Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475339	11/10/2020
Name of Provider or Supplier	**Street Address, City, State**	
Wagoner Community Hospital	1200 W Cherokee, Wagoner, 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 11/09,10/2020. The findings were reviewed with the laboratory director, laboratory manager, chief nursing officer, and infection control/quality director 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 493.1409; D6033: Technical Consultant
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for 7 of 27 events. Findings include: BIASES (1) On 11/09/2020, surveyor #2 reviewed 2018, 2019, and 2020 proficiency testing records and identified the following biases (the biases was identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2019 Chemistry Core Event (i) Glucose- 3 of 5 results exhibited a positive bias (aa) BG-02 - SDI of 2.0 (bb) BG-03 - SDI of 4.9 (cc) BG-04 - SDI of 3.0 (ii) Phosphorus- 3 of 5 results exhibited a positive bias (aa) CH-03 - SDI of 2.7 (bb) CH-04 - SDI of 2.0 (cc) CH-05 - SDI of 2.0 (b) Second 2019 Chemistry Core Event (i) Troponin I - 3 of 5 results exhibited a positive bias (aa) CH-07 - SDI of 2.3 (bb) CH-08 - SDI of 2.0 (cc) CH-10 - SDI of 2.6 (c) First 2020 Chemistry Core Event (i) Glucose - 4 of 5 results exhibited a positive bias (aa) BG-02- SDI of 2.0 (bb) BG-03- SDI of 2.3 (cc) BG-04- SDI of 2,7 (dd) BG-05- SDI of 2.4 (ii) Digoxin - 5 of 5 results exhibited a positive bias (aa) CH-06 - SDI of 2.6 (bb) CH-07 - SDI of 2.4 (cc) CH-08 - SDI of 4.1 (dd) CH-09 - SDI of 3.4 (ee) CH-10 - SDI of 2.1 (iii) Salicylates - 4 of results exhibited a positive bias (aa) CH-06 - SDI of 2.7 (bb) CH-07

	- SDI of 2.8 (cc) CH-08 - SDI of 2.2 (dd) CH-10 - SDI of 2.5 (iv) Gentamicin - 5 of 5 results exhibited a positive bias (aa) CH-06 - SDI of 2.8 (bb) CH-07 - SDI of 2.6 (cc) CH-08 - SDI of 2.8 (dd) CH-09 - SDI of 2.2 (ee) CH-10 - SDI of 2.6 (d) Third 2020 Chemistry Core Event (i) Ionized Calcium - 4 of 5 results exhibited a positive bias (aa) BG-12- SDI of 2.9 (bb) BG-13- SDI of 3.0 (cc) BG-44- SDI of 2.8 (dd) BG-55- SDI of 2.7 (ii) Salicylates - 5 of 5 results exhibited a positive bias (aa) CH-11 - SDI of 2.7 (bb) CH-12 - SDI of 3.6 (cc) CH-13 - SDI of 3.1 (dd) CH-14 - SDI of 2.7 (ee) CH-15 - SDI of 3.0 (iii) Total Protein - 3 of 5 results exhibited a negative bias (aa) CH-11 - SDI of -2.4 (bb) CH-13 - SDI of -2.3 (cc) CH-14 - SDI of -2.4 (e) Second 2020 Hematology Event (i) MCHC - 3 of 5 results exhibited a negative bias (aa) XE-02 - SDI of -2.3 (bb) XE-04 - SDI of -2.9 (cc) XE-05 - SDI of -2.3 (2) Surveyor #2 further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) Surveyor #2 then reviewed the records with the laboratory manager, and asked if the biases had been addressed. The laboratory manager stated on 11/09/2020 at 01:15 pm the biases had not been addressed. FAILURES (1) On 11/09/2020, surveyor #2 reviewed 2018, 2019, and 2020 proficiency testing records for testing performed in the respiratory therapy department. The following failures were identified, in which corrective action documentation could not be located: (a) Second 2019 Chemistry Core Event (i) ProBNP (SM-10) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (ii) Total Protein (CH-10) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (b) Second 2020 Chemistry Core Event (i) LDL Cholesterol (CH-10) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (c) First Coagulation Event (i) Partial Thromboplastin Time (COA-05) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (2) Surveyor #2 asked the laboratory manager if corrective action had been taken for the failures. After reviewing the records, the laboratory manager stated on 11/09/2020 at 01:20 pm corrective action had not been taken for the failures.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to verify the accuracy of Wet Prep analysis at least twice annually. Findings include: (1) On 11/09/2020 at 2:00 pm, the laboratory manager stated to surveyor #1 the laboratory performed Wet Prep analysis; (2) Surveyor #1 reviewed 2019 and 2020 records, which showed the testing had not been verified for accuracy twice in 2019. Wet Prep analysis had not been verified for accuracy prior to 10/15 /2019; (3) Surveyor #1 reviewed the records with the laboratory manager who stated on 11/09/202 at 4:15 pm, Wet Prep analysis had not been verified for accuracy at least twice annually in 2019.
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, observation, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On 11/10 /2020 at 10:30 am, the laboratory manager stated the following to surveyor #1: (a) The Sysmex CA-660 analyzer was used to perform PT/INR (Prothrombin Time /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing (the INR was calculated using the PT reference interval mean); (b) The following reagent lot numbers were put into use in March 2020: (i) PT - Innovin reagent, lot #549737 (ii) PTT - Actin FSL reagent, lot #556971 (iii) Ci-Trol 1 control, lot #564803 (iv) Ci-Trol 3 control, lot #556521 (2) Surveyor #1 reviewed the manufacturer's instructions contained in the "Lot Roll-Over Procedure" for implementing new reagents, which stated, "The following recommendations should be used as a guideline when converting to new lots of reagents for Hemostasis analyzers. These procedures should be followed each year before new lots of reagents are put into use on the existing Hemostasis system". In addition, the manufacturer required the following: (a) Section titled "Verification of Reference Range" (i) "20 Normal Individuals * 10 males; 10 females * Medication History: no aspirin, no hormones, no herbal supplements * 20 is the minimum requirement for statistical validity"; (ii) "Assay samples on current and new lot number reagents simultaneously or within 10 minutes of each other. This data can be used in Section II"; (iii) "Calculate mean and 2 SD range"; (iv) "MNPT for INR calculation should be the geometric mean". (b) Section titled, "Method Correlation" (i) "40 samples: 20 normal, 20 abnormal"; (ii) "Normal samples (Section I) may be used for the Method Correlation and Verification of Reference Range"; (iii) "Abnormal samples should span the Reportable Range of assay"; (iv) "Assay samples on current and new lot number reagents simultaneously or within 1 our of each other"; (v) "Calculate Linear Regression statistics". (c) Section titled "Quality Control" (i) "Assay new lot number of QC material with the new lot of reagent in PTN and APTT protocols"; (ii) "Collect a minimum of 30 data points"; (iii) "Calculate the mean, 2 SD and 3 SD range". (3) Surveyor #1 reviewed the records for the lot changes with the following identified: (a) PT - Innovin reagent, lot #549737 (i) Normal Range Study - There was no evidence of the age, gender, health, and medication status of the donors; (ii) Method Correlation - The records showed the laboratory had used 10 abnormal samples, instead of 20 as required by the manufacturer. (b) PTT - Actin FSL reagent, lot #556971 (i) Normal Range Study - There was no evidence of the age, gender, health, and medication status of the donors; (ii) Method Correlation - The records showed the laboratory had used 9 abnormal samples, instead of 20 as required by the manufacturer. (c) Quality Control (QC) (i) Ci-Trol 1, lot #564803 - The records showed the laboratory had used 23 data points to establish QC ranges for PT and 23 data points to establish QC ranges for PTT instead of 30 data points as required by the manufacturer. (ii) Ci-Trol 3, lot #556521 - The records showed the laboratory had used 23 data points to establish QC ranges for PT and 23 data points to establish QC ranges for PTT instead of 30 data points as required by the manufacturer. (4) Surveyor #1 reviewed the findings with the laboratory manager who stated on 11/10/2020 at 1: 20 pm, the manufacturer's instructions had not been followed for the reagent lot changes as specified above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

	(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (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, the laboratory failed to have quality control procedures that monitored the accuracy and precision of the analytic process for hematology testing for 3 of 3 lot numbers. Findings include: (1) On 11/09/2020 at 10:05 am the laboratory manager stated to the surveyors CBC (Complete Blood Count) testing was performed using the Sysmex XN-1000 analyzer; (2) On 11/10/2020 at 09:30 am, the laboratory manager stated the following to surveyor #1: (a) Three levels of quality control materials were tested each morning; (b) Laboratory established quality control ranges were used to determine acceptability of control results. (3) Surveyor #1 reviewed quality control records for level 1 lot #02331101, level 2 lot #02331102, and level 3 lot #02331103, used from 08/25/2020 through 11/08/2020, which only consisted of the Sysmex e-CHECK peer group reports (Levey-Jennings graphs were not available). Although surveyor #1 could confirm that three levels of quality control testing had been performed each day of patient testing and that the laboratory's submitted control results compared to the control results submitted by other laboratories participating in the peer group program, surveyor #1 could not confirm if the laboratory's control results were acceptable using their established ranges for each analyte tested (i.e., White Blood Cell, Hemoglobin, Mean Corpuscular Hemoglobin, Platelet, etc); (4) Surveyor #1 reviewed the findings with the laboratory manager who stated on 11/10 /2020 at 10:00 am, the laboratory had reviewed QC data with the laboratory established ranges (Levey-Jennings graphs and cumulative data) on the analyzer's computer screen each month during the review period, however, the data had not been printed and maintained by the laboratory.
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, the laboratory failed to perform a negative and positive control material each day of patient serum ketone testing for 23 of 30 days. Findings include:, (1) On 11/09/2020 at 2:05 pm, the laboratory manger stated to surveyor #1 Serum Ketone testing was performed using the K-Chek Biorex Lab ketone tablets; (2) Surveyor #1 reviewed

	quality control (QC) and patient Serum Ketone records from 03/21/2019 through 10/27 /2020, which showed that QC had not been performed on 23 of 30 days. The specific days were 03/21,31/2019; 07/25/2019; 09/21/2019, 10/08,12,13,24/2019; 02/13/2020; 03/03/2020; 04/05,24/2020; 05/22,26,27/2020; 06/19,30/2019; 07/10/2020; 08/05,30 /2020; 10/11,12,25/2020; (3) Surveyor #1 reviewed the findings with the laboratory manager who stated on 11/09/2020 at 3:00 pm QC testing had not been performed each day of patient testing. 39088 Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to perform a negative control 97 of 97 days of patient bloodbank testing. Findings include: (1) On 11/10/2020 at 11:15 am, the laboratory manger stated to surveyor #2 Antibody screen testing was performed using AHG (Anti-Human Globulin) reagent; (2) Surveyor #2 reviewed QC (quality control) records for testing performed from 02 /11/2020 through 11/10/2020 and identified a negative AHG control had not been performed 97 of 97 days; (3) Surveyor #2 reviewed the manufacturer's instructions contained in the package insert for the AHG reagent. On page 4 under the heading "CONTROLS" it stated, "Serologic testing is necessary to recognize reagent deterioration. It is recommended that the reagent be tested with appropriate positive and negative controls according to the methods described in this package insert" (4) Surveyor #2 reviewed the records with the laboratory manager who state on 11/10 /2020 at 01:25 pm a negative AHG control was not being performed.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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--Test control materials in the same manner as patient specimens. (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, the laboratory failed to use control materials of a similar matrix to that of patient specimens 7 of 30 days of patient testing. Findings include: (1) On 11/09/2020 at 2:05 pm, the laboratory manger stated the following to surveyor #1: (a) Serum Ketone testing was performed using the K-Chek Biorex Lab ketone tablets; (b) When quality control (QC) testing was performed on the tablets, a negative and a positive urine control was performed instead of blood based (serum/plasma) controls; (c) The QC materials used by the laboratory were Quantimetrix Dropper Plus Point-of-Care Urinalysis Dipstick Control Levels 1 & 2. (2) Surveyor #1 reviewed QC patient Serum Ketone records from 03/21/2019 through 10/27/2020, which showed that patient testing had been performed on 30 days. QC testing had been performed on 7 of the 30 days using negative and positive urine controls specimens. The specific days were 03/22/2019, 05/15/2019, 05/17/2019, 07/02/2019, 07/02/2020, 09/21/2020, and 10/27/2020; (3) Surveyor #1 reviewed the findings with the laboratory manager who stated on 11/09/2021 at 02:10 pm, the laboratory was using urine based controls instead of serum based control materials. NOTE: The interpretive guidelines at D5465 (493.1256) state "Control materials of a similar matrix to that of patient specimens should be utilized, if available, and the control materials must be treated in the same manner as patient specimens and go through all analytic test phases."
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 laboratory manager and med surg nurse, the laboratory failed to ensure that written policies provided safety for individuals being transfused for 3 of 13 units of packed red blood cells. Findings include: (1) On 11/09/2020 at 11:10 am, the laboratory manager stated to surveyor #2 the laboratory stored units of packed red blood cells in the blood bank refrigerator. The units were to be used for patient transfusions; (2) Surveyor #2 reviewed the hospital policy regarding transfusion reactions. The policy titled, "Blood Product Administration" under the section titled, "ADMINISTRATION OF PACKED RED BLOOD CELLS, AUTOLOGOUS, AND DIRECTED DONOR BLOOD", stated: (a) "12. After initiation vital signs will be documented as follows:" (i) "a. Every 5 minutes for 15 minutes"; (ii) "b. Every 15 minutes times three,"; (iii) "c. Every hour until completion of infusion."; (iv) "d. There will then need to be a vital sign 1 hour post transfusion. The vital signs will be recorded on the blood request form and in the nurse's notes. The unit number and time of transfusion will be recorded in the electronic record.". (3) Surveyor #2 then reviewed records for 13 units of PRBCs (Packed Red Blood Cells) that had been transfused between 03/15/2019 through 05/22/2020 for 6 patients, and identified the following for 3 of 13 units: (a) Vitals not documented on blood request form and in the nurse's notes (i) Patient #503080 - Transfused with 1 unit of PRBCs (unit # W200919256217) on 10/01/2019; (ii) Patient #332108 - Transfused with 1 unit of PRBCs (unit #W204920460502) on 02/27/2020; (iii) Patient ##332108 - Transfused with 1 unit of PRBCs (W204920463571) on 02/27/2020. (4) Surveyor #2 reviewed the findings with the med surg nurse. The med surg nurse stated on 11/10/2020 at 02:20 pm the vitals had been taken but not documented and failed to follow the written policy and procedure for blood administration as indicated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the

	laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 1 of 27 events. Findings include: (1) On 11/09/2020, surveyor #2 reviewed 2018, 2019, and 2020 proficiency testing records. It was identified for 1 of 27 events, the attestation statements had been signed approximately 2-3 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) Hematology/Coagulation Third event of 2018 - The samples had been tested on 11/22 /2018 and the attestation statement had not been signed by the laboratory director until 01/17/2019. (2) Surveyor #2 reviewed the findings with the laboratory manager and 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. The laboratory manager stated on 11/09/2020 at 11:30 am the laboratory director had not signed the attestations within a timeframe to attest samples were treated in the same manner as patient specimens.
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 laboratory manager, 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 laboratory manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 3 of 7 competency evaluations performed. Findings include: (1) Suveyor #2 reviewed records for 7 persons performing moderate complexity testing in 2019 and 2020. The records showed the evaluation for 3 of 7 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #3 - The 10/30/2019 evaluation had been performed by the laboratory manager (this person had earned an associates degree in applied science); (b) Testing Person #4 - The 11/03/2019 and 09/04/2020 evaluations had been performed by the laboratory manager; (c) Testing Person #6 - The 10/19/2020 evaluation had been performed by the laboratory manager. (2) Surveyor #2 reviewed the records with the laboratory manager and explained 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 11/09/2020 at 04:05 pm, the above evaluations had been performed by an individual who did not meet the educational qualifications of a technical consultant.
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 manager, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 5 of 7 testing persons. Findings include: (1) On 11/09/2020 at 10:50 am, the laboratory manager stated the following to surveyor #2: (a) The laboratory performed serum pregnancy testing using the Cardinal Health HCG Combo Kit; (b) The laboratory performed post vasectomy examinations (present or absent); (c) The laboratory performed urine drug screens using the MedTox analyzer. (2) Surveyor #2

	then reviewed personnel records for 7 persons performing the above testing in the laboratory. The records showed that evaluations had been performed as follows: (a) Testing Person #1 - Performed on 03/18/2020 (b) Testing Person #4 - Performed on 09 /04/2020 (c) Testing Person #5 - Performed on 07/16/2020 (d) Testing Person #6 - Performed on 10/19/2020 (e) Testing Person #7 - Performed on 07/28/2020 (3) There was no evidence the evaluations, performed for the above persons, included an assessment of the serum pregnancy, post vasectomy, and urine drug screen testing; (4) The surveyor reviewed the findings with laboratory manager, who stated on 11/09 /2020 at 04:00 pm the above evaluations did not include the serum pregnancy, post vasectomy, and urine drug screen testing as indicated above.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with laboratory manager, the technical supervisor failed to provide technical supervision in accordance with 493.1447 of this subpart. Findings include: (1) The technical supervisor failed to ensure the individual who performed the duties and responsibilities of the technical supervisor met the educational qualifications. Refer to D6111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or

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

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

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

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

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

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

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the laboratory manager, the technical supervisor failed to ensure that individuals who performed the duties and responsibilities of the technical supervisor met the qualifications for 2 of 7 proficiency testing attestation forms; and for 1 of 1 of semiannual competency assessments.

	Findings include: ATTESTATION FORMS (1) On 11/09/2020, 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 - Third 2018, first 2019, second 2019, third 2019, first 2020, second 2020, and third 2020. (3) The documentation showed that the attestation statements for 2 of 4 events (third 2018 and first 2019) had been signed by the laboratory manager instead of the laboratory director/technical supervisor (the laboratory manager had an associates degree in applied science); (4) The findings were reviewed with the laboratory manager who stated to surveyor #2 on 11/09/2020 at 01:40 pm, the attestation statements for the above events had been signed by a person who did not qualify as a technical supervisor. SEMI-ANNUAL BLOOD BANK COMPETENCY (1) On 11/09/2020, surveyor #2 reviewed records for 1 testing person who had been hired to perform high complexity testing (ABO/Rh, Antibody Screen and Compatibility testing) since the previous recertification survey performed 02/26/2018 through 03/01/2018. The records indicated the semi-annual evaluation for the testing person had been performed by an individual who did not meet the regulatory qualification requirements of the technical supervisor: (a) Testing Person #6 - The 10/19/2020 semi-annual evaluation had been performed by the laboratory manager (this person had earned an associate degree in applied science). (2) Surveyor #2 explained to the laboratory manager that all components of the semi-annual competency evaluations must be performed by a person who qualifies as a technical supervisor (493.1449 (q) an individual with an MD or DO with a current medical license in state of laboratory's location and certified in anatomic pathology by ABP or AOBP or equivalent qualifications or resident in a program leading to ABP or AOBP certification in anatomic and clinical pathology who performs duties delegated by the technical supervisor for histopathology). On 11/09/2010 at 04:07 pm, the laboratory manager 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"