Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461318	10/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Abrom Kaplan Memorial Hospital	1310 West 7th Street, Kaplan, 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 CERTIFICATION SURVEY was performed at ABROM KAPLAN MEMORIAL HOSPITAL - CLIA # 19D0461318 on October 15, 2018 through October 19, 2018. ABROM KAPLAN MEMORIAL 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 493.1441 CONDITION: Laboratories performing high complexity testing, Laboratory Director. 42 CFR 493.1409 CONDITION: Laboratories performing moderate complexity testing, Technical Consultant. 42 CFR 493.1447 CONDITION: Laboratories performing high complexity testing, Technical Supervisor.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory

failed to document the collection date and time for patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis for sixty (60) of sixty (60) patients reviewed. Findings: 1. Observation by surveyor on October 15, 2018 revealed the laboratory maintained a Abbott iSTAT Blood Analysis System for testing: pH, pCO2, and pO2. 2. Review of the Laboratory's Policy and Procedure revealed that all samples performed on the Abbott iSTAT Blood Analysis System for pH, pCO2 and pO2 are to be analyzed within ten (10) minutes from collection. 3. Review of Patient Test Records from April 6, 2018 through September 28, 2018 revealed the laboratory failed to have documentation of the collection date and time to be able to determine if patient samples were analyzed within the ten (10) minute time frame set by Laboratory Policy for the following sixty (60) patients. NOTE: Arterial Blood Gas (ABG) consists of pH, pO2, and pCO2. On April 6, 2018 Patient 2 was received in the laboratory at 21:14 and analyzed at 21:18. On April 9, 2018 Patient 3 was received in the laboratory at 12:29 and analyzed at 12:30. On April 15, 2018 Patient 4 was received in the laboratory at 04:17 and analyzed at 04:19. On April 16, 2018 Patient 5 was received in the laboratory at 14:32 and analyzed at 14:38. On April 19, 2018 Patient 6 was received in the laboratory at 14:33 and analyzed at 14:36. On April 20, 2018 Patient 7 was received in the laboratory at 05:02 and analyzed at 05:04. On April 20, 2018 Patient 8 was received in the laboratory at 22:09 and analyzed at 22:12. On April 21, 2018 Patient 9 was received in the laboratory at 09:25 and analyzed at 09: 26. On April 22, 2018 Patient 10 was received in the laboratory at 23:41 and analyzed at 23:44. On April 23, 2018 Patient 11 was received in the laboratory at 00:45 and analyzed at 00:48. On April 24, 2018 Patient 12 was received in the laboratory at 01: 17 and analyzed at 01:23. On April 26, 2018 Patient 13 was received in the laboratory at 01:47 and analyzed at 01:48. On April 30, 2018 Patient 14 was received in the laboratory at 11:41 and analyzed at 15:42. On May 17, 2018 Patient 15 was received in the laboratory at 13:39 and analyzed at 13:42. On May 18, 2018 Patient 16 was received in the laboratory at 13:55 and analyzed at 13:56. On May 19, 2018 Patient 17 was received in the laboratory at 07:11 and analyzed at 07:15. On May 23, 2018 Patient 18 was received in the laboratory at 20:14 and analyzed at 20:17. On May 23, 2018 Patient 19 was received in the laboratory at 20:19 and analyzed at 20:22. On May 30, 2018 Patient 20 was received in the laboratory at 05:39 and analyzed at 05: 42. On June 4, 2018 Patient 21 was received in the laboratory at 17:02 and analyzed at 17:05. On June 6, 2018 Patient 22 was received in the laboratory at 15:43 and analyzed at 19:17. On June 8, 2018 Patient 23 was received in the laboratory at 11:26 and analyzed at 11:28. On June 8, 2018 Patient 24 was received in the laboratory at 19: 53 and analyzed at 19:55. On June 11, 2018 Patient 25 was received in the laboratory at 14:58 and analyzed at 15:00. On June 15 2018 Patient 26 was received in the laboratory at 14:36 and analyzed at 14:37. On June 24, 2018 Patient 27 was received in the laboratory at 13:24 and analyzed at 13:29. On June 25, 2018 Patient 28 was received in the laboratory at 08:23 and analyzed at 08:24. On June 30, 2018 Patient 29 was received in the laboratory at 21:16 and analyzed on July 2, 2018 at 13:42. On July 4, 2018 Patient 30 was received in the laboratory at 02:06 and analyzed at 02:08. On July 10, 2018 Patient 31 was received in the laboratory at 10:55 and analyzed at 11: 50. On July 13, 2018 Patient 32 was received in the laboratory at 13:53 and analyzed at 13:55. On July 16, 2018 Patient 33 was received in the laboratory at 17:23 and analyzed at 17:43. On July 16, 2018 Patient 34 was received in the laboratory at 21:30 and analyzed at 21:50. On July 17, 2018 Patient 35 was received in the laboratory at 12:56 and analyzed at 12:57. On July 23, 2018 Patient 36 was received in the laboratory at 10:45 and analyzed at 10:55. On July 24, 2018 Patient 37 was received in the laboratory at 22:20 and analyzed at 22:21. On July 31, 2018 Patient 38 was received in the laboratory at 15:05 and analyzed at 15:18. On August 7, 2018 Patient 39 was received in the laboratory at 14:14 and analyzed at 14:33. On August 7, 2018

	Patient 40 was received in the laboratory at 22:58 and analyzed at 23:01. On August 8, 2018 Patient 41 was received in the laboratory at 00:33 and analyzed at 00:35. On August 8, 2018 Patient 42 was received in the laboratory at 01:57 and analyzed at 01: 59. On August 8, 2018 Patient 43 was received in the laboratory at 06:04 and analyzed at 06:05. On August 12, 2018 Patient 44 was received in the laboratory at 09: 06 and analyzed at 09:07. On August 13, 2018 Patient 45 was received in the laboratory at 12:01 and analyzed at 12:02. On August 14, 2018 Patient 46 was received in the laboratory at 01:20 and analyzed at 06:50. On August 21, 2018 Patient 47 was received in the laboratory at 13:18 and analyzed at 13:21. On August 27, 2018 Patient 48 was received in the laboratory at 18:10 and analyzed at 18:12. On August 27, 2018 Patient 49 was received in the laboratory at 19:18 and analyzed at 19:21. On August 27, 2018 Patient 50 was received in the laboratory at 21:24 and analyzed at 21: 27. On September 4, 2018 Patient 51 was received in the laboratory at 21:46 and analyzed at 21:47. On September 11, 2018 Patient 52 was received in the laboratory at 19:34 and analyzed at 19:36. On September 11, 2018 Patient 53 was received in the laboratory at 19:34 and analyzed at 19:39. On September 18, 2018 Patient 54 was received in the laboratory at 08:57 and analyzed at 08:59. On September 20, 2018 Patient 55 was received in the laboratory at 20:11 and analyzed at 20:12. On September 20, 2018 Patient 56 was received in the laboratory at 22:07 and analyzed at 22:09. On September 20, 2018 Patient 57 was received in the laboratory at 23:11 and analyzed at 23:40. On September 24, 2018 Patient 58 was received in the laboratory at 10:24 and analyzed at 10:28. On September 24, 2018 Patient 59 was received in the laboratory at 10:24 and analyzed at 10:31. On September 24, 2018 Patient 60 was received in the laboratory at 10:25 and analyzed at 10:33. On September 28, 2018 Patient 61 was received in the laboratory at 09:07 and analyzed at 09:31. 4. Interview with Personnel 2 on October 19, 2018 revealed she was unaware that testing personnel performing ABGs were not documenting the collection date and time. Personnel 2 confirmed testing personnel failed to document the collection date and time for the sixty (60) patients cited above.
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: **REPEAT DEFICIENCY from May 18, 2017** Based on record review and interview with personnel, the laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Findings: 1. Review of the Laboratory's "AKMH Collection Manual" revealed instructions for: a) Specimen labeling b) Specimen Collection Container (tube type) specimen types, and the collection containers for the sample (however not for all analytes the laboratory provides testing for).. c) Specimen Storage and Preservation (however not for all specimen types and not current with manufacturer requirements) d) Specimen Rejection e) Specimen Processing f) Specimen Referral g) Off-Site Specimen Transport: Specimens are to be received into the lab within 2 hours of collection. Further review of the Laboratory's "AKMH Collection Manual" revealed the laboratory failed to: a) Include Laboratory requirements for all analytes the laboratory tests for; Acetaminophen (Acet) Blood Alcohol (ETOH), Digoxin (Dig), Magnesium

	(Mg), Salycilates (Sali), Vancomycin (Vanco), Lipase, Vitamin D (VitD), Prothrombin Time (PT) Partial Thromboplastin Time (PTT) . b) Ensure the laboratory requirements meet the manufacturer's requirements for all analytes; examples of random analytes that the surveyor observed: - Calcium (CA) is to be separated and analyzed promptly. - Potassium (K) needs to be separated within 1 hour of collection - Glucose (Gluc) Glycolysis decreased by approximately 5-7% per hour. - Alanine Amnotransferase (ALT), Creatine Kinase (CK), Creatinine (Creat), Direct Bilirubin (DBil), Total Bilirubin (TBil), Troponin (CTNI), Lipase need to be separated within 2 hours of collection (not received within 2 hours) - Urine Drug Screen (UDS) - are to be received and tested within 24 hours (not just received within 2 hours) otherwise the sample is to be stored frozen. 3. Interviews with personnel 2, and 3 on October 16, 2018 revealed the laboratory provided the Laboratory's "AKMH Specimen Collection Manual" to all outside facilities that the laboratory does testing for. Personnel 2 and 3 confirmed the manual does not include all the information required to maintain the integrity of patient samples.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory's system failed to monitor, assess, and correct problems identified with the preanalytic system. Findings: 1. A review of patient test records indicates systemic problems with the preanalytic system as follows: a) The laboratory failed to document the collection date and time for patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis for sixty (60) of sixty (60) patients reviewed. Refer to D5305. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. The laboratory had a Quality Assurance Policy that routinely monitored the preanalytic system; however, the monitors failed to identify the deficiencies identified with the preanalytic systems. 3. Interview with personnel 2 on October 19, 2018 confirmed the laboratory failed to identify the problems cited with the preanalytic system above.
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 maintain complete policies and procedures for Histology.. Refer to D5403 I. 3. The laboratory failed to ensure the laboratory policy and procedure manual contained complete instructions for Blood Bank. Refer to D5403 II. 4. The failed to ensure patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis are analyzed within ten (10) minutes according to laboratory policy for sixty (60) of sixty (60) patients reviewed. Refer to D5411. 3. The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Diesse Mini-Cube ESR Automated System. Refer to D5423 I. 4. The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Grifols Blood Bank System. Refer to D5423 II. 5. The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy performed utilizing the Sure Vue HCG Combo Kit, for one (1) of sixteen (16) patients reviewed. Refer to D5449. 6. Thelaboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Siemens Stratus CS Acute Care Diagnostic System, for one (1) of fifty two (52) patients reviewed. Refer to D5545. 7. The laboratory failed to document the performance of positive and negative quality control material each day of patient testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing as required by the manufacturer for five (5) of five (5) patient test days reviewed. Refer to D5551. 8. The laboratory failed to initiate a Transfusion Reaction Workups for five (5) of five (5) patients reviewed. Refer to D5559. 9. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Histopathology for one (1) of six (6) patients reviewed. Refer to D5783. 10. The laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Refer to D5793.
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 policy and procedure manual revealed the laboratory did not have detailed instructions for: Proficiency Testing (PT): a) Ordering and ensuring that you are enrolled for Proficiency Testing. b) What to do when you receive samples from the PT Provider. c) How to handle the samples; who will test, when to test, how do you assure no inter and intra laboratory communication takes place d) How to record results to send into the PT Provider to be scored. e) What records to maintain. f) How to evaluate when you receive your scores from the PT Provider. g) What steps to take if corrective action is needed. h) What steps are required when the laboratory has their first and second two (2) out of three (3) failures. Complaint Policies and Procedures

	Communication Policies and Procedures Downtime Policies and Procedures for when test systems go down. Performance Specifications for high complexity and/or Laboratory Developed Tests (LDT) to include the establishment and verification policies and procedures for: a) Accuracy b) Precision: day-to-day, run-to-run, within-run variation and operator variance. c) Reportable Range d) Reference Range e) Analytical Sensitivity f) Analytical Specificity 2. Interview with Personnel 2 on October 16, 2018 confirmed the policy and procedure manual was incomplete
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to maintain complete policies and procedures for Histology. Findings: 1. Review of all Laboratory Policy and Procedure Manuals revealed the laboratory did not include policies and procedures for Histology including but not limited to: a) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. b) Microscopic examination, including the detection of inadequately prepared slides. c) Step-by-step performance of the procedure, and interpretation of results. d) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. e) Calibration and calibration verification procedures. f) Control procedures. g) Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. h) Limitations in the test methodology, including interfering substances. i) Pertinent literature references. j) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. k) Description of the course of action to take if a test system becomes inoperable. 2. Interview with Personnel 2 on October 19, 2017 confirmed the laboratory did not have complete policy and procedures for Histology. II. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete instructions for Blood Bank. Findings: 1. Review of the FDA CLIA

	database for complexity on October 16, 2018 revealed that Grifols gel system, solution, reagents and quality control system for ABO, Rh, Antibody Screen and Crossmatch testing had not been evaluated by the FDA for test complexity categorization. Thus leaving the Grifols test system along with the solutions, reagents and quality control material as high complexity and as a Laboratory Developed Test (LDT). 2. Review of the Blood Bank Policy and Procedure Manuals revealed: a) References to NCCLS GPA-2 and AABB for Blood Bank Policies and Procedures. b) The laboratory utilized Grifols gel system along with Grifols solutions, reagents and quality control material. Further review of the Manual revealed package inserts for all Grifol solutions, reagents and quality control material. c) Policies and Procedures were based on systems that have been approved by the FDA. Further review of the Blood Bank Policy and Procedure Manual revealed the laboratory failed to: a) Maintain current copies of the NCCLS GPA-2 and AABB Technical Manuals. b) Develop policies and procedures for Performance Specifications for high complexity and/or Laboratory Developed Tests (LDT) to include the establishment and verification policies and procedures for: Accuracy, Precision: day-to-day, run-to-run, within-run variation and operator variance, Analytical Sensitivity and Analytical Specificity. 2. Interview with Personnel 2 on October 19, 2017 confirmed the laboratory did not have a complete Blood Bank Policy and Procedure Manual.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis are analyzed within ten (10) minutes according to laboratory policy for sixty (60) of sixty (60) patients reviewed. Findings: 1. Observation by surveyor on October 15, 2018 revealed the laboratory maintained a Abbott iSTAT Blood Analysis System for testing: pH, pCO2, and pO2. 2. Review of the Laboratory's Policy and Procedure revealed that all samples performed on the Abbott iSTAT Blood Analysis System for pH, pCO2 and pO2 are to be analyzed within ten (10) minutes from collection. 3. Review of Patient Test Records from April 6, 2018 through September 28, 2018 revealed the laboratory did not document the specimen collection date and time to be able to determine if patient samples were analyzed within the ten (10) minute time frame set by Laboratory Policy for the following sixty (60) patients. NOTE: Arterial Blood Gas (ABG) consists of pH, pO2, and pCO2. On April 6, 2018 Patient 2 was received in the laboratory at 21:14 and analyzed at 21:18. On April 9, 2018 Patient 3 was received in the laboratory at 12:29 and analyzed at 12:30. On April 15, 2018 Patient 4 was received in the laboratory at 04:17 and analyzed at 04:19. On April 16, 2018 Patient 5 was received in the laboratory at 14:32 and analyzed at 14: 38. On April 19, 2018 Patient 6 was received in the laboratory at 14:33 and analyzed at 14:36. On April 20, 2018 Patient 7 was received in the laboratory at 05:02 and analyzed at 05:04. On April 20, 2018 Patient 8 was received in the laboratory at 22:09 and analyzed at 22:12. On April 21, 2018 Patient 9 was received in the laboratory at 09:25 and analyzed at 09:26. On April 22, 2018 Patient 10 was received in the laboratory at 23:41 and analyzed at 23:44. On April 23, 2018 Patient 11 was received

in the laboratory at 00:45 and analyzed at 00:48. On April 24, 2018 Patient 12 was received in the laboratory at 01:17 and analyzed at 01:23. On April 26, 2018 Patient 13 was received in the laboratory at 01:47 and analyzed at 01:48. On April 30, 2018 Patient 14 was received in the laboratory at 11:41 and analyzed at 15:42. On May 17, 2018 Patient 15 was received in the laboratory at 13:39 and analyzed at 13:42. On May 18, 2018 Patient 16 was received in the laboratory at 13:55 and analyzed at 13: 56. On May 19, 2018 Patient 17 was received in the laboratory at 07:11 and analyzed at 07:15. On May 23, 2018 Patient 18 was received in the laboratory at 20:14 and analyzed at 20:17. On May 23, 2018 Patient 19 was received in the laboratory at 20: 19 and analyzed at 20:22. On May 30, 2018 Patient 20 was received in the laboratory at 05:39 and analyzed at 05:42. On June 4, 2018 Patient 21 was received in the laboratory at 17:02 and analyzed at 17:05. On June 6, 2018 Patient 22 was received in the laboratory at 15:43 and analyzed at 19:17. On June 8, 2018 Patient 23 was received in the laboratory at 11:26 and analyzed at 11:28. On June 8, 2018 Patient 24 was received in the laboratory at 19:53 and analyzed at 19:55. On June 11, 2018 Patient 25 was received in the laboratory at 14:58 and analyzed at 15:00. On June 15 2018 Patient 26 was received in the laboratory at 14:36 and analyzed at 14:37. On June 24, 2018 Patient 27 was received in the laboratory at 13:24 and analyzed at 13: 29. On June 25, 2018 Patient 28 was received in the laboratory at 08:23 and analyzed at 08:24. On June 30, 2018 Patient 29 was received in the laboratory at 21:16 and analyzed on July 2, 2018 at 13:42. On July 4, 2018 Patient 30 was received in the laboratory at 02:06 and analyzed at 02:08. On July 10, 2018 Patient 31 was received in the laboratory at 10:55 and analyzed at 11:50. On July 13, 2018 Patient 32 was received in the laboratory at 13:53 and analyzed at 13:55. On July 16, 2018 Patient 33 was received in the laboratory at 17:23 and analyzed at 17:43. On July 16, 2018 Patient 34 was received in the laboratory at 21:30 and analyzed at 21:50. On July 17, 2018 Patient 35 was received in the laboratory at 12:56 and analyzed at 12:57. On July 23, 2018 Patient 36 was received in the laboratory at 10:45 and analyzed at 10: 55. On July 24, 2018 Patient 37 was received in the laboratory at 22:20 and analyzed at 22:21. On July 31, 2018 Patient 38 was received in the laboratory at 15:05 and analyzed at 15:18. On August 7, 2018 Patient 39 was received in the laboratory at 14: 14 and analyzed at 14:33. On August 7, 2018 Patient 40 was received in the laboratory at 22:58 and analyzed at 23:01. On August 8, 2018 Patient 41 was received in the laboratory at 00:33 and analyzed at 00:35. On August 8, 2018 Patient 42 was received in the laboratory at 01:57 and analyzed at 01:59. On August 8, 2018 Patient 43 was received in the laboratory at 06:04 and analyzed at 06:05. On August 12, 2018 Patient 44 was received in the laboratory at 09:06 and analyzed at 09:07. On August 13, 2018 Patient 45 was received in the laboratory at 12:01 and analyzed at 12:02. On August 14, 2018 Patient 46 was received in the laboratory at 01:20 and analyzed at 06: 50. On August 21, 2018 Patient 47 was received in the laboratory at 13:18 and analyzed at 13:21. On August 27, 2018 Patient 48 was received in the laboratory at 18: 10 and analyzed at 18:12. On August 27, 2018 Patient 49 was received in the laboratory at 19:18 and analyzed at 19:21. On August 27, 2018 Patient 50 was received in the laboratory at 21:24 and analyzed at 21:27. On September 4, 2018 Patient 51 was received in the laboratory at 21:46 and analyzed at 21:47. On September 11, 2018 Patient 52 was received in the laboratory at 19:34 and analyzed at 19:36. On September 11, 2018 Patient 53 was received in the laboratory at 19:34 and analyzed at 19:39. On September 18, 2018 Patient 54 was received in the laboratory at 08:57 and analyzed at 08:59. On September 20, 2018 Patient 55 was received in the laboratory at 20:11 and analyzed at 20:12. On September 20, 2018 Patient 56 was received in the laboratory at 22:07 and analyzed at 22:09. On September 20, 2018 Patient 57 was received in the laboratory at 23:11 and analyzed at 23:40. On September 24, 2018 Patient 58 was received in the laboratory at 10:24 and analyzed at

	10:28. On September 24, 2018 Patient 59 was received in the laboratory at 10:24 and analyzed at 10:31. On September 24, 2018 Patient 60 was received in the laboratory at 10:25 and analyzed at 10:33. On September 28, 2018 Patient 61 was received in the laboratory at 09:07 and analyzed at 09:31. 4. Interview with Personnel 2 on October 19, 2018 revealed she was unaware that testing personnel performing ABGs were not documenting the collection date and time. Personnel 2 confirmed the laboratory was unable to determine if patient samples for ABG are performed within the 10 minute timeframe required.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: I. Based on observations, record review and interview with personnel, the laboratory failed to establish performance specifications for accuracy, precision reportable and reference ranges and analytical sensitivity and specificity for the Diesse Mini-Cube ESR Automated System. Findings: 1. Observation by surveyor during the tour of the laboratory on October 15, 2018 revealed the laboratory performed Erythrocyte Sedimentation Rate (ESR) testing utilizing the Diesse Mini-Cube ESR Automated System. 2. Review of the FDA CLIA Database revealed the Diesse Mini-Cube ESR has not been evaluated by the FDA for test categorization. 3. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory failed to have written policies and procedures for the establishment and verification for tests not evaluated by the FDA. 4. Review of Instrument Implementation Records for the Diesse Mini-Cube ESR Automated System revealed the laboratory verified the precision and accuracy according to the manufacturer. Further review revealed no policy detailing instructions for establishment of accuracy, complete precision, reference range, reportable range or analytic sensitivity or specificity. 5. Review of a random selection of Patient Final ESR Reports from November 10, 2017 through June 6, 2018 revealed the laboratory reported ESR for the following three (3) patients without establishing performance specifications: On June 6, 2018 Patient 82. On May 1, 2018 Patient 83. On November 10, 2017 Patient 84. 6. Review of the Task 1 and 3 submitted to the surveyor on October 15, 2018 revealed the laboratory performs 388 ESR tests annually. 7. Interview with Personnel 2 and 3 on October 16, 2018 revealed they were unaware the Diesse Mini-Cube ESR Automated System had not gone through the FDA test categorization to determine the complexity of the test. Personnel 2 and 3 confirmed the laboratory only verified accuracy and precision but did not "establish" accuracy, precision, reportable and reference ranges, and analytical specificity and sensitivity for the Diesse Mini-Cube ESR Automated System. II. Based on observations, record review and interview with personnel, the laboratory failed to establish performance specifications for accuracy, precision reportable and

	reference ranges and analytical sensitivity and specificity for the Grifols Blood Bank System. Findings: 1. Observation by surveyor during the tour of the laboratory on October 15, 2018 revealed the laboratory performed ABO, Rh, Antibody Screen (AbScr), and Crossmatch (xmatch) testing utilizing the Grifols Gel test system along with Grifols solutions, reagent and quality control material. 2. Review of the FDA CLIA Database revealed the Grifols Blood Bank System including; reagents, solutions, quality control material and the gel test system has not been reviewed and evaluated by the FDA for test categorization. 3. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory did not have written policies and procedures detailing how to establish accuracy, complete precision, reference range, reportable range or analytic sensitivity and specificity for test systems not listed on the FDA CLIA database. 4. Review of Instrument Implementation Records for the Grifols Blood Bank System revealed the laboratory had performed a parallel study utilizing twenty (20) patient samples between the Grifols System and the test tube method. However, this parallel study did not establish (or include) the following studies: accuracy, precision (to include day to day, run to run, within run and operator variance), analytical sensitivity and analytical specificity. The Grifols Blood Bank System parallel study was signed off by the Laboratory Director on August 5, 2017. 5. Review of a random selection of Patient Blood Bank Test Records from November 23, 2017 through October 15, 2018 revealed the laboratory performed and reported the following eight (8) patients for ABO, Rh, AbScr and xmatch testing: On November 23, 2017 Patient 69 - O positive, AbScr positive. On January 12, 2018 Patient 70 - A negative, AbScr negative, xmatch 1 unit Red Blood Cells (RBC). On May 18, 2018 Patient 71 - A positive, AbScr negative, xmatch 2 units RBC. On June 7, 2018 Patient 72 - A positive, AbScr negative, xmatch 2 units RBC. On July 9, 2018 Patient 73 - A positive, AbScr negative, xmatch 1 unit RBC. On August 15, 2018 Patient 74 - B positive, AbScr negative, xmatch 2 units RBC. On September 10, 2018 Patient 75 - O positive, AbScr negative, xmatch 2 units RBC. On October 15, 2018 Patient 76 - O positive, AbScr negative, xmatch 2 units RBC. 6. Review of the Task 1 and 3 submitted to the surveyor on October 15, 2018 revealed the laboratory performs 132 ABO, 132 Rh, 121 AbSCr and 60 xmatches annually. 7. Interview with Personnel 2 and 15 on October 19, 2018 revealed they were unaware the Grifols Blood Bank System had not gone through the FDA test categorization to determine the complexity of the test. Personnel 2 and 15 confirmed the laboratory had not "established" accuracy, precision, analytical specificity and sensitivity for the Grifols Blood Bank System.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 perform a positive and negative control each day of patient testing for Serum Pregnancy performed utilizing the Sure Vue HCG Combo Kit, for one (1) of sixteen (16) patients reviewed. Findings: 1. Observation by the surveyor on October 15, 2018 during the tour of the laboratory noted the laboratory performed Serum Pregnancy

	with the Sure Vue HCG Combo Kit. 2. Review of the Laboratory's Policy and Procedure Manual revealed personnel are to perform two levels of quality control each day of patient testing for patient Serum Pregnancy testing. 3. Review of Patient Serum Pregnancy testing and Quality Control records from April 10, 2017 through September 28, 2018 revealed that Patient 1 was tested and reported for Serum Pregnancy without having a positive and negative control performed. 4. Interview with Personnel 2 on October 18, 20 18 confirmed the laboratory failed to perform Serum Pregnancy Quality Control for Patient 1.
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 observation, record review and interview with personnel, the laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Siemens Stratus CS Acute Care Diagnostic System, for one (1) of fifty two (52) patients reviewed. Findings: 1. Observation by surveyors on October 15, 2018 noted the laboratory utilized the Siemens Stratus CS Acute Care Diagnostic System for D-Dimer testing. 2. Review of the laboratory policy and procedure manual revealed the laboratory is to perform two levels of quality control material every eight (8) hours of patient D-Dimer testing. 3. Review of D-Dimer Quality Control and Patient Test Records from April 2, 2018 through September 28, 2018 revealed the laboratory failed to perform two levels of quality control each eight hours of patient testing for D-Dimer testing for Patient 62 on June 15, 2018 at 01:44 AM. 4. Interview with Personnel 2 on October 18, 2018 confirmed Patient 62 was tested and reported on June 15, 2018 at 01:44 AM without having two levels of quality control performed for D-Dimer testing.
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 document the performance of positive and negative quality control material each day of patient testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility

(Xmatch) testing prior to patient testing each day of patient testing as required by the manufacturer for five (5) of five (5) patient test days reviewed. Findings: 1. Review of the Laboratory's Blood Bank Procedure Manual revealed that quality controls for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing are to be performed (daily) each day of patient testing, and prior to patient testing. 2. Interview with personnel 2 on October 19, 2018 revealed the laboratory utilizes the DG Gel Extended Control Kit for performing Quality Control. Personnel 2 also revealed the laboratory only utilizes Tube 1 and 2 for quality control and patient testing. Personnel 2 stated Tubes 3 and 4 are never used. 3. Review of the Grifols DG Gel Extended Control Kit package insert revealed the kit contains 4 screening cell tubes with the following reactions: For Tube 1: * Blood group determination: Reagent Anti-A; Expected Result - positive Reagent Anti-B; Expected Result - negative Reagent Anti-A,B; Expected Result - positive * Reverse Grouping: Reagent A1 cells; Expected Result - negative Reagent A2 cells; Expected Result - negative Reagent B cells; Expected Result - positive * Blood Group Determination Reagent Anti-D; Expected Result - negative Reagent Anti-C; Expected Result - negative Reagent Anti-E; Expected Result - negative Reagent Anti-c; Expected Result - positive Reagent Anti-e; Expected Result - positive Reagent Anti-K; expected Result - positive or negative * Antibody screening Screening cells 1,, 2 and 3: Dependent on antigen profile For Tube 2: * Blood group determination: Reagent Anti-A; Expected Result - negative Reagent Anti-B; Expected Result - positive Reagent Anti-A,B; Expected Result - positive * Reverse Grouping: Reagent A1 cells; Expected Result - positive Reagent A2 cells; Expected Result - positive Reagent B cells; Expected Result - negative * Blood Group Determination Reagent Anti-D; Expected Result - positive Reagent Anti-C; Expected Result - positive Reagent Anti-E; Expected Result - negative Reagent Anti-c; Expected Result - negative Reagent Anti-e; Expected Result - positive Reagent Anti-K; expected Result - positive or negative * Antibody screening Screening cells 1,, 2 and 3: negative Tubes 1 and 2 would not have a negative and positive result for: Anti- A, B would not have a negative result. Anti- E would not have a positive result. Anti-K can be positive or negative in both tubes 1 and 2; possible to have 2 positives or 2 negative. Antibody Screening; Tube 1 ; cells 1, 2 and 3 - no determination if positive or negative for cells 1, 2 or 3. Tube 2 negative for cells 1, 2 and 3. May not have a positive and negative control for each cell 1, 2 or 3. For Tube 3: * Blood group determination: Reagent Anti-A; Expected Result - negative Reagent Anti-B; Expected Result - negative Reagent Anti-A,B; Expected Result - negative * Reverse Grouping: Reagent A1 cells; Expected Result - positive Reagent A2 cells; Expected Result - positive Reagent B cells; Expected Result - positive * Blood Group Determination Reagent Anti-D; Expected Result - positive Reagent Anti-C; Expected Result - negative Reagent Anti-E; Expected Result - positive Reagent Anti-c; Expected Result - positive Reagent Anti-e; Expected Result - negative Reagent Anti-K; expected Result - positive * Antibody screening Screening cells 1, 2 and 3: Negative For Tube 4: * Blood group determination: Reagent Anti-A; Expected Result - negative Reagent Anti-B; Expected Result - negative Reagent Anti-A,B; Expected Result - negative * Reverse Grouping: Reagent A1 cells; Expected Result - positive Reagent A2 cells; Expected Result - positive Reagent B cells; Expected Result - positive * Blood Group Determination Reagent Anti-D; Expected Result - positive Reagent Anti-C; Expected Result - positive Reagent Anti-E; Expected Result - positive Reagent Anti-c; Expected Result - positive Reagent Anti-e; Expected Result - positive Reagent Anti-K; expected Result - negative * Antibody screening Screening cells 1, 2 and 3: Dependent on antigen profile *NOTE: the package insert does not state to only use Tubes 1 and 2. It states all tubes and their reactions. 4. Review of a random selection of Blood Bank Patient and Quality Control Records from May 23, 2018 through September 10, 2018 revealed the laboratory performed ABO, Rh,

	Antibody Screen (AbScr) and Crossmatch (xmatch) testing without ensuring that a positive and negative control is performed for all Blood Bank testing performed: On May 23, 2018 Patient 78 was tested for ABO, Rh, AbScr and xmatch for 2 units of Packed Red Blood Cells (PRBC).: On May 27, 2018 Patient 77 was tested for ABO, Rh, AbScr and xmatch for 2 units of PRBC. On July 4, 2018 Patient 79 was tested for ABO, Rh, AbScr and xmatch for 3 units of PRBC. On August 17, 2018 Patient 80 was tested for ABO, Rh, AbScr and xmatch for 2 units of PRBC. On September 10, 2018 Patient 81 was tested for ABO, Rh, AbScr and xmatch for 2 units of PRBC. 5. Review of the Task 1 & 3 Form submitted to the surveyor on October 15, 2018 revealed the laboratory performs the following annual test volumes: ABO - 132, Rh - 132, AbScr - 121, and xmatch - 60. 6. Interview with Personnel 2 on October 19, 2018 revealed she was unaware of the package insert requirements. Personnel 2 confirmed only Tubes 1 and 2 from the DG Gel Extended Control are utilized by the laboratory and also confirmed the laboratory did not include a positive and negative test for all Blood Bank testing performed.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (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 initiate a Transfusion Reaction Workups for five (5) of five (5) patients reviewed. Findings: 1. Review of the Laboratory's Blood Bank Policy and Procedure Manual revealed: a) References to NCCLS GPA-2 document for Blood Bank, and AABB Technical Manual. NOTE: The laboratory did not have a copy of the NCCLS GPA- 2 document. The laboratory maintained a copy of the 13th Edition of the AABB Technical Manual. b) A copy of the AABB User Guide for the Circular of Information for the Use of Human Blood and Blood Components" c) A policy "Administration of Blood Products & Suspected Transfusion Reactions" was provided that revealed: * Under Transfusion Reaction for 1) Hemolytic symptoms: chills, shaking, fever, anxiety, headache, chest pain, flank pain, hypotension, nausea/vomiting, abnormal bleeding, hemoglobinuria, oliguria, dyspnea; may progress to cardiovascular collapse, shock, DIC and/or renal failure 2) Non-Hemolytic symptoms: fever, chills rigor headache flank pain, flushing, itching, urticarial, hives, anaphylactic reaction, wheezing, laryngeal edema * Under Beginning the Blood Product Transfusion: "take patient's vital signs prior to start of transfusion, 15 minutes after start, and at completion of transfusion. * Further review of the Laboratory policy revealed the procedure referred to the 13th Edition of the AABB Technical Manual. 2. Review of the 13th Edition of the AABB Technical Manual revealed the following: a) Vital signs to monitor are temperature, blood pressure, pulse and respiration rate. b) Vitals are to be monitored pretransfusion, 15 minutes after starting the transfusion, "Clinical personnel should

	continue to observe the patient periodically throughout the transfusion (e.g., every 30 minutes) and up to an hour after completion." c) The Manual refers to Chapter 27 for the monitoring of symptoms for a possible transfusion reaction which include (but not inclusive): chills, shaking, fever (rise of 1 degree Celsius), anxiety, headache, chest pain, flank pain, hypotension, hypertension, nausea/vomiting, abnormal bleeding, hemoglobinuria, oliguria, dyspnea; may progress to cardiovascular collapse, shock, DIC and/or renal failure, rigors, flushing, itching, urticarial, hives, anaphylactic reaction, wheezing, laryngeal edema, and shortness of breath. 3. Review of a random selection of Patient Blood Bank Transfusion Records revealed: a) Transfusion Records failed to include Respiration Rate as stated in the AABB Manual. b) Patient 77 was transfused with 2 units of Packed Red Blood Cells (PRBC) on 5/27/2018: Beginning Blood Pressure started at 143/81 after the second unit of PRBC the Blood Pressure had dropped to 125/64. Beginning Temperature started at 36.6 after second unit Temperature remained at 36.6 Beginning Pulse started at 102 after the second unit it dropped to 92. c) Patient 78 was transfused with 2 units of PRBC on 5/23/2018: Beginning Blood Pressure started at 91/45 after second unit of PRBC the Blood Pressure rose to 111/59. Beginning Temperature started at 37.1 after first unit the Temperature rose to 37.5 Beginning Pulse started at 85 starting of the second unit it rose to 942. d) Patient 79 was transfused with 3 units of PRBC between 7/4/2018 to 7 /5/2018. Beginning Blood Pressure started at 134/69 during the transfusion of the third unit the Blood Pressure dropped to 94/48. Beginning Temperature started at 36.9 after second unit Temperature remained at 37.2 Beginning Pulse started at 73 after the third unit it rose to 83. e) Patient 80 was transfused 2 units of PRBC on 8/17/2018: Beginning Blood Pressure 177/95 after the first unit Blood Pressure rose to 183/98, after the second unit of PRBC was transfused the Blood Pressure dropped to 139/88. Beginning Temperature started at 36.9 after first unit Temperature rose at 37.1 Beginning Pulse started at 68 after the second unit it rose to 77. f) Patient 81 was transfused with 2 units of PRBC on 9/10/2018: Beginning Blood Pressure 115/61 after the second unit of PRBC the Blood Pressure rose to 141/72. Beginning Temperature started at 36.9 after second unit Temperature dropped to 36.8 Beginning Pulse started at 77 after the second unit it rose to 91. 4. Interview with personnel 2 on October 19, 2018 revealed that Nursing Services utilized the same policy and procedure as the laboratory. Personnel 2 revealed that nursing services were only initiating a possible transfusion reaction if the temperature exceeded 1 degree Celsius. Personnel 2 stated that Nursing Services had no written policies or procedures for what would be considered a rise (hypertension) or decrease (hypotension) in blood pressure or pulse for a patient receiving a transfusion. Their policy does not spell out transfusion reaction criteria and documentation failed to capture clinical changes during transfusion of the cited patients. 5. Interview with Personnel 15 (pathologist) on October 19, 2018 revealed she was unaware of the issues with what vital signs are to monitored and when a possible transfusion reaction should be initiated. Further discussion with personnel 15 revealed that for the patients cited above that policy may need to be changed in order to capture all possible transfusion reactions and that nursing staff may need additional training in possible transfusion reaction workups.
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 Histopathology for one (1) of six (6) patients reviewed. Findings: 1. Observation by surveyors during the laboratory tour on October 15, 2018 revealed the laboratory utilizes the Tissue Tek Cryostat along with the Zeiss Primo Star Microscope for performing Frozen Sections in Histopathology. 2. Review of a random selection of Histopathology Patient Test Record and Quality Control Records for Frozen Sections revealed the laboratory did not take corrective action on January 4, 2018 for Patient 64, when QC failed to meet acceptability criteria for the staining of Frozen Sections. Review of the Quality Control Records revealed that the staining quality was documented as poor. 3. Interview with Personnel 15, 2018 on October 19, 2018 revealed when quality control for staining fails to meet acceptability criteria that it is the practice of the pathologists to recut or restain another section to ensure that the staining process allows for an accurate and reliable result. Personnel 2 and 15 confirmed the laboratory did not document corrective actions for Patient 64 on January 4, 2018
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 record review, and interview with personnel, the laboratory's Quality Assurance monitors failed to identify and correct quality issues in Analytic Systems. Findings: 1. A review of patient test records and quality control records indicated problems with the analytic system as follows: a) The laboratory failed to have a complete policy and procedure manual. Refer to D5401. b) The laboratory failed to maintain complete policies and procedures for Histology.. Refer to D5403 I. c) The laboratory failed to ensure the laboratory policy and procedure manual contained complete instructions for Blood Bank. Refer to D5403 II. d) The failed to ensure patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis are analyzed within ten (10) minutes according to laboratory policy for sixty (60) of sixty (60) patients reviewed. Refer to D5411. e) The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Diesse Mini-Cube ESR Automated System. Refer to D5423 I. f) The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Grifols Blood Bank System. Refer to D5423 II. g) The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy performed utilizing the Sure Vue HCG Combo Kit, for one (1) of sixteen (16) patients reviewed. Refer to D5449. h) The laboratory failed to perform two levels of control materials each eight

	(8) hours of patient testing for D-Dimer testing performed on the Siemens Stratus CS Acute Care Diagnostic System, for one (1) of fifty two (52) patients reviewed. Refer to D5545. i) The laboratory failed to document the performance of positive and negative quality control material each day of patient testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing as required by the manufacturer for five (5) of five (5) patient test days reviewed. Refer to D5551. j) The laboratory failed to initiate a Transfusion Reaction Workups for five (5) of five (5) patients reviewed. Refer to D5559. k) The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Histopathology for one (1) of six (6) patients reviewed. Refer to D5783. 2. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. 3. Interview with personnel 2 on October 19, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
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 record review and interview with personnel, the laboratory failed to include the address of the laboratory location where testing was performed on Histopathology patient final reports for three (3) of six (6) patients. Findings: 1. Review of random selection of patient test reports revealed the laboratory did not include the physical address of the laboratory where interpretation was performed for the following three (3) patients: Patient 63 Patient 64 Patient 65 2. Interview with Personnel 2 and 15 on October 19, 2018 stated the name and address of the laboratory performing the microscopic reading is required by laboratory policy. Personnel 2 confirmed for Patient 63 and 64 the laboratory documented the wrong laboratory as performing the testing. Personnel 2 also confirmed for Patient 65 the laboratory failed to include an address of the laboratory 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 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 laboratory personnel performed testing as required for accurate and reliable results. Refer to D6014. 2. The Laboratory Director failed to ensure that quality control programs were established to assure the quality of laboratory testing. Refer to D6020. 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.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to document the collection date and time for patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis for sixty (60) of sixty (60) patients reviewed. Refer to D5305. 2. The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 3. The failed to ensure patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis are analyzed within ten (10) minutes according to laboratory policy for sixty (60) of sixty (60) patients reviewed. Refer to D5411.
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 quality control programs were established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy performed utilizing the Sure Vue HCG Combo Kit, for one (1) of sixteen (16) patients reviewed. Refer to D5449. 2. Thelaboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Siemens Stratus CS Acute Care Diagnostic System, for one (1) of fifty two (52) patients reviewed. Refer to D5545.
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. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic and analytic system as follows: a) The laboratory failed to document the collection date and time for patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis for sixty (60) of sixty (60) patients reviewed. Refer to D5305. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. c) The failed to ensure patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis are analyzed within ten (10) minutes according to laboratory policy for sixty (60) of sixty (60) patients reviewed. Refer to D5411. d) The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy performed utilizing the Sure Vue HCG Combo Kit, for one (1) of sixteen (16) patients reviewed. Refer to D5449. e) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Siemens Stratus CS Acute Care Diagnostic System, for one (1) of fifty two (52) patients reviewed. Refer to D5545. 2. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5393 and D5793. 3. Interview with personnel 2 on October 19, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
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 and scientific oversight for the laboratory. Refer to D6036.
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 Consultant failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the FORM CMS 209 submitted to the surveyor on July 16, 2018 revealed that personnel 2 fulfilled the duties for Technical Consultant. 2. Observation, record review and interview with personnel revealed the Technical Consultant failed to address the following problems identified in the laboratory: a) The laboratory failed to document the collection date and time for patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis for sixty (60) of sixty (60) patients reviewed. Refer to D5305. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. c) The failed to ensure patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis are analyzed within ten (10) minutes according to laboratory policy for sixty (60) of sixty (60) patients reviewed. Refer to D5411. d) The laboratory failed to perform a positive and negative control each day of patient testing for Serum Pregnancy performed utilizing the Sure Vue HCG Combo Kit, for one (1) of sixteen (16) patients reviewed. Refer to D5449. e) The laboratory failed to perform two levels of control materials each eight (8) hours of patient testing for D-Dimer testing performed on the Siemens Stratus CS Acute Care Diagnostic System, for one (1) of fifty two (52) patients reviewed. Refer to D5545. 3. Review of the Laboratory's Policy and Procedure Manual revealed the laboratory establish a Quality Assurance Plan that covered all phases of testing; however the laboratory failed to identify and correct the problems cited above. Refer to D5393 and D5793. 3. Interview with personnel 2 on October 19, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
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 for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory established studies for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the specialties/subspecialties of Hematology and Immunohematology. Refer to D6086. 2. The Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Refer to D6087. 3. The Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Refer to D6093. 4. 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 D6094. 5. The Laboratory Director failed to ensure that the laboratory took corrective action when quality control (QC) values were unacceptable for

	Histopathology for one (1) of six (6) patients reviewed. Refer to D6096. 6. The Laboratory Director failed to ensure that the laboratory had a complete policy and procedure manual. Refer to D6106.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 the Laboratory Director, the Laboratory Director failed to ensure the laboratory established studies for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the specialties/subspecialties of Hematology and Immunohematology. Findings: 1. The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Diesse Mini-Cube ESR Automated System. Refer to D5423 I. 2. The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Grifols Blood Bank System. Refer to D5423 II. 3. Interview with Personnel 2 and 3 on October 16, 2018 revealed they were unaware the Diesse Mini-Cube ESR Automated System and Grifols Blood Bank System had not gone through the FDA test categorization to determine the complexity of the test. Personnel 2 and 3 confirmed the laboratory failed to "establish" accuracy, precision, reportable and reference ranges, and analytical specificity and sensitivity for both.
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 record review and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required for accurate and reliable results. Findings: 1. The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. 2. The laboratory failed to initiate a Transfusion Reaction Workups for five (5) of five (5) patients reviewed. Refer to D5559. 3. The laboratory failed to include the address of the laboratory location where testing was performed on Histopathology patient final reports for three (3) of six (6) patients. Refer to D5805.
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 review of laboratory policy and procedure manual, quality control and patient test records and interview with personnel, the Laboratory Director failed to ensure that quality control programs are established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to document the performance of positive and negative quality control material each day of patient testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing as required by the manufacturer for five (5) of five (5) patient test days reviewed. Refer to D5551. 2. Interview with Personnel 2 on October 19, 2018 revealed she was unaware of the package insert requirements. Personnel 2 confirmed only Tubes 1 and 2 from the DG Gel Extended Control are utilized by the laboratory and also confirmed the laboratory failed to include a positive and negative test for all Blood Bank testing performed.
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 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. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory had a Quality Assurance Policy however, the monitors failed to identify any of the deficiencies identified with the preanalytic and analytic system as follows: 1. A review of patient test records and quality control records indicated problems with the preanalytic and analytic system as follows: a) The laboratory failed to document the collection date and time for patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis for sixty (60) of sixty (60) patients reviewed. Refer to D5305. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. c) The laboratory failed to have a complete policy and procedure manual. Refer to D5401. d) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures for Histology. Refer to D5403 I. e) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures for Blood Bank. Refer to D5403 II. f) The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Diesse Mini-Cube ESR Automated System. Refer to D5423 I. g) The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Grifols Blood Bank System. Refer to D5423 II. h) The laboratory failed to document the performance of positive and negative quality control material each day of patient testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing as required by the manufacturer for

	five (5) of five (5) patient test days reviewed. Refer to D5551. i) The laboratory failed to initiate a Transfusion Reaction Workups for five (5) of five (5) patients reviewed. Refer to D5559. j) The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Histopathology for one (1) of six (6) patients reviewed. Refer to D5783. 2. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. 3. Interview with personnel 2 on October 19, 2018 confirmed the laboratory failed to identify the deficiencies cited above.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that the laboratory took corrective action when quality control (QC) values were unacceptable for Histopathology for one (1) of six (6) patients reviewed. Refer to D5783.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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 with personnel, the Laboratory Director failed to ensure that the laboratory had a complete policy and procedure manual. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: a) The laboratory failed to have complete policies and procedures. Refer to D5401. b) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures for Histology. Refer to D5403 I. c) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures for Blood Bank. Refer to D5403 II. 2. Interview with Personnel 2 on October 16, 2018 confirmed the policy and procedure manual was incomplete
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical

	Supervisor failed provide technical and scientific oversight for the laboratory. Refer to D6112.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the Technical Supervisor failed to provide technical and scientific oversight for the laboratory. Findings: 1. Review of the CMS Form 209 submitted to surveyors on June 6, 2018 revealed that Personnel 1 was assigned as the Technical Supervisor to provide technical oversight of the laboratory. 2. A review of patient test records and quality control records indicated problems with the preanalytic and analytic system as follows: a) The laboratory failed to document the collection date and time for patient samples performed on the Abbott iSTAT Analyzer for Blood Gas Analysis for sixty (60) of sixty (60) patients reviewed. Refer to D5305. b) The laboratory failed to establish detailed written instructions for the facilities the laboratory provides services for to maintain the integrity of samples and ensure accurate and reliable testing. Refer to D5317. c) The laboratory failed to have a complete policy and procedure manual. Refer to D5401. d) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures for Histology. Refer to D5403 I. e) The laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures for Blood Bank. Refer to D5403 II. f) The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Diesse Mini-Cube ESR Automated System. Refer to D5423 I. g) The laboratory failed to establish and verify performance specifications for accuracy, precision reportable and reference ranges (normal values) and analytical sensitivity and specificity for the Grifols Blood Bank System. Refer to D5423 II. h) The laboratory failed to document the performance of positive and negative quality control material each day of patient testing for ABO, Rh, Antibody Screen (AbScr) and Compatibility (Xmatch) testing prior to patient testing each day of patient testing as required by the manufacturer for five (5) of five (5) patient test days reviewed. Refer to D5551. i) The laboratory failed to initiate a Transfusion Reaction Workups for five (5) of five (5) patients reviewed. Refer to D5559. j) The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Histopathology for one (1) of six (6) patients reviewed. Refer to D5783. 3. The laboratory has a Quality Assurance Policy that identified specific monitors that were routinely performed by the laboratory; however, the monitors failed to identify any of the deficiencies identified with the analytic systems. 4. Interview with personnel 2 on October 19, 2018 confirmed the laboratory failed to identify the deficiencies cited above.