Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0994726	11/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Community Hospital	3100 Sw 89th Street, Oklahoma City, 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	A recertification survey was performed on 11/18/19 through 11/21/19. The findings were reviewed with the laboratory director, chief operating officer, quality assurance manager, laboratory manager, laboratory supervisor, vice-president clinical service /system chief nursing officer, chief quality officer, and vice-president ancillary and support services during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality assurance manager, laboratory manager and laboratory supervisor, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee for 6 of 90 events. Findings include: (1) On the seond day of the survey, surveyor #3 reviewed 2018 and 2019 proficiency testing records, which included the attestation statements. The attestation statements had not been signed by the laboratory director or designee for 6 of 90 events reviewed as follows: (a) 2018 Therapeutic Drug Monitoring Survey

	(LN3-B) Event - The attestation had not been signed by the laboratory director or designee; (b) 2018 Second Aqueous Blood Gas (AQI-B) Event -The attestation had not been signed by the laboratory director or designee; (c) 2018 Rapid Strep A Antigen (D6-B) Event - The attestation had not been signed by the laboratory director or designee; (d) 2018 Erythrocyte Sedimentation Rate (ESR-A) Event - The attestation had not been signed by the laboratory director or designee; (e) 2018 Alcohol/Volatiles (AL2-B) Event - The attestation had not been signed by the laboratory director or designee; (f) 2018 Coagulation, Limited (CGL-B) - The attestation had not been signed by the laboratory director or designee. (2) Surveyor #3 reviewed the findings with the quality assurance manager, laboratory manager and laboratory supervisor and explained that attestation statements must be signed by the laboratory director or designee.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with the quality assurance manager, laboratory manager, laboratory supervisor, chief quality officer, and vice-president clinical service/system chief nursing officer the laboratory failed to ensure written policies were established and followed for preventing transfusion reactions for 4 of 6 patients. Findings include: (1) On the fourth day of the survey, the laboratory manager stated to surveyor #3 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) Surveyor #3 reviewed the hospital policy regarding transfusion reactions. The policy "Blood and Blood Products Administration" defined the parameters of issuing blood products from the blood bank; (3) The surveyor further reviewed the policy which stated: (a) "Blood/blood components must be infused over a time period not to exceed four (4) hours." (b) "PROCEDURE" (i) "3. Verify transfusion consent." (ii) "4. Verify the physician's order to transfuse." (iii) "6. Complete blood requistion slip in its entirety." (iv) "9. The nurse will place a Typenex sticker from the patient's blood band (pt. armband) on the Transfusion Record (beside the blood bank identification number printed on the Transfusion Record) prior to removing blood product from the Blood Bank." (v). "13. Vital signs for baseline data, including blood pressure, pulse, respiratory rate, and temperature. Record vital signs on the Transfusion Record at Pre Transfusion (within 30 minutes before transfusion begins), 5 minutes from the START TIME, 15 minutes from the START TIME, 30 minutes from the START TIME, then every 30 minutes until the transfusion is complete. A separate set of post infusion vital signs must also be documented 30 minutes to 1 hour after the transfusion is complete." (4) Surveyor #3 then reviewed transfusion records for 6 patients with the quality assurance manager, laboratory manager, laboratory supervisor, chief quality officer, and vice-president clinical service/system chief nursing officer. For 4 of the 6 units transfused the policy was not followed by nursing personnel: (a) Unit #W091018331648 - The unit was checked out from the blood bank on 11/01/19 at 01:49 pm with the transfusion completed at 02:35 pm on 11/01/19. (i) There was no documentation the patient's transfusion consent or physician's order had been verified; (ii) There was no

	documentation in the designated area for the transfused volume of packed red blood cells. (b) Unit #W091018287062 - The unit was checked out from the blood bank on 11/29/18 at 11:55 am with the transfusion completed at 02:45 pm on 11/29/18. (i) There was no documentation of the patient's Typenex sticker from the patient's blood band; (ii) There was no documentation of the donor unit number; (iii) The transfusion record documentation showed the transfusion completion date and time was 11/29/19 at 02:45 pm. The post transfusion time that was documentatied on the record was 02: 30 pm (10 minute prior to the completion time). (c) Unit #W091019158797 - The unit was checked out from the blood bank on 04/10/19 at 05:25 pm with the transfusion completed at 09:50 pm on 04/10/19. (i) The documentation showed the transfusion started at 05:00 pm (25 minutes before the checking the unit out of the blood bank); (ii) The documentation showed the transfusion started at 05:00 pm and was completed at 09:50 pm, which exceeded the maximum infusion time limit of 4 hours (at total of 4 hours and 50 minutes); (iii) The documentation showed the transfusion was stopped at 06:30 pm on 04/10/19 for antibiotic adminstration and a CT (Computerized Tomography) scan, then started again at 08:45 pm. (d) Unit #W091019166062 - The unit was checked out from the blood bank on 04/26/19 at 09:40 am with the transfusion completed at 11:50 am on 04/26/19. (i) The documentation showed the post transfusion vitals were taken at 12:00 pm, which was 10 minutes after the completion of the transfusion (the policy required post-transfusion vitals taken 30 minutes to 1 hour after completion). (5) Surveyor #3 explained to the quality assurance manager, laboratory manager, laboratory supervisor, chief quality officer, and vice-president clinical service/system chief nursing officer that in order to ensure a transfusion reaction is promptly identified, nursing personnel must follow their policy.
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 quality assurance manager, laboratory manager and laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results for 1 of 90 events. Findings include: (1) On the second day of the survey, surveyor #3 reviewed 2018 and 2019 proficiency testing records and identified the following failures: (a) 2018 Hematology Auto Differentials (FH3-A) Event (i) Monocytes - The laboratory failed the result for 1 of 5 samples (FH#-03) and attained a 80% score. (2) The records were then reviewed further by the surveyor. There was no evidence corrective action had been taken for the above failures; (3) Surveyor #3 reviewed the records with quality assurance manager, laboratory manager and laboratory supervisor, and asked if corrective action had been taken and documented for the failures. The quality assurance manager, laboratory manager and laboratory supervisor stated corrective action had not been taken.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as

determined under 493.1253.

This STANDARD is not met as evidenced by:
Based on a review of records, manufacturer's instructions, and interview with the quality assurance manager, laboratory manager, and the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: PT/INR (1) On the first day of the survey, the laboratory manager stated the following to the surveyors: (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing was performed using the IL ACL TOP 300 coagulation analyzer; (b) HemosIL Recombiplastin 2G reagent, Lot #N0789707 was currently in use (the analyzer used the ISI (Individualized Sensitivity Index) specific for each reagent lot number and the patient reference mean, to calculate the INR); (2) Surveyor #2 reviewed the manufacturer's instructions for performing reagent lot rollovers. Under "Perform Comparison Study," the instructions were as follows: (a) Comparison studies will demonstrate any difference in results due to differences in reagent formulation and methodology, or differences in the sensitivities of reagents being compared; (b) Collect and handle samples according to accepted laboratory practice for the assay being performed; (c) Normal and abnormal samples are tested; (d) At least 40 specimens should be analyzed, of which at least 50% should be outside the laboratory's normal reference interval; (e) For the abnormal samples, include diseases/treatments known to affect the assay being performed. (3) Surveyor #2 then reviewed the PT reagent lot rollovers from 2018 and 2019 and identified the laboratory failed to follow the manufacturer's instructions for the comparison study. The findings follow: (a) 2018: (i) The rollover for the new PT reagent Recombiplastin 2G (Lot #N1037129) was performed 02/23/18 to 03/06/18; (ii) The reagent was put into use for patient testing on 03/26/18; (iii) Although the laboratory utilized 40 specimens for the comparison studies, the laboratory did not use samples which resulted in 50% (e.g. 20) falling outside the laboratory's normal PT reference interval of 9.8-12.2, but used 5. (b) 2019: (i) The rollover for the new PT reagent Recombiplastin 2G (Lot #N0789707) was performed 02/25/19 to 04/16/19; (ii) The reagent was put into use for patient testing on 07/17/19; (ii) Although the laboratory utilized 40 specimens for the comparison studies, the laboratory did not use samples which resulted in 20 results falling outside the laboratory's normal PT reference interval of 9.4-12.5, but used 9. (4) The findings were reviewed with the laboratory manager and laboratory supervisor who stated to surveyor #2 the laboratory failed to follow the manufacturer's instructions for performing the comparison study during the reagent lot number rollovers performed in 2018 and 2019. PTT (1) The laboratory manager stated to the surveyors: (a) PTT (Partial Thrombin Time) testing was performed using the IL ACL TOP 300 coagulation analyzer; (b) HemosIL Synthasil reagent, Lot #N1081021 was currently in use. (2) Surveyor #2 reviewed the manufacturer's reagent lot rollover instructions and the laboratory's PTT reagent 2018 and 2019 lot rollovers and identified the laboratory failed to follow the manufacturer's instructions for the comparison study. The findings follow: (a) 2018: (i) The rollover for the new PTT reagent HemosIL Synthasil (Lot #N1173603) was performed from 02 /23/18 to 03/06/18; (ii) The reagent was put into use for patient testing on 03/28/18; (iii) Although the laboratory utilized 40 specimens for the comparison studies, the laboratory did not use 20 results outside the laboratory's normal PTT reference interval of 28.3-34.7, but used 5. (b) 2019: (i) The rollover for the new PTT reagent HemosIL Synthasil (Lot #N1081021) was performed 02/25/19 to 04/16/19; (ii) The reagent was put into use for patient testing on 07/17/19; (ii) Although the laboratory utilized 40 specimens for the comparison studies, the laboratory did not use 20 results outside the laboratory's normal PTT reference interval of 25.1-36.5, but used 7. (3)

	The findings were reviewed with the laboratory manager and laboratory supervisor who stated to surveyor #2 the laboratory failed to follow the manufacturer's instructions for performing the comparison study during the 2018 and 2019 reagent lot number rollovers.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality assurance manager, laboratory manager and laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the fourth day of the survey, the laboratory manager stated to surveyor #3 the Helmer Quick Thaw Plasma Thawing system was used to thaw units of Fresh Frozen Plasma (FFP). The units were to be used for patient transfusions; (2) On the fourth day of the survey, surveyor #3 reviewed the manufacturer's maintenance requirements, which were as follows: (a) Annually (i) "Check the bearings on each basket for wear. Replace if necessary." (3) Surveyor #3 then reviewed blood bank records from January 2018 through the fourth day of the survey (11/21/19). (4) Surveyor #3 asked the laboratory supervisor if the annual maintenance had been perfomed in 2018 and 2019. The laboratory manager and laboratory supervisor stated the annual maintenance had not been performed between 01/01/18 through 10/21/19.
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, and interview with the laboratory supervisor and laboratory manager, the laboratory failed to perform function checks as defined by the manufacturer for the iSTAT 1 analyzer. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyors Blood Gas (pH, pCO2, and pO2) and Lactate testing were performed using two iSTAT 1 handheld analyzers and the CG4+ cartridge as follows: (a) Serial #347715 - The primary analyzer used in the Respiratory/ICU (Intensive Care Unit) department of the hospital; (b) Serial #370507 - The back-up analyzer for the Respiratory/ICU department which was housed in the laboratory. (2) Surveyor #1 reviewed the manufacturer's instructions regarding the performance of the thermal probe check. The instructions stated, "The Handheld's thermal probes should be checked every six months"; (3) Surveyor #1 then reviewed thermal probe check records for the analyzers for testing performed in 2018 and to date in 2019. There was no documentation verifying the thermal probe check had been performed as follows: (a) Serial #347715 - Between 05/15/18 and 08/07/19 (b) Serial #370507 - Between 05

	/14/18 and 08/07/19 (4) Surveyor #1 reviewed the findings with the laboratory supervisor and laboratory manager. Both stated the thermal probe checks had not been performed every six months.
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 laboratory supervisor, laboratory manager, and testing person #7, the laboratory failed to ensure the urine centrifuge and blood bank pipettes were functioning properly. Findings include: URINE CENTRIFUGE (1) On the first day of the survey, the laboratory supervisor stated to the surveyors urine sediment examinations were performed in the laboratory. The specimens were processed in the LW Scientific Ultra 8V centrifuge at a speed of 2000 rpm (revolutions per minute) for 10 minutes; (2) On the fourth day of the survey, surveyor #1 reviewed the centrifuge function check policy which required speed and timer checks be performed on the centrifuge every six months; (3) Surveyor #1 reviewed the centrifuge maintenance records for 2018 and to date in 2019. The speed had not been checked at the speed the urine specimens were processed, to ensure the centrifuge was functioning properly at that speed, for 1 of 4 checks performed as follows: (i) 07/19/18 - The speed had been checked at 999 rpm. (4) Surveyor #1 reviewed the findings with the laboratory supervisor and laboratory manager. Both stated the centrifuge speed had not been checked at the speed used to process urine specimens as indicated above. BLOOD BANK PIPETTES (1) On the first day of the survey, the laboratory supervisor stated to the surveyors the Ortho ID-MTS Gel system was used to perform patient Antibody Screen and Compatibility testing and the tube method was used to perform ABO and Rh typing; (2) On the fourth day of the survey, testing person #7 explained the following pipette usage to surveyor #1: (a) The 10 microliter (ul) MLA pipette was used to dispense patient cell suspensions for ABO and Rh typing; (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 Screens 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. (c) The 1000 ul MLA pipette was used to dispense MTS Diluent 2 to prepare cell suspensions of donor cells to perform Compatibility testing. (3) Surveyor #1 reviewed the policy for performing pipette calibration checks, which required the calibration checks be performed every six months; (4) Surveyor #1 reviewed records for 2018 and to date in 2019. There was no documentation the pipette calibrations had been performed prior to 02/01/19; (5) Surveyor #1 reviewed the findings with the laboratory manager who stated there was no documentation to prove the pipette calibrations had been performed prior to 02/01/19.

D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with with the quality assurance manager, laboratory manager, and laboratory supervisor, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: (1) At the beginning of the survey, the laboratory manager, verified to the surveyors chemistry testing, which included the analytes B12 and LDL (Low Density Lipoprotein), was performed using the Ortho Vitros 350 analyzer; (2) On the third day of the survey, surveyor #2 reviewed calibration verification records for testing performed in 2018 and to date in 2019 (since routine calibration procedures were performed using less than three calibrators for the above analytes, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). Surveyor #2 identified calibration verification procedures had not been performed during 2018; (3) Surveyor #2 reviewed the findings with the quality assurance manager, laboratory manager, and the laboratory supervisor, who stated to surveyor #2, the laboratory failed to perform calibration verification procedures for the analytes B12 and LDL at least once every 6 months in 2018.
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 supervisor, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process. Findings include: HEMOGLOBIN A1C TESTING (1) On the first day of the survey, the laboratory supervisor stated to the surveyors Hemoglobin A1c testing was performed using the BioRad D-10 analyzer; (2) On the third day of the survey, the laboratory supervisor stated to surveyor #1 three levels of BioRad Liquichek Diabetes control materials were tested each day of patient testing; (3) Surveyor #1 asked the laboratory supervisor to explain how QC (quality control) results were monitored for variances (e.g., biases, shifts, trends). The laboratory supervisor stated the laboratory participated in the Bio-Rad Unity QC program and reviewed QC data (Levey-Jennings graphs and cumulative statistical data) each month on the computer. However, the data had not been printed and maintained by the laboratory and there was no documentation of the QC reviews; (4) Since there was no documented evidence the QC data had been reviewed for variances during the review period of 2018 through the third day of the survey, surveyor #1 determined the laboratory did not have an effective method of monitoring QC results for variances. COAGULATION TESTING (1) On the first day of the survey, the laboratory manager stated to the surveyors: (a) PT/INR (Prothrombin Time/International Normalized Ratio) and PTT (Partial Thromboplastin) testing were performed using the IL ACL TOP 300 coagulation analyzer; (b) The laboratory analyzed two levels of HemosIL Normal Control Level 1 and Abnormal Control Level 3 each 8 hours of patient testing; (c) The acceptable QC limits were established when the PT and PTT reagent lot numbers were changed. (2) Surveyor #2 asked the laboratory manager how the laboratory monitored QC results for variances. The laboratory manager stated that each month LJ (Levey-Jennings) graphs of the QC results were printed from the analyzer and reviewed. In addition, the laboratory participated in the manufacturer's peer QC data program, Accutrak, which were also reviewed monthly; (3) Surveyor #2 then reviewed QC records from April 2018 through October 2019 and identified the laboratory had not utilized the QC ranges that had been established during the reagent rollover (performed between 02/23/18 to 03/06/18) but used ranges which were wider. The specific findings follow: (a) Normal Control Level 1, Lot #N0670338 was put into use on 03/28/18: (i) PT: (aa) A 2SD (Standard Deviation) range of 11.3-12.9 was established during the lot rollover; (bb) A range of 10.4-14.4 was utilized from 03/28 /18 through 09/30/18. (ii) PTT: (aa) A 2SD range of 28.0-32.0 was established during the lot rollover; (bb) A range of 26.0-34.0 was utilized from 03/28/18 through 09/30 /18. (b) Abnormal Control Level 3, Lot #N0871604 was put into use on 03/28/18: (i) PT: (aa) A 2SD range of 36.6-42.6 was established during the lot rollover; (bb) A range of 31.3-46.9 was utilized from 03/28/18 through 09/30/18. (ii) PTT: (aa) A 2SD range of 53.5-66.7 was established during the lot rollover; (bb) A range of 47.4-73.8 was utilized from 03/28/18 through 09/30/18. (4) Surveyor #2 reviewed the findings with the laboratory manager and the laboratory supervisor and asked them to explain why the laboratory utilized QC ranges that had not been established by the laboratory. The laboratory supervisor stated to surveyor #2, the laboratory had not updated the ranges with those established during the lot rollovers and utilized ranges that were wider than those established by the laboratory.
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, laboratory supervisor, and quality assurance manager, the laboratory failed to define the type of quality control testing when implementing IQCP's. Findings include: SURE-VUE SERUM HCG (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) Qualitative serum pregnancy testing was performed using the Sure-Vue Serum/Urine hCG test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP. The QCP (Quality Control Plan) portion of the IQCP did not include the type of QC (Quality Control) materials; (3) Surveyor #1 reviewed the QCP with the laboratory manager and quality assurance manager. Both stated the QCP did not include the type of QC materials used for the test system. MED TOX PROFILE-V (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) Urine Drug Screen testing was performed using the Med Tox Profile-V Med Tox Scan Drugs of Abuse Test system; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP. The QCP (Quality Control Plan) portion of the IQCP did not include the type of QC (Quality Control) materials; (3) Surveyor #1 reviewed the QCP with the laboratory manager and quality assurance manager. Both stated the QCP did not include the type of QC materials used for the test system. ISTAT 1 CG4+ (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) pH, pCO2, pO2, and Lactate testing were performed using the iSTAT 1 analyzer and the CG4+ cartridge; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP. The QCP (Quality Control Plan) portion of the IQCP did not include the type of QC (Quality Control) materials; (3) Surveyor #1 reviewed the QCP with the laboratory manager and quality assurance manager. Both stated the QCP did not include the type of QC materials used for the test system.
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 supervisor, laboratory manager, and quality assurance manager, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: SURE-VUE SERUM HCG (1) On the first day of the survey, the laboratory supervisor stated the following

to the surveyors: (a) Qualitative serum pregnancy testing was performed using the Sure-Vue Serum/Urine hCG test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 10/14/19). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and quality assurance manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. Both stated the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. MED TOX PROFILE-V (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) Urine Drug Screen testing was performed using the Med Tox Profile-V Med Tox Scan Drugs of Abuse Test system; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 10/14/19). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and quality assurance manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. Both stated the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. ISTAT 1 CG4+ (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) pH, pCO2, pO2, and Lactate testing were performed using the iSTAT 1 analyzer and the CG4+ cartridge; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 10/14/19). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and quality assurance manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. Both stated the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. QUIDEL QUICKVUE + MONONUCLEOSIS (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) Serum Mononucleosis testing was performed using the Quidel QuickVue + Mononucleosis test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 11/07/19). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and quality assurance manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. Both stated the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. REMEL XPECT FLU A&B (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) Influenza A and B testing were performed using the Remel Xpect Flu A&B test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 10/14/19). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and quality assurance manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the

	QCP, including the frequency of the reviews. Both stated the QA plan did not include an evaluation of the QCP, and the frequency of the reviews. ALERE DETERMINE HIV 1/2 AG /AB COMBO (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyors: (a) HIV (Human Immunodeficiency Virus) testing was performed using the Alere Determine HIV 1/2 Ag/Ab Combo test kit; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 11/07/19). The QA (Quality Assessment) portion of the IQCP did not include a schedule for evaluating the QCP (Quality Control Plan) to ensure it continued to provide accurate and reliable results; (3) Surveyor #1 reviewed the records with the laboratory manager and quality assurance manager, and asked if, in addition to the ongoing monitoring, the QA plan addressed how the laboratory will evaluate the QCP, including the frequency of the reviews. Both stated the QA plan did not include an evaluation of the QCP, and the frequency of the reviews.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, written policy and procedure, and interview with the laboratory manager and laboratory supervisor, the laboratory failed to take corrective action necessary to ensure the reporting of accurate and reliable patient test results. Findings include: LABORATORY TEMPERATURE (1) On the first day of the survey, the laboratory manager stated to the surveyors the laboratory performed urinalysis testing using the Clinitek Advantus reagent dipstick reader and Multistix 10SG urine reagent dipsticks; (2) On the third day of the survey, surveyor #2 reviewed the manufacturer's required environmental specifications. The manufacturer required an optimal operating temperature of 22 to 26 degrees C (Centigrade). In addition, the manufacturer's instructions stated, "at temperatures under 22 degrees, Urobilinogen and Leukocytes may be decreased and at a temperature greater than 26 degrees, increased;" (3) Surveyor #2 then reviewed the laboratory's temperature records from 8 months in 2019 (January, February, March, April, May, July, September, and October). The laboratory's acceptable temperature limit as listed on the record was 22 to 26 degrees C. To monitor the temperature, the laboratory utilized a Min/Max thermometer. From the review, surveyor #2 identified the room temperature was colder than the laboratory's acceptable limit on 59 of the 243 days reviewed: (a) January: On 6 of 31 days, the temperature was less than 22 degrees C (i) Days: 20,26,27,28,29,31 (b) February: On 13 of 28 days, the temperature was less than 22 degrees C (i) Days: 1,2,16,18,19,20,21,22,23,24,25,26,27 (c) March: On 14 of 31 days, the temperature was less than 22 degrees C (i) Days: 9,10,11,17,18,20,21,22,23,24,25,26,27,29 (d) May: On 4 of 31 days, the temperature was less than 22 degrees C (i) Days: 11,12,13,31 (e) September: On 10 of 30 days, the temperature was less than 22 degrees C (i) Days: 10,18,19,20,21,23,24,25,26,27 (f) October: On 12 of 31 days, the temperature was less than 22 degrees C (i) Days: 8,15,16,18,21,22,23,26,27,28,29,30 (4) Surveyor #2 then reviewed the laboratory's written policy for temperature monitoring. Under "Corrective Action," it included the

	following instructions: (i) Documentation must include the date and description of the corrective action to include patient impact, and the reading after corrective action was completed; (ii) Document actions taken on the Corrective Action Log (5) Surveyor #2 reviewed the laboratory's corrective action log. There was no documentation that corrective action (i.e., adjust thermostat, recovered temperature, etc.) had been taken, and acceptable temperatures had been achieved; (6) The findings were reviewed with the quality assurance manager, the laboratory manager, and the laboratory supervisor, who stated to surveyor #2 the laboratory failed to ensure corrective action taken for unacceptable temperatures had been effective, and the laboratory failed to meet the manufacturer's temperature specification. HUMIDITY (1) On the third day of the survey, surveyor #2 reviewed the manufacturer's required environmental specifications for the Clintek Advantus urine dipstick reader. The manufacturer required a humidity between 35 and 55%; (2) Surveyor #2 then reviewed the laboratory's humidity records from 8 months in 2019 (January, February, March, April, May, July, September, and October). The laboratory's acceptable humidity range as listed on the temperature record was 35 to 55%. To monitor the humidity, the laboratory utilized a Min/Max hygrometer. From the review, surveyor #2 identified the humidity was lower than 35% as required by the manufacturer on 87 of the 243 days reviewed: (a) January: On 31 of 31 days, the humidity was too low (b) February: On 25 of 28 days, the humidity was too low (i) Days: 1,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28 (c) March: On 27 of 31 days, the humidity was too low (i) Days: 1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18,19,20,21,22,23,25,27,28,30,31 (d) May: On 4 of 31 days, the humidity was too low (i) Days: 10,11,12,13 (3) Surveyor #2 then reviewed the laboratory's written policy for humidity monitoring. Under "Corrective Action," it included the following instructions: (i) If the humidity is outside the acceptable performance range, determine if the humidity can be adjusted by use of a humidifier or a dehumidifier; (ii) Record the date and description of the correction action taken to include patient impact, and the reading after the corrective action was completed. (4) Surveyor #2 reviewed the laboratory's corrective action log. There was no documentation that corrective action (i.e. humidifier used, humidity checked and recovered, etc.) had been taken, and that acceptable humidity had been achieved; (5) The findings were reviewed with the quality assurance manager, the laboratory manager, and the laboratory supervisor, who stated to surveyor #2 the laboratory failed to ensure corrective action taken for unacceptable humidity had been effective, and the laboratory failed to meet the manufacturer's humidity specification.
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 quality assurance manager, laboratory manager and laboratory supervisor, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 2 of 90 events. Findings include:

	(1) On the second day of the survey, surveyor #3 reviewed 2018 and 2019 proficiency testing records. It was identified for 2 of 90 events, the attestation statements had been signed approximately 3-6 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) 2019 Transfusion Medicine (J-A) Event - The samples had been tested on 02/17/19 and the attestation statement had not been signed by the laboratory director until 08/16/19; (b) 2019 Transfusion Medicine (J-B) Event - The samples had been tested on 06/28/19 and the attestation statement had not been signed by the laboratory director until 09/16/19. (2) The surveyor reviewed the findings with quality assurance manager, laboratory manager and laboratory supervisor 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.
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 quality assurance manager, laboratory manager and laboratory supervisor, 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 quality assurance manager, laboratory manager and laboratory supervisor, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 5 of 16 testing persons. Findings include: (1) On the third day of the survey, surveyor #3 reviewed records for 16 persons performing moderate complexity testing in 2018 and 2019. The records indicated the evaluations for 5 of 16 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #12 (i) The 2019 evaluation had been performed by testing person #9 on 03/04/19 (this person had earned an associate degrees in a biological science). (b) Testing Person #15 (i) The 2019 evaluation had been performed by testing person #9 on 09/04/19. (c) Testing Person #17 (i) The 2018 evaluation had been performed by testing person #9 on 02/28/18; (ii) The 2019 evaluation had been performed by testing person #9 on 03 /05/19. (d) Testing Person #20 (i) The 2018 evaluation had been performed by testing person #9 on 02/27/18; (ii) The 2019 evaluation had been performed by testing person #9 on 03/05/19. (2) Surveyor #3 explained to quality assurance manager, laboratory manager and laboratory supervisor 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).
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 quality assurance manager, laboratory manager and laboratory supervisor, the technical consultant failed to ensure evaluations included all moderate complexity testing performed for 2 of 6 testing persons. Findings include: (1) On the third day of the survey, the laboratory manager stated to surveyor #3 urine drug screen testing was performed using the MedTox II ER analyzer until 04/30/19 when the laboratory changed to the MedTox Profile V analyzer: (2) Surveyor #3 then reviewed personnel records for 6 persons performing

	urine drug screen analysis in the laboratory. The records verified that urine drug screen annual evaluations had not been performed in 2018 for testing person #9 and testing person #10; (3) The surveyor reviewed the findings with quality assurance manager, laboratory manager and laboratory supervisor, who stated annual evaluations were not performed as indicated above.