Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475185	03/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Northeastern Health System, Tahlequah	1400 E Downing St, Tahlequah, 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 survey was performed on 03/12,13,14,15,16/2018 The findings were reviewed with the vice president of patient care, assistant vice president of ancillary services, technical consultant #1, technical consultant #2, and technical consultant #3 during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1215; D5024: Hematology 493.1405; D6000: Laboratory Director, Moderate Complexity Testing 493.1409; D6033: Technical Consultant 493.1421; D6063: Testing Personnel, Moderate Complexity Testing 493.1441; D6076: Laboratory Director, High Complexity Testing
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 technical consultant #1, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the second day of the survey, surveyor #2 reviewed 2016, 2017 and 2018 proficiency testing records. The following was identified for 7 of 30 testing events: (a) First 2016 Immunohematology

	Event (i) The attestation was not signed by the laboratory director or designee (b) Second 2016 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (c) Third 2016 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (d) First 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (e) Second 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (f) Third 2017 Immunohematology Event (i) The attestation was not signed by the laboratory director or designee (g) Third 2017 Hematology/Coagulation Event (i) The attestation was not signed by the laboratory director or designee (2) The findings were reviewed with technical consultant #1 who stated the attestations were not signed as indicated above.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory failed to ensure the requirements were met for the specialty of Hematology. Findings include: (1) The laboratory failed to ensure that written procedures no longer in use had been discontinued. Refer to D5409; (2) The laboratory failed to ensure the verified reportable ranges for a new coagulation analyzer were used by the laboratory. Refer to D5421; (3) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (4) The laboratory failed to follow the manufacturer's specifications for establishing normal reference intervals for a new coagulation analyzer. Refer to D5479; (5) The laboratory failed to test one control material each 8 hours of operation; and failed to test patient and control specimens in duplicate when performing manual counts using a hemacytometer. Refer to D5543; (6) The laboratory failed to perform two levels of control material each 8 hours of operation on the coagulation analyzer. Refer to D5545; (7) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791. NOTE: D5024 was cited on the previous recertification survey performed on 04/26-28/16
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 policies and procedures, and interview with technical consultant #1, the laboratory failed to have written policies and procedures for assessing employee competency. Findings include: (1) On the first day of the survey, surveyor #2 reviewed the laboratory's policies and procedures. A policy that explained how

	employees were assessed for competency could not be located; (2) Surveyor #2 asked technical consultant #1 if a competency policy was available for review. Technical consultant #1 stated a policy had not been written. NOTE: For non-waived testing, the regulations require initial training, a semiannual evaluation during the first year, and an annual evaluation thereafter for each testing person for ensuring competency. The policy/procedure for evaluating competency must include, but is not limited to: *Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing *Monitoring the recording and reporting of test results *Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records *Direct observation of performance of instrument maintenance and function checks *Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples *Assessment of problem solving skills
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 technical consultant #1, the laboratory failed to thoroughly review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, surveyor #2 reviewed 2016, 2017 and 2018 proficiency testing records and identified the following failures, in which corrective action documentation could not be located: (a) First 2016 Chemistry Group 1 Event (i) D-Dimer - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (b) Second 2016 Chemistry Group 2 Event (i) Urine Potassium - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (c) Third 2016 Chemistry Group 1 Event (i) Carboxyhemoglobin - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (ii) Hemoglobin - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (iii) Methemoglobin - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (d) Third 2016 Chemistry Group 2 Event (i) C-Peptide - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (ii) TCA (Tricyclic Antidepressants) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (e) First 2017 Hematology/Coagulation Event (i) Urine Sediment - The laboratory failed the result for 1 of 2 samples, and attained a score of 50%. (f) Second 2017 Hematology/Coagulation Event (i) Urine Sediment - The laboratory failed the result for 1 of 2 samples, and attained a score of 50%. (g) First 2017 Chemistry Core Event (i) Glucose - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (ii) Hematocrit - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%; (iii) Hemoglobin - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (h) Second 2017 Chemistry Core Event (i) Osmolality - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (i) Third 2017 Chemistry Core Event (i) Cortisol - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (j) First 2017 Chemistry Miscellaneous Event (i) Mononuclear (CSF/Body Fluid) (%) - The laboratory failed the result for 1 of 2 samples, and attained a score of 50%; (ii) PMN (CSF/Body Fluid) (%) - The laboratory failed the result for 1 of 2 samples, and attained a score of 50%; (iii) Testosterone - The laboratory failed 1 of 3 samples, and attained a score of 33%;

	(iv) Parathyroid Hormone - The laboratory failed 1 of 3 samples, and attained a score of 33%. (2) The surveyors asked technical consultant #1 if corrective action had been taken for the failures. After reviewing the records, technical consultant #1 stated corrective action had not been taken to determine the cause of the failures.
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 written policies and interview with technical consultant #1 and technical consultant #3, the laboratory failed to ensure policies and procedures had been approved, signed, and dated by the laboratory director before use. Findings include: (1) On the first day of the survey, technical consultant #3 stated the following to the surveyors: (a) The laboratory began using the ROM (Rupture of Membranes) Plus test kit on 09/08/16; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) On the fourth day of the survey, surveyor #1 reviewed the IQCP (dated as effective on 08/11/16) and identified the QCP (Quality Control Plan) portion had not been approved, signed, and dated by the laboratory director; (3) Surveyor #1 reviewed the records with technical consultant #1 and technical consultant #3. Both agreed the QCP had not been approved, signed, and dated by the laboratory director. NOTE: D5407 was cited on the previous recertification survey performed on 04/26-28/16.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with technical consultant #1, the laboratory failed to ensure that written procedures no longer in use had been discontinued. Findings include: (1) On the third day of the survey, surveyor #1 reviewed laboratory procedure manuals. The following procedures were identified: (a) Contained in the "Coagulation Procedure Manual" were the following procedures for the Sysmex CA-1500 analyzer: (i) "Protime Test" (ii) "Activated Partial Thromboplastin Time (APTT) Test" (iii) "CA-1500 Basic Operation" (iv) "CA-1500 Maintenance" (v) "Scanned Procedures for CA-1500" (2) Surveyor #1 reviewed the procedures with technical consultant #1 who stated the above procedures should have been indicated as discontinued when the Sysmex CA 1500 analyzer was taken out of service in February 2018. NOTE: 493.1105(a)(2) requires that discontinued procedures be maintained for at least 2 years.
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 technical consultant #1, the laboratory failed to ensure materials had been stored as required. Findings include: MICROBIOLOGY DEPARTMENT HUMIDITY (1) On the first day of the survey, technical consultant #1 stated to the surveyors the following was performed: (a) Automated microbial detection (from blood cultures) was performed on the BacT /Alert 3D analyzer; (b) Automated microbial identification was performed on the Vitek 2 system analyzer; (2) On the third day of the survey, surveyor #2 reviewed the manufacturer's environmental requirements for the analyzer. The following was identified: (a) BacT/Alert -The manufacturer required the relative humidity be maintained between 10 - 90%; (b) Vitek 2 - The manufacturer required the relative humidity be maintain between 20 - 80%. (3) Surveyor #2 reviewed laboratory records from June 2016 through February 2018. The humidity was below 20% (range set to include both analyzers) for 5 of 21 months as follows; (a) April 2016 - The humidity had been documented below 20% for 7 of 30 days (days 1,2,3,4,8,9,12); (b) October 2017 - The humidity had been documented below 20% for 8 of 31 days (days 24,25,26,27,28.29,30,31); (c) November 2017 - The humidity had been documented below 20% for 18 of 30 days (days 8,9,10,11,12,13,16,17,18,19,20,21,22,23,24,25,26,27); (d) December 2017 - The humidity had been documented below 20% for 27 of 31 days (days 1,2,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,22,23,24,25,26,27,28,29,30,31); (e) January 2018 - The humidity had been documented below 20% for 23 of 31 days (days 1,2,3,4,5,6,7,8,9,10,12,13,14,15,16,17,18,22,23,24,25,29,30). (4) Surveyor #2 reviewed the records with technical consultant #1, who stated the humidity had not been maintained below 20% as indicated above. MICROBIOLOGY DEPARTMENT REFRIGERATOR (1) On the third day of the survey, surveyor #2 observed the following stored in the microbiology department refrigerator, with the manufacturer's storage requirements: (a) 2 boxes (20 bottles) of BD BBL Lim Broth (lot #7341570). The manufacturer required storage at 2-8 degrees C (Celsius) and used for the selective enrichment of group B streptococci (Streptococcus agalactiae); (b) 3 boxes (60 cards) of Vitek 2 AST-XN06 (lot#149580403). The manufacturer required storage at 2-8 degrees C and used for the identification and antibiotic susceptibility (gram negative organisms) of antimicrobials; (c) 3 boxes (60 cards) of Vitek 2 AST-GN69 (lot#2410427204). The manufacturer required storage at 2-8 degrees C and used for the susceptibility (gram negative organisms); (d) 3 boxes (60 cards) of Vitek 2 AST-GN69 (lot#5890618103). The manufacturer required storage at 2-8 degrees C and used for the susceptibility (gram negative organisms); (e) 3 boxes (60 cards) of Vitek GP (lot#2420574403). The manufacturer required storage at 2-8 degrees C used for the identification (gram positive bacteria); (f) 2 boxes (40 cards) of Vitek 2 AST-GP67 (lot#1320570103). The manufacturer required storage at 2-8 degrees C and used for susceptibility (gram negative organisms); (g) 162 plates BD (Becton Dickenson & Co.) BBL Prepared Plated Media: TSA II (Trypticase Soy Agar) with Sheep Blood (lot# 8025501). The manufacturer required storage at 2-8 degrees C and used for cultivating fastidious microorganisms; (h) 9 plates BD BBL Chocolate II agar (lot# 7341510). The manufacturer required storage at 2-8 degrees C and used to isolate and cultivation of Neisseria species; (i) 162 plates BD BBL Macconkey II agar

	(lot#8018709). The manufacturer required storage at 2-8 degrees C and used to differentiate medium for the detection of coliform organisms and enteric pathogens; (j) 6 kits Shiga Toxin Quik Chek (lot# 0617015). The manufacturer required storage at 2-8 degrees C and used to detect STEC (Shiga Toxin-producing Escherichia coli) toxins (Stx 1 and Stx 2) directly from fecal samples; (k) 5 kits C. Diff Quik Chek (lot#1017321) The manufacturer required storage at 2-8 degrees C and used for the rapid detection of Clostridium difficile; (l) 1 kit of Patho Dx Strep Grouping (lot#2129137). The manufacturer required storage at 2-8 degrees C and used for the identification of beta-hemolytic streptococci groups from a culture. (2) On the third day of the survey, surveyor #2 reviewed laboratory records from April 2016 through January 2018. The records identified temperatures below the manufacturer required storage temperatures during 5 of 22 months as follows; (a) April 2016 - The temperatures had been documented as 1 degree C for 7 of 30 days (days 1,4,5,15,20,22,25); (b) May 2016 - The temperatures had been documented as 1 degree C for 1 of 31 days (day 11); (c) June 2016 - The temperatures had been documented as 1 degree C for 2 of 30 days (days 9,26); (d) July 2016 - The temperatures had been documented as 1 degree C for 5 of 31 days (days 3,6,11,13,15); (e) January 2018 - The temperatures had been documented as 1 degree C for 3 of 31 days (days 22,25,29); (4) Surveyor #2 reviewed the records with the technical consultant, who stated testing materials had not been stored according to manufacturer's required temperatures as indicated above.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation and interview with technical consultant #1 and technical consultant #3, the laboratory failed to ensure an expired test cartridge was not available for use. Findings include: (1) On the first day of the survey, technical consultant #3 stated to the surveyors the CVICU (Cardiovascular Intensive Care Unit) department used the iSTAT 1 analyzer to perform pH, pCO2, pO2, Glucose, Sodium, Potassium, Ionized Calcium, Hemoglobin, and Hematocrit testing using the CG8+ cartridge and ACT (Activated Clotting Time) testing using the ACT cartridge; (2) Technical consultant #1 and technical consultant #3 escorted surveyor #1 to the CVICU department. One G3+ test cartridge (used to perform pH, pCO, and pO2 testing) was observed in the refrigerator (lot #D16145, expiration date of 01/14/17); (3) Surveyor #1 asked technical consultant #1 and technical consultant #3 if the department performed testing using the test cartridge. Both stated the laboratory discontinued using the G3+ cartridge in 04/2017 and did not know why it was in the department, available for use.
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 technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory failed to ensure the verified reportable ranges for a new coagulation analyzer were used by the laboratory. Findings include: (1) On the first day of the survey, technical consultant #3 stated to the surveyors the laboratory began using the ACL TOP 300 analyzer to perform PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing on 02/22/18; (2) On the third day of the survey, surveyor #1 reviewed validation records for the analyzer and identified the reportable ranges had been verified by the laboratory as follows: (a) PT - 10.2-116.6 (b) PTT - 25.7-171.8 (3) Surveyor #1 then requested a printout from the analyzer to verify the reportable ranges that had been programmed into the analyzer and were currently in use. The printout verified the laboratory was using reportable ranges that were wider than the verified ranges: (a) PT - 8.0-320.0 (v) PTT - 16.0-400.0 (4) Surveyor #1 reviewed the findings with technical consultant #1 and technical consultant #2. Both stated the laboratory was using the manufacturer's default reportable ranges for PT and PTT, instead of the reportable ranges that had been verified by the laboratory; (5) Refer to D5479 for examples of PT and PTT testing performed when the laboratory was not using the verified reportable ranges. NOTE: D5421 was cited on the previous recertification survey performed on 04/26-28 /16. 39088 Based on a review of records and interview with technical consultant #1, the laboratory failed to demonstrate performance specifications prior to patient testing. Findings include: (1) On the first day of the survey, technical consultant #1 stated to surveyors the laboratory performed the detection of Clostridium difficile glutamate dehydrogenase antigen and toxins A and B in a single reaction well using the C.Diff Quik Chek Complete test kit; (2) On the fourth day of the survey, technical consultant #1 stated the following to the surveyors: (a) The C.Diff Quik Chek Complete test kit was available for patient testing on 11/10/17. (3) The surveyors asked to review the performance specification records for the C. Diff Quik Chek Complete kit. Technical consultant #1 stated the laboratory performed positive and negative controls upon receipt but accuracy and precision had not been demonstrated.
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 technical consultant #3, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) On the first day of the survey, technical consultant #3 stated to the surveyors CBC (Complete Blood Count) testing was performed using the Sysmex XN 2000 analyzer; (2) On the fourth day of the survey, surveyor #1 reviewed the manufacturer's maintenance instructions. The manufacturer required a daily shut down procedure be performed; (3) Surveyor #1 then reviewed maintenance records for 9 months (September through December 2016;

	April through June 2017; January and February 2018). There was no evidence the daily maintenance had been performed during 3 of 9 months as follows: (a) October 2016 - Days 13,14 (b) November 2016 - Days 11,27,29 (c) January 2018 - Day 05 (4) Surveyor #1 reviewed the records with technical consultant #3, who stated the daily maintenance had not been performed as indicated above. NOTE: D5429 was cited on the previous recertification survey performed on 04/26-28/16. 39088 Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to ensure equipment maintenance was performed as required by the manufacturer. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors: (a) Albumin, Alkaline Phosphatase, ALT (Alanine Amino Transferase), AST (Aspartate Amino Transferase), BUN (Blood Urea Nitrogen), Calcium, Chloride, CK (Creatine Kinase), CO2, Cholesterol, Creatinine, Direct Bilirubin, Glucose, HDL (High Density Lipoprotein) Cholesterol, Potassium, Sodium, Total Bilirubin, Total Protein, Triglycerides, Amylase, Creatinine, GGT (Gamma-Glutamyl Transferase), Glucose, Iron, LDL (Low Density Lipoprotein), Lipase, Magnesium, Phosphorus, TIBC (Total Iron Binding Capacity), UIBC (Unbound Iron Binding Capacity), Uric Acid, HCG (human chorionic-gonadotropin) quantitative, Thyroxine, Triiodothyronine, Cortisol, TSH (Thyroid Stimulating Hormone), Free T3 (Free Triiodothyronine), Free T4 (Free Thyroxine), Procalcitonin, Acetaminophen, Carbamazepine, Phenobarbital, Phenytoin, Salicylate, Theophylline, Digoxin, Lithium, Gentamicin, Tobramycin, Valproic Acid, Vancomycin, Hemoglobin A1C (Glycated Hemoglobin) testing were performed on the Cobas c501 (CE 1) analyzer; (b) CEA (Carcinoembryonic Antigen), CA 175 (Cancer Antigen), Ferritin, Prealbumin, PSA (Prostate Specific Antigen), Testosterone, Folate, Vitamin B12, Vitamin D, C-Peptide, Parathyroid, Urine Calcium, Urine Creatinine, Urine Glucose, Urine Magnesium, Urine Phosphorus, Urine Total Protein, Urea, Urine Uric Acid, Urine Chloride, Urine Potassium, Urine Sodium, Urine Microalbumin, Urine Drug Screen were performed on the Cobas 601 (CE2) analyzer. (2) Surveyor #2 reviewed the manufacturer's maintenance logs from January 2017 through February 2018 (14 months) for the analyzers and identified the following: (a) Cobas c501 (CE1) Daily - Process Green Rack, Take Refrig/Freezer Temps, Disinfect Work Counters, Check Water Supply, Perform AM Pipe, Check Reagents Levles, Clean C501 Sample Probe and Shield (ALC), Clean ISE Siper Probe (ALC), Clean Reagent Probes (ALC), Clean Cell Rinse Nozzle (H20), Clean ISE Drain Port (D1), Clean E 601: Sample Probe (DI), Reagent Probe (ALC), Sipper Probe (ALC), Prewash Sipper Probes (ALC), Clean all Instrument Surfaces, Run Calibrations/QC: (i) Not documented as performed: (aa) March 2017 - Day 2 (bb) July 2017 - Day 22 (cc) August 2017 - Day 2 (b) Cobas c501 Weekly - Perform System Power Off/On, Clean 501 Cell Cover (ALC, Clean Rinse Station with HIT, Clean IS Bath (DI), PC/CC Reservoir Position (DI), Preclean Mixer (DI), Preclean Separation Station (DI), Assay Cup Vortex, Microbe and mixer, Rinse Station, Replace PC/CC Reservoirs: (i) Not documented as performed: (aa) Between 02/04/18 and 02/18/18 (3) The surveyors reviewed the records with technical consultant #1 who stated there was no evidence the above maintenance had been performed as required.
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 technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory failed to follow the manufacturer's specifications for establishing normal reference intervals for a new coagulation analyzer. Findings include: (1) On the first day of the survey, technical consultant #3 stated the following to the surveyors: (a) The ACL TOP 300 analyzer was put into use to perform PT/INR (Protime /International Normalized Ratio) and PTT (Partial Thromboplastin Time) testing on 02 /22/18; (b) Prior to that date, the Sysmex CA-1500 analyzer had been used to perform the testing; (2) On the third day of the survey, surveyor #1 reviewed the manufacturer's instructions for establishing a normal reference interval which stated: (a) "You must decide before starting which type of study to perform. Will you perform a full reference interval study or will you be verifying a previous reference interval? Either 120 or 20 normal donors following these screening guidelines": (i) "Donors should be healthy and have no known pathological conditions. Don't use samples from in-patients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high dose aspirin, etc. Donors should span the adult age range. Pediatric ranges should be established separately. Donors should be equally divided between male/female". (b) In addition, the instructions stated, "If you choose to do a full reference interval study, test 120 donors. Ideally specimens will be analyzed over a number of days, resulting in values that represent average run-to-run variation. If you choose to verify a range, you may use a 20-donor study under specific conditions. The main conditions are as follows: The original site must have done a full reference range study The original site must have used the identical type of analytical system (method, instrument and reagents)". (3) Based on the manufacturer's guidelines, surveyor #1 determined an initial 120 sample study was required, then subsequent studies may be performed using 20 samples due to the following: (a) The laboratory had previously used the Sysmex CA-1500 analyzer (which was a different analytic system). (4) Surveyor #1 reviewed the implementation records for the analyzer. The following was identified for PT and PTT: (a) The lot numbers that were in use when the analyzer was implemented (and currently in use) were: (i) PT Reagent - Hemosil Readiplastin lot #N0278177 (ii) PTT Reagent - Hemosil Synthasil Lot #N0871938 (b) The normal reference intervals had been established for PT and PTT as follows: (i) 27 donors had been utilized; (ii) 9 of the donors were male and 18 of the donors were female (not equally divided between male and female). (5) Surveyor #1 reviewed the records with technical consultant #1 and technical consultant #3. Both stated the following: (a) The laboratory did not perform the 120 sample study; (b) The laboratory had not ensured the 27 donors were equally divided between male and female. (6) The following were examples of patient testing performed when the normal reference intervals had not been established for the new analyzer as required: (a) Patient #20 - PT/INR and PTT testing performed on 02 /23/18 (b) Patient #21 - PT/INR and PTT testing performed on 02/26/18 (c) Patient #22 - PT/INR and PTT testing performed on 02/27/18 (d) Patient #23 - PT/INR and PTT testing performed on 02/28/18 (e) Patient #24 - PT/INR and PTT testing performed on 03/01/18 (f) Patient #25 - PT/INR and PTT testing performed on 03/04 /18 (g) Patient #26 - PTT testing performed on 03/06/18 (h) Patient #27 - PT/INR testing performed on 03/06/18 (i) Patient #28 - PT/INR and PTT testing performed on 03/09/18 (j) Patient #29 - PTT testing performed on 03/13/18 (k) Patient #30 - PT /INR testing performed on 03/13/18 (l) Patient #31 - PT/INR and PTT testing performed on 03/14/18 (m) Patient #32 - PTT testing performed on 03/15/18 (n) Patient #33 - PT/INR testing performed on 03/15/18 NOTE: D5479 was cited on the

	previous recertification survey performed on 04/26-28/16.
D5507	BACTERIOLOGY CFR(s): 493.1261(b)(c) (b) For antimicrobial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimicrobial agent(s) before, or concurrent with, initial use, using approved control organisms. (b)(1) Each day tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(2) The laboratory's zone sizes or minimum inhibitory concentration for control organisms must be within established limits before reporting patient results. (c) 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 technical consultant #1, the laboratory failed to perform quality control checks each day patient antimicrobial susceptibility testing was performed. Findings include: (1) On the first day of the survey, technical consultant #1 stated to the surveyors that antibiotic susceptibility testing, from culture isolates, was performed on the Vitek 2 using the AST-ST02 card for Gram positive Streptococcus species; (a) The AST-ST02 card was available for patient use on 10/18/16. (2) On the fourth day of the survey, surveyor #2 reviewed quality control (QC) and patient test records for testing performed from September 2017 through January 2018. The review indicated QC testing using the appropriate organisms had not been performed each day of patient susceptibility testing; (3) Technical consultant #1 stated that susceptibility QC testing was performed weekly, not each day of patient testing; (4) Surveyor #1 then asked technical consultant #1 if an IQCP (Individualized Quality Control Plan) had been developed for susceptibility testing. Technical consultant #1 stated an IQCP had not been developed. Therefore, surveyor #2 determined QC testing must be performed each day of patient testing, using the appropriate control organisms; (5) Surveyor #1 reviewed the test records again. For 4 of 5 days of patient susceptibility testing reviewed, QC testing had not been performed: (a) Patient #34 - Set-up on 11/19/17 (b) Patient #35 - Set-up on 11/26 /17 (c) Patient #36 - Set-up on 12/13/17 (d) Patient #37 - Set-up on 01/16/18
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 technical consultant #1 and technical consultant #3, the laboratory failed to test one control material each 8 hours of operation; and failed to test patient and control specimens in duplicate when performing manual counts using a hemacytometer. Findings include: (1) On the first day of the survey, technical consultant #3 stated to the surveyors manual spinal fluid cell counts for White Blood Cells (WBC) and Red Blood Cells (RBC) were performed using a hemacytometer; (2) On the fourth day of the survey, surveyor #1

	reviewed records for manual spinal fluid cell counts performed in April 2017, June 2017, December 2017, and January 2018. There was no evidence that either a control material had been performed or tested in duplicate when performed, or that patient specimens had been tested in duplicate for 15 of 15 days of testing as follows: (a) Patient #5 - Performed on 04/04/17. Patient and controls had not been tested in duplicate (b) Patient #6 - Performed on 04/08/17. Controls had not been tested in duplicate; (c) Patient #7 - Performed on 04/11/17. Controls had not been tested in duplicate; (d) Patient #8 - Performed on 04/23/17. Controls had not been tested in duplicate; (e) Patient #9 - Performed on 04/28/17. Controls had not been tested; (f) Patient #10 - Performed on 06/03/17. Controls had not been tested; (g) Patient #11 - Performed on 06/05/17. Controls had not been tested; (h) Patient #12 - Performed on 06/18/17. Patient and controls had not been tested in duplicate; (i) Patient #13 - Performed on 06/24/17. Controls had not been tested in duplicate; (j) Patient #14 - Performed on 12/01/17. Controls had not been tested in duplicate; (k) Patient #15 - Performed on 12/14/17. Controls had not been tested in duplicate; (l) Patient #16 - Performed on 12/22/17. Controls had not been tested in duplicate; (m) Patient #17 - Performed on 12/27/17. Controls had not been tested in duplicate; (n) Patient #18 - Performed on 01/13/18. Patient and controls had not been tested in duplicate; (o) Patient #19 - Performed on 01/19/18. Controls had not been tested in duplicate. (3) Surveyor #1 reviewed the records with technical consultant #1 and technical consultant #3. Both stated there was no evidence that a control had been tested or no evidence the specimens and controls had been tested in duplicate as indicated above.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (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 technical consultant #1 and technical consultant #3, the laboratory failed to perform two levels of control material each 8 hours of operation on the coagulation analyzer. Findings include: (1) On the first day of the survey, technical consultant #3 stated to the surveyors the laboratory began using the ACL TOP 300 analyzer to perform PT (Prothrombin Time) and PTT (Partial Thromboplastin Time) testing on 02/22/18. Prior to that time, the laboratory used the Sysmex CA 1500 analyzer to perform the testing; (2) On the third day of the survey, surveyor #1 reviewed patient and quality control (QC) coagulation records for three months (November 2017, December 2017, and January 2018). During 2 of 3 months, two levels of QC had not been performed each 8 hours of operation for 2 of 61 days of patient testing. The findings were: (a) November (i) 11/26/17 - PT and PTT QC had been performed at 07:19 am and 10:38 pm (due at 03:19 pm) (aa) Patient #2 - PTT testing performed at 03:30 pm and 09:31 pm (bb) Patient #3 - PT and PTT testing performed at 04:33 pm (b) December (i) 12/14/17 - PTT QC had been performed at 02:09 pm (due at 10:09 pm) (aa) Patient #4 - PTT testing performed at 10:32 pm (3) Surveyor #1 reviewed the records with technical consultant #1, who stated two levels of QC had not been performed each eight hours of patient testing.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #3, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers. Findings include: (1) On the first day of the survey, technical consultant #3 stated to surveyor #1, pH, pCO2, pO2, Carboxyhemoglobin, Methemoglobin, Oxyhemoglobin, Total Hemoglobin, Creatinine, Calcium, Chloride, Glucose, Sodium, Potassium, and Lactate testing were performed using three analyzers as follows: (a) The Radiometer ABL 837 Flex analyzer was used in the Cardiopulmonary department. The analyzer was put into use for patient testing on 06/26/16; (b) The Radiometer ABL 90 Flex analyzer was used at the point of care in the CVICU (cardiovascular intensive care unit) by the Cardiopulmonary staff. The analyzer was put into use for patient testing on 11/25/16; (c) The Radiometer ABL 90 Flex analyzer was used in the laboratory. The analyzer was put into use for patient testing on 06/27/16. (2) On the second day of the survey, surveyor #1 asked technical consultant #3 if the relationship between the test results using the three different analyzers had been evaluated at least twice annually during 2017 through the current date. Technical consultant #3 stated the relationship between the analyzers had not been evaluated.
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, policies and procedures, manufacturer's instructions, observation, and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP's; and failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: IQCP FOR ISTAT (1) On the first day of the survey, technical consultant #3 stated the following to surveyor #1: (a) Six iSTAT 1 analyzers were used to perform testing at the point of care as follows: (i) Surgery, Med ICU Intensive Care Unit), Cath Lab, and CVICU (Cardiovascular Intensive Care Unit) departments performed pH, pCO2, pO2, Glucose, Sodium, Potassium, Ionized Calcium, Hemoglobin, and Hematocrit testing using the CG8+ cartridge and ACT (Activated Clotting Time) testing using the ACT cartridge; (ii) The Cardiopulmonary department performed pH, pCO2, pO2, Glucose, Sodium, Potassium, Ionized Calcium, Hemoglobin, and Hematocrit testing using the CG8+ cartridge. (b) IQCP's (Individual Quality Control Plans) had been developed for the test systems. (2) Surveyor #1 reviewed the IQCP's (dated as approved on 12/16 /15). The QA (Quality Assessment) portions of the IQCP's 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 06/01/16; (3) Surveyor #1 reviewed the records with technical consultant #1 and technical consultant #3, and asked if there was a policy to address how the laboratory will monitor the IQCP's, including the frequency of the reviews and if QA reviews had been performed since 06/01/16. Technical consultant #1 and technical consultant #3 stated a policy had not been written and QA reviews had not been performed. IQCP FOR ROM PLUS (1) On the first day of the survey, technical consultant #3 stated the following to the surveyors: (a) The laboratory began using the ROM (Rupture of Membranes) Plus test kit on 09/08/16; (b) An IQCP had been developed for the test system. (2) On the fourth day of the survey, surveyor #1 reviewed the IQCP (dated as effective on 08/11/16). 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 of 08/11/16; (3) Surveyor #1 reviewed the records with technical consultant #1 and technical consultant #3, 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 effective date of 08/11/16. Technical consultant #1 and technical consultant #3 stated a policy had not been written and QA reviews had not been performed. IQCP FOR FETAL FIBRONECTIN (1) On the first day of the survey, technical consultant #3 stated the following to the surveyors: (a) The laboratory performed Fetal Fibronectin testing using the CytecTLiQ system; (b) An IQCP had been developed for the test system. (2) On the fourth day of the survey, surveyor #1 reviewed the IQCP (dated as effective on 12/16/15). 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 06/01/16; (3) Surveyor #1 reviewed the records with technical consultant #1 and technical consultant #3, 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 06/01/16. Technical consultant #1 and technical consultant #3 stated a policy had not been written and QA reviews had not been performed. IQCP FOR MED TOX (1) On the first day of the survey, technical consultant #3 stated the following to the surveyors: (a) The laboratory performed Urine Drug Screen testing using the Med Tox Scan Drugs of Abuse test system; (b) An IQCP had been developed for the test system. (2) On the fourth day of the survey, surveyor #1 reviewed the IQCP (dated as effective on 12/16/15). 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 06/01/16; (3) Surveyor #1 reviewed the records with technical consultant #1 and technical consultant #3, 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 06/01/16. Technical consultant #1 and technical consultant #3 stated a policy had not been written and QA reviews had not been performed. ANALYTIC QUALITY ASSESSMENT (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to ensure policies and procedures had been approved, signed, and dated by the laboratory director before use. Refer to D5407; (b) The laboratory failed to ensure that written procedures no longer in use had been discontinued. Refer to D5409; (c) The laboratory failed to ensure materials had been stored as required. Refer to D5413; (d) The laboratory failed to ensure an expired test cartridge was not available for use. Refer to D5417; (e) The laboratory failed to ensure the verified reportable ranges for a new coagulation analyzer were used by the laboratory; and failed todemonstrate

	performance specifications for a new test kit. Refer to D5421; (f) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (g) The laboratory failed to follow the manufacturer's specifications for establishing normal reference intervals for a new coagulation analyzer. Refer to D5479; (h) The laboratory failed to perform quality control checks each day patient antimicrobial susceptibility testing was performed. Refer to D5507; (i) The laboratory failed to test one control material each 8 hours of operation; and failed to test patient and control specimens in duplicate when performing manual counts using a hemacytometer. Refer to D5543; (j) The laboratory failed to perform two levels of control material each 8 hours of operation on the coagulation analyzer. Refer to D5545; (k) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers. Refer to D5775. NOTE: D5791 was cited on the previous recertification survey performed on 04/26-28/16. 39088 Based on a review of records, manufacturer's instructions and interview with technical consultant #1, the laboratory failed to have a policy for monitoring the effectiveness of their IQCP's. Findings include: IQCP MEDIA (1) On the first day of the survey, technical consultant #1 stated the following to surveyors: (a) Chocolate II media was used for the isolation and cultivation of Neisseria species; (b) Macconkey II media was used for the isolation and differentiation of coliform organisms and enteric pathogens; (c) HardyCHROM MRSA media was used for the isolation and identification of Staphylococcus aureus and the qualitative direct detection of methicillin-resistant Staphylococcus aureus (MRSA); (d) HardyCHROM Candida media was used for the isolation and identification of Candida albicans; (b) IQCP's (Individual Quality Control Plans) had been developed for the media. (2) Surveyor #2 reviewed the IQCP's (dated as approved on 12/16/15). The QA (Quality Assessment) portions of the IQCP's 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 08/16/16; (3) The surveyors reviewed the records with technical consultant #1, and asked if there was a policy to address how the laboratory will monitor the IQCP's, including the frequency of the reviews and if QA reviews had been performed since 08/16/16. Technical consultant #1 stated a policy had not been written and QA reviews had not been performed. IQCP VITEK 2 (1) On the first day of the survey, technical consultant #1 stated the following to surveyors: (a) Microbial antibiotic susceptibility was performed on the Vitek 2 analyzer; (b) An IQCP (Individual Quality Control Plans) had been developed for the test system. (2) Surveyor #2 reviewed the IQCP (dated as approved on 12/16/15). The QA (Quality Assessment) portions 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 08/16/16; (3) The surveyors reviewed the records with technical consultant #1, 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 08/16/16. Technical consultant #1 stated a policy had not been written and QA reviews had not been performed.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on a review of records, test reports, and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory failed to make appropriate reference ranges available. Findings include: (1) On the first day of the survey, technical consultant #3 stated to the surveyors the laboratory began using the ACL TOP 300 analyzer to perform PT (Prothrombin Time), PTT (Partial Thromboplastin Time) and Fibrinogen testing on 02/22/18; (2) On the third day of the survey, technical consultant #3 verified to surveyor #1 the current reagent lot numbers were put into use during the implementation of the analyzer: (a) PT Reagent - Hemosil Readiplastin lot #N0278177 (b) PTT Reagent - Hemosil Synthasil lot #N0871938 (c) Fibrinogen Reagent - O.F.A. Thrombin lot #N1072756 (3) Surveyor #1 reviewed the implementation records and identified the following normal reference ranges had been established: (a) PT - 10.2-12.4 seconds (b) PTT - 25.7-36.2 seconds (c) Fibrinogen - 220.8-418.5 mg/dl (4) Surveyor #1 then reviewed a patient PT, PTT, and Fibrinogen report from testing performed on 03/13/18 (Patient #1). The PT reference range on the report was 10.2-12.9 seconds, the PTT reference range on the report was 25.1-36.5 seconds, and the Fibrinogen reference range on the report was 200-393 mg/dl; (5) Surveyor #1 reviewed the findings with technical consultant #1 and technical consultant #3. Both stated the established normal reference ranges for PT, PTT, and Fibrinogen were not included on the patient report.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory director failed to provide overall management and direction for moderate complexity testing. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure test methods were performed as required to ensure accurate and reliable results were reported. Refer to D6014; (3) 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. Refer to D6016; (4) The laboratory director failed to ensure proficiency testing reports were reviewed. Refer to D6018; (5) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (6) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021. (7) The laboratory director failed to ensure test reports included pertinent information required for interpretation. Refer to D6026; (8) The laboratory director failed to ensure policies and procedures had been approved and were current. Refer to D6031. NOTE: D6000 was cited on the previous recertification survey performed on 04/26-28/16.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)

	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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the verified reportable ranges for a new coagulation analyzer were used by the laboratory; and failed to ensure tthe performance specifications were demonstrated for a new test kit. Refer to D5421. NOTE: D6013 was cited on the previous recertification survey performed on 04/26-28/16.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure an expired test cartridge was not available for use. Refer to D5417; (2) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429; (3) The laboratory director failed to ensure the manufacturer's specifications were followed for establishing normal reference intervals for a new coagulation analyzer. Refer to D5479. NOTE: D6014 was cited on the previous recertification survey performed on 04/26-28/16.
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 technical consultant #1, 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. Findings include: (1) On the second day of the survey, surveyor #2 reviewed 2016, 2017 and 2018 proficiency testing records. It was identified for 4 of 30 events, the attestation statements had been signed approximately 2-8 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) First 2016 Blood Oximetry Event - The samples had been tested on 02/04/16 and the attestation statement had not been signed by the laboratory director until 04/22/16; (b) Third 2016 Chemistry Group 1 Event - The samples had been tested on 09/23/16 and the attestation statement had not been signed by the laboratory director until 01/13/17; (c) Second 2017 Chemistry Core Event -The samples had been tested on 06/02/17 and the attestation statement had not been signed by the laboratory director until 10/19/17; (d) Second 2017 Microbiology Event - The samples had been tested on 07/05/17 and the attestation statement had not been signed by the laboratory director until 03/05/18. (2) The surveyors reviewed the findings with technical consultant #1 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; (3) In addition to the above, the laboratory director failed to ensure proficiency testing attestation statements had been signed and dated by the laboratory director. Refer to D2015.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory director failed to ensure proficiency testing reports were reviewed. Findings include: (1) On the second day of the survey, surveyor #2 reviewed 2016, 2017 and 2018 proficiency testing records. The Performance Evaluations for 21 of 30 events not been signed and dated as reviewed by the laboratory director: (a) First 2016 Chemistry Group 1 Event (b) Second 2016 Chemistry Group 1 Event (c) Third 2016 Chemistry Group 1 Event (d) First 2016 Chemistry Group 2 Event (e) Second 2016 Chemistry Group 2 Event (f) Third 2016 Chemistry Group 2 Event (g) First 2016 Hematology/Coagulation Event (h) Second 2016 Hematology/Coagulation Event (i) Third 2016 Hematology/Coagulation Event (j) First 2016 Microbiology Event (k) Second 2016 Microbiology Event (l) Third 2016 Microbiology Event (m) First 2016 Immunology/Immunohematology Event (n) Second 2016 Immunology /Immunohematology Event (o) First 2017 Hematology/Coagulation Event (p) Second 2017 Hematology/Coagulation Event (q) First 2017 Microbiology Event (r) First 2017 Immunology/Immunohematology Event (s) First 2017 Chemistry Core Event (t) Third

	2017 Chemistry Core Event (u) First 2017 Chemistry Miscellaneous Event (2) The surveyors reviewed the records with technical consultant #1, who stated the Performance Evaluations, as indicated above had not been signed and dated as reviewed by the laboratory director; (3) In addition to the above, the laboratory director failed to ensure proficiency testing results were thoroughly reviewed and evaluated. Refer to D5211.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #3, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure materials had been stored as required. Refer to D5413; (2) The laboratory director failed to ensure two levels of control material were performed each 8 hours of operation on the coagulation analyzer. Refer to D5545; (3) The laboratory director failed to ensure a system was in place that twice a year evaluated and defined the relationship between test results using different analyzers. Refer to D5775. NOTE: D6020 was cited on the previous recertification survey performed on 04/26-28/16.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was a policy for monitoring the effectiveness of their IQCP's; and failed ensure there was an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791. NOTE: D6021 was cited on the previous recertification survey performed on 04/26-28/16.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)

	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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on a review of records, test reports, and interview with technical consultant #1, technical consultant #2, and technical consultant #3, the laboratory director failed to ensure test reports included pertinent information required for interpretation. Findings include: (1) The laboratory director failed to ensure appropriate reference ranges were available. Refer to D5805.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of written policies and interview with technical consultant #1 and technical consultant #3, the laboratory director failed to ensure policies and procedures had been approved and were current. Findings include: (1) The laboratory director failed to ensure there were written policies and procedures for assessing employee competency. Refer to D5209; (2) The laboratory director failed to ensure policies and procedures had been approved, signed, and dated by the laboratory director before use. Refer to D5407; (3) The laboratory director failed to ensure written procedures no longer in use had been discontinued. Refer to D5409. NOTE: D6031 was cited on the previous recertification survey performed on 04/26-28/16.
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 technical consultant #1, 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 individuals who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure that persons performing moderate complexity testing had been evaluated semiannually

	during the first year of testing. Refer to D6053; (3) The technical consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Refer to D6054.
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 technical consultant #1, the technical consultant failed to ensure the individuals who performed the duties and responsibilities of the technical consultant, met the qualifications. Findings include: (1) On the second day of the survey, surveyor #2 reviewed records for 95 persons performing moderate complexity testing in 2016 and 2017. The records verified the evaluations for 14 of 95 persons had been performed by individuals who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #1 (i) The 10/06/17 evaluation had been performed by testing person #3 (this person had earned an associate degree); (b) Testing Person #2 (i) The 01/17/17 evaluation had been performed by testing person #3; (c) Testing Person #4 (i) The 09 /27/17 evaluation had been performed by testing person #3; (d) Testing Person #5 (i) The 10/10/17 evaluation had been performed by testing person #3; (e) Testing Person

	#6 (i) The 10/05/17 evaluation had been performed by testing person #3; (f) Testing Person #7 (i) The 10/06/17 evaluation had been performed by testing person #3; (g) Testing Person #8 (i) The 10/12/17 evaluation had been performed by testing person #3; (h) Testing Person #9 (i) The 10/12/17 evaluation had been performed by testing person #3; (i) Testing Person #11 (i) The 10/20/17 evaluation had been performed by testing person #3; (j) Testing Person #14 (i) The 01/02/17 evaluation had been performed by testing person #19 (this person had earned an associate degree); (k) Testing Person #16 (i) The 01/20/17 evaluation had been performed by testing person #19; (l) Testing Person #19 (i) The 01/20/17 evaluation had been performed by testing person #19; (m) Testing Person #23 (i) The 01/02/17 evaluation had been performed by testing person #19; (n) Testing Person #28 (i) The 10/17/17 evaluation had been performed by testing person #19. (2) The surveyors explained to technical consultant #1 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 technical consultant #1, 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 #2 - The initial training for this person was completed on 07/11/16. There was no evidence that a semiannual evaluation had been performed (due 01/2017); (b) Testing Person #8 - The initial training for this person was completed on 09/01/16. There was no evidence that a semiannual evaluation had been performed (due 03/2017); (c) Testing Person #25 - The initial training for this person was completed on 10/17/16. There was no evidence that a semiannual evaluation had been performed (due 04/2017); (d) Testing Person #35 - The initial training for this person was completed on 03/29/17. There was no evidence that a semiannual evaluation had been performed (due 09/2017). (2) Surveyor #2 reviewed the records with technical consultant #1, who stated there were no records to prove the above person 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 technical consultant #1, the technical

	consultant failed to evaluate testing persons performing moderate complexity testing at least annually. Findings include: HEMATOLOGY (1) On the first day of the survey, technical consultant #1 stated to the surveyors: (a) CBC (Complete Blood Count), Reticulocyte Count, and Body Fluid Cell Count testing were performed on the Sysmex XN 2000i analyzer; (b) Manual WBC differentials were performed. (2) Surveyor #2 reviewed personnel records for 13 persons who performed testing in 2016 and 2017 and identified the following: (a) Testing Person #3 - There was no evidence of an annual evaluation in 2017; (b) Testing Person #10 - There was no evidence of an annual evaluation in 2017. (3) The records were reviewed with technical consultant #1 who stated there was no evidence annual evaluations had not been performed as indicated above. ALL TESTING NOT INCLUDED IN EVALUATIONS (1) On the first day of the survey, techical consultant #3 stated to surveyor #2 the laboratory test menu included: Cold Agglutin, Bleeding Time, Mononucleosis, Nasal Smear, Pin Worm Prep testing; (2) Surveyor #2 reviewed personnel records for 13 persons who performed the above testing in 2016 and 2017. For 13 of the 13 persons, there was no evidence the annual evaluations performed in 2017, included an assessment of Cold Agglutin, Bleeding Time, Mononucleosis, Nasal Smear, and Pin Worm Prep testing; (2) The surveyors reviewed the findings with technical consultant #3 who stated the annual evaluations performed in 2017 did not include the testing as stated above.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the laboratory failed to ensure individuals who performed moderate complexity testing met the educational qualifications. Findings include: (1) The laboratory failed to ensure testing persons met the educational qualifications. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1, the

	laboratory failed to ensure a testing person met the required educational qualifications to perform moderate complexity testing. Findings include: (1) On the first day of the survey, technical consultant #1 stated to surveyor #2 that 82 persons performed moderate complexity point of care testing in the hospital; (2) Surveyor #2 reviewed personnel records for 82 testing persons. Education documents (a minimum of a high school diploma/transcript or equivalent (GED)) could not be located in the records for 24 of 82 testing persons; (3) Surveyor #2 reviewed the findings with technical consultant #1. Technical consultant #1 stated educational documents were not available for the above testing person.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #3, the laboratory director failed to provide overall management and direction for high complexity testing. Findings include: (1) The laboratory director failed to ensure that quality control programs were established and maintained. Refer to D6093; (2) The laboratory director failed to ensure a quality assessment program was established and maintained. Refer to D6094. NOTE: D6076 was cited on the previous recertification survey performed on 04/26-28/16.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #3, the laboratory director failed to ensure that quality control programs were established and maintained. Findings include: (1) The laboratory failed to perform quality control checks each day patient antimicrobial susceptibility testing was performed. Refer to D5507; (2) The laboratory director failed to ensure one control material each 8 hours of operation; and failed to test patient and control specimens in duplicate when performing manual counts using a hemacytometer. Refer to D5543. NOTE: D6093 was cited on the previous recertification survey performed on 04/26-28/16.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #3, the laboratory director failed to ensure that a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure there was an effective mechanism for performing quality assessment due to the issues identified during the survey. Refer to D5791. NOTE: D6094 was cited on the previous recertification survey performed on 04/26-28/16.
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 technical consultant #3, the technical supervisor failed to ensure testing persons performing high complexity testing had been evaluated at least annually during 2017. Findings include: (1) Technical consultant #3 stated to surveyor #2 the laboratory test menu included the following high complexity testing: (a) Bacterial identification and antibiotic susceptibility testing using the Vitek 2 analyzer; (b) Automated microbial detection from blood cultures using eh BacTAlert 3D system; (c) India Ink to detect the presence of Cryptococcus neoformans; (d) Gram Stain to detect the presence of bacteria in samples and to characterize bacteria from isolates as gram positive or gram negative. (2) Surveyor #2 reviewed personnel records for 13 persons who performed testing in 2016 and 2017 and identified the following for 2 of 13 persons: (a) Testing Person #7 - There was no evidence of an annual evaluation in 2017; (b) Testing Person #10 - There was no evidence of an annual evaluation in 2017. (3) The surveyors reviewed the findings with technical consultant #3 who stated there was no evidence annual evaluations had not been performed as indicated above.