Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656628	04/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Seiling Municipal Hospital	809 Ne Hwy 60, Seiling, 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 04/07,08,09/2021. The laboratory was found out of compliance with the following CLIA regulations: 493.1409; D6033: Technical Consultant 493.1447; D6108: Technical Supervisor The findings were reviewed with the technical consultant and laboratory manager during an exit conference performed at the conclusion of the survey.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to review proficiency testing results for 1 of 21 events. Findings include: (1) On 04/07/2021, surveyor #2 reviewed 2019 and 2020 proficiency testing records and identified the following failure: (a) Third 2019 Chemistry Core Event (i) Creatine Kinase - The laboratory failed the results for 1 of 5 samples (CH-11); (2) Surveyor #2 could not locate evidence in the records proving the failure had been addressed; (3) Surveyor #2 reviewed the records with technical consultant, and asked if corrective action had been taken and documented for the failure. The technical consultant stated on 04/07/2021 at 02:10 pm corrective action had not been taken.
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 technical consultant, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for 1 of 21 events reviewed. Findings include: (1) On 04/07/2021, surveyor #2 reviewed 2019 and 2020 proficiency testing records. The following was identified for 1 of 21 events: (a) Third 2020 Hematology Event for Urine Sediment - 1 of 2 results had not been graded by the proficiency testing program: (i) For 1 of 2 results (US-06), the following was identified: (aa) US-06- 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 technical consultant who stated on 04/07/2021 at 01:30 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 above.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual, and interview with the laboratory manager and technical consultant, the laboratory failed to have complete written quality control policies and procedures. Findings include: (1) On 04/07/2021 at 09:45 am, the laboratory manager stated to surveyor #1 arterial blood gas (pH, pO2, and pCO2) testing was performed using the Opti CCA-TS2 analyzer; (2) Surveyor #1 reviewed the procedure titled, "OPTI MEdical CCA-TS2 Critical Care Analyzer". Under the heading "Quality Control" the following had not been included: (a) Number and frequency of testing controls; (b) Criteria to determine acceptable control results. (3) The surveyor reviewed the findings with the laboratory manager and technical consultant. Both stated on 04/07/2021 at 03:25 pm, the procedures had not been written.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and technical consultant, the laboratory failed to follow the manufacturer's instructions for verifying morphology flags for four of 26 patient reports. Findings include: (1) On 04/07/2021 at 10:35 am, the laboratory supervisor stated to surveyor #1 that CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) Surveyor #2 reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Anisocytosis - "Verify RBC morphology on slide" (b) Anemia - "Verify RBC morphology on slide" (b) Microcytosis - "Verify RBC morphology on slide" (f) Neutrophilia - "Review manual smear" (h) Thrombocytopenia - "Verify on slide" (3) Surveyor #2 randomly reviewed 26 patient records which contained morphology flags from CBC testing performed on 01/04/2020, 02/08/2020, 03/21/2020, 07/18/2020, 08/22/2020, and 09/26/2020. For four of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the four records were: (a) Testing was performed on 04/25/2020 at 10:49 pm, with a Microcytosis flag obtained; (b) Testing was performed on 04/25/2020 at 12:36 pm, with an Anemia and Microcytosis flags obtained; (c) Testing was performed on 04/25/2020 at 11:23 pm, with a Neutrophilia flag obtained; (d) Testing was preformed on 08/22/2020 at 06:40 am, with a Anisocytosis flag obtained. (4) On 04/08/2021, surveyor #2 reviewed the records with the technical consultant, who stated on 04/08/2021 at 09:45 am that the flags obtained for the above four patients had not been verified.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with the laboratory manager, the laboratory failed to label containers with the identity, expiration date, and lot number of the contents. Findings include: (1) On 04/07/2021 at 10:30 am, the laboratory manager stated to surveyor #1 the laboratory performed manual differential testing; (2) Surveyor #1 observed the laboratory on 04/07/2021 at 10:35 am and identified 3 unlabeled Copeland jars, appearing to contain materials used to stain peripheral blood smears; (3) The laboratory manager stated to surveyor #1 on 04/07/2021 at 10:35 am, the containers contained materials that were used to stain peripheral blood smears for performing manual differential testing: (4) Surveyor #1 explained to the laboratory

	manager the containers must be labeled with the identity, expiration date, and lot number of the staining materials.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to ensure reagents had not exceeded their expiration date for 1 of 23 days of testing. Findings include: (1) On 04/07/2021 at 09:50, the laboratory manager sstated to surveyor #1 Crossmatch testing was performed in the laboratory which included ABO Typing using the tube method. Ortho A1 Cells and B Cells were used to perform ABO reverse grouping; (2) On 04/08/2021, surveyor #1 reviewed quality control and patient testing records for testing performed from 01/03 /2020 through 01/30/2021 and identified expired A1 Cells and B Cells had been used 1 of 23 days of testing reviewed. The quality control and patient testing had been performed on 01/17/2020 using the expired following reagents: (a) Ortho A1 Cells, lot #8A048, expiration date 01/14/2020 (b) Ortho B Cells, lot #8A048, expiration date 01 /14/2020 (3) Surveyor #1 reviewed the records with the technical consultant who stated on 04/08/2021 at 12:05 expired reagents had been used 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, policies and procedures, and interview with the laboratory manager and technical consultant, the laboratory failed to ensure the demonstrated reportable ranges were utilized for 2 of 2 new test analyzers. Findings include: ORTHO VITROS XT-3400 ANALYZER (1) On 04/07/2021 at 09:45 am, the laboratory manager stated to surveyor #1 the laboratory began using the Vitros Xt-3400 analyzer to perform Alcohol, ALP (Alkaline Phosphatase), Ammonia, Amylase, AST (Aspartate Aminotransferase), Calcium, Creatinine, Magnesium, HDL (High Density Liproprotein) Cholesterol, Iron, Glucose, Salicylate, Total Bilirubin, Total Protein, Triglyceride, Lipase, and CK (Creatine Kinase) testing on 08/11/2020; (2) On 04/08/2021, surveyor #1 reviewed the performance specification records for above testing and identified the laboratory had demonstrated the following reportable ranges: (a) Alcohol - 10-300 (b) ALP - 26.2-1504.7 (c) Ammonia - 9-482 (d) Amylase - 26.9-929.7 (e) AST - 17.3-813.1 (f) Calcium - 1.98-13.84 (g) Creatinine - 0.39-13.1 (h) Magnesium - 0.73-9.66 (i) HDL Cholesterol - 6.5-121 (j) Iron - 25.6-582.3 (k)

	Glucose - 29.7-596 (l) Salicylate - 1.17-34.8 (m) Total Bilirubin - 1.07-16.82 (n) Total Protein - 2.06 - 10.4 (o) Triglyceride - 26.2-298.6 (p) Lipase - 25-1965 (q) CK - 45.3-1620 (3) Surveyor #1 then requested documentation to show the reportable range that had been programmed into the analyzer, which showed the laboratory was using the following reportable ranges: (a) Alcohol - 10-300 (b) ALP - 20-1500 (c) Ammonia - 9-500 (d) Amylase - 30-1200 (e) AST - 3-750 (f) Calcium - 1.0-14.0 (g) Creatinine - 0.2-14.0 (h) Magnesium - 0.2-10.0 (i) HDL Cholesterol - 5-110 (j) Iron - 10-600 (k) Glucose - 20-625 (l) Salicylate - 1.0-40 (m) Total Bilirubin - 0.1-27.0 (n) Total Protein - 2.0-11.0 (o) Triglyceride - 10-525 (p) Lipase - 10-2000 (q) CK - 20-1600 (4) Surveyor #1 reviewed the findings with the laboratory manager and technical consultant. Both stated on 04/08/2021 at 01:55 pm, the laboratory was not using the reportable range that had been demonstrated by the laboratory. OPTI CCA TS2 ANALYZER (1) On 04/07/2021 at 09:45 am, the laboratory manager stated to surveyor #1 the laboratory began using the Opti CCA-TS2 analyzer to perform Blood Gas (pH, pO2, and pCO2) testing on 12/29/2020; (2) Survyeor #1 reviewed the performance specification records and identified the following for the reportable ranges: (a) pH - The laboratory had demonstrated a reportable range of 7.049-7.8 (b) pCO2 - The laboratory had demonstrated a reportable range of 10.7-117.6 (c) pO2 - The laboratory had demonstrated a reportable range of 52.2-541.7 (3) Surveyor #1 then requested the reportable ranges that were being utilized by the laboratory. The technical consultant provided surveyor #1 with the following reportable ranges from the "Technical Manual Standard Operatin Policies/Procedures": (a) pH - The laboratory was using a reportable range of 6.6-7.8 (b) pCO2 - The laboratory was using a reportable range of 10-200 (c) pO2 - The laboratory was using a reportable range of 10-700 (4) Surveyor #1 reviewed the findings with the laboratory manager and technical consultant. Both stated on 04/07/2021 at 02:50 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, written policy, and interview with the technical consultant and laboratory manager, the laboratory failed to perform pipette checks as required by the manufacturer. Findings include: (1) On 04/07/2021 at 09:50 am, the laboratory manager stated the following to surveyor #1: (a) Antibody Screen and Compatibility testing were performed in the blood bank area of the laboratory using the Ortho ID-MTS gel system; (b) The ID Tipmaster pipette (a multiple delivery pipette) was used for the testing as follows: (i) The 25 ul setting was used to dispense patient plasma for Antibody Screen and Compatibility testing; (ii) The 50 ul setting was used to dispense commercial screen cells for Antibody Screens and donor cell suspensions for Compatibility testing. (2) Surveyor #1 reviewed the manufacturer's instructions for performing function checks on the pipette. The manufacturer required periodic accuracy and precision checks; (3) Surveyor #1 asked the laboratory manager if the laboratory had a policy to define the frequency for performing the checks. The laboratory manager provided the policy titled, "MTS Dispesers/Pipettes" which stated, "Each pipette utilized in the testing procedure of the

	Immunohematology Department will be checked each six (6) months as part of a routine quality control schedule"; (4) Surveyor #1 reviewed blood bank records from January 2020 to date, which showed the pipettes had not been checked prior to 12/28 /2020; (5) Surveyor #1 reviewed the records with the technical consultant who stated the pipettes had not been checked every 6 months as required by policy.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the technical consultant and laboratory manager, the laboratory failed to follow the function check protocol to ensure the urine centrifuge was functioning properly. Findings include: (1) On 04/07/2021 at 10:00 am, the laboratory manager stated the following to surveyor #1: (a) The laboratory performed microscopic urine sediment examinations; (b) The laboratory used the Select Medical Products PSS 602 centrifuge to process urines at a speed of 1500 rpm (revolutions per minute) for 5 minutes; (2) Surveyor #1 reviewed the function check policy titled, "Centrifuge Speed and Timer Checks" which stated, "Centrifuge will be checked at least twice yearly for rpm function and timer function"; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2019 and 2020. There was no documentation speed and timer checks had been performed prior to 11/03/2020. In addition, In addition, for 1 of 2 checks performed, the following was identified: (a) 11/03/2020 - The speed had been checked at 2101 rpm, which was not the speed urine specimens were processed. (4) Surveyor #1 reviewed the findings with the technical consultant and laboratory manager. Both stated on 04/07/2021 at 12;35 pm, the laboratory did not ensure the urine centrifuge was functioning properly 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 laboratory manager and technical

	consultant, the laboratory failed to perform quality control for 4 of 20 months as stated in the IQCP for D-dimer testing; and the QCP for D-dimer and Troponin I did not define the type of quality control when implementing the IQCP. Findings include: QUALITY CONTROL PERFORMANCE (1) On 04/07/2021 at 09:40 am, the laboratory manger stated the following to surveyor #1: (a) The laboratory performed D-dimer testing using the Quidel Triage Meter Pro analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system, effective 06/13/2019, and external QC (quality control) was performed monthly and with new lot numbers of test materials. (2) Surveyor #1 reviewed QC records from June 2019 through March 2021 and identified that QC had not been tested monthly, as stated in the IQCP. QC had not been tested between: (a) 01/28/2020 and 03/23/2020 (b) 04/27/2020 and 06/03/2020 (c) 08/11/2020 and 10/07/2020 (d) 01/29/2021 and 03 /18/2021 (3) Surveyor #1 reviewed the records with the laboratory manager and technical consultant and asked if there were additional records to prove that QC had been performed monthly. The laboratory manager and technical consultant stated on 04/07/2020 at 02:00 pm that QC had not been performed monthly as stated in the IQCP. DEFINE TYPE OF CONTROL (1) On 04/07/2021 at 09:49 am, the laboratory manager stated the following to surveyor #1: (a) The laboratory performed D-dimer and Troponin I testing using the Quidel Triage Meter Pro analyzer; (b) IQCP's (Individualized Quality Control Plan) had been developed for the test systems and external QC (quality control) was performed monthly and with new lot numbers of test materials. (2) Surveyor #1 reviewed the QCP (Quality Control Plan) portion of the IQCP's with the following identified: (a) D-dimer - The QCP did not inlude the type of QC (Quality Control) materials; (b) Troponin I - The QCP did not include the type of QC materials. (3) Surveyor #1 reviewed the QCP with the technical consultant and laboratory manager. Both stated on 04/07/2021 at 01:55 pm, the QCP did not include the type of QC materials used for D-dimer and Troponin I. 39088 Based on a review of records and interview with the technical consultant, the laboratory failed to ensure data supported the QC frequency as defined in the QCP portion of the IQCP. Findings include: (1) On 04/07/2021 at 10:40 am, the laboratory manager stated to surveyor #1: (a) The laboratory performed urine drug screens using the MedTox analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #2 reviewed the IQCP (dated as effective on 07/15/2019) and identified the QCP (Quality Control Plan) required two levels of external QC (Quality Control) materials be performed weekly; (3) Surveyor #2 then reviewed the supporting documentation for the QCP and identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (b) Two levels of QC had been tested 10 times on one day (07/02/2019). (4) On 04/07/2021, surveyor #2 reviewed the records with the technical consultant and asked if additional documentation was available to support the reduced external QC frequency of weekly. The technical consultant stated on 04/07/2021 at 01:45 pm, QC had not been tested for at least seven days.
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 laboratory manager and technical consultant, the laboratory failed to perform control procedures each day of blood bank testing for 2 of 23 days of patient testing. Findings include: (1) On 04/07/2021 at 09: 50 am, the laboratory manager 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)); (2) On 04/09/2021, surveyor #1 reviewed records for blood bank testing performed from 01/03/2020 through 01/30/2021 and identified quality control had not been performed for 2 of 23 days when patient Crossmatch testing had been performed. The specific days were 01/03,17/2020; (3) Surveyor #1 reviewed the records with the technical consultant, who stated on 04/09/2021 at 12:10 pm, quality control had not been performed as indicated above.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and technical consultant, the laboratory failed to have procedures to detect an ABO incompatibility between the donor's cell type and the recipient serum or plasma type for 7 of 7 months. Findings include: (1) On 04/07/2021 at 09:50 am, the laboratory manager stated to surveyor #1 the Ortho MTS Anti-IgG gel cards were used to perform patient antibody screen and compatibility testing; (2) On 04/08 /2021, surveyor #1 reviewed the manufacturer's instructions contained in the package insert for the MTS Anti-IgG gel cards. The instructions stated, "The MTS Anti-IgG Gel Test System can be used in both direct and indirect antiglobulin test systems to detect the presence or absence of IgG on human red blood cells"; (3) Surveyor #1 reviewed the blood bank log book for patient compatibility testing performed from 01 /03/2020 through 01/30/2021. For 23 of 23 patients reviewed, the records showed the laboratory exclusively used the Anti-IgG gel cards to perform patient compatibility testing, and therefore, did not include a method to detect ABO incompatibilities based on IgM antibodies (in order to achieve this, an immediate spin crossmatch, containing the donor's red blood cells and the recipient's serum or plasma, or an electronic crossmatch must be performed in conjunction with the IgG crossmatch); (4) The findings were reviewed with the technical consultant who stated on 04/08/2021 at 13: 15 pm, an immediate spin crossmatch (using the buffer gel card) had not been performed for the 23 patients; (5) The specific days of testing were: (a) January 2020 - 01/03,04,05,10,17 (b) April 2020 - 04/01 (c) May 2020 - 05/14,23 (d) September 2020 - 09/19,23 (e) October 2020 - 10/05,09,23 (f) December 2020 - 12/04,12,19,23,28,29 (g) January 2021 - 01,04,20,21,30 NOTE: The following reference was published in

	the CLIA Network Newsletter dated July-August 2009: "The gel card only detects incompatibility based on IgG antibodies. It does not detect incompatibility based on IgM antibodies, which is important in determining ABO compatibility. Therefore, the use of the gel card alone is not adequate to demonstrate incompatibility between the donor's cell type and the recipient's serum type, and the laboratory must also perform an immediate spin or electronic crossmatch to determine ABO compatibility." NOTE: The Interpretive Guidelines at 493.1271 require standard operating procedures for compatibility testing: "Procedures to demonstrate incompatibility between the donor's cell type and the recipients's serum or plasma type. These procedures may consist of a serologic crossmatch, or a computer crossmatch."
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: ALARM CHECKS (1) On 04/07 /2021 at 09:55 am, the laboratory manager stated to surveyor #1 units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 04/08/2021, surveyor #2 asked the technical consultant how often alarm checks were performed on the blood bank refrigerator. The technical consultant stated to surveyor #1 on 04/08/2021 at 03:00 pm, the low and high refrigerator alarm checks were to be performed quarterly (Note: units of packed cells must be stored at 1-6 degrees Centigrade). (3) Surveyor #2 reviewed records for 2019, 2020 and 2021. There was no evidence alarm checks had been performed between 08 /27/2020 and 01/08/2021; (4) Surveyor #2 reviewed the findings with technical consultant who stated on 04/08/2021 at 3:55 pm, there was no documentation to prove alarm checks had been performed as shown above. THERMOGRAPH CHARTS (1) On 04/07/2021 at 10:20 am, surveyor #2 observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts. Each chart monitored the temperature for a 7 day period; (2) On 04/08/2021, surveyor #2 reviewed refrigerator charts from 08/26/2019 through 11/06/2019; and 12/04/2019 through 12/19/2019. The review showed that two of 12 refrigerator charts had not been changed by the 7th day of usage as follows: (a) Chart #3 - The chart was put into use on 09/09/2019 and removed on 09/18/2019 (9 days); (b) Chart #12 - The chart was put into use on 12/11/2019 and removed on 12/19/2019 (8 days). (3) Surveyor #2 reviewed the charts with the technical consultant who stated on 04/08/2021 at 04:05 pm, the charts had not been changed by the 7th day as stated above.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established

procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on a review of written policies and interview with the executive clinical officer, the laboratory failed to ensure that written policies provided safety for individuals being transfused for four of 10 units of packed red blood cells. Findings include: (1) On 04/07/2021 at 09:55 am, the laboratory manager stated to surveyor #1 the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 04/08/2021, surveyor #2 reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood Product Transfusion" (a) Under the section titled, "POLICY", it stated: (i) "8. The hospital for blood transfusion must be obtained, completed, witnessed and signed by the patient or patient representative and one consent is sufficient per hospital stay." (b) Under the section titled, "PROCEDURE", stated: (i) "f) Blood must be started within thirty (30) minutes after receiving from Blood Bank." (c) Under the section titled, "Blood Verification", it stated: (i) "a) Before beginning the transfusion, it is extremely important to correctly identify the patient and the blood product by qualified personnel by an RN and second verification by a RN or LPN."; (ii) "b) Both nurses must indicate on the Transfusion Record that this verification process has been completed by signing the form (2 signatures required)." (d) Under the section titled, "Monitoring during Infusion", it stated: (i) The nurse observes the patient closely. Vital signs are take immediately prior to obtaining the blood within fifteen (15) minutes after initiating the transfusion, every 15 minutes for the first hour then every 30 minutes during the remainder of the transfusion, and then one (1) hour AFTER the transfusion had been discontinued."; (3) Surveyor #2 then reviewed records for 10 units of PRBCs (Packed Red Blood Cells) that had been transfused between 09/14 /2020 through 03/26/2021 for five patients, and identified the following: (a) Completed consent (i) Patient# 30016485 - Transfused with 2 units PRBCs (unit# W091021183425 and unit# W091021184982) on 03/14/2021. The physician/provider signature, date, and time was not completed; (ii) Patient# 30026712 - Transfused with 2 units PRBCs (unit# W091021183720 and unit# W091021183729) on 03/26/2021. The physician/provider signature, date, and time was not completed. (b) Transfusion started within 30 minutes (i) Patient# 30016485 - Transfused with 1 unit of PRBC (unit# W1091021183425) on 03/04/2021. The blood was picked up on 03/04/2021 at 08:30 am. The transfusion was started on 03/04/2021 at 09:15 am (45 minutes later). (c) Two person blood verification (i) Patient# 30016485 - Transfused with 2 units PRBCs (unit# W091021183425 and unit# W091021184982) on 03/14/2021. The blood verification was performed by one RN; (ii) Patient# 30026712 - Transfused with 2 units PRBCs (unit# W091021183720 and unit# W091021183729) on 03/26 /2021. The blood verification was performed by one RN (d) Vital signs taken immediately prior to obtaining the blood (i) Patient#30014176 - The blood was picked up on 10/23/2020 at 06:05 pm and the first vital was taken at 06:10 pm (5 minutes later); (ii) Patient# 30015278 - The blood was picked up on 12/23/2020 at 03:55 pm and the first vital was taken at 04:00 pm (5 minutes later); (iii) Patient# 30016485 -

	The blood was picked up on 03/04/2021 at 08:30 am and the first vital was taken at 09: 00 am (30 minutes later); (iv) Patient# 30016712 - The blood was picked up on 03/26 /2021 at 11:30 am and the first vital was taken at 11:40 am (10 minutes later). (4) Surveyor #2 reviewed the findings with the executive clinical officer. The executive clinical officer stated on 04/08/2021 at 11:30 am the written policy and procedure for blood administration had not been followed as indicated above.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and technical consultant, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP for D-dimer and Troponin I. Findings include: (1) On 04/07/2021 at 09:40 am, the laboratory manager stated the following to surveyor #1: (a) D-dimer and Troponin I testing were performed using the Quidel Triage Meter Pro analyzer; (b) IQCP's (Individualized Quality Control Plan) had been developed for the test systems. (2) Surveyor #1 reviewed the IQCP's (dated as approved on 06/13/2019). The QA (Quality Assessment) portion of the IQCP's did not include a schedule for evaluating the QCP's (Quality Control Plan) to ensure they continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and technical consultant and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP's, including the frequency of the reviews. The laboratory manager and technnical consultant stated on 04/07/2021 at 01: 55 pm, the QA plans did not include an evaluation of the QCP's, and the frequency of the reviews for D-dimer and Troponin I.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b)

The technical consultant must-- (b)(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 (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, 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 (b)(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 (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant 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, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for three of six competency evaluations. Findings include: (1) On 04/07/2021, surveyor #2 reviewed records for three persons performing moderate complexity testing in 2019, 2020, and 2021. The records showed the evaluations for three of six persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #3 - The 02/10/2020 and 09/21/2020 evaluations had been performed by the laboratory manager (this person had earned a bachelors degree in clinical laboratory science but did not have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible); (b) Testing Person #5 - The 10/17/2019 and 05/31/2020 evaluations had been performed by the laboratory manager; (c) Testing Person #6 - The 12/27/2019 and 12/18/2020 evaluations had been performed by the laboratory manager. (2) Surveyor #2 explained to the laboratory manager that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service). The laboratory manager

	stated to surveyor #2 on 04/07/2021 at 04:30 pm, the evaluations had been performed by an individual who did not meet the years of experience of a technical consultant.
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 and laboratory manager, the technical supervisor failed to provide technical supervision in accordance with 493.1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the educational qualifications. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the

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

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

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

Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)

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

experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant and laboratory manager, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor met the qualifications for three of five of semiannual competency assessments. Findings include: (1) On 04/07/2021, surveyor #2 reviewed records for five 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 #1 - The 03/05/2020 semi-annual evaluation had been performed by the technical consultant (this person had

	earned a bachelor degree in applied science); (b) Testing Person #3 - The 02/10/2020 semi-annual evaluation had been performed by the laboratory manager (this person had earned a bachelor degree in applied science); (c) Testing Person #5 - The 10/17 /2019 semi-annual evaluation had been performed by the laboratory manager; (2) Surveyor #2 explained to the laboratory manager and technical consultant 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 04 /08/2021 at 12:25 pm, the technical consultant 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"