow the manufacturer's instructions for coagulation testing for two of two reagent lot changes. Findings include: AMMONIA TESTING (1) On 12/17/2020 at 10:40 am, technical consultant #1 stated to the surveyor that Ammonia testing was performed on the Vitros 5600 analyzer; (2) On 12/17/2020, the surveyor reviewed the manufacturer's instructions for the Ammonia testing under the section titled "Specimen Handling and Storage" stated: (a) Ammonia - "Centrifuge specimens and remove the plasma from the cellular material within 15 minutes of collection." (3) On 12/18/2020, the surveyor reviewed 5 patient reports tested between 03/18/2020 through 09/25/2020.

The records showed for 1 of 5 reports: (a) 03/18/2020 - The specimen was collected at 09:53 am, received into the laboratory 10:20 am, and resulted 11:10 am (50 minutes after collection). (4) The surveyor asked technical consultant #1 if the laboratory had documentation to prove specimens were centrifuged according to the manufacturer's instructions. Technical consultant #1 stated on 12/18/2020 at 02:15 pm, it was the laboratory's practice to process specimens as soon as they were received into the laboratory, but there was no documentation to prove the specimen had been centrifuged within 15 minutes of collection. COAGULATION (1) On 12/17/2020 at 10:55 am, technical consultant #1 stated to the surveyor PT/INR (Protime /International Normalized Ratio) and PTT (Partial Thromboplastin Time) were performed on the ACL Elite analyzer; (2) On 12/17/2020 at 11:10 am, the surveyor observed in the laboratory refrigerator the current reagent in use: (a) PT reagent - Hemosil RecombiPlasTin lot# N0696619 put into use 07/30/2020; (b) PTT reagent - Synthasil lot# N0797526 put into use on 07/30/2020; (3) On 12/18/2021, the surveyor reviewed the manufacturer's manual titled, "HEMOSTASIS PERFORMANCE VERIFICATION MANUAL" under the section titled, "CHANGING REAGENT or LOT NUMBER OF REAGENT" which stated: (a) "When changing to a new lot number of reagent or a new reagent, it is important to establish a new normal reference interval, establish new assay control ranges, perform a comparison study for all tests, and to establish the heparin therapeutic range (APTT reagents)". (i) "COMPARISON STUDY" (aa) "1. Collect and handle specimens according to accepted laboratory practice for the assay being performed." (bb) "2. Include diseases /treatment known to affect the assay being performed." (cc) "3. At least 50% of the samples should be outside of the laboratory normal reference interval, if possible." (dd) "4. At least 40 specimens should be analyzed. More samples will improve the confidence in the data." (ee) "5. Treat samples in the same manner for both systems (e. g. if fresh sample is used with one system, the same fresh sample should be used with the second system; or use a frozen sample for both)."; (4) On 12/18/2020, the survey reviewed the records for new reagent lot numbers for PT and PTT and identified the following: (a) The laboratory performed the comparison studies on 07/30/2020 with 4 abnormal specimens for PT and 4 abnormal specimens for PTT; and 26 normal specimens for PT and 26 normal specimens for PTT. (5) On 12/18/2020, the surveyor reviewed the finding with technical consultant #1. Technical consultant stated on 12 /18/2020 at 05:11 pm, the laboratory did not perform the comparison study according to the manufacturer's instructions as indicated above.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
 Based on a review of records and interview with technical consultant #1 and testing person #16 (cardiopulmonary director), the laboratory failed to ensure the verified reportable ranges were used by the laboratory for one of one new test method. Findings include: (1) On 12/17/2020 at 10:20 am, technical consultant #1 stated pH,

pCO₂, and pO₂ testing were performed in the laboratory using the ABL80 Flex analyzer; (2) On 12/17/2020, the surveyor reviewed the performance specification records and identified the laboratory had demonstrated the following reportable ranges: (a) pH - 6.8 - 7.790 (b) PCO₂ - 11.5 - 42.2 mmHg (c) PO₂ - 22.0 - 162.0 mmHg (3) The surveyor requested the reportable ranges that were being utilized by the laboratory. Technical consultant #1 provided the laboratory with the manufacturer's reportable ranges as follows: (a) pH - 6.0 - 8.0 (b) pCO₂ - 0 - 150 mmHg (c) pO₂ - 0 - 760 mmHg (4) On 12/18/2020, the surveyor reviewed the findings with testing person #16. Testing person #16 stated on 12/18/2020 at 12:55 pm the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.

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 technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On 12/17/2020 at 10:00 am, technical consultant #1 stated to the surveyor the laboratory performed urinalysis testing using the Clinitek Advantus analyzer; (2) On 12/17/2020, the surveyor reviewed the manufacturer's maintenance requirements. The requirements for daily maintenance were as follows: (a) "Performing the Daily Cleaning" (i) "Clean the following parts at least once each day or after running 300 strips, whichever is more frequent:" (aa) "Push bar" (bb) "Fixed platform" (cc) "Moving table" (dd) "Urine strip hold down plate" (3) The surveyor then reviewed maintenance records for 11 months (January 2020 through November 2020). There was no evidence the daily maintenance had been performed: (a) Between 09/06/2020 and 09/08/2020; (b) Between 09/13/2020 and 09/15/2020; (c) Between 09/20/2020 and 09/22/2020. (4) The surveyor reviewed the records with technical consultant #1. Technical consultant #1 stated on 12/17/2020 at 03:20 pm, the daily maintenance had not been performed as required;

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 technical consultant #1, the

laboratory failed to ensure the chemistry and blood bank centrifuges were functioning properly. Findings include: URINE CENTRIFUGE (1) On 12/17/2020 at 10:40 am, technical consultant #1 stated to the surveyor that the Drucker 642 E (serial number 520910-476) centrifuge was used to process chemistry specimens at a speed of 3500 rpm (Revolutions Per Minute) and a time of 10 minutes; (2) On 12/17/2020, the surveyor asked technical consultant #1 to explain how often function checks (speed and timer checks) were performed on the centrifuge. Technical consultant #1 stated on 12/17/2020 at 10:45 am, it was the laboratory's policy to check the speed and timer of the centrifuges semi-annually; (3) On 12/17/2020, the surveyor reviewed the records for the function checks that had been performed in 2019 and identified the centrifuge time had been checked as follows: (a) 04/17/2019 for 2 minutes; (b) 10/10/2019 for 2 minutes. (4) The surveyor reviewed the records with technical consultant #1 and asked if the timer had been checked at a time of 10 minutes according to the laboratory's procedure for processing chemistry specimens. On 12/17/2020 at 04:30 pm, technical consultant #1 stated the centrifuge had not been checked at 10 minutes as indicated above. BLOOD BANK MTS CENTRIFUGE (1) On 12/17/2020 at 10:40 am, technical consultant #1 stated to the surveyor the Ortho MTS centrifuge was used to process specimens for Antibody Screen testing at a speed of 895 rpm (revolutions per minute) and a time of 10 minutes; (2) On 12/17/2020, the surveyor asked technical consultant #1 to explain how often function checks (speed and timer checks) were performed on the centrifuge. Technical consultant #1 stated on 12/17/2020 at 10:45 am, it was the laboratory's policy to check the speed and timer of the centrifuges semi-annually; (3) The surveyor reviewed the records for the function checks that had been performed in 2019 and identified the centrifuge time had been checked as follows: (a) 10/01/2019 for 15 seconds. (4) The surveyor reviewed the records with technical consultant #1, and asked if there were additional speed and timer check records. On 12/17/2020 at 04:32 pm, technical consultant #1 stated the centrifuge had not been checked at 10 minutes as indicated 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 the director of nursing, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 8 of 14 units of packed red blood cells. Findings include: (1) On 12/17/2020 at 10:55 am, technical consultant #1 stated to the surveyor the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) The surveyor reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood/Blood Components - Transfusion" under the following sections titled, (a) "1. Informed Consent" stated, (i) "A. An

informed consent shall be completed prior to administration of Blood/Blood Components, Inpatient informed consent is valid for the duration of the current hospital admission." (b) "15. Recording Vital Signs" which stated, (i) "A. For each unit of red blood cells, pheresis platelets, fresh frozen plasma, and cryoprecipitate to be administered, (vital signs, blood pressure, pulse, and temperature) shall be obtained and documented on the Transfusion Record:" (aa) "1. prior to transfusion" (bb) "2. every 5 minutes x 3 after initiation of the transfusion, every 15 x 2 after infusion begins, then hourly thereafter." (cc) "3. upon completion of the transfusion(s)." (3) The surveyor review 9 patients records for 14 units of PRBCs (Packed Red Blood Cells) that had been transfused between 06/25/2019 through 11/12/2020 and identified the following: (a) Informed Consent (i) Patient #50052 - Transfused with 1 unit of PRBCs (unit #W091020129749) on 02/01/2020. An informed consent could not be located at the time of the survey; (ii) Patient #1006185 - Transfused with 1 unit PRBCs (unit #W091020169403) on 03/22/2020. An informed consent could not be located at the time of the survey; (iii) Patient #8473 - Transfused with 1 unit PRBCs (unit #W091020310268) on 10/15/2020. An informed consent could not be located at the time of the survey. (b) Vital Signs (i) Patient #1010973 - Transfused with 1 unit of PRBCs (unit #W0919244224) on 06/25/2019. The unit was started at 10:10 am and the first vital was documented as 10:15 am (15 minutes after initiation of the transfusion); (ii) Patient #50052 - Transfused with 1 unit of PRBCs (unit #W091020129749) on 02/01/2020. Documentation of vital signs could not be located at the time of the survey; (iii) Patient #1049077 - Transfused with 1 unit of PRBCs (unit #W091020222765) on 06/26/2020. The unit was started at 04:15 pm with vitals taken at 04:15 pm, 04:20 pm, 04:25 pm, 04:55 pm (30 minutes later); (iv) Patient #1006185 - Transfused with 1 unit PRBCs (unit #W091020169403) on 03/22/2020. Documentation of vital signs could not be located at the time of the survey; (v) Patient #5201 - Transfused with 1 unit PRBCs (unit #W091020289402) on 08/13/2020. Documentation of vital signs could not be located at the time of the survey; (vi) Patient #1045580 - Transfused with 1 unit PRBCs (unit # W091020340981) on 09/10 /2020. The unit was started at 01:36 am with the first vital sign taken at 01:46 am (10 minutes later). (4) On 12/17/20, the surveyor reviewed the findings with the director of nursing. The director of nursing stated on 12/17/2020 at 03:15 pm the written policy and procedure for blood administration had not been followed as indicated above.

D6108

LABORATORY TECHNICAL SUPERVISOR
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of records and interview with technical consultant #1, the technical supervisor failed to provide technical supervision in accordance with 493.1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the educational qualifications. Refer to D6111.

D6111

TECHNICAL SUPERVISOR QUALIFICATIONS
CFR(s): 493.1449

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

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

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

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

requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii) (B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (l)(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 (l)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such

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

medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with technical consultant #1, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor, met the qualifications for 3 of 6 proficiency testing attestation forms; and for 2 of 2 of semiannual competency assessments. Findings include: ATTESTATION FORMS (1) On 12/17/2020, the surveyor reviewed the Laboratory Personnel Report (Form CMS-209), that had been completed by the laboratory. The form listed the same individual as the laboratory director and the technical supervisor; (2) The surveyor then reviewed proficiency testing records for the following events: (a) Immunohematology - First 2019, second 2019, third 2019, first 2020, second 2020, and third 2020. (3) The documentation showed that the attestation statements for 3 of 6 events (first, second, and third 2019) had been signed by technical consultant #1 instead of the laboratory director/technical supervisor (the director of laboratory services had bachelor degree in science); (4) The findings were reviewed with technical consultant #1 who stated to the surveyor on 12/17/2020 at 01:30 pm, the attestation statements for the above events had been signed by a person who did not qualify as a technical supervisor. SEMI-ANNUAL BLOOD BANK COMPETENCY (1) On 12/17/2020, the surveyor reviewed records for 2 testing person who had been hired to perform high complexity testing (ABO/Rh, Antibody Screen and Compatibility testing) since the previous recertification survey performed 10/23/2018 through 10/26/2018. 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 #3 - The 07/20/2020 semi-annual evaluation had been performed by technical consultant #1 (this person had earned a bachelor of science); (b) Testing Person #10 - The 07/06/2019 semi-annual evaluation had been performed by technical consultant #1. (2) The surveyor explained to technical consultant #1 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 12/17/2020 at 04:07 pm, technical consultant #1 stated to the surveyor the semi-annual evaluations 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"