Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475547	06/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Integris Health Ponca City Hospital	1900 N 14th Street, Ponca 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	The validation survey was performed on 06/24,25,26,27/19. The laboratory was found out of compliance with the following CLIA regulation: 493.1409; D6033: Technical Consultant The findings were reviewed with the chief quality officer, risk manager, pathology assistant, CCU manager, MS director (cardiac rehab/swing bed), BFC director, laboratory director, POC (point of care)/LIS (laboratory information system) coordinator, microbiologist, urinalysis lead, hematology/coagulation lead, quality, director of facilities, CEO, CFO, medical staff coordinator, chief nursing officer, human resources director, emergency department director, and administrative laboratory director during an exit conference performed on 06/27/19.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the administrative laboratory director, the laboratory failed to have a written general supervisor and technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) On the second day of the survey, surveyor #2 reviewed personnel records for competency assessments performed during 2017, 2018, and 2019. There was no evidence competencies had been performed for the general supervisor and technical consultant, based on their job responsibilities; (2) Surveyor #2 asked the administrative laboratory director if a written policy to evaluate general supervisor and technical consultant based on job responsibilities was available. The administrative laboratory director stated a policy to evaluate the general supervisor and technical consultant based on job responsibilities had not been written; and competencies had not been performed.

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 administrative laboratory director, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2018 and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2018 Chemistry Core Event (i) Acetaminophen - 3 of 5 results exhibited a positive bias (aa) CH-06 - SDI of 2.2 (bb) CH-07 - SDI of 2.2 (cc) CH-09 - SDI of 2.5 (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 administrative laboratory director, and asked if the biases had been addressed. The administrative laboratory director stated the biases had not been addressed.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of policies and interview with the administrative laboratory director and LIS/POC coordinator, the laboratory failed to ensure policies had been approved, signed, and dated by the laboratory director before use. Findings include: (1) On the third day of the survey, the LIS (laboratory information system)/POC (point of care) coordinator stated the following to surveyor #1: (i) The ROM (Rupture of Membranes) Plus test kit was performed at the point of care in the Birth and Family Unit of the hospital to detect amniotic fluid in vaginal secretions of pregnant women with signs of ROM; (ii) An IQCP had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as effective on 06/08/16) and identified the QCP (Quality Control Plan) had not been approved, signed, and dated by the laboratory director; (3) Surveyor #1 reviewed the records with the administrative laboratory director and LIS/POC coordinator. Both stated the QCP had not been approved, signed, and dated by the laboratory director.
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 administrative laboratory director and hematology/coagulation lead, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents. Findings include: (1) On the first day of the survey, the administrative laboratory director stated to the surveyors the Sysmex CA-1500 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); (2) On the third day of the survey, surveyor #1 observed the refrigerator where the testing reagents were maintained and identified the following reagents which appeared to be currently in use: (a) PT - Innovin reagent, lot #549724 (b) PTT - Actin FSL reagent, lot #556943A (c) Ci-Trol 1 control, lot #548080 (d) Ci-Trol 3 control, lot #556507 (3) The hematology/coagulation lead stated to surveyor #1 the above reagent lot numbers were currently in use, and had initially been put into use November 2018; (4) 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 "Normal Range Study" (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 the Normal Range Study"; (iii) "Assay samples on current and new lot number reagents simultaneously or within 1 our of each other"; (iv) "Calculate Linear Regression". (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) "When a minimum of 30 data points have been collected, set the mean and 2 SD range". (5) Surveyor #1 reviewed the records for the lot changes with the following identified: (a) PT - Innovin reagent, lot #549724 (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 #556943A (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 11 abnormal samples, instead of 20 as required by the manufacturer. (c) Quality Control (QC) (i) Ci-Trol 1, lot #548080 - The records showed the laboratory had used 26 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 #556507 - The records showed the laboratory had used 25 data points to establish QC ranges for PT and 24 data points to establish QC ranges for PTT instead of 30 data points as required by the manufacturer. (6) The findings were reviewed with the hematology /coagulation lead, who stated the manufacturer's instructions had not been followed for the reagent lot changes as specified above.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper

	storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, observation, and interview with the chemistry lead technologist, the laboratory failed to ensure materials were being stored as required. Findings include: (1) On the third day of the survey, the surveyors observed the outpatient draw station. The following were examples of materials being stored in the area, along with the manufacturer's storage requirements: (a) BD Vacutainer K2 EDTA tubes (80 tubes of lot#9065800) with a storage requirement of 4-25 degrees (C) Celsius); (b) BD Vacutainer SST tubes (50 tubes of lot# 9059877) with a storage requirement of 4-25 degrees C); (c) BD Vacutainer Buff Na Citrate tubes (54 tubes of lot #9004631) with a storage requirement of 4-25 degrees C); (d) BD E Swab Collection and Transport System swabs (9 swabs of lot #181282332) with a storage requirement of 5-25 degrees C. (2) The surveyors reviewed temperature records for January 2019 to date and could not locate documented temperature records for the outpatient draw station; (3) The surveyors asked the chemistry lead technologist if the temperature of the draw station was being monitored. The chemistry lead technologist stated the laboratory was not monitoring the temperature of the outpatient draw station.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the administrative laboratory director, the laboratory failed to demonstrate the performance specifications prior to implementing serum acetone testing. Findings include: (1) At the beginning of the survey, the administrative laboratory director stated to surveyor #2 serum acetone testing was performed using the AimTab Ketone Tablet; (2) The administrative laboratory director stated to surveyor #2 acetone testing was put into use on 03/10/19; (3) Surveyor #2 asked the administrative laboratory director for the performance specification (accuracy) records for the AimTab Kentone Tablet; (4) The administrative laboratory director stated validation records could not be located to demonstrate accuracy.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)

	For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the administrative laboratory director and hematology/coagulation lead, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) On the first day of the survey, the administrative laboratory director stated to the surveyors CBC (Complete Blood Count) testing was performed using the Sysmex KX-21N analyzer as a back-up to the Sysmex XT-2000i analyzer; (2) On the second day of the survey, surveyor #1 reviewed the manufacturer's maintenance instructions as stated on the manufacturer's maintenance logs. The requirements for weekly maintenance were: (a) Clean Instrument Interior/Exterior (3) Surveyor #1 then reviewed maintenance records between May 2018 through May 2019. There was no evidence weekly maintenance had been performed between: (a) 01/25/19 and 02/0719 (b) 03/21/19 and 04/11/19 (c) 04/25/19 and 05/02/19 (4) Surveyor #1 reviewed the records with the hematology/coagulation lead, who stated the above maintenance had not been performed as required.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of records and interview with the LIS/POC coordinator, the laboratory failed to perform calibration verification procedures at least once every 6 months. Findings include: TROPONIN I (1) On the third day of the survey, the LIS (laboratory information system)/POC (point of care) coordinator stated to surveyor #1 Troponin I testing was performed using the iSTAT 1 analyzer and the cTnI test cartridge as follows: (a) At the point of care in the Emergency Department using two iSTAT 1 analyzers (serial numbers 353472 and 356327); (b) In the laboratory using

	two iSTAT 1 analyzers (serial numbers 356233 and 363169). (2) Surveyor #1 reviewed calibration verification records for 2017, 2018, and to date in 2019 (since calibration procedures were not routinely performed, calibration verification procedures, using three or more levels of calibration materials, were required every 6 months). There was no evidence calibration verification procedures had been performed after 08/16/18 (due 02/2019); (3) Surveyor #1 reviewed the records with the LIS/POC coordinator who stated calibration verification procedures had not been performed every six months for Troponin I. LACTATE (1) On the third of the survey, the LIS/POC coordinator stated to surveyor #1 Lactate testing was performed in the using the iSTAT 1 analyzer and the CG4+ test cartridge as a back-up method to the ABL 800 analyzer; (2) Surveyor #1 reviewed calibration verification records for 2017, 2018, and to date in 2019. There was no evidence calibration verification procedures had been performed after 03/08/17 (due 09/2017); (3) Surveyor #1 reviewed the records with the LIS/POC coordinator who stated calibration verification procedures had not been performed every six months for Lactate. BNP (1) On the third day of the survey, the LIS (laboratory information system)/POC (point of care) coordinator stated to surveyor #1 BNP (B-Type Natriuretic Peptide) testing was performed in the laboratory using two iSTAT 1 analyzers (serial numbers 356233 and 363169) and the BNP test cartridge; (2) Surveyor #1 reviewed calibration verification records for 2017, 2018, and to date in 2019. There was no evidence calibration verification procedures had been performed after 08/17/18 (due 02/2019); (3) Surveyor #1 reviewed the records with the LIS/POC coordinator who stated calibration verification procedures had not been performed every six months for BNP.
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 administrative laboratory director, LIS/POC coordinator, and microbiologist, the laboratory failed to ensure IQCP's included the required components; and failed to ensure data supported the QC frequency as defined in the QCP portion of the IQCP's. Findings include: REQUIRED COMPONENTS NOT INCLUDED IN IQCP (1) Serum Pregnancy Testing (a) On the first day of the survey, the administrative laboratory director stated the following to the surveyors: (i) Qualitative serum pregnancy testing was performed in the laboratory using the Fisher Healthcare SureVue Serum hCG test kit; (ii) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (b) Surveyor #1 reviewed the IQCP for the test system and identified a QCP (Quality Control Plan) had not been included in the IQCP (it consisted of a Risk Assessment and QA (Quality Assurance) plan only; (c) Surveyor #1 reviewed the records with the laboratory administrative director and LIS/POC coordinator. Both stated a QCP had not been included in the IQCP. (2) MedTox Scan (a) On the first day of the survey, the laboratory administrative director stated the following to the surveyors: (i) Urine

	Drug Screen testing was performed in the laboratory using the MedTox Scan system; (ii) An IQCP had been developed for the test system. (b) Surveyor #1 reviewed the IQCP for the test system and identified a QA plan had not been included in the IQCP (it consisted of a Risk Assessment and QCP only); (c) Surveyor #1 reviewed the records with the laboratory administrative director and LIS/POC coordinator. Both stated a QA plan had not been included in the IQCP. (3) iSTAT 1 and G3+ Cartridge (a) On the third day of the survey, the LIS/POC coordinator stated the following to surveyor #1: (i) Blood Gas (pH, pCO2, and pO2) testing was performed using the iSTAT 1 analyzer and the G3+ test cartridge in the laboratory using 2 analyzers (serial numbers 356233 and 363169); and at the point of care in the CCU (Critical Care Unit) department of the hospital using 1 analyzer (serial number 351911); (ii) An IQCP had been developed for the test system. (b) Surveyor #1 reviewed the IQCP for the test system and identified a QCP had not been included in the IQCP (it consisted of a Risk Assessment and QA plan only); (c) Surveyor #1 reviewed the records with the administrative laboratory director and LIS/POC coordinator. Both stated a QCP had not been included in the IQCP. (4) ROM Plus (a) On the third day of the survey, the LIS/POC coordinator stated the following to surveyor #1: (i) The ROM (Rupture of Membranes) Plus test kit was performed at the point of care in the Birth and Family Unit of the hospital to detect amniotic fluid in vaginal secretions of pregnant women with signs of ROM; (ii) An IQCP had been developed for the test system, (b) Surveyor #1 reviewed the IQCP for the test system and identified a QA plan had not been included in the IQCP (it consisted of a Risk Assessment and QCP only); (c) Surveyor #1 reviewed the records with the LIS/POC coordinator who stated a QA plan had not been included in the IQCP. (5) Identification and Susceptibility Testing (a) On the fourth day of the survey, the microbiologist stated the following to the surveyors: (i) The Microscan system was used with the Negative Urine Panel and the Positive Combo Panel Type 33 to assist in the identification and susceptibility testing of microorganisms; (ii) An IQCP had been developed for the test system. (b) Surveyor #1 reviewed the IQCP for the test system and identified a QCP had not been included in the IQCP (it consisted of a Risk Assessment and QA plan only); (c) Surveyor #1 reviewed the records with the microbiologistwho stated a QCP had not been included in the IQCP. DATA DID NOT SUPPORT QC FREQUENCY (1) On the fourth day of the survey, the microbiologist stated the following to the surveyors: (a) The laboratory began performing Lactoferrin testing using the Alere Leuko EZ Vue test kit on 04/04/19; (b) An IQCP had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as effective on 02/29/19) and identified the QCP required positive and negative external QC (quality control) materials be performed once each month (i.e., approximately every 30 days) and with new lot numbers of test kits; (3) Surveyor #1 then reviewed the supporting documentation for the QCP and identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (b) Positive and negative QC had been tested for 1 day (not at least 30 days). (4) Surveyor #1 reviewed the records with the microbiologist who stated QC had not been tested for at least 30 days.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 microbiologist, the laboratory failed to perform positive and negative controls each day the India Ink stain was used for patient testing. Findings include: (1) On the fourth day of the survey, the microbiologist stated the laboratory performed microscopic interpretations of CSF (Cerebrospinal Fluid) specimens that had been stained with India Ink stain; (2) Surveyor #2 reviewed test records for 11 days of patient testing (microscopic interpretations) performed from September 2018 through June 2019. There was no evidence positive and negative controls had been performed for 11 of 11 days of patient testing: (a) Patient tested on 09/13/18 at 05:52 p.m. (b) Patient tested on 10/11 /18 at 02/01 p.m. (c) Patient tested on 10/11/18 at 02:20 p.m. (d) Patient tested on 11 /15/18 at 02:51 p.m. (e) Patient tested on 02/07/19 at 02:06 p.m. (f) Patient tested on 02/14/19 at 07:57 p.m. (g) Patient tested on 03/05/19 at 08:59 p.m. (h) Patient tested on 03/07/19 at 05:00 p.m. (i) Patient tested on 03/28/19 at 02:59 p.m. (j) Patient tested on 04/03/19 at 03:04 p.m. (k) Patient tested on 04/04/19 at 03:11 p.m. (l) Patient tested on 06/25/19 at 02:04 p.m. (3) Surveyor #2 reviewed the findings with the microbiologist, who stated positive and negative controls had not been performed for the India Ink stain.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (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 microbiologist, the laboratory failed to check each batch of media for its ability to support growth; failed to check each batch of media for its ability to inhibit specific organisms or to produce a biochemical response; and failed to document the physical characteristics of media when compromised and report any deterioration in the media to the manufacturer for chocolate media. Findings include: (1) On the fourth day of the survey, the microbiologist stated to the surveyors BBL Chocolate II media was used to cultivate microorganisms in patient sputum, wound, and genital culture specimens; (2) The surveyors asked the microbiologist if quality control (QC) checks (the ability to support growth; and as appropriate, the ability to inhibit specific organisms or to produce a biochemical response) were performed on each batch of chocolate media received into the laboratory. The microbiologist stated QC testing had not been performed. The surveyors then asked the microbiologist if an IQCP (Individualized Quality Control Plan) had been developed for the chocolate media. The microbiologist stated an IQCP had not been developed because the laboratory believed the chocolate media had been included with the IQCP from the previously exempt media. Therefore, the surveyors determined QC checks must be performed on each batch of media received, as appropriate; (3) In order to track each batch of media received in 2019, the surveyors asked the microbiologist if the receipt of each batch of media had been documented. The microbiologist stated the media labels were maintained, with

	the receipt date documented on each, and provided the surveyors with the following media labels for 3 lot numbers of chocolate media received in 2019: (a) Lot #83346621 received on 02/11/19 (b) Lot #9022658 received on 03/06/19 (c) Lot #9040774 received on 04/03/19
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the administrative laboratory director and hematology/coagulation lead, the laboratory failed to follow the manufacturer's quality control specifications. Findings include: (1) On the first day of the survey, the administrative laboratory director stated the following to the surveyors: (a) The laboratory used the Polymedco Sedimat II analyzer to perform automated ESR (Erythrocyte Sedimentation Rate) testing; (b) The Polymedco Sed-Chek 2 control materials (level 1 and level 2) were performed each day of patient testing. (2) On the second day of the survey, surveyor #1 reviewed the manufacturer's instructions for the control materials. They stated "An expected range is provided separately on a data sheet generated by multiple analysts' testing over several days using automated and manual ESR methods. Variation in inter-lab results will be greater than the precision for any one laboratory's procedure. Results depend on differences in equipment, reagents, supplies, and techniques. Therefore, a lab should establish its own acceptable ranges"; (3) Surveyor #1 then reviewed quality control records for 2 lot numbers of control materials used from 01/20/19 through the second day of the survey. The records showed the laboratory had used the package insert means and limits for each level of control instead of establishing their own means and limits as stated in the manufacturer's package insert: (a) Level 1 and level 2 (lot #11503181) - Used from 01/20/19 through 04/11/19; (b) Level 1 and level 2 (lot #11501191) - Put into use on 04/12/19 and was currently in use. (4) Surveyor #1 reviewed the findings with the hematology/coagulation lead, who stated the laboratory had not established their own means and limits of acceptability, but instead used the manufacturer's package insert limits.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the hematology/coagulation lead, the laboratory failed to test control specimens in duplicate when performing manual body fluid cell counts using a hemacytometer. Findings include: (1) On the second day of the survey, the hematology/coagulation lead stated to surveyor #1 body fluid cell

	counts were performed using a hemacytometer; (2) Surveyor #1 reviewed records for 10 patient body fluid cell counts performed in 2019. There was no evidence control materials had been tested in duplicate for 7 of 10 days of patient testing as follows: (a) Synovial Fluid cell count performed on 03/04/19; (b) Pleural Fluid cell count performed on 03/10/19; (c) Peritoneal Fluid cell count performed on 04/16/19; (b) Pleural Fluid cell count performed on 04/28/19; (e) Peritoneal Fluid cell count performed on 05/06/19; (f) CSF (Cerebral Spinal Fluid) cell count performed on 05/06 /19 (g) Synovial Fluid cell count performed on 06/13/19. (3) Surveyor #1 reviewed the records with the hematology/coagulation lead who stated that, although it was the policy of the laboratory to test control materials in duplicate, it had not been documented.
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 administrative laboratory director and LIS/POC coordinator, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP. Findings include: SERUM PREGNANCY (1) On the first day of the survey, the administrative laboratory director stated the following to the surveyors: (a) Qualitative serum pregnancy testing was performed in the laboratory using the Fisher Healthcare SureVue Serum 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 07/20/16). 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. There was no evidence of QA reviews since the IQCP effective date; (3) Surveyor #1 reviewed the records with theadministrative laboratory director and LIS/POC coordinator, and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if QA reviews had been performed since the IQCP had been implemented. Both stated a policy had not been written and QA reviews had not been performed. I STAT 1 AND CG4+ CARTRIDGE (1) On the third of the survey, the LIS (laboratory information system) /POC (point of care) coordinator stated the following to surveyor #1: (a) Blood Gas (pH, pCO2, pO2) and Lactate testing were performed in the using the iSTAT 1 analyzer and the CG4+ test cartridge as a back-up method to the ABL 800 analyzer; (b) An IQCP had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 07/20/16). The QA portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable results. There was no evidence of QA reviews since the IQCP effective date; (3) Surveyor #1 reviewed the records with the administrative laboratory director and LIS/POC coordinator, and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if QA reviews had been performed since the IQCP had been implemented. Both stated a policy had not been written and QA reviews had not been performed. TROPONIN I (1) On the third day of the survey, the LIS/POC coordinator stated the following to surveyor #1: (a) Troponin I testing was performed using the iSTAT 1 analyzer and the cTnI test

	cartridge as follows: (i) At the point of care in the Emergency Department using two iSTAT 1 analyzers (serial numbers 353472 and 356327); (ii) In the laboratory using two iSTAT 1 analyzers (serial numbers 356233 and 363169). (b) IQCP's had been developed for the test systems. (2) Surveyor #1 reviewed the IQCP (dated as approved on 07/20/16). The QA portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable results. There was no evidence of QA reviews since the IQCP effective date; (3) Surveyor #1 reviewed the records with the administrative laboratory director and LIS/POC coordinator, and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if QA reviews had been performed since the IQCP had been implemented. Both stated a policy had not been written and QA reviews had not been performed. BNP (1) On the third day of the survey, the LIS /POC coordinator stated the following to surveyor #1: (a) BNP (B-Type Natriuretic Peptide) testing was performed in the laboratory using two iSTAT 1 analyzers (serial numbers 356233 and 363169) and the BNP test cartridge; (b) An IQCP had been developed for the test system. (2) Surveyor #1 reviewed the IQCP (dated as approved on 07/20/16). The QA portion of the IQCP did not include a schedule for evaluating the QCP to ensure it continued to provide accurate and reliable results. There was no evidence of QA reviews since the IQCP effective date; (3) Surveyor #1 reviewed the records with the administrative laboratory director and LIS/POC coordinator, and asked if there was a policy to address how the laboratory will monitor the IQCP, including the frequency of the reviews and if QA reviews had been performed since the IQCP had been implemented. Both stated a policy had not been written and QA reviews had not been performed.
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 adminstrative laboratory director, 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 administrative laboratory director, the laboratory failed to ensure the individual who performed competencies met the educational qualifications of a technical consultant for 4 of 5 testing persons. Findings include: (1) On the second day of the survey, the surveyor reviewed records for 5 persons performing moderate complexity urinalysis testing in 2017, 2018 and 2019. The records indicated the evaluations for 4 of 5 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #2 (i) The 2018 urinalysis evaluation had been performed on 04/16/18 by testing person #1 (this person had earned an associate degree in applied science). (b) Testing Person #3 (i) The 2018 urinalysis evaluation had been performed on 11/21/18 by testing person #1 (c) Testing Person #6 (i) The 2018 urinalysis evaluation had been performed on 04/06/18 by testing person #1. (d) Testing Person #10 (i) The 2017 urinalysis evaluation had been performed on 03/21 /17 by testing person #1. (2) Surveyor #2 explained to the administrative laboratory director 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).
D6053	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 semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the administrative laboratory director, the technical consultant failed to ensure that persons performing moderate complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) On the second day of the survey, Surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #11- The initial training for this person was completed on 02/06/17. There was no evidence that a semiannual evaluation had been performed (due 08/17). (2) Surveyor #2 reviewed the records with the administrative laboratory director who stated there were no records to prove the above persons had been evaluated semiannually.
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 administrative laboratory director, the technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: (1) On the second day of the survey, surveyor #2 reviewed personnel records for 18 persons who performed moderate complexity testing during 2017 and 2018. For 5 of the 18 persons (testing person #2, testing person #4, testing person #9, testing person #10 and testing person #12), there was no evidence an annual evaluation had been performed in 2017; (2) Surveyor #2 reviewed the findings with the administrative laboratory director. The administrative laboratory director stated the annual evaluation had not been performed as indicated above in 2017 for the testing persons.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the administrative laboratory director, the technical supervisor failed to ensure that persons performing high complexity testing had been evaluated semiannually during the first year of testing. Findings include: (1) On the second day of the survey, surveyor #2 reviewed personnel records. The following was identified: (a) Testing Person #4 - The initial training for this person was completed on 02/06/17. There was no evidence that a semiannual evaluation had been performed (due 08/17); (b) Testing Person #8 - The initial training for this person was completed on 09/05/17. There was no evidence that a semiannual evaluation had been performed (due 03/18). (2) Surveyor #2 reviewed the records with the administrative laboratory director who stated there were no records to prove the above persons had been evaluated semiannually.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on a review of records and interview with the administrative laboratory director, the technical supervisor failed to evaluate testing persons performing high complexity testing at least annually. Findings include: (1) On the second day of the survey, surveyor #2 reviewed personnel records for 18 persons who performed high complexity testing during 2017 and 2018. For 5 of the 18 persons (testing person #1, testing person #2, testing person #3, testing person #9 and testing person #11), there was no evidence an annual evaluation had been performed in 2017; (2) Surveyor #2 reviewed the findings with the administrative laboratory director. The administrative laboratory director stated the annual evaluation had not been performed as indicated above in 2017 for the testing persons.