

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0474836	(X3) Date Survey Completed 06/25/2021
Name of Provider or Supplier Saint Francis Hospital Vinita	Street Address, City, State 735 North Foreman, Vinita, 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 06/24,25,2021. The findings were reviewed with the quality coordinator, current laboratory supervisor, and incoming laboratory supervisor during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1447; D6108: Technical Supervisor
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, written policy and interview with the laboratory supervisor, the laboratory failed to follow their written technical consultant and general supervisor competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On 06/25/2021, surveyor #2 reviewed personnel records for competency assessments performed during 2019 and 2020. There was no evidence competencies had been performed for the technical consultant and general supervisor, based on their job responsibilities; (2) Surveyor #2 asked the laboratory supervisor if a written policy to evaluate the technical consultant and general supervisor based on job responsibilities was available. The general supervisor provided the policy for the surveyors review; (3) Suvveyor #2 reviewed the policy titled, PERSONNEL COMPETENCY ASSESSMENT", which stated, "7.1. Competency of the technical or general supervisor is assessed via annual performance review."; (4) Srveyor #2 asked the laboratory supervisor if annual competencies based on job responsibilities had been performed during the review period. The laboratory supervisor stated on 06/25/2021 at 09:50 am, annual competencies had not been performed.</p>

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory supervisor, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of five Hematology events reviewed. Findings include: (1) On 06/25/2021, surveyor #2 reviewed proficiency testing records for the first 2019, second 2019, first 2020, second 2020, and third 2020 event. The following was identified for one of five Hematology events: (a) First 2020 Hematology Event for Blood Cell Identification - One of five results had not been graded by the proficiency testing program: (i) ECI-01- Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) Surveyor #2 reviewed the records with the laboratory supervisor who stated on 06/25/2021 at 02:27 pm, the laboratory had not evaluated the result that was not graded by the proficiency testing program and corrective action had not been taken as indicated.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on a review of records, written policy, and interview with the laboratory supervisor, the laboratory failed to follow their written Immunohematology maintenance procedure. Findings include: (1) On 06/24/2021 at 09:40 am, the laboratory supervisor stated to surveyor #1, the laboratory performed Immunohematology testing (ABO/RH, Antibody Screen, and Immediate Spin Compatibility) using the tube method and the Ortho MTS Gel system for the Antibody Screen and AHG (Anti Human Globulin) Compatibility testing; (2) Surveyor #2 reviewed the policy titled "Scheduled Maintenance/QC". (a) Under the heading "WEEKLY" the policy stated: (i) "The MTS 1 mL and .5mL pipette dispenser tubing will be cleaned once a week." (ii) "Document date and initials on the QC log." (b) Under the heading "MONTHLY" the policy stated: (i) "The MTS 1mL and .5mL: dispense is checked for the appropriate dispensed level." (ii) "Document in the blood bank QC binder in the designated area." (3) On 06/24/2021, surveyor #2 then reviewed 2020 and 2021 weekly and monthly maintenance records and identified the following: (a) Weekly maintenance had not been documented: (i) Between 09/07/2020 and 09/23/2020 (ii) Between 11/09/2020 and 11/20/2020 (iii) Between 02/01/2021 and 02/12/2021 (b) Monthly maintenance had not been documented: (i)

Between 06/02/2020 and 08/26/2020 (4) Surveyor #2 reviewed the findings with the laboratory supervisor who stated on 06/24/2021 at 04:45 pm, the weekly and monthly maintenance had not been performed 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 the laboratory supervisor, the laboratory failed to ensure the reportable ranges were utilized for a new test method. Findings include: (1) On 06/24/2021 at 09:30 am, the laboratory supervisor stated to surveyor #1 the laboratory began using the iSTAT 1 analyzer and EG7+ cartridge to perform Blood Gas (pH, pCO₂, pO₂) testing on 07/29/2020; (2) On 06/25/2021 surveyor #1 reviewed the performance specification records for the new test system and identified the laboratory had demonstrated the following reportable ranges: (a) pH - 6.546-7.988 (b) pCO₂ - 16.1-93.2 (c) pO₂ - 78-371 (3) Surveyor #1 then requested documentation to show the reportable ranges that were being utilized by the laboratory. The laboratory was using the following manufacturer's reportable ranges: (a) pH - 6.5-8.2 (b) pCO₂ - 5-130 (c) pO₂ - 5-800 (4) Surveyor #1 reviewed the findings with the laboratory supervisor, who stated on 06/25/2021 at 11:15 am, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing weekly maintenance procedures for the Cell Dyn Ruby analyzer. Findings include: (1) On 06/24/2021 at 09:50 am, the laboratory supervisor stated to surveyor #1 CBC (Complete Blood Count) testing was performed on the Cell Dyn Ruby analyzer; (2) On 06/25/2021, surveyor #1 reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance log titled, "Cell Dyn Ruby Maintenance Log". The weekly requirements were as follows: (a) Clean Loader Components (3) Surveyor #1 then reviewed maintenance records from January 2020 through May 2021. The weekly maintenance had not been documented as performed between: (a) 01/30/2020 and 02/11/2020 (b) 02/26/2020 and 03/12/2020 (c) 07/03/2020 and 07/15/2020 (d) 09/19/2020 and 10/09/2020 (e) 11/12/2020 and 11

/30/2020 (f) 12/15/2020 and 12/28/2020 (g) 01/26/2021 and 02/09/2021 (h) 04/21/2021 and 05/05/2021 (i) 05/13/2021 and 05/27/2021 (4) Surveyor #1 reviewed the findings with the laboratory supervisor who stated on 06/25/2021 at 01:50 pm the weekly maintenance had not been documented as performed as identified above.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory supervisor, the laboratory failed to perform calibration verification procedures at least once every six months for two of three calibration verifications. Findings include: (1) On 06/24/2021 at 10:05 am, the laboratory supervisor stated to surveyor #1, Buprenorphine testing was performed using the Abbott Ci4100 analyzer; (2) On 06/25/2021, surveyor #2 reviewed 2019, 2020, and 2021 calibration verification records for Buprenorphine (since routine calibration procedures were performed using less than three calibrators for the above analyte, calibration verification procedures, using three or more levels of calibration materials, was required every 6 months). There was no evidence calibration verification procedures had been performed since 09/20/2019 through the day of the survey (06/25/2021); (3) Surveyor #2 reviewed the records with laboratory supervisor who stated on 06/25/2021 at 3:12 pm, calibration verification had not been performed every 6 months as indicated above.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when

they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the quality coordinator and laboratory supervisor, the laboratory failed to ensure an IQCP included the required components. Findings include: (1) On 06/24/2021 at 09:35 am, the laboratory supervisor stated the following to surveyor #1: (i) Qualitative serum pregnancy testing was performed using the Beckman Coulter ICON 25 hCG test kit; (ii) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP for the test system and identified a QCP (Quality Control Plan) and QA (Quality Assessment) plan had not been included in the IQCP (it consisted of a Risk Assessment only); (3) Surveyor #1 reviewed the records with the quality coordinator, who stated on 06/24/2021 at 09:50 am, a QCP and QA plan could not be located.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the blood bank supervisor, the laboratory failed to perform control procedures each day of blood bank testing for four of 75 days of patient testing. Findings include: (1) On 06/24/2021 at 09:50 am, the laboratory supervisor stated to surveyor #1 the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) using the tube method; (2) Surveyor #2 reviewed records for blood bank testing performed between 06/02/2020 through 11/27/2020 and identified quality control had not been performed for four of 75 days when patient Type and Screen, Crossmatch testing, or retype of donor units for transfusion had been performed as follows: (a) Patient #1 - A Type and Screen was performed on 06/19/2020; (b) Patient #2 - Retype of two donor units for transfusion was performed on 09/03/2020; (c) Patient #3 - Retype of four donor units for transfusion was performed on 11/15/2020; (d) Patient #4 - A Type, Screen, and Crossmatch was performed on 12/05/2020. (3) Surveyor #2 reviewed the records with the blood bank supervisor who stated on 06/24/2021 at 05:55 pm, quality control had not been performed as indicated above.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a review of a patient report and interview with the quality coordinator, laboratory supervisor, and coagulation superuser, the laboratory failed to provide therapeutic reference intervals for INR test results. Findings include: (1) On 06/24/2021 at 1:00 pm, the laboratory supervisor stated to surveyor #1 INR-International Normalized Ratio testing was performed using the Stago STA Compact Max analyzer; (2) Surveyor reviewed one patient report with INR results for a patient tested on 06/17/2021. The report did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (3) The report was reviewed with the quality coordinator and coagulation superuser. Both stated to surveyor #1 on 06/24/2021 at 02:45 pm, the patient report did not include a therapeutic range for INR.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for five of 28 events. Findings include: (1) On 06/25/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing events. For five of 28 events, the attestation statements had been signed approximately 2-4 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2019 Microbiology Event - The sample testing had been completed on 06/24/2019, and the attestation statement had not been signed by the laboratory director/designee until 08/23/2019; (b) First 2020 Microbiology Event - The sample testing had been completed on 02/17/2020, and the attestation statement had not been signed by the laboratory director/designee until 06/10/2020; (c) Second 2020 Microbiology Event - The sample testing had been completed on 06/28/2020, and the attestation statement had not been signed by the laboratory director/designee until 09/13/2020; (d) Third 2020 Microbiology Event - The sample testing had been completed on 10/02/2020, and the attestation statement had not been signed by the laboratory director/designee until 12/03/2020; (e) Second 2020 Chemistry Event - The sample testing had been completed on 10/18/2020, and the attestation statement had not been signed by the laboratory director/designee until 12/09/2020. (2) Surveyor #2 reviewed the findings with the laboratory supervisor who stated on 06/25/2021 at 02:27 pm the attestations had been signed approximately 2-4 months after the proficiency samples had been tested. The surveyor explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory supervisor, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 10 of 10 testing persons. Findings include: (1) On 06/24/2021 at 09:50 am, the laboratory supervisor stated to surveyor #1 qualitative serum pregnancy testing, using the Beckman Icon 25 test kit, was performed in the laboratory; (2) On 06/25/2021, surveyor #2 reviewed the 2020 and 2021 personnel records for 10 persons performing qualitative serum pregnancy testing in the laboratory. The records showed that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 01/31/2020 and 02/25/2021 (b) Testing Person #2 - Performed on 01/22/2020 and 01/15/2021 (c) Testing Person #3 - Performed on 01/01/2020 and 01/01/2021 (d) Testing Person #4 - Performed on 01/03/2020 and 01/08/2021 (e) Testing Person #5 - Performed on 01/21/2020 and 01/11/2021 (f) Testing Person #6 - Performed on 05/30/2021 (g) Testing Person #7 - Performed on 01/01/2020 and 01/21/2021 (h) Testing Person #8 - Performed on 01/22/2020 and 01/15/2021 (i) Testing Person #9 - Performed on 01/09/2020 and 01/29/2021 (j) Testing Person #10 - Performed on 01/21/2020 and 01/14/2021 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of the qualitative serum pregnancy testing; (4) Surveyor #2 reviewed the findings with laboratory supervisor, who stated on 06/25/2021 at 10:00 am, the above evaluations did not include serum pregnancy assessments.

D6108

LABORATORY TECHNICAL SUPERVISOR
CFR(s): 493.1447

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

This CONDITION is not met as evidenced by:

Based on a review of records and interview with laboratory supervisor, 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 the laboratory supervisor, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor, met the qualifications for four of six proficiency testing attestation forms; and failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor, met the qualifications for two of two semi-annual competency assessments. Findings include: **PROFICIENCY TESTING** (1) On 06/25/2021, surveyor #2 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) Surveyor #2 then reviewed proficiency testing records for the following events: (a) Immunohematology - Second 2019, Third 2019, First 2020, Second 2020, Third 2020, and First 2021 (3) The documentation showed that the attestation statements for four of six events (second 2019, first 2020, third 2020, and first 2021) had been signed by the technical consultant instead of the laboratory director/technical supervisor (the technical consultant had bachelor degree in science); (4) On 06/25/2021, the findings were reviewed with the laboratory supervisor who stated to surveyor #2 on 06/25/2021 at 02:37 pm, the attestation statements for the above events had been signed by a person who did not qualify as a technical supervisor. **PERSONNEL COMPETENCY** (1) On 06/25/2021, surveyor #2 reviewed records for two testing person who had been hired to perform high complexity testing (ABO/Rh, Antibody Screen and Compatibility testing) since the previous recertification survey performed. The records indicated the semi-annual evaluation for the testing person had been performed by an individual who did not meet the regulatory qualification requirements of the technical supervisor: (a) Testing Person #6 - The 05/30/2021 semi-annual evaluation had been performed by the technical consultant (this person had earned a bachelor degree in applied science); (b) Testing Person #8 - The 06/10/2020 semi-annual evaluation had been performed by the technical consultant. (2) On 06/25/2021, surveyor #2 explained to the laboratory supervisor 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 06/25/2021 at 10:25 am, the laboratory supervisor stated to surveyor #2 the semi-annual evaluation had not been performed by someone who met the qualifications of a technical supervisor as indicated above. NOTE: The regulations only allow for an individual qualifying as a general supervisor to perform initial training and annual competency evaluations as stated at 493.1463 "Standard; General supervisor responsibilities: (b)(3) Providing orientation to all testing personnel; and (b)(4) Annually evaluating and documenting

the performance of all testing personnel"