Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 37D0472824	**(X3) Date Survey Completed** 04/04/2019
Name of Provider or Supplier Memorial Hospital Of Texas County Authority	**Street Address, City, State** 520 Medical Drive, Guymon, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	The recertification survey was performed on 04/01/19 through 04/04/19. The findings were reviewed with laboratory director, laboratory supervisor, technical consultant #1, technical consultant #2, testing person #2, testing person #3, testing person #7, respiratory/radiology supervisor, quality risk management director, chief executive officer, chief operating officer and interim administrative chief operating officer during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1411; D6076: Laboratory Director, High Complexity 493.1271; D5026: Immunohematology
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to ensure proficiency testing attestation statements had been signed by the laboratory director or designee. Findings include: (1) On the first day of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records. The following was identified for 4 of 14 testing events: (a) Third 2017 Immunohematology Event (i) The attestation was not signed by the laboratory

	director or designee. (b) Third 2017 Chemistry Core Event (i) The attestation was not signed by the laboratory director or designee. (c) Third 2017 Microbiology Event (i) The attestation was not signed by the laboratory director or designee. (d) Third 2017 Hematology/Coagulation Event (i) The attestation was not signed by the laboratory director or designee. (2) The findings were reviewed with the laboratory supervisor who stated the attestations had not been signed as indicated above.
D3035	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(ii) In addition, the laboratory must retain immunohematology records, blood and blood product records, and transfusion records as specified in 21 CFR 606.160(b)(3)(ii), (b)(3)(iv), (b)(3)(v), and (d). This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to maintain Immunohematology records. Findings include: IMMUNOHEMATOLOGY QUALITY CONTROL RECORDS Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor that the laboratory performed the following blood bank testing: (a) Type and Screen Testing - consisted of ABO/Rh and Antibody Screen; (b) Crossmatch Testing - consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)). (2) On the third day of the survey, the surveyor reviewed quality control records for blood bank testing performed during July 2017 through March 2018 and identified the following: (a) Quality control records were not available from 09/01/17 through 09/30/17 (3) The surveyor asked the laboratory supervisor if quality control records were available for review from 09/01/17 through 09/30/17. The laboratory supervisor stated the quality control records were not available; (4) The following were examples of patient testing performed when quality control records had not been maintained: (a) Patient #1 - A Type and Screen was performed on 09/02/17; (b) Patient #2- A Type and Screen was performed on 09/04/17; (c) Patient #3 - A Type and Screen was performed on 09/05/17; (d) Patient #4 - A Type and Screen was performed on 09/06/17; (e) Patient #5 - A Type and Screen was performed on 09/07/17; (f) Patient #6 - A Type and Screen was performed on 09/08/17; (g) Patient #7 - A Type and Screen was performed on 09/09/17; (h) Patient #8 - A Type and Screen was performed on 09/11/17; (i) Patient #9 - A Crossmatch was performed on 09/11/17; (j) Patient #10 - A Type and Screen was performed on 09/12/17; (k) Patient #11 - A Crossmatch was performed on 09/12/17; (l) Patient #12 - A Type and Screen was performed on 09/13/17; (m) Patient #13 - A Type and Screen was performed on 09/14/17; (n) Patient #14 - A Type and Screen was performed on 09/15/17; (o) Patient #15 - A Type and Screen was performed on 09/18/17; (p) Patient #16 - A Type and Screen was performed on 09/19/17; (q) Patient #17 - A Type and Screen was performed on 09/20/17; (r) Patient #18 - A Type and Screen was performed on 09/21/17; (s) Patient #19 - A Crossmatch was performed on 09/21/17; (t) Patient #20 - A Type and Screen was performed on 09/22/17; (u) Patient #21 - A Type and Screen was performed on 09/23/17; (v) Patient #22 - A Type and Screen was performed on 09/24/17; (w) Patient #23 - A Type and Screen was performed on 09/25/17; (x) Patient #24 - A Type and Screen was performed on 09/26/17; (y) Patient #25 - A Type and Screen was performed on 09/27/17; (z) Patient #26 - A Type and Screen was performed on 09/28/17. THERMOGRAPH TEMPERATURE CHART (1) On the second day of the survey, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder

	connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor reviewed 13 refrigerator charts dated from 12/23/18 through 04/01/19. The review indicated that a chart was not available for review between 01/21/19 through 01/28/19: (3) The surveyor asked the laboratory supervisor if the Blood Bank chart between 01/21/19 through 01/28/19 was available for review. The laboratory supervisor stated the thermograph charts could not be located for the above date.
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: Based on a review of records, policies and procedures, manufacturer's instructions and interview with the laboratory supervisor, the laboratory failed to ensure the requirements were met for the specialty of Immunohematology. Findings include: (1) The laboratory failed to define a function check protocol to ensure the centrifuges were functioning properly. Refer to D5435; (2) The laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screening and Immunohematology testing. Refer to D5449; (3) The laboratory failed to have procedures to detect an ABO incompatibility between the donor's cell type and the recipient serum or plasma type. Refer to D5551; (4) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555; (5) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results. Findings include: BIASES (1) On the first day of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) First 2018 Chemistry Core Event (i) Calcium - 3 of 5 results exhibited a negative bias (aa) CH-11 - SDI of -2.1 (bb) CH-14 - SDI of -2.5 (cc) CH-15 - SDI of -2.2 (b) Third 2018 Hematology Event (i) MCV (Mean Corpuscular Volume) - 4 of 5 results exhibited a positive bias (aa) CH-11 - SDI of 2.8 (bb) CH-12 - SDI of 2.5 (cc) CH-13 - SDI of 3.1 (dd) CH-15 - SDI of 2.1 (c) First 2019 Chemistry Core Event (i) Direct Bilirubin - 4 of 5 results exhibited a negative bias (aa) CH-02 - SDI of -2.8 (bb) CH-03 - SDI of -2.2 (cc) CH-04 - SDI of -2.0 (dd) CH-05 - SDI of -4.5 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then

	reviewed the records with the laboratory supervisor, and asked if the biases had been addressed. The laboratory supervisor stated the biases had not been addressed. FAILURES (1) On the first day of the survey, the surveyor reviewed 2017, 2018, and 2019 proficiency testing records. The following failures were identified, in which corrective action documentation could not be located: (a) Second 2018 Event (i) BNP (Brain Natriuretic Peptide) - The laboratory failed the result for 1 of 5 samples, and attained a score of 80%. (2) The surveyor asked the laboratory supervisor if corrective action had been taken for the failure. After reviewing the records, the laboratory supervisor stated corrective action had not been taken for the failure.
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 a review of written policies and procedures and interview with the laboratory supervisor and respiratory/radiology supervisor, the laboratory failed to have complete written policies and procedures. Findings include: (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyor: (a) Arterial Blood Gas testing was performed on the GEM Premier 4000 analyzer in the respiratory therapy department. (2) On the third day of the survey, the surveyor reviewed the written Arterial Blood Gas procedure manual. The following policies and /or procedures could not be located: (a) Reference intervals (normal values) (b) Imminently life-threatening test results, or panic or alert values (c) Desciption of the course of action to take if the system becomes inoperable (3) The surveyor reviewed the findings with the respiratory/radiology supervisor, and asked if the above policies and/or procedures were available. The respiratory/radiology supervisor stated the policies and/or procedures defining the above had not been written.
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 a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to follow the manufacturer's instructions for Hematology. Findings include: (1) On the first day of the survey, the laboratory supervisor stated CBC (Complete Blood Count) testing was performed on the Beckman Coulter DxH600 analyzer; (2) On third day of the survey, the surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer: (a) "Platelet Clumps"- " SCAN SLIDE FOR PLATELETS" (3) The surveyor randomly reviewed 34 patient records flags from CBC testing performed during 03/01/19 through 03/31/19. For 1 of 34 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flag: (a) Patient #29 - Testing was performed on 03/05/19 at 08:37 am (4) The surveyor reviewed the records with the laboratory supervisor who stated the flag obtained for the above patient had not been documented as verified.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor and respiratory/radiology supervisor, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: HUMIDITY (1) On the first day of the survey, the laboratory supervisor stated the following to the surveyor: (a) Arterial Blood Gas testing was performed using the GEM Premier 4000 analyzer in the respiratory therapy department. (2) On the third day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required a relative humidity of 5-95%; (3) The surveyor reviewed laboratory records from January 2018 through December 2018. There was no evidence that the humidity, where the analyzer was maintained, had been monitored at an acceptable range of 5-95%; (4) The surveyor asked the respiratory/radiology supervisor if the humidity, where the GEM Premier 4000 analyzer was maintained, was being monitored. The respiratory/radiology supervisor stated the humidity was not being monitored. TEMPERATURE (1) On the third day of the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the room temperature be maintained at 15-25 C (Celsius); (2) The surveyor reviewed the temperature records from September 2018 through March 2019 and identified the following: (a) Temperatures had not been documented between: (i) 10/26/18 and 10/28/18 (ii) 12/01 /18 and 12/05/18 (iii) 01/11/19 and 01/14/19 (3) The surveyor reviewed the findings with the respiratory/radiology supervisor who stated the above temperatures had not been documented.

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: Based on a review of records, policy and procedure manual, and interview with the laboratory supervisor, the laboratory failed to define a function check protocol to ensure the centrifuges were functioning properly. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor: (a) The Ample Scientific Champion centrifuge was used to process urine specimens for urine microscopic testing at a speed of 1500 rpm (Revolutions Per Minute) and a time of 10 minutes; (b) The Ample Scientific Iris STAT spin centrifuge was used to process blood specimens for routine chemistry testing at a speed of 5700 rpm and a time of 5 minutes; (c) The Ortho Diagnostic MTS Centrifuge was used to process blood specimens for Immunohematology testing at a speed of 900 rpm and a time of 10 min. (2) The surveyor reviewed the policy and procedure manual and could not locate a function check protocol that defined how often function checks (speed and timer checks) were to be performed on the centrifuges; (3) The surveyor asked the laboratory supervisor if the laboratory had a function check protocol for the centrifuges. The laboratory supervisor stated to the surveyor the laboratory did not have a policy to check the speed and timer of the centrifuges.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screening and Immunohematology testing. Findings include: URINE DRUG SCREEN (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the laboratory performed Urine Drug Screen testing using the MedTox Scan analyzer; (2) The surveyor asked the laboratory supervisor if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The laboratory supervisor stated an IQCP had not been developed. Therefore, the surveyor determined negative and positive QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records for 01/01/19 through 04/02/19. The review indicated negative and positive QC

	materials had not been performed 1 of 92 days of patient testing reviewed; (4) The surveyor reviewed the records with the laboratory supervisor who stated negative and positive QC materials had not been performed each day of patient testing; (5) The following patient Urine Drug Screen testing had been performed when negative and positive QC materials had not been tested: (a) Patient #30 - testing performed on 02/13 /19 BLOOD BANK TESTING (1) On the first day of the survey, the laboratory supervisor stated to the surveyor that the laboratory performed the following Immunohematology testing: (a) Type and Screen Testing - consisted of ABO/Rh and Antibody Screen. (2) On the second day of the survey, the surveyor reviewed Immunohematology records for testing performed during 10/13/17 through 12/30/17. Quality control testing had not been performed for 2 of 17 days when patient Type and Screen testing had been performed as follows: (a) Patient #31 - A Type and Screen was performed on 12/27/17; (b) Patient #32 - A Type and Screen was performed on 12/28/17. (3) The surveyor reviewed the records with the laboratory supervisor, who stated there was no evidence quality control testing had been performed as indicated above. NOTE: D5449 was cited on the recertification survey performed on 06/12,13,14/17.
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 a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory failed to have procedures to detect an ABO incompatibility between the donor's cell type and the recipient serum or plasma type. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor the Ortho MTS Anti-IgG gel card was used to perform patient antibody screen and compatibility testing; (2) The surveyor reviewed the manufacturer's instructions contained in the package insert for the MTS Anti-IgG gel cards. The instructions stated, "The MTS Anti-IgG Gel Test System can be used in both direct and indirect antiglobulin test systems to detect the presence or absence of IgG on human red blood cells"; (3) On the second day of the survey, the surveyor reviewed the blood bank log book for patient compatibility testing performed from 01/07/19 through 04/01/19. For 10 of 10 patients reviewed (23 of 23 units), the records indicated the laboratory only used the Anti-IgG gel cards to perform patient compatibility testing, and therefore, did not include a method to detect ABO incompatibilities based on IgM antibodies (in order to achieve this, an immediate spin crossmatch, containing the donor's red blood cells and the recipient's serum or plasma, or an electronic crossmatch must be performed in conjunction with the IgG crossmatch); (4) The findings were discussed with the laboratory supervisor, who was not aware that an immediate spin crossmatch must be performed to detect IgM

	antibodies; (5) The 10 patients in which an immediate spin crossmatch had not been performed were: (a) Patient #33 - 2 units crossmatched 01/07/19 (b) Patient #34 - 2 units crossmatched 01/07/19 (c) Patient #35 - 3 units crossmatched 01/10/19 (d) Patient #36 - 3 units crossmatched 01/10/19 (e) Patient #37 - 2 units crossmatched 01 /17/19 (f) Patient #38 - 1 unit crossmatched 02/01/19 (g) Patient #39 - 2 units crossmatched 02/02/19 (h) Patient #40 - 3 units crossmatched 02/16/19 (i) Patient #41 - 2 units crossmatched 02/25/19 (j) Patient #42 - 3 units crossmatched 04/01/19 NOTE: The following reference was published in the CLIA Network Newsletter dated July-August 2009: "The gel card only detects incompatibility based on IgG antibodies. It does not detect incompatibility based on IgM antibodies, which is important in determining ABO compatibility. Therefore, the use of the gel card alone is not adequate to demonstrate incompatibility between the donor's cell type and the recipient's serum type, and the laboratory must also perform an immediate spin or electronic crossmatch to determine ABO compatibility." NOTE: The Interpretive Guidelines at 493.1271 requires standard operating procedures for compatibility testing: "Procedures to demonstrate incompatibility between the donor's cell type and the recipients's serum or plasma type. These procedures may consist of a serologic crossmatch, or a computer crossmatch."
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 a review of records and interview with the laboratory supervisor, the laboratory failed to ensure units of blood were stored under appropriate conditions. Findings include: BLOOD BANK ALARM CHECK (1) On the first day of the survey, the laboratory supervisor stated to the surveyor that units of packed red blood cells were stored in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On the second day of the survey, the laboratory manager stated to the surveyor Blood Bank alarms were checked quarterly for high/low activation; (3) The surveyor reviewed the refrigerator alarm check records for 2017 and 2018. The records indicated the alarm checks had not been performed quarterly. They had not been performed between 09/01/17 and 06/04/18; (4) The surveyor reviewed the records with the laboratory supervisor who stated the alarm checks had not been performed quarterly as required. BLOOD BANK THERMOGRAPH CHARTS (1) On the second day of the survey, the surveyor observed the thermograph temperature recorder for the blood bank refrigerator. The refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The surveyor reviewed 13 refrigerator charts dated from 12/23/18 through 04/01/19. The review indicated that 2 of 13 charts had not been changed by the 7th day of usage as follows: (a) Chart #4 - The chart was put into use on 01/15/19 and removed on 01/21/19 (14 days); (b) Chart #5 - The chart was put into use on 01/28/19 and removed on 02/15/19 (18 days). (3) The surveyor reviewed the charts with the laboratory supervisor, who stated the chart had not been changed

	by the 7th day of usage as indicated above. NOTE: D5449 was cited on the recertification survey performed on 06/12,13,14/17.
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 a review of the policy and procedure, records and interview with the laboratory supervisor, the laboratory failed to document patient Immunohematology testing. Findings include: (1) On the first day of the survey, the laboratory supervisor stated to the surveyor that the laboratory performed the following blood bank testing: (a) Type and Screen Testing - consisted of ABO/Rh and Antibody Screen; (2) On the second day of the survey, the surveyor reviewed the Immunohematology Reporting policy which stated, "1. Document all testing on the Blood Bank Work Log as you are performing the ABO/Rh and include: (a) Patient name (b) Patient BBK ID band number (if applicable) (c) Each reaction as you read the card and interpret the agglutination (d) Patient Type and Rh as you interpreted (e) Your initials." (2) The surveyor then reviewed Immunohematology Transfusion Service Testing Records (Work Log) from July 2017 through March 2018 and identified the following: (a) Patient #27 - A Type and Screen was performed on 07/07/17 and the Rh typing result was not documented. (3) The surveyor asked the laboratory supervisor if the Rh typing result had been documented. The laboratory supervisor stated the Rh typing result had not been documented in Immunohematology Transfusion Service Testing Records.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, records, manufacturer instructions and interview with the laboratory supervisor and respiratory/radiology supervisor the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have complete written policies and procedures. Refer to D5403; (b) The laboratory failed to follow the manufacturer's instructions for Hematology. Refer to D5411; (c) The laboratory failed to ensure an analyzer was stored as required by the manufacturer. Refer to D5413; (d) The laboratory failed to define a function check protocol to ensure the centrifuges were functioning properly. Refer to D5435; (e) The laboratory failed to perform a negative and positive control material each day of patient Urine Drug Screening and Immunohematology testing. Refer to D5449; (f) The laboratory failed to have procedures to detect an ABO incompatibility between

	the donor's cell type and the recipient serum or plasma type. Refer to D5551; (g) The laboratory failed to ensure units of blood were stored under appropriate conditions. Refer to D5555; (h) The laboratory failed to document patient Immunohematology testing. Refer to D5789.
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 a review of records, manufacturer's instructions, written policies and procedures and interview with laboratory supervisor, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure that testing systems developed and performed in the laboratory provided quality laboratory services for all aspects of test performance to include the analytic and post anlaytic phases of testing. Refer to D6082; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6087; (3) The laboratory director failed to ensure quality control programs were established and maintained. Refer to D6093; (4) The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Refer to D6095. NOTE: D6076 was cited on the recertification survey performed on 06/12,13,14/17.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on a review of the policy and procedure and interview with the laboratory supervisor, the laboratory director failed to ensure that testing systems developed and performed in the laboratory provided quality laboratory services for all aspects of test performance to include the analytic and post anlaytic phases of testing. Findings include: (1) The laboratory director failed to ensure patient Immunohematology testing had been documented. Refer to D5789.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by:

	Based on a review of records, policy and procedure manual, and interview with the laboratory supervisor, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Findings include: (1) The laboratory director failed to ensure a function check protocol had been defined to ensure the centrifuges were functioning properly. Refer D5435.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director failed to ensure quality control programs were established and maintained. Findings include: (1) The laboratory director failed to ensure Immunohematology records had been maintained. Refer to D3035; (2) The laboratory director failed to ensure a negative and positive control material had been performed each day of patient Urine Drug Screening and Immunohematology testing. Refer to D5449.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory supervisor, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Findings include: (1) The laboratory director failed to ensure the laboratory had procedures to detect an ABO incompatibility between the donor's cell type and the recipient serum or plasma type. Refer to D5551; (2) The laboratory director failed to ensure units of blood were stored under appropriate conditions. Refer to D5555.