Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0451122	09/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Mercy Hospital	218 E Pack, Moundridge, KS	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, erythrocyte sedimentation rate (ESR) quality control (QC) documentation, patient test logs, and interview with General Supervisor (GS) #1, the laboratory failed to test the ESR proficiency testing samples it received from the proficiency testing (PT) program in the same manner as it tested patient specimens. Findings Include: 1. Review of the laboratory's policy titled "Proficiency Testing", signed by the Laboratory Director (LD) on 09/10/2005, found the following directions: II. Handling of Proficiency Testing Specimens - Specimens received for purposes of proficiency testing will be handled and tested in the same manner as patient samples unless specific handling requirements are specified in the literature. 2. Review of the laboratory's procedure titled "Excite Mini Erythrocyte Sedimentation Rate", signed by the Laboratory Director (LD) on 08/27/2018, found the following directions: Quality Control: ... Control samples both normal and abnormal, need to be run once every month and the values fall within acceptable limits. 3. Review of the laboratory's ESR QC documentation and patient test logs found the laboratory performed extra QC when PT samples were tested as follows: 07/19/2017 Two patient tests were performed. Following the two patient tests, QC and 2 PT samples (API 03 and 04) were

	performed. QC was performed again on 07/27/2017. No documentation indicating the reason for the extra QC analysis was present. 4. GS #1 stated they were unsure why testing personnel (TP) had run extra QC with the PT and stated they were unaware that TP were running extra QC with PT samples. GS #1 further stated the laboratory does not run QC with each patient sample. The interview occurred 09/13/2018 at 10: 08 AM.
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: The cumulative deficient practices identified under the specialty of Immunohematology have been determined to constitute an Immediate Jeopardy. Based on review of the laboratory's policies and procedures, quality control documentation, patient test records and final test reports, instrument function check documentation, transfusion records, temperature documentation, and quality assessment documentation, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1271, and 493.1281 through 493.1299. Findings Include: 1. The laboratory failed to ensure a written procedures manual for all immunohematology tests, assays, and examinations performed by the laboratory was available to, and followed by, laboratory personnel. (Refer to D5401) 2. The laboratory failed to ensure that the Becton Dickinson (BD) Affirm VPIII, chemistry, immunohematology, erythrocyte sedimentation rate (ESR), hematology complete blood count (CBC) and manual differential, and coagulation procedures included corrective action to take when control results fail to meet the laboratory's criteria for acceptability, the laboratory's system for entering results in the patient record and reporting patient results, and the description of the course of action to take if a test system becomes inoperable. (Refer to D5403) 3. The laboratory failed to ensure that immunohematology reagents, solutions, and control materials, were not be used when they had exceeded their expiration date. (Refer to D5417) 4. The laboratory failed to ensure immunohematology pipette function checks were within the laboratory's established limits. (Refer to D5435, Item 2) 5. The laboratory failed to ensure immunohematology centrifuge function checks were within the laboratory's established limits. (Refer to D5435, Item 3) 6. The laboratory failed to perform quality control each day of patient testing for the immunohematology test procedures that produce graded or titered results. (Refer to D5451) 7. The laboratory failed to ensure that blood and blood products were stored under appropriate conditions, between 1 and 6 degrees Celsius (C). (Refer to D5555, Item 1) 8. The laboratory failed to store blood and blood products under appropriate conditions that included an adequate, audible temperature alarm system that monitored blood and blood product storage temperatures over a 24-hour period. (Refer to D5555, Item 2) 9. The laboratory failed to maintain an information or record system that included the records and dates of all immunohematology specimen testing (to include the identity of the personnel who performed the test(s)) and the results of testing performed. (Refer to D5787)
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 review of the laboratory's 2017 and 2016 immunohematology patient test records and immunohematology policies and procedures, the laboratory failed to ensure a written procedures manual for all immunohematology tests, assays, and examinations performed by the laboratory was available to, and followed by, laboratory personnel. Findings Include: 1. The surveyor requested the laboratory's ABO/Rh policies and procedures from General Supervisor (GS) #1. GS #1 provided the surveyor with two procedures written by the manufacturer titled "ABO Forward and Reverse Grouping / D Antigen Typing" and "ABO Forward Grouping / D Antigen Typing". Directions dictating situations or parameters for the use of the forward and reverse blood typing gel card versus the forward grouping blood typing gel cards was not defined in the policies and procedures. 2. Review of the procedure titled "ABO Forward and Reverse Grouping / D Antigen Typing" found the following directions: ABO Forward and Reverse Grouping / D Antigen Typing Test Procedure 6. Add 10-12.5 ul of 4% +/-1% red blood cells diluted in MTS Diluent 2 PLUS to the Anti-A, Anti-B, Anti-D, and Control microtubes. Interpretation of Results The test cannot be interpreted in agglutination occurs in the control gel microtube. 3. Review of the laboratory's 2017 and 2016 immunohematology patient test records titled "Transfusion Service Testing Record" found the laboratory failed to perform and document the D control according to the laboratory's procedure on 20 out of 114 packed red blood cell (PRBC) donor units as follows: 10/02/2017 Unit ending in 813005 Rh Typing: Anti-D: 4+ D Control: BLANK Unit ending in 38500* Rh Typing: Anti-D: 4+ D Control: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 12/01/2017. 07/29/2017 Unit ending in 70800P Rh Typing: Anti-D: 4+ D Control: BLANK Unit issued for transfusion. Unit ending in 52000M Rh Typing: Anti-D: 0 D Control: BLANK Unit issued for transfusion. The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 12/01/2017. 03/30 /2017 Unit ending in 676007 Rh Typing: Anti-D: 4+ D Control: BLANK Unit issued for transfusion. Unit ending in 39000E Rh Typing: Anti-D: 4+ D Control: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 07/28/2017. 03/17/2017 Unit ending in 102006 Rh Typing: Anti-D: 4+ D Control: BLANK Unit ending in 15700D Rh Typing: Anti-D: 4+ D Control: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 07/28/2017. 03/16/2017 Unit ending in 210007 Rh Typing: Anti-D: 4+ D Control: BLANK Unit ending in 911007 Rh Typing: Anti-D: 4+ D Control: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 07/28/2017. 08/30/2016 Unit ending in 758002 Rh Typing: Anti-D: 4+ D Control: BLANK Unit ending in 823000 Rh Typing: Anti-D: 0 D Control: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 11/04/2016. 08/03/2016 Unit ending in 72800Q Rh Typing: Anti-D: 0 D Control: BLANK Unit issued for transfusion. Unit ending in 93700E Rh Typing: Anti-D: 0 D Control: BLANK Unit issued for transfusion. The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 11/04/2016. 06/06/2016 Unit ending in 61200F Rh Typing: Anti-D: 0 D Control: BLANK Unit issued for transfusion. Unit ending in 80200C Rh Typing: Anti-D: 0 D

	Control: BLANK Unit issued for transfusion. The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 06/10/2016. 05/05/2016 Patient Rh Typing: Anti-D: 4+ D Control: BLANK Unit ending in 37500T Rh Typing: Anti-D: 4+ D Control: BLANK Unit was issued for transfusion. Unit ending in 81600R Rh Typing: Anti-D: 4+ D Control: BLANK Unit was issued for transfusion. Unit ending in 44400F Rh Typing: Anti-D: 4+ D Control: BLANK Unit ending in 113005 Rh Typing: Anti-D: 4+ D Control: BLANK Unit was issued for transfusion. The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 06/10/2016.
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: Based on review of the laboratory's policies and procedures and interview with General Supervisor (GS) #1, the laboratory failed to ensure that the Becton Dickinson (BD) Affirm VPIII, chemistry, immunohematology, erythrocyte sedimentation rate (ESR), hematology complete blood count (CBC) and manual differential, and coagulation procedures included corrective action to take when control results fail to meet the laboratory's criteria for acceptability, the laboratory's system for entering results in the patient record and reporting patient results, and the description of the course of action to take if a test system becomes inoperable was included in the laboratory's procedures. Findings Include: 1. The surveyor requested the laboratory's policies and procedures for the Becton Dickinson (BD) Affirm VPIII, chemistry, immunohematology, ESR, automated CBC, manual differential, and coagulation tests performed by the laboratory. GS #1 stated the laboratory used the manufacturer's instruction with supplemental quality control (QC) procedures as the laboratory's policies and procedures for the following tests/departments: - BD Affirm VPIII The interview occurred 09/13/2018 at 10:37 AM. - Immunohematology (ABO/Rh, antibody screen, direct antiglobulin test (DAT), and compatibility crossmatch) The interview occurred 09/13/2018 at 11:17 AM. - Chemistry The interview occurred 09 /13/2018 at 5:02 PM. - Coagulation The interview occurred 09/13/2018 at 5:08 PM. - Hematology The interview occurred 09/13/2018 at 5:10 PM. GS #1 provided copies of the manufacturer's instructions and supplemental policies and procedures to the

	surveyor. 2. Review of the manufacturer's instructions and the laboratory's supplemental policies and procedures found the procedures failed to address all required, and applicable, elements as follows: - BD Affirm VPIII manufacturer's instructions failed to address: --Corrective actions to take when control results fail to meet the laboratory's criteria for acceptability --The laboratory's system for entering results in the patient record and reporting patient results --The description of the course of action to take if a test system becomes inoperable - Immunohematology (ABO/Rh, antibody screen, DAT) manufacturer's instructions and supplemental procedures titled "ABO Forward and Reverse Grouping / D Antigen Typing", "ABO Forward Grouping / D Antigen Typing", "Direct Antiglobulin Test", and "Antibody Detection Method - Two Cell Screen" failed to address: --Corrective actions to take when control results fail to meet the laboratory's criteria for acceptability --The laboratory's system for entering results in the patient record and reporting patient results --The description of the course of action to take if a test system becomes inoperable - Chemistry manufacturer's instructions and supplemental procedures titled "Chemistry Procedures" and "Quality Control - Chemistry" failed to address: --The laboratory's system for entering results in the patient record and reporting patient results --The description of the course of action to take if a test system becomes inoperable - Hematology (automated CBCs) manufacturer's instructions and supplemental procedures titled "Operation of the Sysmex XS-1000i Hematology Analyzer" and "Quality Control - Hematology Procedures" failed to address: --The laboratory's system for entering results in the patient record and reporting patient results --The description of the course of action to take if a test system becomes inoperable - Hematology (manual differential) policy and procedure titled "Criteria for Review of Wright's Stained Slides" failed to address: --Corrective actions to take when control results fail to meet the laboratory's criteria for acceptability --The laboratory's system for entering results in the patient record and reporting patient results --The description of the course of action to take if a test system becomes inoperable - Coagulation manufacturer's instructions and supplemental procedures titled "Prothrombin Time (PT) Test", "Activated Partial Thromboplastin Time (APTT)", and "Quality Control - Coagulation Procedures" failed to address: --The laboratory's system for entering results in the patient record and reporting patient results --The description of the course of action to take if a test system becomes inoperable - ESR policy and procedure titled "Excite Mini Erythrocyte Sedimentation Rate" failed to address: --Corrective actions to take when control results fail to meet the laboratory's criteria for acceptability --The laboratory's system for entering results in the patient record and reporting patient results --The description of the course of action to take if a test system becomes inoperable
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert instructions, review of the laboratory's immunohematology quality control (QC) records, and interview with General Supervisor (GS) #1, the laboratory failed to ensure that immunohematology reagents, solutions, and control materials were not be used when they had exceeded their expiration date. Findings Include: 1. Review of the manufacturer's package insert

instructions titled "Red Blood Cell Diluent MTS (Trademark) Diluent 2 PLUS", "Anti-Human Globulin Anti-IgG (Rabbit) MTS (Trademark) Anti-IgG Card", "Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card" and "Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal Grouping Card" found the following directions and statements: Red Blood Cell Diluent MTS (Trademark) Diluent 2 PLUS Precautions - Do not use beyond expiration date Materials Required but not Provided - Refer to the appropriate package insert for the ID-Micro Typing System (Trademark) test being used. Anti-Human Globulin Anti-IgG (Rabbit) MTS (Trademark) Anti-IgG Card Precautions - Do not use beyond expiration date. Materials Required but not Provided - Quality Control Material known to give the appropriate positive and negative test results for each reagent requiring quality control. Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card Materials Required but not Provided - MTS (Trademark) Diluent 2 PLUS Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal Grouping Card Materials Required but not Provided - MTS (Trademark) Diluent 2 PLUS 2. Review of the laboratory's 2018, 2017, and 2016 QC records titled "Blood Bank Reagent Quality Control Log" and patient test records titled "Transfusion Service Testing Record" found expired reagents were used as follows: 01 /25/2018 MTS Diluent Plus Lot #: MDP143 Expiration Date: 2018-01-24 The expired reagent was used to test one patient for ABO and Rh. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 08/27/2018. 03/30/2017 MTS Diluent Plus Lot #: MDP128 Expiration Date: 03/24/2017 The expired reagent was used to test one patient and two packed red blood cell (PRBC) units for ABO and Rh. One unit was issued to the patient for transfusion. A handwritten note on the QC log, dated 04/01/2017 and signed by GS #1, stated "MTS Diluent Plus expired. QC performance acceptable. No reactions noted and no patient harm. Put into a corrective action to do a monthly check. When ordering from supplier to recheck outdates and order in advance." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 03/17/2017 Anti IgG (Rabbit) Lot#: 020916001-21 Expiration Date: 02/28/2017 The expired reagent was used to perform two compatibility crossmatches between a patient and PRBC donor units. A handwritten note on the QC log, dated 07/18/2017 and signed by GS #1, stated "IgG cards had expired ..." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 03/16/2017 Anti IgG (Rabbit) Lot#: 020916001-21 Expiration Date: 02/28/2017 The expired reagent was used to perform a patient's antibody screen and two compatibility crossmatches between the patient and PRBC donor units. A handwritten note on the QC log, dated 07/18/2017 and signed by GS #1, stated "IgG cards had expired ..." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 03/11/2017 Anti IgG (Rabbit) Lot#: 020916001-21 Expiration Date: 02/28/2017 The expired reagent was used to perform two compatibility crossmatches between the patient and PRBC donor units. The units were issued to the patient for transfusion. A handwritten note on the QC log, dated 07 /18/2017 and signed by GS #1, stated "IgG cards had expired ..." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 03/10 /2017 Anti IgG (Rabbit) Lot#: 020916001-21 Expiration Date: 02/28/2017 The expired reagent was used to perform a patient's antibody screen. The patient was issued two units of PRBC on 03/11/2017 for transfusion. A handwritten note on the QC log, dated 07/18/2017 and signed by GS #1, stated "IgG cards had expired ..." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18 /2017. 07/17/2016 MTS Diluent Plus Lot #: MDP116 Expiration Date: 2016-07-06 The expired reagent was used to test one newborn patient for a direct antiglobulin test (DAT). A handwritten note on the QC log, dated 07/30/2016 and initialed by GS #1, stated "7-17-16's analysis apparently run on expired diluent plus. Patient had no

adverse problems. New diluent ordered." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 06/13/2016 Negative Control Lot #: BA9864 Expiration Date: 03/27/2016 The expired control was used to test reagents on a day that a patient ABO, Rh, and antibody screen was performed. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 06/07/2016 Negative Control Lot #: BA9864 Expiration Date: 03/27 /2016 The expired control was used to test reagents on a day that one PRBC donor unit was tested for ABO/Rh and a compatibility crossmatch between the patient and the PRBC donor unit was performed. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 06/06/2016 Negative Control Lot #: BA9864 Expiration Date: 03/27/2016 The expired control was used to test reagents on a day that two patients ABO, Rh, and antibody screen were performed. Four PRBC donor units were tested for ABO/Rh and compatibility crossmatches between the patient and donor units were performed. Four out of four units crossmatched were issued to the patients for transfusion. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 06/01/2016 Negative Control Lot #: BA9864 Expiration Date: 03/27/2016 The expired control was used to test reagents on a day that a patient ABO, Rh, and antibody screen was performed. Two PRBC units were tested for ABO/RH and compatibility crossmatches between the patient and the two PRBC donor units were performed. The two units were issued to the patient for transfusion. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 05/26/2016 Negative Control Lot #: BA9864 Expiration Date: 03/27/2016 The expired control was used to test reagents on a day that two patients were tested for ABO, Rh, and antibody screen. Two donor units were tested for ABO/Rh and compatibility crossmatches between the two units of PRBC donor units and the second patient were performed. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 04/08/2016 Negative Control Lot #: BA986A Expiration Date: 03/27/2016 A handwritten note on the QC log, dated 04/30/2016 and initialed by GS #1, stated " ...New negative control ordered." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 04/07/2016 Negative Control Lot #: BA986A Expiration Date: 03/27/2016 The expired control was used to test reagents on a day that one patient was tested for ABO, Rh, and antibody screen and three units of PRBC donor units were tested for ABO/Rh. Compatibility crossmatches between the three units of PRBC donor units and the patient were performed. A handwritten note on the QC log, dated 04/30/2016 and initialed by GS #1, stated " ...New negative control ordered." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 04/05/2016 Negative Control Lot #: BA986A Expiration Date: 03/27 /2016 The expired control was used to test reagents on a day that five units of PRBC donor units were tested for ABO/Rh and compatibility crossmatches between were performed between those units and a patient. Two of the five units were issued to the patient for transfusion. A handwritten note on the QC log, dated 04/30/2016 and initialed by GS #1, stated " ...New negative control ordered." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 04/04 /2016 Negative Control Lot #: BA986A Expiration Date: 03/27/2016 The expired control was used to test reagents on a day that one patient was tested for ABO, Rh, and antibody screen. Three units of PRBC donor units were tested for ABO/Rh and compatibility crossmatches between were performed between those units and the patient. Three of the three units were issued to the patient for transfusion. A handwritten note on the QC log, dated 04/30/2016 and initialed by GS #1, stated " ... New negative control ordered." The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 03/26/2016, 03/23/2016, 03/12/2016, 03 /09/2016, 03/08/2016, 03/07/2016, and 02/26/2016 Positive Control Lot #: DB301A1

	Expiration Date: 01/30/2016 A second, in-dated lot number (DB310A1, expiration 02 /04/2018) was listed next to the expired control. No open or in-use date was documented for the in-dated control. The expired control may have been used to test reagents that were used for three patients' DATs and five patients' ABO, Rh, and antibody screens. Four units of PRBC donor units were tested for ABO/Rh and compatibility crossmatches between were performed between those units and the patients. Two of the four units were issued to the patient for transfusion. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 02/24/2016 Positive Control Lot #: DB301A1 Expiration Date: 01/30/2016 The expired control was used to test reagents that were used for testing ABO, Rh, and antibody screen for one patient and DAT on another patient. One unit of Rhogam was issued for the first patient. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 02/14/2016 Positive Control Lot #: DB301A1 Expiration Date: 01/30/2016 The expired control was used to test reagents that were used for testing DAT on one patient. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 02/12/2016 Positive Control Lot #: DB301A1 Expiration Date: 01/30/2016 The expired control was used to test reagents that were used for testing ABO, Rh, and antibody screen for one patient and ABO, Rh on two PRBC donor units. Compatibility crossmatches were performed between the patient and the two donor units. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 01/31/2016 Positive Control Lot #: DB301A1 Expiration Date: 01/30/2016 The expired control was used to test reagents that were used for testing ABO, Rh, and antibody screen for one patient and ABO, Rh on three PRBC donor units. Compatibility crossmatches were performed between the patient and the three donor units. Two of the three units were issued to the patient for transfusion. The QC log was reviewed, signed and approved by the Laboratory Director (LD) on 07/18/2017. 3. GS #1 confirmed that expired immunohematology reagents were used for patient testing. The interview occurred 09/13/2013 at 12:11 PM.
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: Item 1 Based on review of the laboratory's method validation documentation and interview with General Supervisor (GS) #1, the laboratory failed to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the performance characteristics precision, reportable range, and verify that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population prior to reporting patient test results when it introduced the unmodified, FDA-cleared D-Dimer Triage test system. Findings Include: 1. GS #1 stated that the laboratory began testing D-Dimers using a Triage analyzer in November 2016. The surveyor requested the laboratory's method validation documentation for the D-Dimers performed using the Triage analyzer. The

	interview occurred 09/13/2018 at 5:35 PM. 2. Review of the method validation documentation for the D-Dimers performed on the Triage analyzer found: The laboratory performed two levels on quality control (QC), a high and low, on 10/25 /2016. The laboratory analyzed 15 samples on 10/25/2016. Three samples were excluded from the study due to the wrong type of sample preservative used. The laboratory then sent the remaining 12 samples to a reference laboratory for D-Dimer testing. After converting the reference laboratory results to the appropriate units, the laboratory used an online correlation coefficient calculator to calculate the correlation coefficient (r) between the reference laboratory results and in-house testing results. The calculated correlation coefficient was determined to be 0.98060669773818. A handwritten note that stated "Pass" was located next to the correlation coefficient value. The laboratory director (LD) reviewed, signed, and dated the documents on 11 /04/2016. No documentation demonstrating precision, reportable range, or reference interval studies were found. 3. GS #1 stated the laboratory did not have any additional method validation documentation for the D-Dimers performed on the Triage analyzer. GS #1 stated they thought that performing a correlation study was sufficient. The interview occurred 09/13/2018 at 5:35 PM. Item 2 Based on review of the laboratory's method validation documentation and interview with General Supervisor (GS) #1, the laboratory failed to review, evaluate, and approve the data collected for method validations of the new coagulation analyzer prior to patient testing. Findings Include: 1. Review of the laboratory's method validation documentation for the new coagulation analyzer, dated 05/30/2018 through 06/01/2018, found the laboratory performed and collected data on the precision, accuracy, reportable range, and reference intervals of the new analyzer. No documentation demonstrating evaluation, review, or approval of the data collected was present. 2. GS #1 stated the laboratory began using the new coagulation analyzer for patient testing in June 2018. GS #1 confirmed the laboratory and/or laboratory director had not documented the evaluation, review, or approval of the method validations before using the analyzer for patient testing. The interview occurred 09/13/2018 at 4:54 PM.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Item 1 Based on review of the laboratory's policies and procedures and interview with General Supervisor (GS) #1, the laboratory failed to define function check protocols that ensured equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. Findings Include: 1. The surveyor requested the laboratory's policies and procedures for centrifuge, pipette, timer, and thermometer function checks from GS #1. GS #1 provided the following policies and procedures: Centrifuge Maintenance and Cleaning - Signed and approved by the Laboratory Director (LD) 09/10/2018 Ortho ID-MTS Equipment Quality Control Review of the provided policies and procedures failed to find function check

protocols for the laboratory's thermometers, timers (not used for immunohematology), and pipettes (not used for immunohematology). 2. GS #1 stated the laboratory did not have policies or procedures for the function checks of thermometers, timers, or pipettes. The interview occurred 09/13/2018 at 1:46 PM. GS #1 also stated the laboratory throws away digital thermometers once their calibration has expired. The surveyor requested the laboratory's policy that states this. GS #1 stated the laboratory did not have a policy that directs personnel to dispose of timers once the calibration has expired. The interview occurred 09/13/2018 at 1:48 PM. Item 2 Based on review of the manufacturer's package insert instructions, the laboratory's policies and procedures, immunohematology function check documentation, and interview with General Supervisor (GS) #1 and Technical Supervisor (TS) #2, the laboratory failed to ensure immunohematology pipette function checks were within the laboratory's established limits. Findings Include: 1. Review of the immunohematology manufacturer's package insert instructions found the following requirements: MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card Materials Required but not Provided - Pipet: 10 to 12.5 ?L, 25 ?L and/or 50 ?L Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal Grouping Card Materials Required but not Provided - Pipet: 10 to 12.5 ?L, 25 ?L and/or 50 ?L Anti-Human Globulin Anti-IgG (Rabbit) MTS (Trademark) Anti-IgG Card Materials Required but not Provided - Pipet: 10 to 12.5 ?L, 25 ?L and 50 ?L 2. Review of the laboratory's policy and procedure titled "Ortho ID-MTS Equipment Quality Control" found the following directions: MTS ID-Tipmaster Pipettor 1. Check calibration of the 3 volumes of the ID-Tipmaster Pipettor; 12.5 ul, 25 ul, and 50 ul. 2. Acceptable ranges: 12.5 +/- 12% 25 +/- 5% 50 +/- 5% 3. Review of the laboratory's 2018, 2017, and 2016 immunohematology pipette function check documentation titled "Pipet Volume Calibration Record" and "Pipette Volume Delivery Check" found the following results that fell outside of the laboratory defined acceptability criteria: 08/22/2018 Pipette ID: MTS 000801 - 12.5 ul Volume (ul): 12.5 1:28 PM Result (Handwritten): 13.63 Result (Printed Analyzer Data): 14.44 ul Pass/Fail (Handwritten): ? Comments: high delivery Signed by TS #2 The result of 14.44 ul falls outside of the laboratory defined acceptability criteria. 1:32 PM Result (Handwritten): 13.63 Result (Printed Analyzer Data): 14.43 ul Pass/Fail (Handwritten): ? Comments: high delivery Signed by TS #2 The result of 14.43 ul falls outside of the laboratory defined acceptability criteria. 1:33 PM Result (Handwritten): 13.63 Result (Printed Analyzer Data): 12.63 ul*** Pass /Fail (Handwritten): ? Comments: high delivery Signed by TS #2 *** The printed analyzer result is the mean of five measured values: 12.96, 14.21, 13.57, 13.84, and 13.56. The analyzer reported an incorrect mean result of 12.63 ul. The correct mean result should be 13.63 ul.*** 1:35 PM Result (Handwritten): 13.63 Result (Printed Analyzer Data): 14.80 ul Pass/Fail (Handwritten): ? Comments: high delivery Signed by TS #2 The result of 14.80 ul falls outside of the laboratory defined acceptability criteria. 08/22/2018 Pipette ID: MTS 000801 - 25 ul Volume (ul): 25 1:37 PM Result (Handwritten): 27.8 Result (Printed Analyzer Data): 27.8 ul Pass/Fail (Handwritten): ? Comments: high delivery Signed by TS #2 The result of 27.8 ul falls outside of the laboratory defined acceptability criteria. 08/22/2018 Pipette ID: MTS 000801 - 50 ul Volume (ul): 50 1:28 PM Result (Handwritten): 51.6 Result (Printed Analyzer Data): 51.66 ul Pass/Fail (Handwritten): ? Comments: high delivery Signed by TS #2 4. No documentation of corrective actions for the out-of-range pipette function checks was present on the function check documentation. No corrective action protocols for failed pipette function checks were found in the laboratory's policies and procedures. 5. The surveyor asked TS #2 what actions were taken when a pipette fails to pass a function check. TS #2 stated they notify GS #1 of the failure and it is up to the GS to decide what to do. If the GS decides to replace the pipette then TS #2 will revisit the laboratory and perform a function check on the new pipette. TS #2 stated that if the

results of the pipette function checks are not out by much then they do not worry about the pipette. TS #2 stated they did not think the laboratory had a policy and procedure for corrective actions when pipettes fail function checks. The interview occurred 09/13/2018 at 1:44 PM. 6. The surveyor asked GS #1 if the immunohematology MTS pipette was still in laboratory and still in use. GS #1 stated the pipette was still in use and the laboratory had not ordered a new MTS pipette or taken any corrective actions for the failed function check. The interview occurred 09 /13/2018 at 1:47 PM. 7. Thirteen patient ABO tests were performed and reported between 08/23/2017 and the date of survey. Thirteen patient Rh tests were performed and reported between 08/23/2017 and the date of survey. Twelve patient antibody screens were performed and reported between 08/23/2017 and the date of survey. Seventeen packed red blood cell (PRBC) donor units were test for ABO and reported between 08/23/2017 and the date of survey. Seventeen PRBC donor units were tested for Rh and reported between 08/23/2017 and the date of survey. Seventeen compatibility crossmatches between patients and PRBC donor units were performed and reported between 08/23/2017 and the date of survey. Eleven units of donor PRBC were issued to three patients for transfusion between 08/23/2017 and the date of survey. Item 3 Based on review of the manufacturer's package insert instructions, the laboratory's policies and procedures and immunohematology function check documentation, the laboratory failed to ensure immunohematology centrifuge and centrifuge timer function checks were within the laboratory's established limits. Findings Include: 1. Review of the manufacturer's package insert instructions found the following requirements: MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card Materials Required but not Provided - MTS (Trademark) Centrifuge or ORTHO (Trademark) Workstation Blood Grouping Reagent MTS (Trademark) A/B /D Monoclonal Grouping Card Materials Required but not Provided - MTS (Trademark) Centrifuge or ORTHO (Trademark) Workstation Anti-Human Globulin Anti-IgG (Rabbit) MTS (Trademark) Anti-IgG Card Materials Required but not Provided - MTS (Trademark) Centrifuge or ORTHO (Trademark) Workstation 2. Review of the laboratory's policy and procedure titled "Ortho ID-MTS Equipment Quality Control" found the following directions: MTS Centrifuge: 2. Acceptable speed range: 895 +/- 25 RPM 3. Use a timer or stopwatch to measure the centrifuge timer. 4. Acceptable range: 10 min +/- 10 sec. 5. Contact OCD Customer Technical Services if the speed or timer are not within the specified ranges. 3. Review of the laboratory's 2018 immunohematology centrifuge function check documentation titled "ID-MTS Quality Control Record: MTS Centrifuge: Periodic Checks" found the following documentation: 03/28/2018 Centrifuge RPM Display: 899 Centrifuge Tachometer Display: 897 Results Acceptable? Yes or No: Yes Tech Name: TS #2 initials 08/22/2018 Centrifuge RPM Display: 899 Centrifuge Tachometer Display: 866 Results Acceptable? Yes or No: Yes Tech Name: TS #2 initials The result of 866 falls outside of the laboratory's defined acceptability criteria. No documentation of corrective actions was present. 4. Review of the laboratory's 2018 immunohematology centrifuge function check documentation titled "ID-MTS Quality Control Record: MTS Centrifuge: Periodic Checks" found the following incomplete documentation: 08 /22/2018 Centrifuge Timer: BLANK Stopwatch Timer: 10 min Results Acceptable? Yes or No Yes 03/28/2018 Centrifuge Timer: BLANK Stopwatch Timer: 10 min Results Acceptable? Yes or No Yes 08/23/2017 Centrifuge Timer: BLANK Stopwatch Timer: 10 min Results Acceptable? Yes or No Yes 03/01/2017 Centrifuge Timer: BLANK Stopwatch Timer: 10 min Results Acceptable? Yes or No Yes 08/31 /2016 Centrifuge Timer: BLANK Stopwatch Timer: 10 min Results Acceptable? Yes or No Yes 02/24/2016 Centrifuge Timer: BLANK Stopwatch Timer: 10 min Results Acceptable? Yes or No Yes 5. Three patient ABO tests were performed and reported between 03/28/2018 and the date of survey. Three patient Rh tests were performed

	and reported between 03/28/2018 and the date of survey. Three patient antibody screens were performed and reported between 03/28/2018 and the date of survey. Six packed red blood cell (PRBC) donor units were test for ABO and reported between 03 /28/2018 and the date of survey. Six PRBC donor units were tested for Rh and reported between 03/28/2018 and the date of survey. Six compatibility crossmatches between patients and PRBC donor units were performed and reported between 03/28 /2018 and the date of survey. Six units of donor PRBC were issued to three patients for transfusion between 03/28/2018 and the date of survey. Item 4 Based on review of the laboratory's policies and procedures, general laboratory pipette function check documentation, and interview with General Supervisor (GS) #1 and Technical Supervisor (TS) #2, the laboratory failed to ensure that general laboratory pipette function checks were within the laboratory's established limits. Findings Include: 1. Review of the laboratory's policies and procedures failed to find a general laboratory pipette function check policy or procedure. 2. GS #1 stated the laboratory performs pipette function checks annually but the laboratory did not have a policy or procedure for general laboratory pipette function checks. The interview occurred 09/13/2018 at 1: 46 PM. 3. Review of the laboratory's 2018, 2017, and 2016 general laboratory pipette function check documentation titled "Pipet Volume Calibration Record" and "Pipette Volume Delivery Check" found the following results that fell outside of the laboratory defined acceptability criteria: As listed on the "Pipette Volume Delivery Check" form: Acceptable Limits: Pipette Stated Volume 10 - 50 ul Acceptable Limits + 5% Pipette Stated Volume 51 - 250 ul Acceptable Limits + 5% Pipette Stated Volume 251 - 1000 ul Acceptable Limits + 3% 08/22/2018 Pipette ID: MLA 200 Volume (ul): 200 Result (Handwritten): 212.0 Result (Printed Analyzer Data): 212.3 ul Pass/Fail: Fail Comments: Will take to WPM for adjustment and retest Signed by TS #2 08/23/2017 Pipet Model/#: MLA 10 Pipet Size (ul): 10 ul Measured Volume (ul): 10.9 ul Pass /Fail: Pass The result of 10.9 ul falls outside of the laboratory's defined acceptability criteria. No documentation of corrective actions was present. Pipet Model/#: MLA 20 Pipet Size (ul): 20 ul Measured Volume (ul): 21.1 ul Pass/Fail: Pass The result of 21.1 ul falls outside of the laboratory's defined acceptability criteria. No documentation of corrective actions was present. Pipet Model/#: MLA 500 Pipet Size (ul): 500 ul Measured Volume (ul): 516 ul Pass/Fail: Pass The result of 516 ul falls outside of the laboratory's defined acceptability criteria. No documentation of corrective actions was present. 09/29/2016 Pipet Model/#: MLA 10 Pipet Size (ul): 10 ul Measured Volume (ul): 10.98ul Pass/Fail: Pass The result of 10.8 ul falls outside of the laboratory's defined acceptability criteria. No documentation of corrective actions was present. Pipet Model/#: MLA 20 Pipet Size (ul): 20 ul Measured Volume (ul): 21.4 ul Pass /Fail: Pass The result of 21.4 ul falls outside of the laboratory's defined acceptability criteria. No documentation of corrective actions was present. Pipet Model/#: MLA 500 Pipet Size (ul): 500 ul Measured Volume (ul): 518 ul Pass/Fail: Pass The result of 518 ul falls outside of the laboratory's defined acceptability criteria. No documentation of corrective actions was present. 4. GS #1 and TS #2 stated the laboratory removed the MLA 200 pipette from the laboratory when it failed calibration in 2018. The interview occurred 09/13/2018 at1:46 PM. 5. The surveyor asked TS #2 what actions were taken when a pipette fails to pass a function check. TS #2 stated they notify GS #1 of the failure and it is up to the GS to decide what to do. If the GS decides to replace the pipette then TS #2 will revisit the laboratory and perform a function check on the new pipette. TS #2 stated that if the results of the pipette function checks are not out by much then they do not worry about the pipette. TS #2 stated they did not think the laboratory had a policy and procedure for corrective actions when pipettes fail function checks. The interview occurred 09/13 /2018 at 1:44 PM.

D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) documentation and interview with General Supervisor (GS) #1, the laboratory failed to establish the number and type of control materials necessary for the automated erythrocyte sedimentation rate (ESR), manual serum hCG, and Becton Dickinson (BD) Affirm VPIII test methods. Findings Include: 1. Review of the laboratory's IQCP documentation titled "System Excyte Mini Automated ESR Analyzer" found a section titled "QC Plan" which stated: 4. QC should be run every new shipment, new lot and every month of the current lot. Results recorded in the results manual. Past QC data collected and proficiency testing show that QC testing can be run once a month without clinically significant error. No mention of the number and type of control material required for the automated ESRs was found in the laboratory's IQCP that was signed and approved by the Laboratory Director (LD) on 12/15/2015. 2. Review of the laboratory's IQCP documentation titled "BD Affirm VPIII" found a section titled "QC Plan" which stated: 4. QC should be run every new shipment, new lot and every month of the current lot. Results recorded in the results manual. Past QC data collected and proficiency testing show that QC testing can be run once a month without clinically significant error. No mention of the number and type of control material required for the BD Affirm VPIII was found in the laboratory's IQCP that was signed and approved by the Laboratory Director (LD) on 12/15/2015. 3. Review of the laboratory's IQCP documentation titled "Alere hCG Combo Cassette" found a section titled "QC Plan" which stated: 4. QC should be run every new shipment, new lot and every month of the current lot. Results recorded in the results manual. Past QC data collected and proficiency testing show that QC testing can be run once a month without clinically significant error. No mention of the number and type of control material required for the manual serum hCGs was found in the laboratory's IQCP that was signed and approved by the Laboratory Director (LD) on 12/15/2015. 4. GS #1 confirmed the laboratory's IQCP for automated ESRs, BD Affirm VPIII, and manual serum hCGs did not include the number or types of controls that should be used in the performance of quality control (QC). The interview occurred 09/13/2018 at 10:37 AM.
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 review of the manufacturer's package insert instructions, the laboratory's individualized quality control plan (IQCP), and quality control documentation, the laboratory failed to ensure the erythrocyte sedimentation rate (ESR) individualized quality control plan (IQCP) required performance of control procedures that, at minimum, met the frequency specified by the manufacturer or established. Findings Include: 1. Review of the manufacturer's package insert instruction for reagents used with the Excyte Mini titled "Excyte ESR Tubes" found the following quality control (QC) requirements specified: Quality Control ELITechGroup recommends running two levels of controls (normal and abnormal) each day of use. The recommended controls are the Accu-Sed Plus ESR controls. 2. Review of the laboratory's IQCP documentation titled "System Excyte Mini Automated ESR Analyzer" found a section titled "QC Plan" which stated: 4. QC should be run every new shipment, new lot and every month of the current lot. Results recorded in the results manual. Past QC data collected and proficiency testing show that QC testing can be run once a month without clinically significant error. The IQCP failed to meet, at minimum, the manufacturer's QC requirements. 3. Review of the laboratory's ESR QC documentation titled "Erythrocyte Sedimentation Logsheet" for 2018, 2017, and 2016 found the laboratory was performing two levels of QC one time per month.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert instructions, the laboratory's immunohematology quality control (QC) records, and immunohematology patient test records, the laboratory failed to perform quality control each day of patient testing for the immunohematology test procedures that produce graded or titered results. Findings Include: 1. Review of the Ortho-Clinical Diagnostics package insert instructions for Reagent Red Blood Cells 0.8% Affirmagen, Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card, and Red Blood Cell Diluent MTS (Trademark) Diluent 2 found the following directions: Reagent Red Blood Cells 0.8% Affirmagen Quality Control Procedures 0.8% AFFIRMAGEN, 0.8% AFFIRMAGEN 3 and 0.8% AFFIRMAGEN 4 should be tested on each day of use with positive and negative controls according to the method described in the Procedure section. Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card Materials Required but not Provided - 3% Affirmagen Reagent Red Blood Cells - 0.8% Affirmagen Reagent Red Blood Cells - 0.8%

	Affirmagen 3 Reagent Red Blood Cells - Quality Control Material known to give the appropriate positive and negative test results for each reagent requiring quality control. Examples include, but are not limited to, AlbaQ-Chek Simulated Whole Blood Controls. - MTS (Trademark) Diluent 2 PLUS Quality Control To confirm the reactivity and specificity of the microtubes containing Anti-A and Anti-B, it is recommended that each lot of cards be tested each day of use with antigen positive and antigen negative red blood cells ... To confirm the reactivity and specificity of the microtubes containing Anti-D, it is recommended that each lot of gel cards be tested on each day of use with D-positive or weak D-positive, and D-negative red blood cells ... To confirm the reactivity of the microtubes containing MTS (Trademark) Buffered Gel, it is recommended that each lot be tested each day of use with known positive and negative antibody samples with the appropriate red blood cells. Reactivity must be present with the positive sample only. Red Blood Cell Diluent MTS (Trademark) Diluent 2 Quality Control Proper controls are essential in the performance of all laboratory procedures. MTS (Trademark) Diluent 2 should be visually checked on each day of use to ensure it has not become discolored, turbid, or show any other signs of bacterial contamination. Daily Quality Control should consist of known positive and negative red blood cells diluted with each lot of MTS (Trademark) Diluent 2 and tested with the ID-Micro Typing System (Trademark) test being used. 2. Review of the laboratory's patient test log titled "Transfusion Service Testing Record" found a patient was tested for ABO and Rh on 06/26/2016. 3. Review of the laboratory's immunohematology QC records titled "Blood Bank Reagent Quality Control Log" for June 2016 no immunohematology QC was performed and documented on 06/26/2016.
D5547	HEMATOLOGY CFR(s): 493.1269(c)(d) (c) For manual coagulation tests-- (c)(1) Each individual performing tests must test two levels of control materials before testing patient samples and each time a reagent is changed; and (c)(2) Patient specimens and control materials must be tested in duplicate. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Item 1 Based on review of the laboratory's erythrocyte sedimentation rate (ESR) and complete blood count (CBC) manual differential quality control (QC) documentation, policies and procedures, individualized quality control plans (IQCP), and interview with General Supervisor (GS) #1, the laboratory failed to document all ESR and CBC manual differential control procedures performed, including lot numbers, date prepared/opened, expiration dates, and documentation demonstrating that controls were tested when shipments of reagents or stains were opened or when the laboratory prepared these materials. Findings Include: 1. Review of the laboratory's ESR QC documentation for 2018, 2017, and 2016 found documentation indicating the laboratory had opened a new lot of ESR reagent tubes on the following dates but failed to document the reagent expiration dates: 04/25/2018 - Lot A171035A 09/19 /2017 - Lot A16123MJ 07/19/2016 - Lot A1602455 Review of the laboratory's ESR QC documentation for 2018, 2017, and 2016 found documentation indicated the laboratory had opened a new lot of ESR reagent tubes on the follow date but failed to document the reagent lot number and expiration date: 04/13/2017 Review of the laboratory's ESR QC documentation for 2018, 2017, and 2016 found the laboratory failed to document the QC lot numbers and expiration dates as follows: 09/19/2017 No lot number, expiration date, or expected result range was documented for the QC

	Norm or QC High reagents. 04/13/2017 No lot number was documented for the QC Norm or QC High reagents. 2. Review of the laboratory's ESR procedure titled "Excite Mini Erythrocyte Sedimentation Rate" found no mention of documenting reagent lot numbers, expiration dates, and open/prepared dates. 3. Review of the laboratory's ESR IQCP found the use of expired reagents listed as a test system risk factor, however, the documentation of reagent lot numbers, expiration dates, and open /prepared dates was not listed as a quality control plan (QCP) requirement. 4. Review of the laboratory's 2018 and 2017 CBC manual differential QC documentation on the manual differential test logs titled "Manual Differential Log" found no documentation of the lot numbers, expiration dates, or opened/prepared dates of the stains and reagents used for manual differential slide preparation. 5. GS #1 confirmed the ESR QC documentation lacked some lot numbers and expiration dates of reagents used. The interview occurred 09/13/2018 at 10:07 AM. Item 2 Based on review of the laboratory's policies and procedures and D-Dimer quality control (QC) and patient test logs, the laboratory failed to document all D-Dimer control procedures performed, including lot numbers, date prepared/opened, expiration dates, and documentation demonstrating that controls were tested when shipments of reagents or stains were opened or when the laboratory prepared these materials. Findings Include: 1. Review of the laboratory's policy titled "Quality Control - Coagulation Procedures" found no mention or reference to documenting reagent and control lot numbers, expiration dates, or in-use dates. 2. Review of the laboratory's 2018 QC and patient test logs titled "Triage D-Dimer Patient/QC Log Sheet" found: - No expiration dates documented for control materials used in 2018. - 2 out of 4 expiration dates missing for the documented reagent lot numbers in 2018. - No in-use or opened dates for control materials or reagents used in 2018. - No reagent lot numbers or QC expected result ranges documented for the QC performed on 08/08/2018. - No reagent or control lot numbers documented for the QC performed on 06/06/2018. - No reagent or control lot numbers and no expected QC result ranges documented for the QC performed on 06/01/2018. - No control lot numbers documented for the QC performed on 05/01/2018. - No reagent or control lot numbers documented for the QC performed on 03/23/2018. - No reagent or control lot numbers documented for the QC performed on 02/26/2018. - No control lot numbers documented for the QC performed on 01/23/2018. - No control or reagent lot numbers documented for the QC performed on 12/25/2017.
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: Item 1 Based on review of the laboratory's Jewett thermographic temperature charts and interview with General Supervisor (GS) #1, the laboratory failed to ensure that blood and blood products were stored under appropriate conditions, between 1 and 6 degrees Celsius (C). Findings Include: 1. Review of the laboratory's immunohematology Jewett thermographic temperature charts for 2018 and 2017 found the blood bank refrigerator used to store blood products and

	immunohematology reagents exceeded the upper 6 degree C temperature limit on the following occasions: 05/30/2018 at approximately 12:00 PM the refrigerator temperature exceeded the 6 degree C threshold. No documentation of corrective actions or explanation of the temperature spike was present. 2. The surveyor asked GS #1 for corrective action documentation for the temperature spike on 05/30/2018. GS #1 stated they were not aware there had been a temperature spike, the refrigerator's alarm did not go off. GS #1 stated the alarm should go off at 5.5 degrees C. GS #1 stated they weren't sure why the alarm did not go off and the laboratory did not have any corrective action documentation for the temperature deviance. The interview occurred 09/13/2018 at 2:37 PM. Item 2 Based on review of the laboratory's Jewett thermographic temperature charts, refrigerator temperature logs, immunohematology patient test logs, and interview with General Supervisor (GS) #1, the laboratory failed to store blood and blood products under appropriate conditions that included an adequate, audible temperature alarm system that monitored blood and blood product storage temperatures over a 24-hour period. Findings Include: 1. Review of the laboratory's 2017 and 2016 Jewett thermographic temperature charts found handwritten documentation, dated 12/11/2016, that stated "units transferred to Almond fridge." 2. GS #1 stated the blood bank refrigerator looked like it was malfunctioning so testing personnel (TP) transferred the blood products to a different refrigerator (Almond) on 12/11/2016. The Surveyor asked GS #1 if the "Almond" refrigerator had a temperature alarm system and a thermographic continuous temperature monitoring chart system. GS #1 stated the "Almond" refrigerator did not have an alarm system or a thermographic temperature monitoring system. GS #1 stated that the "Almond" refrigerator temperature was measured using a mercury thermometer. The Surveyor asked GS #1 when the mercury thermometer had been calibrated last. GS #1 stated the thermometer had never been calibrated. GS #1 stated that hospital personnel monitored the temperature of the "Almond" refrigerator by checking and documenting the temperature displayed on the mercury thermometer every 4 hours while the blood products were stored in the refrigerator. Review of the "Almond" refrigerator temperature log titled "Almond Refrigerator Temperature" found that on 12/13/2016 the refrigerator temperature was documented at 5:45 PM. The temperature was not taken or documented again until 12/14/2016 at 3:10 AM. A total of 9 hours and 25 minutes elapsed between temperature checks. GS #1 stated the blood was returned to the blood bank refrigerator on 01/04/2017 but removed and placed back in the "Almond" refrigerator again on 01/05/2017. The blood was once again returned to the blood bank refrigerator on 01/07/2017. The interview occurred 09 /13/2018 at 2:34 PM. 3. Review of the laboratory's immunohematology patient test records titled "Transfusion Service Testing Record" found 2 units of blood were issued to 1 patient while improperly stored in the "Almond" refrigerator.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of the laboratory's immunohematology patient test logs and

	interview with General Supervisor (GS) #1, the laboratory failed to maintain an information or record system that included the records and dates of all immunohematology specimen testing (to include the identity of the personnel who performed the test(s)) and the results of testing performed. Findings Include: 1. Review of the laboratory's 2016 immunohematology test records titled "Transfusion Service Testing Record" found the tests performed on the following dates failed to indicate the identity of the personnel who performed the test: *Please note: ABS - Antibody Screen Date of Test Test: Performed: 05/11/2016 ABO, Rh, ABS 05/05 /2016 compatibility crossmatch 03/08/2016 ABO, Rh, ABS 01/31/2016 ABO, Rh, ABS The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 06/10/2016. 2. Review of the laboratory's 2017 immunohematology test records titled "Transfusion Service Testing Record" found the following incomplete test documentation: 10/30/2017 Unit ending in 88000L Rh Grouping: Anti-D: 4+ D Control: 0 Interpretation: BLANK Unit ending in 15400P Rh Grouping: Anti-D: 4+ D Control: 0 Interpretation: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 12/01/2017. 03/30/2017: Patient ABO Grouping: Anti-A: 0 Anti-B: BLANK A1: 0 B: 4+ Interpretation: BLANK Rh Grouping: Anti-D: 4+ D Control: 0 Interpretation: BLANK Unit ending in 676007 ABO Grouping: Anti-A: 0 Anti-B: BLANK Interpretation: BLANK Rh Typing: Anti-D: 4+ D Control: BLANK Interpretation: BLANK Unit ending in 39000E ABO Grouping: Anti-A: 0 Anti-B: BLANK Interpretation: BLANK Rh Typing: Anti-D: 4+ D Control: BLANK Interpretation: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 07/28/2017. 03/17/2017: Unit ending in 102006 ABO Grouping: Anti-A: 4+ Anti-B: 0 Interpretation: BLANK Rh Typing: Anti-D: 4+ D Control: BLANK Interpretation: BLANK Unit ending in 15700D ABO Grouping: Anti-A: 4+ Anti-B: 0 Interpretation: BLANK Rh Typing: Anti-D: 4+ D Control: BLANK Interpretation: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 07/28/2017. 03/16/2017: Unit ending in 210007 ABO Grouping: Anti-A: 4+ Anti-B: 0 Interpretation: BLANK Rh Typing: Anti-D: 4+ D Control: BLANK Interpretation: BLANK Unit ending in 911007 ABO Grouping: Anti-A: 4+ Anti-B: 0 Interpretation: BLANK Rh Typing: Anti-D: 4+ D Control: BLANK Interpretation: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 07/28/2017. 2. GS #1 stated the laboratory documents patient test results on the blood bank log and then transcribes the results to the final test report, which are carbon copy slips that are then scanned into the patients' electronic medical records (EMR). GS #1 stated the blood bank log and carbon copy slips are the only locations patients' blood bank results are documented. The interview occurred 09/13/2018 at 3:50 PM.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology test records, hematology final electronic test reports, and interview with General Supervisor (GS) #1, the laboratory failed to retain all records of manual differential patient testing. 1. Review of the laboratory's August 2017 through August 2018 manual differential test logs titled

	"Manual Differential Log" and final electronic test reports found the following discrepancies: Test Log 08/10/2018 at 9:45 AM Segs: 77 LympL 15 Mono: 8 Comments: Rouleaux slight Hypo 1+ Final Test Report 08/10/2018 Segs Man: 77 Lymph Man: 15 Monocyte Man: 8 Hypochrom: 1+ Rouleaux: slight Smudge Cells: 6 smudge cells No documentation in the laboratory's test record indicates the result of 6 smudge cells. Test Log 08/08/2018 No patients tested. Final Test Report 08/08/2018 Segs Man: 73 Bands Man: 2 Lymph Man: 11 Monocyte Man: 11 Eos Man: 3 Hypochrom: slight Rouleaux: slight No documentation in the laboratory's test record indicates the analytic source of the manual differential results reported on 08/08/2018. Test Log 05/22/2018 No patients tested. Final Test Report 05/22/2018 Segs Man: 94 Bands Man: 2 Lymph Man: 2 Monocyte Man: 2 No documentation in the laboratory's test record indicates the analytic source of the manual differential results reported on 08/08/2018. Test Log 10/12/2017 at 10:00 AM Band: 12 Segs: 45 Lymp: 18 Mono: 15 Comments: 2 aniso 1 NRBC 5 IMM 1 poly 2 macro Final Test Report 10/12/2017 Segs Man: 45 Band Man: 12 Lymph Man: 18 Monocyte Man: 15 Anisocyte: 2+ NRBC Man: 1 Immature Cells: 5 Polychrom: 1+ Macrocyte: 2+ Microcyte: 1+ Atyp Lymph Man: 5 No documentation in the laboratory's test record indicates the analytic source of the results 1+ microcytes and 5 atypical lymphocytes. Test Log 10/11/2017 at 12:50 PM Band: 9 Segs: 55 Lymp: 13 Mono: 9 Eos:2 Comments: 9 RL 3 imm Hypo 1+ Final Test Report 10/11/2017 Segs Man: 55 Band Man: 9 Lymph Man: 13 Monocyte Man: 9 Eos Man: 2 Atyp Lymph Man: 9 Immature Cells: 3 Hypochrom: 1+ Polychrom: 1+ Anisocyte: 2+ No documentation in the laboratory's test record indicates the analytic source of the results 1+ polychromasia and 2+ anisocytosis. Test Log 10/10/2017 No patients tested. Final Test Report 10/10/2017 collected 11:25 PM Segs Man: 45 Bands Man: 23 Lymph Man: 26 Monocyte Man: 6 Poik: 1+ Rouleaux: 1+ Anisocytosis: 2+ No documentation in the laboratory's test record indicates the analytic source of the manual differential results reported on 10/10/2017. Test Log 10 /10/2017 No patients tested. Final Test Report 10/10/2017 collected 7:13 AM Segs Man: 21 Bands Man: 39 Lymph Man: 14 Monocyte Man: 9 Basophil Man: 1 Immature Cells: 8 Atyp Lymph Man: 8 Hypochrom: 1+ Poik: 1+ Polychrom: 1+ Rouleaux: 1+ Toxic Gran: 1+ Anisocytosis: 2+ Macrocyte: 1+ Hyperchromic: 1+ Smudge Cells: 1+ Test Log 10/09/2017 One patient tested at 2:20 PM. Patient information does not match the patient information on the final test report below. Final Test Report 10/09/2017 collected 7:00 AM Segs Man: 51 Bands Man: 23 Lymph Man: 17 Monocyte Man: 6 Eos Man: 3 Poik: 2+ Rouleaux: 1+ Anisocytosis: 2+ No documentation in the laboratory's test record indicates the analytic source of the manual differential results reported for the specimen collected on 10/09/2017 at 7: 00 AM. 2. GS #1 stated the testing personnel (TP) document the results of the manual differential immediately after they examine the slide on the laboratory's manual differential test record. The results are then manually transcribed from the test record into the electronic final test report. The interview occurred 09/13/2018 at 5:59 PM.
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: Item 1 Based on review of the laboratory's Individualized Quality Control Plan

(IQCP) documentation, quality assessment (QA) policies and procedures, and interview with General Supervisor (GS) #1, the laboratory failed to establish and follow a quality assessment (QA) plan that monitored the effectiveness of the implemented IQCP. Findings Include: 1. Review of the laboratory's IQCP documentation titled "System Excyte Mini Automated ESR Analyzer" found a chart that contained the test system's risk assessment and a section titled "QC Plan". No reference to a quality assessment (QA) plan that monitored the quality control plan (QCP) was found. 2. Review of the laboratory's IQCP documentation titled "BP Affirm VPIII" found a chart that contained the test system's risk assessment and a section titled "QC Plan". No reference to a QA plan that monitored the quality control plan (QCP) was found. 3. Review of the laboratory's IQCP documentation titled "Alere hCG Combo Cassette" found a chart that contained the test system's risk assessment and a section titled "QC Plan". No reference to a QA plan that monitored the quality control plan (QCP) was found. 4. Review of the laboratory's QA policy titled "Laboratory Quality Assurance Plan" found no mention of monitoring the effectiveness of the laboratory's IQCPs. 5. GS #1 confirmed the laboratory did not have or follow a QA plan that monitored or assessed the effectiveness of the laboratory's IQCPs. The interview occurred 09/13/2018 at 10:37 AM. Item 2 Based on review of the laboratory's quality assessment (QA) policies and procedures and CLIA survey findings, the laboratory failed to establish and follow effective 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. Findings Include: 1. Review of the laboratory's quality assessment (QA) policy and procedure titled "Laboratory Quality Assurance Plan" found the following statements: Scope of Quality Assurance 2. Quality Control - Quality control results will be reviewed by the director/technical consultant each month to evaluate and review the effectiveness of corrective actions." Based on the CLIA survey findings, the laboratory's quality control QA practices were found to be ineffective. Refer to D5401, D5441, D5445, D5547 Items 1 and 2, D5451, and D5559. 2. Review of the laboratory's quality assessment (QA) policy and procedure titled "Laboratory Quality Assurance Plan" found the following statements: Month Monitors 1. One report for each inpatient and outpatient results will be pulled at random for the past month's lab work and evaluated by laboratory personnel on a monthly basis using the "Monthly QA Worksheet" (see page 13 of this section). 2. The chief technologist will evaluate the completed worksheets and summarize the monthly review on the "QA Summary By Month" (see page 14 of this section). Based on the CLIA survey findings, the laboratory's quality control QA practices were found to be ineffective. Refer to D5551, D5787, and D5789. 3. Review of the laboratory's quality assessment (QA) policy and procedure titled "Laboratory Quality Assurance Plan" found the following statements: List of suggested indicators and threshold values Quality Control Director reviews and signs all QC records 97% Based on review of the laboratory's quality control documentation, evidence of the Laboratory Director's (LD) review of quality control documentation was present on immunohematology quality control records. 4. Review of the laboratory's quality assessment (QA) policy and procedure titled "Laboratory Quality Assurance Plan" found the following statements: List of suggested indicators and threshold values Proficiency Testing PT samples are tested in the same manner as patient samples 100% Based on the CLIA survey findings, the laboratory's quality control QA practices were found to be ineffective. Refer to D2006. 5. Based on the CLIA survey findings, the laboratory's quality control QA practices were found to be ineffective and failed to monitor, assess, and when indicated correct problems identified in the analytic systems. Refer to D5403, D5417, D5421 (Items 1 and 2), D5435 (Items 1, 2, 3, and 4), D5555 (Items 1 and 2), and D6054.

D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of the laboratory's method validation documentation, competency assessment documentation, and interview with General Supervisor (GS) #1, the Technical Consultants (TC) failed to reevaluate the performance of individuals responsible for moderate complexity testing prior to reporting patient test results when test methodology and instrumentation changed. Findings Include: 1. GS #1 stated the laboratory introduced a new test method for D-Dimer analysis in November 2016 and a new coagulation analyzer for prothrombin time (PT) and partial thromboplastin time (APTT) in June 2018. The interviews occurred 09/13/2018 at 5:35 PM and 4:54 PM respectively. 2. Review of the laboratory's method validation documentation for the new D-Dimer test method found the new test method was approved by the Laboratory Director (LD) for patient testing on 11/04/2016. Review of the laboratory's method validation documentation for the new coagulation analyzer found method validations were completed on 06/01/2018. 3. Review of the laboratory's competency assessment documentation for 2018 and 2016 found competency assessments were performed on testing personnel (TP) on the following dates: TP #1 03/28/2018 03/30/2016 TP #2 02 /21/2018 12/07/2016 TP #3 02/21/2018 12/07/2016 TP #4 02/21/2018 12/07/2016 No documentation indicating competency assessments performed on TP prior to patient testing for the new D-Dimer test methodology in November 2016 or coagulation analyzer in June 2018 was present. 4. GS #1 stated training had been performed and documented for the new analyzer but confirmed that no competency assessments performed prior to patient testing for the new coagulation analyzer had been performed and documented. The interview occurred 09/13/2018 at 4:58 PM.
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 review of the laboratory's policies and procedure, immunohematology, hematology, chemistry patient test records, immunohematology, hematology, and chemistry electronic final test reports, immunohematology quality control records, immunohematology emergency release documentation, and immunohematology blood unit temperature documentation, the Laboratory Director failed to provide overall management and direction in accordance with 493.1445 of this subpart. Findings Include: 1. The Laboratory Director failed to ensure the overall operation and administration of the laboratory, to include the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (Refer to D6079)

D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedure, immunohematology, hematology, chemistry patient test records, immunohematology, hematology, and chemistry electronic final test reports, immunohematology quality control records, and immunohematology blood unit temperature documentation, and interviews with General Supervisor (GS) #1 and Technical Supervisor (TS) #2, the Laboratory Director (LD) failed to ensure the overall operation and administration of the laboratory, to include the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. Findings include: 1. The LD failed to ensure the employment of personnel who are competent to perform test procedures. (Refer to D6054) 2. The LD failed to ensure the employment of personnel who record and report test results promptly accurately and proficiently. (Refer to D5547 Items 1 and 2, D5451, D5551, D5559, D5787, and D5789) 3. The LD failed to assure compliance with applicable regulations. (Refer to D2006, D5401, D5403, D5417, D5421 Items 1 and 2, D5435 Items 1, 2, 3, and 4, D5441, D5445, D5555 Items 1 and 2, and D5791 Items 1 and 2)