Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0452987	09/11/2018
Name of Provider or Supplier	**Street Address, City, State**	
Russell Regional Hospital	200 S Main, Russell, 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
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's blood gas instrument printouts and electronic medical record (EMR) final test reports, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. Findings Include: 1. The laboratory failed to have an adequate manual or electronic system(s) in place that ensured blood gas test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. (Refer to D5801, Item 2)
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 policy and procedure manuals, quality control documentation, patient test records and final test reports, temperature monitoring documentation, emergency release documentation, manufacturer's package insert

	instructions, and interview with General Supervisor (GS) #1, 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 the written procedure for immunohematology length of crossmatch testing was followed by laboratory personnel. (Refer to D5401, Item 1) 2. The laboratory failed to ensure the written procedure for immunohematology pretransfusion testing for recipients was followed by laboratory personnel. (Refer to D5401, Item 2) 3. The laboratory failed to ensure the written procedure for immunohematology compatibility (crossmatch) testing was followed by laboratory personnel. (Refer to D5401, Item 3) 4. The laboratory failed to ensure that immunohematology testing was 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. (Refer to D5411) 5. The laboratory failed to ensure that immunohematology reagents and solutions were not used when they had exceeded their expiration date. (Refer to D5417) 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 results of immunohematology control materials met the laboratory's test system criteria for acceptability before reporting patient test results. (Refer to D5481) 8. The laboratory failed to determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents and unknown serum with known A1 and B red cells, for confirmation of ABO group. (Refer to D5551, Item 1) 9. The laboratory failed to determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents and unknown serum with known A1 and B red cells, for confirmation of ABO group. (Refer to D5551, Item 2) 10. The laboratory failed to store immunohematology blood and blood products under appropriate conditions that include an adequate temperature alarm system. (Refer to D5555, Item 1) 11. The laboratory failed to document all immunohematology control procedures performed. (Refer to D5559) 12. The laboratory failed to have immunohematology corrective action policies and procedures, necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports, available to and followed by testing personnel (TP). (Refer to D5779) 13. The laboratory failed to maintain an information or record system that included the positive identification of specimen, 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) 14. The laboratory failed to have an adequate manual or electronic system(s) in place to ensure immunohematology test results are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. (Refer to D5801, Item 1) 15. The laboratory failed to document the immediate alert of the physician requesting the emergency release O negative units when it was determined the emergency O negative unit was incompatible with the patient's sample, which constitutes an imminently life-threatening condition. (Refer to D5813)
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:
Item 1 Based on review of the laboratory's immunohematology policies and procedures and patient test logs, the laboratory failed to ensure the written procedure for immunohematology length of crossmatch testing was followed by laboratory personnel. Findings Include: 1. Review of the laboratory's policy and procedure titled "Length of Crossmatch, Frequency of Testing and Massive Transfusions" found the following directions: Policy A new blood specimen for crossmatching must be collected every three days. Day 0 is the day of the draw. The patient's positive identification band and the corresponding crossmatches are good for 3 days after collection of the sample. 2. Review of the laboratory's immunohematology patient test logs titled "Transfusion Service Testing Record" for 2018 found a patient had an ABO /Rh, antibody screen, and two crossmatches performed on 01/02/2018. The two packed red blood cell (PRBC) units crossmatched to the patient on 01/02/2018 ended in 32800Q and 13600A. PRBC unit issuing documentation found the units were issued for transfusion on 01/11/2018 at 1:29 PM and 3:24 PM respectively. The crossmatch was 9 days old on the date of issue, which exceeded the laboratory's stated standard of 3 days. Item 2 Based on review of the laboratory's immunohematology policies and procedures, patient test logs, and interview with General Supervisor (GS) #1, the laboratory failed to ensure the written procedure for immunohematology pretransfusion testing for recipients was followed by laboratory personnel. Findings Include: 1. Review of the laboratory's policies and procedures found a policy titled "Pretransfusion testing", signed by the Laboratory Director (LD) on 02/15/2016, which stated: Procedure Testing for recipient and donor shall include, at least, the following: 1. Recipient a. Anti-A b. Anti-B c. Anti-AB d. Anti-D e. Rh (D) control f. A1 Cells g. B Cells h. Antibody Screening Cells, to include at least two cells, for unexpected antibody detection: to be tested at Immediate Spin and 37 degrees Celsius (C) (with Ortho Gel IGG). 2. Review of the laboratory's 2018, 2017, and 2016 immunohematology patient test logs titled "Transfusion Service Testing Record" found the laboratory failed to perform the Rh (D) control on the following 18 patients: 08/30/2018 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 09/10/2018. 07/03/2018 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 09/10/2018. 06/15/2018 1 patient tested for Rh with no Rh (D) control documented 4 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 09/10/2018. 06/12/2018 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 09/10/2018. 03/27/2018 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 03/14/2018 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 03/10/2018 1 patient tested for Rh with no Rh (D) control documented The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 01/01/2018 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 12/14/2017 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 09/26/2017 1 patient tested for Rh with no Rh (D) control documented The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 06/27/2017 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed,

signed and dated the test log on 03/29/2018. 06/25/2017 1 patient tested for Rh with no Rh (D) control documented 3 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 04/19/2017 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 04/07 /2017 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 03/28/2017 1 patient tested for Rh with no Rh (D) control documented 1 unit issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 02/13/2017 1 patient tested for Rh with no Rh (D) control documented 2 units issued for transfusion The Laboratory Director (LD) reviewed, signed and dated the test log on 03/02/2017. 04/20/2016 1 patient tested for Rh with no Rh (D) control documented The Laboratory Director (LD) reviewed, signed and dated the test log on 11/09/2016. 04/08/2016 1 patient tested for Rh with no Rh (D) control documented The Laboratory Director (LD) reviewed, signed and dated the test log on 11/09/2016. 3. Review of the laboratory's 2018 immunohematology patient test logs titled "Transfusion Service Testing Record" found the laboratory failed to perform anti-AB (forward grouping) analysis on 49 out of 49 patients in 2018. The Laboratory Director (LD) reviewed, signed and dated the laboratory's immunohematology patient test records on 03/29/2018, 05/02/2018, and 09/10/2018. 4. GS #1 confirmed the laboratory had not documented Rh (D) controls for all patient testing. The interview occurred 09/11/2018 at 4:18 PM. Item 3 Based on review of the laboratory's immunohematology policies and procedures and patient test logs, the laboratory failed to ensure the written procedure for immunohematology compatibility (crossmatch) testing was followed by laboratory personnel. Findings Include: 1. Review of the laboratory's policies and procedures found a policy titled "Pretransfusion testing", signed by the Laboratory Director (LD) on 02/15/2016, which stated: Procedure Testing for recipient and donor shall include, at least, the following: 2. Donor c. Compatibility testing using donor cells from the originally attached segment and recipient plasma, Immediate Spin and 37 degrees Celsius (C) (with Ortho Gel IGG). 2. Review of the laboratory's 2017 and 2016 immunohematology patient test logs titled "Transfusion Service Testing Record" found the laboratory failed to perform initial spin and 37 degree C testing on the following 4 patients: 04/17/2018 Unit ending in 37300A Compatibility Testing IS: BLANK AHG: 0 Interpretation: Comp Unit ending in 914000 Compatibility Testing IS: BLANK AHG: 0 Interpretation: Comp Units ending in 37300A and 914000 were issued for transfusion on 04/17/2018 at 3:47 PM and 1:50 PM respectively. The Laboratory Director (LD) reviewed, signed and dated the test log on 05/02/2018. 10/13 /2017 Unit ending in 37300N Compatibility Testing IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp Unit ending in 88800F Compatibility Testing IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp **Please note: OCC - Ortho Coombs Control Cell** Units ending in 37300N and 88800F were issued for transfusion on 10/14/2017 at 6:48 PM and 4:29 PM respectively. The Laboratory Director (LD) reviewed, signed and dated the test log on 03/29/2018. 08/09/2016 Unit ending in 26500V Compatibility Testing IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp Unit ending in 82700Q Compatibility Testing IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp Unit ending in 63400N Compatibility Testing IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp **Please note: OCC - Ortho Coombs Control Cell** Units ending in 26500V and 82700Q were issued for transfusion on 08/09/2016 at 2:19 PM and 4:27 PM respectively. The Laboratory Director (LD) reviewed, signed and dated the test log on 11/09/2016. 08/07 /2016 Unit ending in 47500W Compatibility Testing IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp Unit ending in 34400N Compatibility Testing

	IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp Unit ending in 92600Q Compatibility Testing IS: 0 37: BLANK AHG: BLANK OCC: 0 Interpretation: Comp **Please note: OCC - Ortho Coombs Control Cell** Units ending in 47500W and 34400N were issued for transfusion on 08/08/2016 at 10:50 AM and 1:02 PM respectively. The Laboratory Director (LD) reviewed, signed and dated the test log on 11/09/2016. Item 4 Based on review of the laboratory's immunohematology test logs, incompatible unit release documentation, and interview with General Supervisor (GS) #1, the laboratory failed to ensure a written procedures manual for the issuing of incompatible immunohematology packed red blood cell (PRBC) units was available to, and followed by, laboratory personnel. Findings Include: 1. Review of the laboratory's immunohematology patient test logs titled "Transfusion Service Testing Record" found the following incompatible packed red blood cell (PRBC) units were issued for transfusion: 07/16/2018 Unit ending in 548000C Compatibility Testing Crossmatch Interpretation: Incompatible Issued for transfusion on 07/16/2018 at 12:00 PM Unit ending in 942008 Compatibility Testing Crossmatch Interpretation: Incompatible Issued for transfusion on 07/16/2018 at 2:25 PM 07/05/2018 Unit ending in 46400A Compatibility Testing Crossmatch Interpretation: Incomp Issued for transfusion on 07/05/2018 at 4:32 PM Unit ending in 88700R Compatibility Testing Crossmatch Interpretation: Incomp Issued for transfusion on 07/05/2018 at 9:00 PM 2. When questioned by the surveyor about the issuing of the incompatible PRBC units for transfusion, GS #1 provided documentation titled "Physicians Release for Incompatible Blood" for 4 out of 4 incompatible units issued for transfusion. Each were signed by the requesting physician. 2. The surveyor requested the laboratory's policy/procedure for the issuing of incompatible units from GS #1. GS #1 stated the laboratory did not have a policy /procedure for issuing incompatible units of PRBC. The interview occurred 09/11 /2018 at 4:25 PM.
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 procedure and interview with General Supervisor (GS) #1, the laboratory failed to include the laboratory's system for

	entering results in the patient record, reporting patient results and the description of the course of action to take if a test system becomes inoperable in the chemistry procedure manuals. Findings Include: 1. On the date of survey the surveyor requested the laboratory's chemistry policies and procedures. GS #1 stated the laboratory uses the manufacturer's package insert instructions as the procedure manual. The interview occurred 09/11/2018 at 11:54 AM. 2. Review of the following package insert instructions for the Abbott Architect reagents found no mention of the laboratory's system for entering results in the patient record and the course of action to take if a test system becomes inoperable: Acetaminophen Albumin BCP Alanine aminotransferase Alkaline phosphatase Ammonia ultra Aspartate aminotransferase B12 Total Beta-hCG BNP Urea Nitrogen Calcium iCarbamazepine Anti-CCP Carbon dioxide Cholesterol CRP Vario iDigoxin Direct bilirubin Ethanol Ferritin Free T3 Free T4 Folate Gamma-glutamyl transfersase Glucose Ultra HDL Hemoglobin A1C HIV Ag/Ab Combo Immunoglobulin G Immunoglobulin M Lactic Acid Lipase Magnesium STAT Myoglobin iPhenobarbital iPhenytoin Phosphorous Rheumatoid factor Salicylate Total bilirubin Transferrin Triglyceride STAT Troponin-I TSH Uric acid Valproic acid Vancomycin
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 review of the manufacturer's package insert instruction, the laboratory's immunohematology policies and procedures, and patient test logs, the laboratory failed to ensure that immunohematology testing was 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. Findings Include: 1. Review of the Ortho-Clinical Diagnostics Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card package insert instructions found the following directions: Interpretation of Results Mixed Field Red blood cell agglutinates at the top of the gel or dispersed throughout the gel microtube accompanied by a button of negative red blood cells in the bottom of the microtube. See Note below. Note: Caution must be taken in interpreting a reaction as mixed field. Additional patient history and testing will be necessary for resolution. 2. Review of the laboratory's immunohematology policies and procedures found a procedure titled "ABO Forward and Reverse Grouping / D Antigen Typing (Simultaneous ABO Forward and Reverse Grouping / D Antigen Typing Using a Single Gel Card)", which stated: Comments Interpretation of mixed-field reactions must be done with caution. The presence of fibrin, clots, or particulates may result in some red blood cells layering at the top of the gel. Mixed-field reactions are generally only observed in tests containing a dual population of red blood cells, such as a transfused patient, bone marrow recipient or when a pooled red blood cell sample is used for testing. No direction or corrective action procedures for mixed field reactions were found in the laboratory's procedure. 3. Review of the laboratory's immunohematology patient test logs titled "Transfusion Service Testing Record" found the following documentation: 01/25/2015 ABO Grouping Anti-B: 3+ Mixed No additional patient testing or documentation for the mixed field reaction was present.

	The patient was issued two units of packed red blood cells (PRBC) ending in 03100N and 38500Z on 01/25/2018 at 2:16 PM and 4:12 PM respectively.
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, the laboratory's immunohematology quality control (QC) records, and patient test records, the laboratory failed to ensure that immunohematology reagents and solutions were not used when they had exceeded their expiration date. Findings Include: 1. Review of the Ortho-Clinical Diagnostics package insert instructions for the Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal Grouping Card found the following directions: Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal Grouping Card Precautions - Do not use beyond expiration date. 2. Review of the laboratory's 2017 and 2018 immunohematology QC records titled "Blood Bank QC Form" found expired reagents were used on 3 days as follows: - 06/14/2017 and 06/15/2017 One lot number of A/B/D (Unit type cards) was listed Lot: 062416053-04 Expiration date: 6-13-17 On 06/20/2017 an in-dated lot of A/B/D (Unit type cards) was listed. The QC log was reviewed, signed, and dated by the Laboratory Director (LD) on 03/29/2018. - 07/23/2018 One lot number of A/B/D (Unit type cards) was listed Lot: 08117053-02 Expiration date: 7-17-18 On 07/31/2018 an in-dated lot of A/B/D (Unit type cards) was listed. The QC log was reviewed, signed, and dated by the Laboratory Director (LD) on 09/10/2018. 3. As listed on the laboratory's test records titled "Transfusion Service Testing Record", one packed red blood cell (PRBC) unit was tested as follows: 7-23-18 a PRBC unit ending in 18300T was tested for ABO/Rh.
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 policies and procedures, 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 laboratory's immunohematology policies and procedures found a policy titled "Quality Control of MTS Manual Gel Test System Reagents", signed by the Laboratory Director (LD) on 09/13/2016, which stated: Principle The purpose of daily quality control (QC) in the blood bank is to confirm the reliability of the test system. The test

	system includes reagents, procedures, and equipment. Testing known samples is an acceptable method of quality control. The procedures used with the reagents described are based on the principle of hemagglutination. These procedures are applicable to selected gel card applications. Directions for quality control of gel test reagents are outlined in the package insert for each MTS reagent. 2. Review of the Ortho-Clinical Diagnostics package insert instructions for Anti-Human Globulin Anti-IgG (Rabbit) MTS (Trademark) Anti-IgG Card, Reagent Red Blood Cells 0.8% Affirmagen, Reagent Red Blood Cells 0.8% Selectogen, 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: Anti-Human Globulin Anti-IgG (Rabbit) MTS (Trademark) Anti-IgG Card Quality Control To confirm the specificity and reactivity of the MTS (Trademark) Anti-IgG Card, 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. 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. Reagent Red Blood Cells 0.8% Selectogen CONTROL OF ERROR 1. 0.8% SELECTOGEN should be tested on day of use with weak antibodies following the procedure for the respective test method. Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card 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. 3. Review of the laboratory's 2017 immunohematology test records titled "Transfusion Service Testing Record" found that patient testing for ABO/Rh was performed on 11/09/2017 and 11/10/2017; patient testing for antibody screen was performed on 04/04/2017, 11 /09/2017, and 11/10/2017; and patient testing for compatibility crossmatch was performed on 11/09/2017 and 11/10/2017. 4. Review of the laboratory's 2017 QC records titled "Blood Bank QC Form" found no documentation of immunohematology QC testing for ABO/Rh, antibodies, or compatibility (crossmatch) for the dates 11/09 /2017 and 11/10/2017. An entry on the QC form date 04/04/2017 was crossed out with a curvy line. The QC records for April and November 2017 were reviewed, signed, and dated by the Laboratory Director (LD) on 03/29/2018.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test

	results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's immunohematology policies and procedures, quality control (QC) documentation, and patient test logs, the laboratory failed to ensure that results of immunohematology control materials met the laboratory's test system criteria for acceptability before reporting patient test results. Findings Include: 1. Review of the laboratory's procedure titled "Quality Control of MTS Manual Gel Test System Reagents", signed by the Laboratory Director (LD) on 09/13/2016, found the following directions: Interpretation of Results for ABO and D Red Blood Cell QC Test Procedure and for Antibody Detection QC Test Procedure Group AB Plasma know to Lack unexpected antibodies A1 Cells B Cells 0 0 Comments If unexpected results are observed, the problem may be due to improper test performance, faulty equipment, reagent contamination or deterioration. The source of the problem should be determined before test results are reported. 2. Review of the manufacturer's package insert instructions for the Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card found the following directives: Quality Control 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. Limitations of the Procedure 1. False positive or false negative test results may occur from bacterial or chemical contamination of test materials, aged blood specimens, inadequate incubation time or temperature, improper centrifugation, improper storage of materials, or omission of test samples. 2. False positive results may occur if a card that shows signs of drying is used in testing. 3. Review of the laboratory's immunohematology QC records for 2017 titled "Blood Bank QC Form" found the laboratory received QC results that failed to meet the criteria of acceptability listed above: 03/02/2017 AB Free Plasma/Source Dil 2 A1 B 4+ 2+ Performance S or U A1 B S S The QC log was reviewed, signed, and dated by the Laboratory Director (LD) on 03/21/2017. 4. Review of the laboratory's immunohematology patient test logs for 2017 titled "Transfusion Service Testing Record" found the following patient testing occurred on 03/02/2017: Patient was tested for ABO Packed Red Blood Cell (PRBC) unit ending in 11000F was tested for ABO PRBC unit ending in 21700Q was tested for ABO The PRBC units ending in 11000F and 21700Q were issued to the patient for transfusion on 03/03/2017 at 12:34 PM and 9:41 AM respectively.
D5485	CONTROL PROCEDURES CFR(s): 493.1256(h) If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. The performance of alternative control procedures must be documented. 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 document an alternative mechanism to detect immediate errors and monitor test system performance over time for tests or procedures that do not have control materials available. Findings Include: 1. Review of the laboratory's policies and procedures for wet and KOH preparations, pin worm examinations, and post vasectomy analysis found the following: The

	procedure titled "Wet Prep Examination of Body Fluids" stated: Measurements and Records Control and patient results are written down on the Miscellaneous Urinalysis Daily Worksheet located on the clipboard near the microscope. No other reference to the performance of quality control (QC) was present in the procedure. The procedure titled "Pinworm Prep" stated: Controls: N/A No other reference to the performance or documentation of alternative controls was present. The procedure titled "Semen Analysis for Post Vasectomy Check" failed to make any reference to the performance or documentation of alternative QC. 2. GS #1 stated the laboratory performs pin worm examinations, wet and KOH preparations, and post vasectomy examination in duplicate but does not document the duplicate analysis. The interview occurred 09/11 /2018 at 10:17 AM.
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 review of the laboratory's immunohematology policies and procedures, patient test records, and interview with General Supervisor (GS) #1, the laboratory failed to determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents and unknown serum with known A1 and B red cells, for confirmation of ABO group. Findings Include: 1. Review of the laboratory's policies and procedures found a policy titled "Pretransfusion testing", signed by the Laboratory Director (LD) on 02/15/2016, which stated: Procedure Testing for recipient and donor shall include, at least, the following: 1. Recipient a. Anti-A b. Anti-B c. Anti-AB d. Anti-D e. Rh (D) control f. A1 Cells g. B Cells h. Antibody Screening Cells, to include at least two cells, for unexpected antibody detection: to be tested at Immediate Spin and 37 degrees Celsius (C) (with Ortho Gel IGG). 2. Review of the laboratory's immunohematology patient test records titled "Transfusion Service Testing Record" found the laboratory failed to perform analysis on A1 and B cells with the unknown serum or plasma (reverse typing) as follows: 06 /12/2018 Serum/Plasma with A1 B blank blank This patient was issued two units of emergency release O negative packed red blood cells (PRBC) on 06/12/2018 at 12:35 AM and 1:09 AM. The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 09/10/2018. 04/07/2017 Serum/Plasma with A1 B blank blank This patient was issued two units of PRBC on 04/07/2017 at 2:44 PM and 5:10 PM. The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 04/01/2017 Serum/Plasma with A1 B blank blank The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 12/23/2016 Serum/Plasma with A1 B A2 4+ blank 4+ The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/21 /2017. 06/28/2016 Serum/Plasma with A1 B A2 0 blank 4+ The patient test records

	were reviewed, signed and dated by the Laboratory Director (LD) on 11/09/2016. 04 /08/2016 Serum/Plasma with A1 B A2 blank 4+ 4+ The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 11/09/2016. 3. GS #1 confirmed the result documentation listed above and stated that the laboratory does not use A2 cells for immunohematology testing. The interview occurred 09/11/2018 at 4:07 PM. GS #1 also confirmed that a few patients were missing ABO reverse type testing documentation. The interview occurred 09/11/2018 at 4:09 PM. Item 2 Based on review of the laboratory's immunohematology policies and procedures and patient test records, the laboratory failed to determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents and unknown serum with known A1 and B red cells, for confirmation of ABO group. Findings Include: 1. Review of the laboratory's policies and procedures found a policy titled "Pretransfusion testing", signed by the Laboratory Director (LD) on 02/15/2016, which stated: Procedure Testing for recipient and donor shall include, at least, the following: 2. Donor a. Confirmation of ABO group (forward grouping), using cells from the originally attached segment. b. Confirmation of Rh type (using Anti-D). 2. Review of the laboratory's immunohematology patient test records titled "Transfusion Service Testing Record" found the laboratory failed to determine the D (Rho) type by testing unknown red cells with anti-D (anti Rho) blood typing reagent on donor units as follows: 06/15/2018 Unit ending in 70400M Rh Typing Cells with Anti-D Anti-D: blank Unit ending in 70500K Rh Typing Cells with Anti-D Anti-D: blank The units ending in 70400M and 70500K were issued for transfusion on 06/15/2018 at 7:55 PM and 9:40 PM respectively. The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 09/10/2018. 02/26/2018 Unit ending in 82100I ABO Grouping Cells with Anti-A Anti-B blank blank Rh Typing Cells with Anti-D Anti-D: blank The unit ending in 82100I was crossmatched and available for issue. The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 07/04/2017 Unit ending in 92000E Rh Typing Cells with Anti-D Anti-D: blank Unit ending in 87200(illegible) Rh Typing Cells with Anti-D Anti-D: blank The units ending in 92000E and 87200(illegible) were crossmatched and available for issue. The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 02/01/2017 Unit ending in 366005 ABO Grouping Cells with Anti-A Anti-B 4+ blank Unit ending in 77400F ABO Grouping Cells with Anti-A Anti-B 4+ blank The units ending in 366005 and 77400F were issued for transfusion on 02/02/2017 at 10:30 AM and 12:55 PM respectively. The patient test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/21/2017.
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: Based on review of the laboratory's immunohematology thermographic temperature charts, temperature corrective action documentation, and interview with General Supervisor (GS) #1, the laboratory failed to store immunohematology blood and blood

	products under appropriate conditions that include an adequate temperature alarm system. Findings Include: 1. Review of the laboratory's 2017 thermographic temperature charts for the blood bank refrigerator found the blood bank refrigerator exceeded the acceptable range of 1 to 6 degrees Celsius (C) on the following occasions: 08/22/2017 The temperature rose above 6 degrees C at approximately 11: 00 PM. No documentation of corrective actions or notation for the temperature deviance was present on the thermographic chart. 10/06/2017 The temperature rose above 6 degrees C at approximately 1:00 PM. No documentation of corrective actions or notation for the temperature deviance was present on the thermographic chart. 2. Review of the laboratory's immunohematology manual temperature monitoring documentation titled "Blood Bank Daily Temperature Record" found no documentation of corrective actions or explanation for the out of range blood bank temperatures on 08/22/2017 and 10/06/2017. 3. GS #1 stated the laboratory did not have documentation explaining the out of range blood bank temperatures on 08/22 /2017 and 10/06/2017 or corrective action documentation for the out of range temperatures on these days. The interview occurred 09/11/2018 at 1:12 PM.
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 review of the laboratory's immunohematology policies and procedures and patient test records, the laboratory failed to document all immunohematology control procedures performed. Findings Include: 1. Review of the laboratory's immunohematology policy titled "Signing Out Donor Units", signed by the Laboratory Director (LD) on 02/15/2016, found the following directions: Procedure 2. The unit is examined visually to detect any abnormal color or appearance. If normal, notation is made in the appropriate place in the sign-out log. 3. The nurse initials the "released to" in the sign-out log with initials. The date and time of release must also be documented. 4. Laboratory personnel initial the "released by" section in the sign-out log. 2. Review of the laboratory's 2017 and 2016 immunohematology test records found the following incomplete quality control (QC) documentation: 08/16/2018 No time of issue documented for the unit ending in 19000K The test records were reviewed, signed and dated by the Laboratory Director (LD) on 09/10/2018. 10/02 /2017 No date of issue documented for the unit ending in 92000B The test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 06 /09/2017 No issued by initials, visual inspection, or issued to initials documented for the unit ending in 082003 The test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 05/15/2017 No date of issue documented for the unit ending in 96200R The test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 04/12/2017 No date of issue documented for

	the unit ending in 96100Z The test records were reviewed, signed and dated by the Laboratory Director (LD) on 03/29/2018. 05/15/2016 No date of issue documented for the unit ending in 39500Q The test records were reviewed, signed and dated by the Laboratory Director (LD) on 11/09/2016.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's package insert instructions, the laboratory's immunohematology policies and procedures, patient test records, request for corrective action documentation, and interview with General Supervisor (GS) #1, the laboratory failed to have immunohematology corrective action policies and procedures, necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports, available to and followed by testing personnel (TP). Findings Include: 1. Review of the Ortho-Clinical Diagnostics package insert instructions for Blood Grouping Reagent MTS (Trademark) A/B/D Monoclonal and Reverse Grouping Card found the following directions: Interpretation of Results Note: Serum grouping tests (except those on infants) performed in conjunction with cell grouping should always agree. Discrepancies between serum and cell grouping should be resolved before determination of the blood group. If the Forward and Reverse Grouping do not give concordant results, further investigation and testing should be performed to verify the correct ABO Grouping. 2. Review of the laboratory's immunohematology policies and procedures found: A procedure titled "ABO Forward and Reverse Grouping / D Antigen Typing (Simultaneous ABO Forward and Reverse Grouping / D Antigen Typing Using a Single Gel Card)", which stated: WARNING: ABO serum grouping tests performed in conjunction with ABO red blood cell grouping should always agree. Discrepancies between ABO forward and reverse groupings should be resolved according to routine ABO discrepancy policies and procedures before interpretation of the blood group. Under the section titled Interpretation of Results, the procedure included a chart of expected blood group results. For blood group O Positive, the expected results were as follows: Red Cell Reactions Anti-A Anti-B Anti-D 0 0 + Reverse Grouping Buffered Buffered Gel A1 B + + For blood group A Positive, the expected results were as follows: Red Cell Reactions Anti-A Anti-B Anti-D + 0 + Reverse Grouping Buffered Buffered Gel A1 B 0 + 3. Review of the laboratory's 2018 immunohematology test records titled "Transfusion Service Testing Record" found discrepancies between three patients' forward and reverse types as follows: 07/23 /2018 - Blood Grouping The patient's forward type was resulted as A - 0 B - 0 D - 4+ The patient's reverse type was resulted as A - 0 B - 3+ The patient's ABO and Rh was resulted as O Pos No documentation of repeat analysis, corrective actions, or further investigation was present. The patient was issued one unit of blood for emergency transfusion on 07/23/2018 at 6:59 PM. Physician release for an incompatible unit was completed by the requesting physician on 07/23/2018. The Laboratory Director (LD) reviewed, signed and dated the incompatible blood release form on 09/10/2018 at 2:10 PM. The test record was reviewed and signed by the Laboratory Director (LD) on 09 /10/2018. 06/15/2018 - Blood Grouping The patient's forward type was resulted as A - 0 B - 0 D - 3+ The patient's reverse type was resulted as A - 0 B - 3+ The patient's

	ABO and Rh was resulted as O Pos No documentation of repeat analysis, corrective actions, or further investigation was present. The patient was issued two units of blood for transfusion on 06/15/2018 at 7:55 PM and 9:40 PM. The patient was issued an additional two units of blood for transfusion on 06/16/2018 at 12:01 PM and 2:03 PM. The test record was reviewed and signed by the Laboratory Director on 09/10/2018. 05 /03/2018- Blood Grouping The patient's forward type was resulted as A - 4+ B - 0 D - 4+ The patient's reverse type was resulted as A - 0 B - 0* The patient's ABO and Rh was resulted as A Pos The * at the bottom of the test record stated "*Patient has extremely weak reverse B reaction. Provider is currently treating patient with Velcade." No documentation of repeat analysis, corrective actions, or further investigation was present. The patient was issued two units of blood for transfusion on 05/04/2018 at 1:57 PM and 4:13 PM. The test record was reviewed and signed by the Laboratory Director (LD) on 09/10/2018. 4. The surveyor requested immunohematology corrective action documentation and ABO discrepancy policy and procedure from GS #1. GS #1 stated the laboratory did not have any corrective action documentation for the discrepant reverse types or a policy/procedure that addressed ABO discrepancies. The interview occurred 09/11/2018 at 4:25 PM.
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, policies and procedures, and interview with General Supervisor (GS) #1, the laboratory failed to maintain an information or record system that included the positive identification of specimen, 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 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: 10/18/2016 ABO, Rh, ABS 09/08/2016 ABO, Rh, ABS 06/17/2016 ABO, Rh, ABS The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 11/09/2016. 2. Review of the laboratory's 2017 and 2016 immunohematology test records found the following incomplete test documentation: 12/29/2017: Unit ending in 463005 Rh (D): Anti-D: 2+ Interpretation: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 03/29/2018. 10/13 /2017 Unit ending in 37300Z ABO Grouping: Anti-A: 0 Anti-B: 0 Interpretation: BLANK Rh Typing: Anti-D: 0 Interpretation: Blank Unit ending in 88800F ABO Grouping: Anti-A: 0 Anti-B: 0 Interpretation: BLANK Rh Typing: Anti-D: 0 Interpretation: Blank The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 03/29/2018. 12/23/2016: Unit ending in 38800* ABO Grouping: Anti-A: 0 Anti-B: 0 Interpretation: BLANK Rh Typing: Anti-D: 0 Interpretation: Blank The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 03/21/2017.

	11/11/2016: Unit ending in 73400B Compatibility Testing: IS: 0 AHG: 0 Interpretation: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 03/21/2017. 05/17/2016: Patient Antibody Detection: 1 AHG: 0 2 AHG: 0 Interpretation: BLANK The test logs containing the information listed above was reviewed and signed by the Laboratory Director (LD) on 11/09/2016. 3. GS #1 confirmed that the laboratory's immunohematology test logs were incomplete. The interview occurred 09/11/2018 at 4:11 PM.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Item 1 Based on review of the laboratory's immunohematology test logs and electronic final test reports, the laboratory failed to have an adequate manual or electronic system(s) in place that ensured immunohematology test results were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. Findings Include: 1. Review of the laboratory's immunohematology patient test logs titled "Transfusion Service Testing Record" found an ABO/Rh, antibody screen, and two compatibility crossmatch tests were performed on 06/12/2018 at 12:29 AM. The results of the compatibility crossmatch for the unit ending in 44100O was: IS: 0 AHG: 2+ Interpretation: Not comp. The results of the compatibility crossmatch for the unit ending in 28700I was: IS: 0 AHG: 0 Interpretation: Comp No other units than the two listed above were tested on 06/12 /2018 for compatibility crossmatch. 2. Review of the laboratory's electronic final test report for the patient testing performed on 06/12/2018 found two immunohematology results each with a unique order number resulted as follows: Order # ending in 26 Resulted 06/12/2018 at 0932 Crossmatch: Compatible Product: PRBC Order # ending in 71 Resulted 06/12/2018 at 0933 Crossmatch: Compatible Product: PRBC Item 2 Based on review of the laboratory's blood gas analyzer print outs and electronic final test reports, the laboratory failed to have an adequate manual or electronic system(s) in place that ensured blood gas test results and other patient-specific data were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. Findings Include: 1. Review of 13 blood gas analyzer patient result printouts found a patient sample was analyzed on 05/19/2017 at 8:25 PM. The analyzer printout contained a handwritten patient name and the following blood gas results: pH: 7.266 pCO2: 92.8 mmHg pO2: 98 mmHg BE: 15 mmol/L HCO3: 42.2 mm/L TCO2: 45 mmol/L sO2: 96% Please note the results above contained critical values for pCO2 and HCO3 as defined by the laboratory in the policy titled "Alert Values Policy". Handwritten documentation was present documenting notification of a physician at 8:30 PM. 2. Review of the electronic final test report, provided by the laboratory, for the patient sample analyzed on 05/19/2017 at 8:25 PM found the following results reported at 9:11 PM: pH: 7.42 pCO2: 72.5

	mmHg pO2: 35 mmHg BE: 22 mmol/L HCO3: 46.6 mm/L TCO2: 49 mmol/L sO2: 65% 3. The laboratory failed to accurately transcribe 7 out of 7 analytes for 1 out of 13 patient results reviewed. Item 3 Based on review of the laboratory's erythrocyte sedimentation rate (ESR) patient test logs, electronic final test reports, and interview with General Supervisor (GS) #1, the laboratory failed to have an adequate manual or electronic system(s) in place that ensured ESR results were accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination. 1. Review of the laboratory's ESR patient test logs titled "ESR Daily Worksheet" found an ESR performed on 08/30/2017 with a handwritten result of 3 documented, which was then overwritten with a result of 4. GS #1 and a second surveyor both examined the test log and concurred the intended final result was 4. 2. Review of the electronic final test report resulted on 08/30/2017 at 2:37 PM found the ESR result was entered as 3. 3. GS #1 confirmed the ESR result was not accurately transcribed from the test record to the final test report. The interview occurred 09/11 /2018 at 12:22 PM.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, immunohematology emergency O negative release documentation, patient test logs, and interview with General Supervisor (GS) #1, the laboratory failed to document the immediate alert of the physician requesting the emergency release O negative units when it was determined the emergency O negative unit was incompatible with the patient's sample, which constitutes an imminently life-threatening condition. Findings Include: 1. Review of the laboratory's policy titled "Alert Values Policy" found crossmatch compatibility results of incompatible were not listed as a critical value requiring physician notification. Review of the laboratory's procedure titled "Antiglobulin Crossmatch Using MTS Anti-IgG Card (Trademark)" found no directions or requirements for physician notification of incompatible crossmatch results for emergency release O negative units. 2. Review of the laboratory's immunohematology patient test logs titled "Transfusion Service Testing Record" found the laboratory issued two units of packed red blood cells (PRBC) for emergency transfusion, ending in 44100O and 28700I, on 06/12/2018 at 1:09 AM and 12:35 AM respectively. Compatibility testing results for the unit ending in 44100O were documented as 2+ under the AHG heading and the interpretation stated "Not Comp." No documentation of requesting physician notification of the incompatible crossmatch result was present on the patient test log. Under the comments section a handwritten note stated, "Not given destroyed out fridge long" The Laboratory Director reviewed, signed and dated the test log on 09/10/2018. 3. Review of the laboratory's emergency release documentation for the aforementioned patient found no documentation of requesting physician notification of the incompatible compatibility crossmatch result. 4. GS #1 stated they notified the requesting physician immediately, in person, of the incompatible crossmatch results. When the surveyor requested documentation, to include the date, time, and person notified, of the physician notification GS #1 stated they had not documented the notification. The interview occurred 09/11/2018 at 4:46 PM.

D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the Form CMS-209 Laboratory Personnel Report, the laboratory's competency assessment documentation, and interview with General Supervisor (GS) #1 and Testing Personnel (TP) #9, the Technical Consultants failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings Include: 1. Review of the laboratory's Form CMS-209 Laboratory Personnel Report dated 09/10/2018 found 9 individuals that were not listed on the previous survey's Form CMS-209. The GS confirmed Testing Personnel (TP) #1, 3, 4, 5, 6, 7, 9, 11, and 12 were new TP since the previous survey. The GS provided the following start dates for the new TP on 09/11/2018 at 8:29 AM: TP #1: 09/2017 TP #3: 11/2017 TP #4: 2016 TP #5: 06/2016 TP #6: 08/2018 TP #7: 08/2018 TP #9: unknown GS #1 stated TP #9, 10, 11, and 12 were respiratory therapists that only perform blood gas analysis. TP #9 provided the following hire dates for TP #11 and 12 on 09/11/2018 at 10:58 AM: TP #11: 06/2017 TP #12: 08/2017 2. Review of the laboratory's 2018, 2017, and 2016 competency assessment documentation found the following: TP #11 Competency assessed: 06/16/2017* 06/16/2018* *Competency was assessed by TP #9 who is not listed on the Form CMS-209 as a technical consultant. Based on documentation of education provided on the date of survey, TP #9 does not qualify to fulfil the role of technical consultant. Missing competency: 12/2017 GS #1 confirmed the laboratory did not have any additional 2017 or 2018 competency assessment documentation for TP #11 on 09/11/2018 at 9:18 AM. TP #12 Competency assessed: 06/01/2018* *Competency was assessed by TP #9 who is not listed on the Form CMS-209 as a technical consultant. Based on documentation of education provided on the date of survey, TP #9 does not qualify to fulfil the role of technical consultant. Missing competency: 02/2018 GS #1 confirmed the laboratory did not have any additional 2018 competency assessment documentation for TP #12 on 09/11/2018 at 9: 19 AM.
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: D6054 - Standard Based on review of the Form CMS-209 Laboratory Personnel Report, the laboratory's competency assessment documentation, and interview with General Supervisor (GS) #1 and Testing Personnel (TP) #9, the Technical Consultants failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually after the first year the individual tests patient specimens. Findings Include: 1. Review of the laboratory's Form CMS-209 Laboratory Personnel Report dated 09/10/2018 found 12 individuals listed as testing

	personnel. GS #1 stated TP #9, 10, 11, and 12 were respiratory therapists that only perform blood gas analysis. The interview occurred 09/11/2018 at 8:29 AM. 2. Review of the laboratory's 2018, 2017, and 2016 competency assessment documentation found the following: TP #9 Competency assessed: 04/14/2016* 09/23 /2016* 06/01/2018* *Competency was assessed by TP #10 who is not listed on the Form CMS-209 as a technical consultant. Based on documentation of education provided on the date of survey, TP #10 does not qualify to fulfil the role of technical consultant. Missing competency: 2017 GS #1 confirmed the laboratory did not have 2017 competency assessment documentation for TP #9 on 09/11/2018 at 9:13 AM. TP #10 Competency assessed: 05/09/2016* 06/02/2017* 06/01/2018* *Competency was assessed by TP #9 who is not listed on the Form CMS-209 as a technical consultant. Based on documentation of education provided on the date of survey, TP #9 does not qualify to fulfil the role of technical consultant.
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, immunohematology emergency release documentation, and immunohematology blood unit temperature documentation, and an anonymous interview with a laboratory personnel, 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. Findings include: 1. The Laboratory Director failed to ensure employment of personnel who are competent to perform test procedures. Refer to D6053, D6054, D6127, and D6128. 2. The Laboratory Director failed to ensure employment of personnel who record and report test results promptly, accurately and proficiently. Refer to D5401 (Items 2 and 3), D5411, D5551 (Items 1 and 2), D5779, D5787, D5801 (Items 1, 2, and 3), and D5813. 3. The Laboratory Director failed to assure compliance with applicable regulations. Refer to D5401 (Items 1 and 4), D5403, D5417, D5451, D5481, D5485, D5555, and D5559. 4. During anonymous interviews on the date of survey, laboratory personnel stated the Laboratory Director fails to provide oversight and direction to the laboratory. The personnel stated the Laboratory Director had only been on-site at the laboratory three times since September 2017 to review laboratory documentation. The personnel stated the third visit to review documentation was the day prior to the CLIA survey. The personnel stated they were very frustrated due to the lack of oversight, direction, and communication received from the Laboratory Director.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: D6127 - Standard Based on review of the Form CMS-209 Laboratory Personnel Report, the laboratory's competency assessment documentation, and interview with General Supervisor (GS) #1 and Testing Personnel (TP) #9, the Technical Supervisors failed to evaluate and document the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings Include: 1. Review of the laboratory's Form CMS-209 Laboratory Personnel Report dated 09/10/2018 found 9 individuals that were not listed on the previous survey's Form CMS-209. The GS confirmed Testing Personnel (TP) #1, 3, 4, 5, 6, 7, 9, 11, and 12 were new TP since the previous survey. The GS provided the following start dates for the new TP on 09/11/2018 at 8:29 AM: TP #1: 09/2017 TP #3: 11/2017 TP #4: 2016 TP #5: 06/2016 TP #6: 08/2018 TP #7: 08/2018 TP #9: unknown TP #9 provided the following hire dates for TP #11 and 12 on 09/11 /2018 at 10:58 AM: TP #11: 06/2017 TP #12: 08/2017 GS #1 stated TP #9, 10, 11, and 12 were respiratory therapists that only perform blood gas analysis. The interview occurred 09/11/2018 at 8:29 AM. 2. Review of the laboratory's 2018, 2017, and 2016 competency assessment documentation found the following: TP #4 Competency assessed: 05/27/2016 04/30/2018 Missing competency: 11/2016 2017 GS #1 confirmed the laboratory did not have 11/2016 or 2017 competency assessment documentation for TP #4 on 09/11/2018 at 8:58 AM. TP #5 Competency assessed: 07

	/18/2016 12/05/2016 04/27/2018 Missing competency: 06/2017 GS #1 confirmed the laboratory did not have 2017 competency assessment documentation for TP #5 on 09 /11/2018 at 9:05 AM.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of the Form CMS-209 Laboratory Personnel Report, the laboratory's competency assessment documentation, and interview with the General Supervisor (GS) and Testing Personnel (TP) #9, the Technical Supervisors failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually after the first year the individual tests patient specimens. Findings Include: 1. Review of the laboratory's Form CMS-209 Laboratory Personnel Report dated 09/10/2018 found 12 individuals listed as testing personnel. GS #1 stated TP #9, 10, 11, and 12 were respiratory therapists that only perform blood gas analysis. The interview occurred 09/11/2018 at 8:29 AM. 2. Review of the laboratory's 2018, 2017, and 2016 competency assessment documentation found the following: TP #2 Competency assessed: 09/21/2016 04/30/2018 Missing competency: 2017 GS #1 confirmed the laboratory did not have 2017 competency assessment documentation for TP #2 on 09/11/2018 at 9:14 AM.