Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0465060	03/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sabine Medical Center	240 Highland Drive, Many, 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 complaint survey was performed at Sabine Medical Center - CLIA # 19D0465060 on March 12, 2018 through March 15, 2018. Sabine Medical Center 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 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director
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 record review and interview with personnel, the laboratory failed to document each step in testing and reporting of proficiency testing (PT). Findings: 1. Review of the laboratory's PT records for 2017 revealed the laboratory did not have documentation of the following: a) 2017 Immunology/Immunohematology 3rd Event: Laboratory Director signature on the attestation and performance review statements. b) 2017 Immunology/Immunohematology 1st Event: Attestation not signed by Laboratory Director c) 2017 Hematology/Coagulation 2nd Event: Laboratory Director

	signature on the attestation statement, Performance Review and Laboratory Corrective Action d) 2017 Hematology 3rd Event: Laboratory Director signature on the attestation statement e) 2017 Microbiology 3rd Event: Laboratory Director signature on the attestation statement, Urine ID Performance Review and laboratory Corrective Action. f) 2017 Microbiology 2nd Event: Laboratory Director signature on attestation statement and laboratory corrective action documentation. g) 2017 Chemistry 1st Event: Inservice Report not signed by applicable Testing Personnel or Laboratory Director, PT Variance report not signed by Laboratory Director h) 2017 Chemistry 3rd Event: Laboratory Director signature on the attestation statement 2. In interview on March 13, 2018 at 11:45 am, Personnel 2 stated the laboratory director was not on site to sign all documents but comes quarterly and reviews all proficiency testing documents. Personnel 2 confirmed all signatures were not obtained throughout 2017.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to verify the accuracy of the performance of Urine Microscopic analysis, tube method for Antibody Screen (AbScr) and Sputum testing at least twice annually. Findings: 1. Review of the laboratory's test menu and Proficiency Testing records revealed the laboratory was not enrolled in the following analytes tested in the laboratory: Urine Microscopic analysis, tube method for AbScr and Sputum testing . 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not have a policy for twice a year verification of the accuracy of Urine Microscopic analysis, tube method for AbScr and Sputum testing . 3. In interview on March 14, 2017 at 3:05 pm, Personnel 2 stated the laboratory enrolls in Proficiency Testing for all analytes. Personnel 2 confirmed that the above analytes were not currently being verified.
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 laboratory personnel, the laboratory failed to document the collection time of five (5) of five (5) patient samples received from outside the laboratory. 1. Observation by surveyor on March 13, 2018 revealed the laboratory received patient samples from outside the laboratory. 2. Record review of samples received from outside the laboratory revealed the following five of five patients had the same collection and receive time documented: a) Patient 19: Collected 01/10/17 at 5:17, Received at 01/10/17 at 5:17 b) Patient 20: Collected 01/10/17 at 5:17, Received at 01/10/17 at 5:17 c) Patient 21: Collected 01/10/17 at 5:

	17, Received at 01/10/17 at 5:17 d) Patient 22: Collected 01/10/17 at 5:17, Received at 01/10/17 at 5:17 e) Patient 23: Collected 01/10/17 at 5:17, Received at 01/10/17 at 5:17 3. Interview with Personnel 2 on March 14, 2018 confirmed the laboratory should document the actual collection and received times and should would not be possible to collect and receive all five patients at the same times.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide complete detailed written instructions for providers to maintain the integrity of samples met manufacturer requirements. Findings: 1. Direct observation of surveyor on March 13, 2018 revealed the laboratory received specimens collected outside the facility. 2. Review of the laboratory's policy and procedures revealed the laboratory did not have written instructions detailing specimen acceptability for testing to include the following: (a) Patient preparation. (b) Specimen collection. (c) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (d) Specimen storage and preservation. (e) Conditions for specimen transportation. (f) Specimen processing. (i) Specimen acceptability and rejection. (g) Specimen referral. 3. Interview with Personnel 2 on March 13, 2018 confirmed that the laboratory receives samples collected outside the facility such as home healths, nursing homes and rural health clinics. Personnel 2 confirmed that the above criteria were not provided to laboratory clients.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems, identified with the preanalytic system. Findings: 1. The laboratory failed to document the collection time of five (5) of five (5) patient samples received from outside the laboratory. Refer to D5311 2. The laboratory failed to provide complete detailed written instructions for providers to maintain the integrity of samples met manufacturer requirements. Refer to D5317. 3. Interview with Personnel 2 confirmed the laboratory did not identify the above items within the preanalytic system.
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 have a complete policy and procedure manual. Refer to D5401 2. The laboratory failed to perform patient samples for Coagulation testing within four (4) hours of collection as required by the manufacturer for twelve (12) of fourteen (14) patients reviewed. Refer to D5411 I 3. The laboratory failed to follow the manufacturer's instructions for flags that appeared in Complete Blood Count (CBC) result reporting for three (3)of six (6) patients. Refer to D5411 II 4. The laboratory failed to label control material for the GEM Premier 3500 with expiration dates for proper use. Refer to D5415 5. The laboratory failed to ensure calibrators have not exceeded their expiration date. Refer to D5417 I 6. The laboratory failed to have complete performance specification verification studies for the Sysmex 660 instrument. Refer to D5421 7. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) for Microscan testing. Refer to D5445 8. The laboratory failed to check each batch of Media for sterility, ability to support growth of specific organisms, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477 9. The laboratory failed to perform ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing following Emergency Release for one (1) of three (3) patients reviewed. Refer to D5551 10. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555 11. The laboratory failed to ensure that Blood Bank reagents are not used beyond their expiration dates. Refer to D5417 II
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to have a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manuals revealed the laboratory did not have detailed policies for the following: Blood Bank Procedures: detailed instructions to include, but not limited to: Laboratory responsibility for compatibility testing of emergency release blood, Proper documentation of alarm checks. General Laboratory Procedures: each procedure should reflect the instrumentation and requirements for the current platforms. New instrumentation requires updated policies and procedures. Performance specifications: detailed policy how the laboratory will verify accuracy, complete precision, reportable range and refernce range of new instrumentation prior to use and acceptable criteria of each. Specimen rejection policy to reflect that of manufacturer requirements (IE: specimen stability). Hematology: policy detailing the actions to be taken for Complete

	Blood Count (CBC) with suspect, definitive and system flags reflecting that of the manufacturer requirements. Establishment and verification of reference intervals for initial and each new lot of coagulation reagents. Microbiology: detailed instructions for Sputum testing to include, but not limited to, how the laboratory is to assess and document specimen acceptability. 2. Interview with Personnel 2 on March 15, 2018 confirmed the laboratory policies and procedures were in progress of being updated. Personnel 2 confirmed the above areas were not detailed in the current policies.
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 patient samples for Coagulation testing within four (4) hours of collection as required by the manufacturer for twelve (12) of fourteen (14) patients reviewed. Findings: 1. Observation by surveyor on March 28, 2017 established the laboratory utilized the Siemens Sysmex CA-600 System for Coagulation testing of Activated Partial Thrombin Time (APTT) and DDimer. 2. Review of the Siemens Sysmex CA-600 System installation guide under specimen storage states for APTT and D-Dimer testing that "samples should be analyzed within four (4) hours of collection." 3. Review of random patient reports from December 2017 through February 2018 revealed the following twelve (9) of eighteen (18) patients were not tested within four hours of collection as required by the manufacturer: Patient 7, DDimer performed 2 days, 18 hours 51 minutes after collection time. Patient 8, DDimer performed 4 days, 14 hours 15 minutes after collection time. Patient 9, DDimer performed 4 days, 11 hours 31 minute after collection time. Patient 10, DDimer performed 4 days, 9 hours 28 minutes after collection time. Patient 11, DDimer performed 4 days, 12 hours 55 minutes after collection time. Patient 12, DDimer performed 10 hours 26 minutes after collection time. Patient 13, DDimer performed 8 hours 47 minutes after collection time. Patient 14, APTT performed 4 hours 32 minutes after collection time. Patient 15, APTT performed 4 hours 42 minutes after collection time. 4. Interview with Personnel 2 on March 14, 2018 revealed the laboratory was not aware of the manufacturer requirement to test APTT and DDimer samples within 4 hours of collection. Personnel 2 confirmed the patients above were not tested within 4 hours. Personnel 2 stated the DDimers were frozen to be completed at a later date; however, the laboratory was unaware the manufacturer has specific criteria for the freezing and thawing of coagulation samples. II. Based on observation, record review and interview, the laboratory failed to follow the manufacturer's instructions for flags that appeared in Complete Blood Count (CBC) result reporting for three (3)of six (6) patients. Findings: 1. Observation during the laboratory tour on March 12, 2018 revealed the laboratory maintained a Beckman Coulter DxH Analyzer for Hematology. 2. Review of the Beckman Coulter DxH Operations Manual revealed for CBC test results [which included White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Mean Cell Volume (MCV), Mean Corpuscular Hemoglobin Concentration (MCHC), Mean Corpuscular Hemoglobin (MCH), Red Cell Distribution Width (RDW), Platelet Count (PLT), Granulocytes percent (GR%), Lymphocytes percent (LY%) Monocyte

	percent (MO%), Granulocytes Absolute Number (GR#), Lymphocytes Absolute Number (LY#), Monocyte Absolute Number (MO#), and Mean Platelet Volume (MPV) under "What Flags Mean" that the laboratory is to take action for the following flags: a) Suspect Flags: including but not limited to Left Shift, Immature Cells b) Definitive Flags: including but not limited to Hypochromia, Microcyctosis, RBC fragments, NRBCs c) System Flags: including but not limited to Abnormal NRBC patter, Low DC Event (N &P) Low Events (N & P) 3. Review of the laboratory's policy revealed the laboratory did not have a detailed protocol for the action to be taken for patient results with suspect, definitive and system flags. 4. Review of patient test records revealed the following three (3)of six (6) patients were reported with suspect, defnitive or system flags without peripheral smear review or manual differential: Patients 16-18. 5. Personnel 2 stated in interview at 11:15 am that the laboratory was currently in the process of updating this policy with the medical review board; however, at this time, it was up to testing personnel discretion whether a scan or manual differential is needed for each patient.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to label control material for the GEM Premier 3500 with expiration dates for proper use. Findings: 1. Observation by surveyor during the laboratory tour on March 12, 2018 revealed the laboratory utilizes the GEM Premier 3500 instrument with Critical Care GEM Calibration Valuation Product (CVP) stored at room temperature for blood gas testing. 2. Review of the GEM CVP's package insert under the Storage and Stability section revealed "Unopened ampules are stable until the expiration date shown on the label when stored at 2-8 degrees Celsius, or up to 12 months at room temperature (20-28 degrees Celsius) providing storage does not exceed the expiration date. DO NOT FREEZE." 3. Further observation of the following GEM CVP reagents in-use revealed the laboratory did not label with the receipt date or a twelve (12) month expiration date for room temperature storage: GEM CVP 1 Lot # 1835 (2 boxes) GEM CVP 2 Lot # 2835 (1 box) GEM CVP Multipak Lot #834 (1box) 4. In interview on March 14, 2018, Personnel 2 confirmed the laboratory stores the CVP reagents at room temperature and does not label the CVP reagents with a twelve (12) month expiration date.
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:

	I. Based on observation and interview with personnel, the laboratory failed to ensure calibrators have not exceeded their expiration date. Findings: 1. Observation by surveyor during the laboratory tour on March 12, 2018 revealed the following expired item in the main freezer: Hemoglobin A1C Linearity Set Lot number 34685 Expiration 10/31/2017 (Level 1-6) 2. In interview on March 14, 2018, Personnel 2 stated the laboratory is to discard all expired items. II. Based on record review, and interview with laboratory personnel, the laboratory failed to ensure that Blood Bank reagents are not used beyond their expiration dates. Findings: 1. Review of Blood Bank Quality Control Records from January 1, 2017 through December 31, 2017 revealed the laboratory documented the use of the following expired regaents for the following dates: a) From March 15, 2017 through March 18, 2017 the laboratory documented the use of Surgiscreen, Confidence Cells 1 & 2, and Anti serum with the expiration date of March 14, 2017. b) On April 12, 2017 the laboratory documented the use of Surgiscreen, Confidence Cells 1 & 2, and Anti serum with the expiration date of Aprill 11, 2017. c) On November 29, 2017 the laboratory documented the use of Coombs Control cells with the expiration date of November 27, 2017. 2. Review of Patient Blood Bank Test Records from January 1, 2017 through December 31, 2017 revealed the following five (5) patients were tested and reported utilizing the expired reagent cells or diluent: Patients 1-5 3. Further review of Blood Bank records revealed Blood Bank Proficiency Testing was performed on April 12, 2017 with expired reagents. 4. Interviews with Personnel 2 on March 14, 2017 confirmed the laboratory documented the utilization of expired Reagent Cells and Diluent for the dates and patients cited above.
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 have complete performance specification verification studies for the Sysmex 660 instrument. Findings: 1. Observation by surveyor during the laboratory tour on March 12, 2017 revealed the laboratory utilizes the Sysmex 660 Coagulation instrument for patient testing of Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and DDimer. 2. Review of the laboratory's data revealed the following studies performed: a) simple precision b) Method Comparison for accuracy 3. Review of the laboratory's data revealed the following information was not included: a) Complete Precision: day-to-day and operator variance b) Reference Interval: verification study of manufacturer's ranges fell outside 95% confidence. No reference interval established by the laboratory. New instrument is a different platform and reagent than previous instrument. c) Reportable Range 4. In interview on March 14, 2018, Personnel 2 confirmed the data reviewed was performed primarily by the manufacturer for installation. Personnel 2 stated the

	laboratory thought all studies required had been performed. 5. Review of the Task 1 & 3 test list provided by the laboratory revealed the laboratory performs 1780 test annually on the Sysmex 660 Coagulation instrument.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to have a complete Individualized Quality Control Plan (IQCP) for Microscan testing. Findings: 1. Observation by surveyor during the laboratory tour on March 12, 2018 revealed the laboratory utilizes the Microscan for culture organism identification (ID) and susceptibility. 2. Review of the laboratory's IQCP revealed the data assessed was for the previous ID and susceptibility instrument, a Vitek. 3. Further review of the laboratory's IQCP documents revealed the following components were not included: a) In-house QC data to support the reduction of performing external controls b) Effective Quality Assessment Plan c) Supporting documentation such as manufacturer requirements for quality control frequency. 4. In interview on March 14, 2018, Personnel 2 confirmed the IQCP reviewed was developed for the previous system, Vitek and that the laboratory did not reassess the IQCP when they replaced the new Microscan. 5. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 843 ID and Susceptibility tests annually.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to check each batch of Media for sterility, ability to support growth of specific organisms, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Findings: 1. Observation by the surveyor on March 12, 2018 revealed the laboratory utilized the following media for organism growth in Microbiology: Mannitol Salt, MacConkey II, TSA II and Blood Agar Plates (BAP). 2. Review of the Laboratory Policy and

	Procedure Manual revealed the laboratory failed to include written quality control policies and procedures for the above media to include: a). Checking each batch of media for sterility. b) Check to see that each batch of media to assure that it supports growth of the organisms the laboratory identifies. c) Check the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. 3. Interview with personnel 2 on March 14, 2018 revealed the laboratory thought these media types were still exempt from quality control requirements. Personnel 2 confirmed the laboratory had not performed an IQCP to utilize the manufacturer's quality control for media. 4. Review of the Task 1 and 3 form revealed the laboratory plates approximately 2,000 cultures annually.
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 laboratory personnel, the laboratory failed to perform ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing following Emergency Release for one (1) of three (3) patients reviewed. Findings: 1. Review of the Laboratory policy and procedure manual revealed the laboratory did not have specific instructions detailing the laboratory's responsibility for follow up of ABO, Rh, AbScr and Xmatch once blood has been issued as Emergency Release from the laboratory. 2. Review of Emergency Release records from 2016 and 2017 revealed two (2) of three (3) patients which were issued Emergency Release blood were followed by ABO, Rh, AbScr and Xmatch as soon as possible to ensure absolute compatability of the blood products. 3. Further review of these records revealed the follow patient had no follow up of ABO, Rh, AbScr and Xmatch testing to ensure compatability: Patient 6 - Emergency Release July 17, 2016 4. In interview on March 14, 2018, Personnel 2 stated the laboratory should always follow emergency release blood products with appropriate compatability testing. Personnel 2 also confirmed that this policy is not detailed the steps that should be taken after emergency release, but all personnel are aware this testing should be performed.
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 2016 and 2017 revealed the Blood Bank Refrigerator did not have documentation of quarterly alarm checks as follows: a) 2017: June 1, 2017, Septermber 5, 2017 and December 7, 2017 alarm checks do not reflect the needle on the circular chart to have met the temperatures documented as alarmed. b) 2016: June and December alarm check have no indication on the circular chart of an alarm check performed. c) Dates of alarm check performance are not documented for each alarm check, only target dates. 3. Interviews with Personnel 2 on March 13, 2017 at 2:05 pm stated that the hospital Biomed team performs the quarterly arlarm checks. Personnel 2 confirmed the circular charts do not reflect the temperatures documented for alarm checks. Personnel 2 also confirmed that the documentation provided by Biomed for alarm checks does not include the date the alarm check is performed.
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 observation, record review, and interview with personnel, the laboratory failed to follow established policies to monitor, assess, and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to have a complete policy and procedure manual. Refer to D5401 2. The laboratory failed to perform patient samples for Coagulation testing within four (4) hours of collection as required by the manufacturer for twelve (12) of fourteen (14) patients reviewed. Refer to D5411 I 3. The laboratory failed to follow the manufacturer's instructions for flags that appeared in Complete Blood Count (CBC) result reporting for three (3)of six (6) patients. Refer to D5411 II 4. The laboratory failed to label control material for the GEM Premier 3500 with expiration dates for proper use. Refer to D5415 5. The laboratory failed to ensure calibrators have not exceeded their expiration date. Refer to D5417 6. The laboratory failed to have complete performance specification verification studies for the Sysmex 660 instrument. Refer to D5421 7. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP) for Microscan testing. Refer to D5445 8. The laboratory failed to check each batch of Media for sterility, ability to support growth of specific organisms, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477 9. The laboratory failed to perform ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing following Emergency Release for one (1) of three (3) patients reviewed. Refer to D5551 10. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555 11. The laboratory failed to ensure that Blood Bank reagents are not used beyond their expiration dates. Refer to D5417 II 12. Interview with

	Personnel 2 confirmed that the laboratory did not identify the above deficient practices internally.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory failed to report Urine Drug Screen (UDS) results as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on March 12, 2018 revealed the laboratory utilized the Alere iCassette for UDS testing which includes: Amphetamines, Barbiturates, Benzodiazipnes, Cocaine, Marijuana (THC), Methylenedioxymethamphetamine (MDMA), Opiates, Oxycodone, Phencyclidine (PCP), Propoxyphene (PPX), and Tricyclic Antidepressants (TCA). 2. Review of the Alere iCassette Drug Screen package insert under the Intended Use section revealed "This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated." 3. Review of random patient test reports for UDS revealed the laboratory included the following statements: "This test provides only a qualitative, preliminary, non-confirmed analytical result.." However, the comment did not include the complete comment of the manufacturer. 4. In further interview on March 12, 2018, Personnel 2 confirmed all UDS reports have the identified comment of a preliminary result; however, the full statement as listed in the manufacturer's package insert was not included. 5. Review of the laboratory's Task 1 and 3 form revealed the laboratory performs 959 UDS annually.
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 the accuracy of each test performed by the laboratory is verified at least twice annually. Refer to D6007 2. The Laboratory Director failed to ensure that complete verification procedures were

	performed. Refer to D6013 3. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014 4. The Laboratory Director failed to ensure all proficiency testing reports are reviewed by the appropriate staff. Refer to D6018 5. The Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Refer to D6020. 6. 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 7. The Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to 6026 8. The Laboratory Director failed to ensure that personnel competency was assessed as required. D6030 9. The Laboratory Director failed to ensure a complete policy and procedure manual was available to all personnel. Refer to D6031
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that the accuracy of each test performed by the laboratory is verified at least twice annually. Refer to D5217
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 laboratory 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 perform patient samples for Coagulation testing within four (4) hours of collection as required by the manufacturer for twelve (12) of fourteen (14) patients reviewed. Refer to D5411 I 2. The laboratory failed to follow the manufacturer's instructions for flags that appeared in Complete Blood Count (CBC) result reporting for three (3)of six (6) patients. Refer to D5411 II 3. The laboratory failed to label control material for the GEM Premier 3500 with expiration dates for proper use. Refer to D5415 4. The laboratory failed to ensure calibrators have not exceeded their expiration date. Refer to D5417
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 record review and interview with personnel, the Laboratory Director failed to ensure all proficiency testing reports are reviewed by the appropriate staff. Refer to D2015
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that the quality control was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to have a complete Individualized Quality Control Plan (IQCP). Refer to D5445 I.
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 laboratory 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 D5391 and D5793.
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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure final reports for urine drug screen tests included pertinent information required for interpretation. Refer to D5805.
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 that personnel competency was assessed as required. Findings: 1. The Technical Consultant failed to ensure that competency of testing personnel was assessed as required. Refer to D6046

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 record review and interview, the Laboratory Director failed to ensure a complete policy and procedure manual was available to all personnel. Refer to D5401
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, the Technical Consultant failed to ensure that competency of testing personnel was assessed as required. Findings: 1. Record review revealed the following competencies were not completed: a) 2017 Annual competency for Personnel 3 b) Semi-annual competency for Personnel 4 documented on same day as initial competency. 2. Interview with Personnel 2 confirmed the above competencies were not accurately accounted for.
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 observation, record review and interview with personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed test methods as required. Refer to D6087 2. The Laboratory Director failed to ensure that quality control programs are maintained in Immunohematology. Refer to D6093
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that 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 test methods as required. Findings: 1. The laboratory failed to check each batch of Media for sterility, ability to support growth of specific organisms, and document the physical characteristics of the media when compromised and report any deterioration of the media to the manufacturer. Refer to D5477 2. The laboratory failed to perform ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing following Emergency Release for one (1) of three (3) patients reviewed. Refer to D5551 3. The laboratory failed to assure the quarterly blood bank alarm checks recorded on the circular temperature charts. Refer to D5555
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 record review and interview with personnel, the Laboratory Director failed to ensure that quality control programs are maintained in Immunohematology. Refer to D5417 II