Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2139728	12/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Christus Bossier Emergency Hospital	2531 Viking Drive, Bossier City, LA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A VALIDATION SURVEY was performed at Christus Bossier Emergency Hospital - CLIA # 19D2139728 on December 17, 2018 through December 18, 2018. Christus Bossier Emergency Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic Systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing, Technical Consultant.
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: I. Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to assess competency for the Technical Consultant were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed Personnel 2 serves as Technical Consultant. 2. Review of the laboratory's policies and procedures revealed the laboratory did not have a policy for competency assessment of Technical Consultant. 3. Review of personnel records revealed competency assessments for the duties of Technical Consultant on Personnel 2 were not documented. 4. In interview on December 17, 2018 at 1:10 pm, Personnel 2 stated that competency assessments were not performed for the Technical Consultant. II. Based on record review and interview with personnel, the laboratory failed to establish and follow written policies and procedures to assess competency for testing personnel. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not include the following six (6) procedures as a minimal requirement for assessing the competency of all personnel

	performing laboratory testing: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. In interview on December 17, 2018 at 1:54 pm, Personnel 2 stated the laboratory has established a new policy for competency assessments. Personnel 2 confirmed the competency assessments performed did not include the required information.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty nine (29) of four hundred seventy seven (477) patients reviewed. Findings: 1. Observation by the surveyor on December 17, 2018 revealed the laboratory was performing Lactic Acid testing on the Siemens Dimension EXL 200 Chemistry Analyzer. 2. Review of the Siemens Dimension Lactic Acid package insert revealed "Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes. Keep sample on ice and analyze promptly." 3. Review of patient records for Lactic Acid from March 1, 2018 through December 17, 2018 revealed the laboratory did not receive the following patients within 15 minutes in order to separate as required by the manufacturer: On November 20, 2018 Patient 101 was collected at 20:05 pm and received at 20:34 pm - exceeding the fifteen (15) minutes required by the manufacturer by fourteen (14) minutes. On November 21, 2018 Patient 102 was collected at 12:20 pm and received at 12:43 pm - exceeding the fifteen (15) minutes required by the manufacturer by eighteen (18) minutes. On November 23, 2018 Patient 103 was collected at 02:25 am and received at 03:08 am - exceeding the fifteen (15) minutes required by the manufacturer by twenty eight (28) minutes. On November 17, 2018 Patient 104 was collected at 14:45 pm and received at 16:50 pm - exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour fifty (50) minutes. On November 17, 2018 Patient 105 was collected at 18:40 pm and received at 19:03 pm - exceeding the fifteen (15) minutes required by the manufacturer by eight (8) minutes. On November 17, 2018 Patient 106 was collected at 21:39 pm and received at 22:01 pm - exceeding the fifteen (15) minutes required by the manufacturer by seven (7) minutes. On November 18, 2018 Patient 107 was collected at 10:20 am and received at 10:40 am - exceeding the fifteen (15) minutes required by the manufacturer by five (5) minutes. On November 8, 2018 Patient 108 was collected at 04:45 am and received at 05:22 am

	- exceeding the fifteen (15) minutes required by the manufacturer by twenty two (22) minutes. On September 22, 2018 Patient 109 was collected at 16:15 pm and received at 18:27 pm - exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour fifty seven (57) minutes. On September 23, 2018 Patient 110 was collected at 23:50 pm and received September 24, 2018 at 00:24 am - exceeding the fifteen (15) minutes required by the manufacturer by nineteen (19) minutes. On September 18, 2018 Patient 111 was collected at 22:58 pm and received at 23:18 pm - exceeding the fifteen (15) minutes required by the manufacturer by five (5) minutes. On September 18, 2018 Patient 112 was collected at 23:32 pm and received September 19, 2018 at 00:03 am - exceeding the fifteen (15) minutes required by the manufacturer by twenty (20) minutes. On September 7, 2018 Patient 114 was collected at 09:58 am and received at 11:35 am - exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour twenty two (22) minutes. On September 7, 2018 Patient 115 was collected at 10:30 am and received at 12:04 pm - exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour nineteen (19) minutes. On September 7, 2018 Patient 116 was collected at 12:30 pm and received at 13:14 pm - exceeding the fifteen (15) minutes required by the manufacturer by twenty nine (29) minutes. On September 5, 2018 Patient 117 was collected at 02:17 am and received at 04:13 am - exceeding the fifteen (15) minutes required by the manufacturer by one (1) hour forty one (41) minutes. On September 5, 2018 Patient 118 was collected at 19:33 pm and received at 20:38 pm - exceeding the fifteen (15) minutes required by the manufacturer by fifty (50) minutes. On September 3, 2018 Patient 119 was collected at 03:10 am and received at 03:48 am - exceeding the fifteen (15) minutes required by the manufacturer by twenty three (23) minutes. On September 4, 2018 Patient 120 was collected at 15:40 pm and received at 16:25 pm - exceeding the fifteen (15) minutes required by the manufacturer by thirty (30) minutes. On July 26, 2018 Patient 121 was collected at 16:12 pm and received at 16:40 pm - exceeding the fifteen (15) minutes required by the manufacturer by thirteen (13) minutes. On July 27, 2018 Patient 122 was collected at 16:45 pm and received at 17:03 pm - exceeding the fifteen (15) minutes required by the manufacturer by three (3) minutes. On July 18, 2018 Patient 124 was collected at 22:15 pm and received at 22:41 pm - exceeding the fifteen (15) minutes required by the manufacturer by eleven (11) minutes. On July 20, 2018 Patient 125 was collected at 09:25 am and received at 10:21 am - exceeding the fifteen (15) minutes required by the manufacturer by forty one (41) minutes. On June 1, 2018 Patient 126 was collected at 18:14 pm and received at 18:48 pm - exceeding the fifteen (15) minutes required by the manufacturer by nineteen (19) minutes. On May 23, 2018 Patient 127 was collected at 16:38 pm and received at 17:16 pm - exceeding the fifteen (15) minutes required by the manufacturer by twenty three (23) minutes. On April 20, 2018 Patient 128 was collected at 18:40 pm and received at 19: 21 pm - exceeding the fifteen (15) minutes required by the manufacturer by twenty six (26) minutes. On April 16, 2018 Patient 129 was collected at 22:00 pm and received at 22:27 pm - exceeding the fifteen (15) minutes required by the manufacturer by twelve (12) minutes. On March 22, 2018 Patient 130 was collected at 20:42 pm and received at 21:06 pm - exceeding the fifteen (15) minutes required by the manufacturer by nine (9) minutes. 4. In interview on December 18, 2018 at 1:41 pm, Personnel 2 confirmed the above patient samples were not received for Lactic Acid testing within the fifteen (15) minutes required by the manufacturer.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a

	procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to perform a one hundred twenty (120) donor study for Prothrombin Time (PT) normal mean and failed to utilize acceptable donors with complete documentation per manufacturer requirements. Refer to D5411 I. 2. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for three (3) of sixty three (63) patients reviewed. Refer to D5411 II. 3. The laboratory failed to perform complete reference range studies for the Stago Compact Max Coagulation analyzer. Refer to D5421. 4. The laboratory failed to document instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL 200. Refer to D5429. 5. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555. 6. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Chemistry testing. Refer to D5783. 7. The laboratory's Quality Assurance monitors failed to identify and correct quality issues. Refer to D5793.
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: I. Based on observation, record review, and interview with personnel, the laboratory failed to perform a one hundred twenty (120) donor study for Prothrombin Time (PT) normal mean and failed to utilize acceptable donors with complete documentation per manufacturer requirements. Findings: 1. Observation by surveyor during laboratory tour on December 17, 2018 revealed the laboratory utilized the Stago Compact Max analyzer for PT and International Normalized Ratio (INR) testing. 2. In interview on December 18, 2018 at 8:30 am, Personnel 2 stated the Stago Compact Max analyzer was installed by the field service representative for testing in January 2018. 3. Review of installation document revealed a "Stago Method Validation Protocol" policy which referenced the following CLSI 28-A3 recommendations for donor requirements as well as the following requirements: a) Minimum of 120 donors b) Use well screened samples c) No medications (CLSI states "including oral contraceptives and estrogen") d) Healthy (CLSI states "Donors should have no pathological conditions or include inpatient or pre surgery patients") e) Should include samples that are representative of your patient population. (CLSI states "The donor used should span the adult age range within a fairly even distribution of males and females") f) CLSI also includes that samples should be collected over a period of time and include variability of age of reagents. 4. Review of the laboratory's policy for normal mean PT study (NMPT) revealed the laboratory must "test an appropriate number of "normal" donor

	specimens to verify the manufacturer's claims for normal values; however, a minimum of 20 donors is required. The "Reference Study Questionnaire" must be completed and signed prior to collecting donor specimens. Certain conditions and/or medications will disqualify donors from participation in the study." 5. Review of the current STA-Neoplastine lot 252228 records revealed the following: a) twenty three (23) donors included b) only nine (9) of twenty three (23) donors had a donor questionnaire form completed c) two (2) of the nine (9) donors, donors #4 and #5 did not meet the "normal" donor criteria based on the accompanied questionnaire 6. In interview on December 18, 2018 at 9:00 am, Personnel 2 stated it was difficult to get normal donors for the study so the Laboratory Director stated that if all levels are within normal range then use them in the study. Personnel 2 confirmed the laboratory did not perform the 120 study required for new analyzer or utilize acceptable donors with all documentation to support the study. 7. Review of the Task 1 & 3 form provided to sureyor revealed the laboratory performs 795 PT/INR tests annually. II. Based on observation, record review and interview with personnel, the laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for three (3) of sixty three (63) patients reviewed. Findings: 1. Observation by the surveyor on December 17, 2018 revealed the laboratory was performing Ammonia testing on the Siemens Dimension EXL 200 Chemistry Analyzer. 2. Review of the Siemens Dimension Ammonia package insert revealed that samples are to be analyzed within 30 minutes of centrifugation. 3. Review of patient records for Ammonia testing from March 1, 2018 through December 17, 2018 revealed the laboratory did not analyze Ammonia samples within 30 minutes for the following three (3) patients: On June 4, 2018 Patient 98 was collected at 14:30 PM, and analyzed at 15:58 PM - exceeding the thirty (30) minutes by fifty eight (58) minutes. On March 25, 2018 Patient 99 was collected at 07:18 AM, and analyzed at 08:23 AM - exceeding the thirty (30) minutes by thirty five (35) minutes. On October 12, 2018 Patient 100 was collected at 19:00 PM, and analyzed at 20:03 PM - exceeding the thirty (30) minutes by thirty three (33) minutes. 4. In interview on December 18, 2018 at 1:41 pm, Personnel 2 confirmed the above patients exceeded the time requirements stated by the manufacturer for Ammonia testing.
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 observation, record review and interview with personnel, the laboratory failed to perform a complete reference range study for the Stago Compact Max Coagulation analyzer. Findings: 1. Observation by surveyor on December 17, 2018 revealed the laboratory utilizes the Stago Compact Max analyzer for coagulation testing to include Prothrombin Time (PT). 2. Review of the laboratory's policy for Method Performance Specifications revealed under "Reference Range (Normal Values)" that the laboratory must verify that the manufacturer's reference intervals are

	appropriate for the laboratory's patient population. This may be accomplished by testing an appropriate number of "normal" donor specimens to verify the manufacturer's claims for normal values; however, a minimum of 20 donors is required. The "Reference Study Questionnaire" must be completed and signed prior to collecting donor specimens. Reference intervals should be validated over several days, at different times of the day. Sex-dependent reference ranges should be established by testing a minimum of 20 healthy male donors and 20 healthy female donors." 3. Review of the Stago Compact Max performance studies revealed the laboratory had documentation to support the following studies: a) accuracy b) complete precision c) reportable range 4. Further review of the Stago Compact Max studies revealed the laboratory performed a reference range study utilizing twenty three (23) normal donors; however, the laboratory had only nine (9) of twenty three (23) donor questionnaire forms completed. 5. In interview on December 18, 2018 at 9:00 am, Personnel 2 stated that it was difficult to obtain donors for the study so the laboratory utilized patient results that were within the normal range for PT testing. Personnel 2 confirmed the studies were not performed as required.
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 observation, record review and interview with personnel, the laboratory failed to perform and document instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL 200. Findings: 1. Observation by surveyor during the laboratory tour on December 17, 2018 revealed the laboratory utilized the Siemens Dimension EXL 200 analyzer for Electrolye (IMT) testing. 2. Review of insturment manual for the Dimension EXL 200 revealed under "Replacing the Quiklyte Integrated Multisensor: The maximum number of samples for a new Quiklyte sensor is 1,000. The maximum time on an instrument is 5 days". 3. Review of the maintenance logs for September 2018 through November 2018 revealed the laboratory put the Quicklyte sensor in use on September 3, 2018 and replacedagain on September 13, 2018 which exceeded the manufacturer's requirement by five (5) days. 4. Review of patient records from September 8, 2018 through September 13, 2018 revealed the following ninety two (92) patients resulted without the required maintenance performed: a) Patients 1 - 92 5. In interview on December 18, 2018 at 2: 15 pm, Personnel 2 stated she was unable to find documentation of maintenance being performed. Personnel 2 confirmed the above patients were resulted without required insturment maintenance.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Findings: 1. Review of the Blood Bank's Policy and Procedure Manual revealed quarterly alarm checks were to be performed on blood bank refrigerator. 2. Review of the Blood Bank's Circular Temperature Charts for 2018 revealed the Blood Bank Refrigerator did not have documentation of quarterly alarm checks as follows: a) July 23, 2018 alarm check: circular chart showed a fluctuation of temperature but no documentation to indicate alarm check being performed. b) September 11, 2018 alarm check: circular chart does not show an indication of an alarm check being performed. c) November 20, 2018 alarm check: circular chart does not show an indication of an alarm check being performed. 3. In interview on December 18, 2018 at 4:45 pm, Personnel 2 stated the quarterly alarm checks are performed by the hospital BioMed team. Personnel 2 further stated the laboratory staff does not review the circular charts after the alarm checks are performed to ensure temperature fluctuations are documented. 4. In further interview, Personnel 2 confirmed the circular charts do not reflect the temperatures documented for alarm checks.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to take corrective action when quality control (QC) values were unacceptable for Chemistry testing. Findings: 1. Observation by surveyor during the laboratory tour on December 17, 2018 revealed the laboratory utilizes the Siemens Dimension EXL 200 instrument for Chemistry testing. 2. Review of quality control records for September 2018 for the Dimension EXL 200 insturment revealed the laboratory did not take corrective action when QC was not within acceptable range for the following one (1) of thirty (30) days reveiwed: a) September 16, 2018 at 01:16 am: - MMB Cardiac Control L reported as 2.3 abnl reaction b) September 16, 2018 at 02:40 am: - Repeated MMB Cardiac Control L reported as 2.2 abnl reaction 3. Review of the laboratory's "EXL Daily QC Documentation" revealed the testing personnel documented that both QC levels for MMB were resulted with an abnormal reaction and after repeating, QC Level 1 was resulted again with abnormal reaction. Testing personnel was unable to repeat Level 1 QC due to empty test count on MMB flex. 4. Review of patient records from September 15, 2018 through September 16, 2018 revealed the following five (5) of five (5) patients resulted prior to QC failure with no documentation of patient assessment performed: a) Patients 93 - 97 4. In interview on December 18, 2018 at 2:15 pm, Personnel 2 stated she could not find documentation

	that patient assessments were performed for the identified day of testing. Personnel 2 confirmed MMB QC was resulted with an abnormal reaction with no corrective action taken to assess patient impact.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues. Findings: 1. The laboratory failed to perform a one hundred twenty (120) donor study for Prothrombin Time (PT) normal mean and failed to utilize acceptable donors with complete documentation per manufacturer requirements. Refer to D5411 I. 2. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for three (3) of sixty three (63) patients reviewed. Refer to D5411 II. 3. The laboratory failed to perform complete reference range studies for the Stago Compact Max Coagulation analyzer. Refer to D5421. 4. The laboratory failed to document instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL 200. Refer to D5429. 5. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555. 6. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Chemistry testing. Refer to D5783.
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 observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 5. The Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D6030.

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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty nine (29) of four hundred seventy seven (477) patients reviewed. Refer to D5311. 2. The laboratory failed to perform a one hundred twenty (120) donor study for Prothrombin Time (PT) normal mean and failed to utilize acceptable donors with complete documentation per manufacturer requirements. Refer to D5411 I. 3. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for three (3) of sixty three (63) patients reviewed. Refer to D5411 II. 4. The laboratory failed to document instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL 200. Refer to D5429. 5. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555.
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 observation, record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established and maintained to assure the quality of laboratory services provided. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5783.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency, and whenever necessary, identify needs for remedial training or continuing education to improve skills. Refer to D5209 I and D5209 II.
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 observation, record review, and interview with personnel, the Technical Consultants failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultants failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6044. 4. The Technical Consultant failed to ensure performance of competency assessments for personnel performing moderate complexity testing. Refer to D6046.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to perform a one hundred twenty (120) donor study for Prothrombin Time (PT) normal mean and failed to utilize acceptable donors with complete documentation per manufacturer requirements. Refer to D5411 I. 2. The laboratory failed to ensure that patient samples for Ammonia testing are analyzed within thirty (30) minutes according to the manufacturer for three (3) of sixty three (63) patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure patient samples for Lactic Acid testing are received and separated within 15 minutes according to the manufacturer for twenty nine (29) of four hundred seventy seven (477) patients reviewed. Refer to D5411 III. 4. The laboratory failed to document instrument maintenance as defined by the manufacturer for the Siemens Dimension EXL 200. Refer to D5429.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D5421.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure performance of competency assessments for personnel performing moderate complexity testing. Refer to D5209 II.