Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2056204	11/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Crescent Medical Center Lancaster	2600 West Pleasant Run Road, Lancaster, TX	

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	An unannounced investigation of complaint TX00291030 was conducted onsite. An entrance conference was held on 11/14/2018 with the Laboratory Manager and Director of Quality/Compliance. Based upon the onsite investigation conducted 11/14 /2018 - 11/16/2018, this facility was found NOT to be compliance with CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1217 Immunohematology 493.1441 Laboratory Director, (high complexity) 493.1459 General Supervisor An exit conference was held on 11/16/2018 with the Laboratory Manager and Director of Quality/Compliance. The exit conference attendees were advised the laboratory was out of compliance and advised of conditions and deficiencies found during the survey. An opportunity for questions and comments was provided. Complaint TX00291030 was substantiated 2567 report to be sent to Regional CMS office.
D3023	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(2) The facility must establish and follow policies to ensure positive identification of a blood or blood product recipient. This STANDARD is not met as evidenced by: Based on review of facility records and interview with staff, the facility failed to ensure positive identification of a patient's specimen prior to patient immunohematology testing and the receipt of blood products. Findings included: 1. Review of facility records revealed on 06/06/2018 a blood type, antibody screen and crossmatch were ordered for Patient # 2036791. Patient #2036791 had no previous transfusion history (blood type, antibodies, crossmatches). Patient #2036791 was initially typed as O Negative and O Negative donor units were crossmatched and transfused from the patient specimen collected 06/06/2018 at 2020 hours. Patient # 2036791 blood type was changed to O Positive on 06/13/2018. 2. During an interview on 11/15/2018 at 1257 in the conference room, the laboratory manager was asked to

	explain events that occurred relating to the immunohematology testing for Patient #2036791. The laboratory manager stated that the patient was initially typed as O Negative and that the next morning the testing person told her that she may have mistyped the patient. The laboratory manager then recollected a blood specimen and retyped the patient as O Positive. The laboratory manager was asked how did the testing person know that the blood type was incorrect. She stated, "I don't know." The laboratory was asked for documentation of date and time of the recollected specimen. No documentation was provided. The laboratory was asked if the patient's antibody screen was repeated and the transfused units were re-crossmatched (compatibility testing) with the recollected specimen. The laboratory manager stated that only the ABO was verified with the recollected specimen. The laboratory manager was asked who was notified of the mistype. She stated that the patient's doctor was notified of the error. 3. The laboratory manager was asked to provide all documentation (specimen mislabel investigation, interview with collection personnel, root cause analysis, etc.) related to the mistyping of Patient # 2036791. No documentation was provided. 4. The facility policy titled "Blood/Blood Components-Ordering, Obtaining and Administering" stated the following: "ii. Ordering i. A physician must give the order to initiate any blood transfusion ii. Once the blood bank order has been placed in the EHR (Electronic Health Records), the following must obtained: 1. Informed consent on the attached consent form 2. A blood band for the patient 3. Two purple top blood sample tubes ... ... iv. Preparation at the Bedside i. At the bedside, two licensed nurses (one must be a Registered Nurse) or a nurse and physician are to check the blood product against the patient's blood band, original physicians order, and verify that the consent form has been signed. ii. Compare information on the component tag with the unit. Verifiying 1. Patient Name 2. Medical record Number 3. Date of birth 4. Unit number 5. Blood band number 6. Unit expiration iii. Do not transfuse if there are any discrepancies" The facility failed to ensure the positive identification of the patient's specimen prior to transfusion of the blood products.
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 review of laboratory records, patient records, and staff interview, the laboratory failed to meet the requirements for the specialty of immunohematology as evidenced by: 1. The laboratory failed to ensure blood bank quality control material had not exceeded their expiration date. Refer to D5417. 2. The laboratory failed to ensure that unexpected antibody screening and compatibility testing were performed on a recollected patient specimen as part of a blood typing error. Refer to D5551 3. The laboratory failed to ensure all blood specimen collection and testing records were maintained. Refer to D5787.
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 random review of laboratory blood bank quality control (QC) records (04 /2018) and confirmed in staff interview, the laboratory failed to ensure blood bank quality control material had not exceeded their expiration date for 2 of 16 days. Findings included: 1. Review of the laboratory's blood bank record titled "Daily QC Worksheet" revealed the following: A1 Reagent Red Cells in Use Lot number: V192776 Expiration Date: 04/16/18 B Reagent Red Cells in Use Lot number: V192781 Expiration Date: 04/16/18 Daily Test: 04/17/18 A1 = 4+ B= 4+ Daily Test: 04/18/2018 A1 = 4+ B= 4+ The laboratory utilized quality control material beyond the expiration date. 2. The above findings were confirmed in an interview with the laboratory manager on 11/15/2018 at 0956 hours in the conference room.
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 laboratory records and staff interview, the laboratory failed to ensure that unexpected antibody screening and compatibility testing were performed on a recollected patient specimen as a result of blood typing error. 1. Review of laboratory records revealed on 06/06/2018 a blood type, antibody screen and crossmatch was ordered for Patient # 2036791. Patient #2036791 had no previous transfusion history (blood type, antibodies, compatibility testing). Patient #2036791 was initially typed as O Negative and five O Negative donor units were tested for compatibility and transfused from the patient specimen collected 06/06/2018 at 2020 hours. Review of Patient # 2036791's history index card and the laboratory information system (LIS), the blood type was changed to O Positive on 06/13/2018. 2. During an interview on 11/15/2018 at 1257 in the conference room, the laboratory manager was asked to explain events that occurred relating to the immunohematology testing for Patient #2036791. The laboratory manager stated that the patient was initially typed as O Negative and that the next morning the testing person told her that she may have mistyped the patient. The laboratory manager then recollected a blood specimen and retyped the patient as O Positive (documentation of the recollection was not available). The laboratory was asked if the patient's antibody screen was repeated and the transfused units were re-crossmatched for compatibility with the recollected specimen. The laboratory manager stated that only the ABO/Rh blood typing was verified using the recollected specimen. The laboratory did not ensure that unexpected antibody screening and compatibility testing were performed on the recollected patient #2036791 specimen. This confirmed the above findings.

D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, calibration reports, quality control (QC) data, corrective action log, patient test reports, and in interview with staff, the laboratory failed to evaluate and document evaluation of all patient sodium test results affected by new lot of sodium (Na+) reagent on the Ortho Vitros 5600 from 03/18/2018 through 03/30/2018. Findings included: 1. Review of the laboratory's procedure manual for the Orthos Vitros 5600 analyzer did not include a policy for documentation of correction action for handling consistently low sodium or any other analytes patient test results. 2. Review of calibration reports for Orthos Vitros 5600 Sodium reagent revealed a new lot (Lot #42113760) was loaded for use on 03/18/2018 6:54 am. Review of calibration reports for Orthos Vitros 5600 Sodium reagent (Lot #42113760) included the following documentation, "Patient result running low on this particular lot of reagent. See Action Log. [Technical Consultant signature] 3/30/18." 3. Review of the Ortho Vitros 5600 analyzer "Instrumentation /Control Corrective Action Log" for 03/30/2018 stated, "PROBLEM: Patient Na+ Results running low on lot #42113760; CORRECTIVE ACTION: Calibrated and QC - ok. Patient reports were corrected." Corrective action for patient sodium test results included repeat analysis for only 6 patient specimens. The patients were initially analyzed from 03/30/2018 12:22 am through 03/30/2018 8:27 am, and all sodium results were flagged as "LO" (low). Reports for the 6 patients were corrected revealing all sodium levels within normal reference range post-calibration and repeat analysis. 4. During an interview on 11/15/2018 at 4:57 pm, the Technical Consultant (TC) was asked whether there was further review of patient sodium levels that may have been affected between 03/18/2018 and 03/29/2018 for that sodium reagent lot, she stated, "No." 5. Review of patient sodium test results from 03/29/2018 (analyzed between 1:40 am and 10:33 pm) revealed sodium levels were all flagged low (reference range for Na+: 137 - 145 mEq/L), as follows: Patient 24532: 134 mEq/L Patient 24542: 135 mEq/L Patient 24546: 135 mEq/L Patient 24451: 132 mEq/L Patient 24434: 133 mEq/L Patient 24426: 133 mEq/L Patient 24424: 131 mEq/L Patient 24436: 125 mEq/L Patient 24422: 127 mEq/L Patient 24548: 132 mEq/L Patient 24555: 134 mEq/L Patient 24561: 133 mEq/L Patient 24571: 132 mEq/L Patient 24579: 127 mEq/L Patient 24597: 128 mEq/L Patient 24588: 133 mEq/L Patient 24606: 131 mEq/L The above patients were a random sampling. The laboratory did not evaluate all patient sodium levels that were affected by the sodium reagent from 03/18/2018 through 03/29/2018. The laboratory did not ensure accurate and reliable test results.
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 laboratory records, patient test records, and staff interview, the laboratory failed to ensure all blood specimen collection and testing records were maintained. Findings included: 1. Review of laboratory records revealed on 06/06 /2018 a blood type, antibody screen and crossmatch was ordered for Patient # 2036791. Patient #2036791 was initially typed as O Negative and O Negative donor units were tested for compatibility and transfused from the patient specimen collected 06/06/2018 at 2020 hours. Review of Patient # 2036791's history index card and the laboratory information system (LIS), the blood type was changed to O Positive on 06 /13/2018. 2. During an interview on 11/15/2018 at 1257 in the conference room, the laboratory manager was asked to explain events that occurred relating to the immunohematology testing for Patient #2036791. The laboratory manager stated that the patient was initially typed as O Negative and that the next morning the testing person told her that she may have mistyped the patient. The laboratory manager then requested a blood specimen recollection and retyped the recollected patient specimen as O Positive. 3. Further review of laboratory records and patient test records revealed no documentation of the following for the recollected specimen: a. The positive identification of the specimen b. The date and time of the specimen collection and receipt into the laboratory c. The records and all dates of all specimen testing The laboratory was asked to provide documentation. No documentation was provided. This confirmed the above findings.
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: I. Based on review of laboratory Blood Bank records, patient records and staff interview, the laboratory failed to have an effective Quality Assessment system in place to monitor, assess and correct problems identified in the Blood Bank analytical system. Findings included: 1. Review of the laboratory Blood Bank records revealed the following for Patient # 2036791: Patient Blood Bank history index card: Dated 06 /13/2018, blood type "O POS", "ABO/RH verified O POS" "Date of transfusion 06/13 /2018; screen results: Neg" Corrected Report from LIS: Following Results Reported in Error: RH Type Negative 06/06/18 2320 Correct Positive 06/13/18 0643 Patient # 2036791 was initially typed as O Negative and O Negative donor units were crossmatched and transfused from the patient specimen collected 06/06/2018 at 2020 hours. Patient # 2036791's blood type was changed to O Positive on 06/13/2018. 2. Review of the laboratory Blood Bank record titled "Blood Administration Worksheet" revealed a blood specimen was collected 06/06/2018 at 2020 hours from Patient #2036791 for blood typing, antibody screening, and compatibility testing for

transfusion of packed red blood cells (PRBC). The laboratory documented that the patient had no previous transfusion history. On 06/06/2018 at 2311 hours, Patient #2036791 was typed as O negative with a negative antibody screen. Four units of O negative packed red blood cells were tested for compatibility at this time. A fifth unit was tested for compatibility 06/07/2018 at 2019 hours. 3. Review of the patient record titled "Patient Progress Notes" and "Initial Physical Assessment" revealed Patient #2036791 was transfused 5 units of O Negative PRBC's from 06/07/2018 0054 hours through 06/07/2018 2220 hours. 4. During an interview on 11/15/2018 at 1257 in the conference room, the laboratory manager was asked why the history index card for patient # 2036791 indicated a blood type of O Positive but the crossmatch records indicated a blood type of O Negative. The laboratory manager stated that the patient was initially typed as O Negative and that the next morning the testing person told her that she may have mistyped the patient. The laboratory manager then recollected a blood specimen and retyped the patient as O Positive. The laboratory manager was asked how did the testing person know that the blood type was incorrect. She stated, "I don't know." The laboratory was asked for documentation of date and time of the recollected specimen. No documentation was provided. The laboratory was asked if the patient's antibody screen was repeated and the units were re-crossmatched with the recollected specimen. The laboratory manager stated that only the ABO was verified. The laboratory manager was asked who was notified of the mistype. She stated that the patient's doctor was notified of the error. During an interview on 11/16/2018 at 1547 in the conference room, the laboratory manager was asked if the laboratory director (LD) was notified of the blood type error. She stated the LD was NOT notified. The laboratory manager was asked why the history index card was dated 06 /13/2018 and the corrected report generated on 06/13/2018. She stated, "I don't know." The laboratory manager was asked if a new history index card was made after the error. She stated, "I don't know." Again, the laboratory manager was asked when the second specimen for verification was collected. She stated, "I don't know." The laboratory did not have an effective QA system to monitor, assess and correct problems identified in the Blood Bank analytical system. 5. The laboratory was asked to provide all Quality Assessment documentation related to the mistyping of Patient # 2036791. No Quality Assessment documentation was provided. This confirmed the above findings. II. Based on review of Siemans CA 600 coagulation analyzer corrective action records from 08/2018 through 11/2018, laboratory daily control reports, and staff interview, the laboratory failed to have an effective Quality Assessment system in place to identify and correct coagulation analytical system problems that contributed to excessive quality control out of range values. Findings included: 1. Review of the laboratory record for the Siemans CA 600 coagulation analyzer from 08/2018 through 11/2018 titled "Action Log" and daily coagulation quality control records revealed the following 38 of 38 quality control events with unacceptable quality runs. 08/08/2018 Problem: "QC level 3, PT out" Action: "reran /new innovin. Out made new QC level 3, reran, OK" 08/20/2018 Problem: "QC level 1&3 , PTT out" Action: "added fresh actin FSL, reran, OK" 08/27/2018 "evening PTT level 3 and PT level one was out. Repeat testing was not performed. One patient was tested. Further investigation needed." 09/05/2018 Problem: "PT level one-out" Action: "rerun ok" 09/08/2018 Problem: "PT level 3 out" Action: "new innovin-reran-okay" 09 /10/2018 Problem: "PTT level 3 out" Action: "added fresh Actin FSL, reran, OK" 09 /10/2018 Problem: "PTT level 3 out" Action: "reran w/fresh Actin FSL-out, Put QC reagent back in fridge, then reran after sitting 15 minutes-out, made new QC, reran, OK" 09/11/2018 Problem: "Level 1 PT out" Action: "reran- OK" 09/12/2018 Problem: "Level 1 PT low" Action: "reran w/fresh level 1 QC reagent. OK" 09/16 /2018 Problem: "Level 1 PT/ Level 2 PTT" Action: "rpt-PTT 55.3, PT 10.9. Changed INV reagent rpt (2) PT 1. 10.5; 2. 46.9" 09/16/2018 Problem: "Level 1 PTx2" Action:

	"switch reagents" 09/17/2018 Problem: "Level 1 PT level out" Action: "reran, OK" 09 /18/2018 Problem: "level 3 PT out" Action: "reran-still out. New innovin-reran-okay" 09/18/2018 Problem: "Level 1 PTT out" Action: "reran, out, Fresh Actin FSL, reran, OK" 09/23/2018 Problem: "Level 3 PTT out" Action: "reran w/fresh Actin, out; made new level 3, reran, OK" 09/27/2018 Problem: "Level 3 PTT too low QC fail" Action: "PTT QC level 3 fail, reran with same QC level 3, fails, open fresh level 3 same lot. QC good" 09/29/2018 Problem: "level 3 PT out" Action: "New innovin, reran, QC, okay" 10/03/2018 Problem: "PTT levels 1 & 3 out high" Action: "Replaced Actin FSL with fresh. Repeated QC. Level 1 in Level 3 out high. Made fresh QC repeated both levels-OK" 10/04/2018 Problem: "PTT level 3 high" Action: "Reran w/fresh FSL Actin, level 3 high still, made new QC reagent, reran, OK" 10/04/2018 Problem: "PT level 1 high; PTT level 3 high" Action: "Added fresh Innovin & Actin, reran, OK" 10 /05/2018 Problem: "PTT level one & three high" Action: "Reran w/Fresh Actin still high, opened new Actin FSL added, reran still high both levels. Made up new level 1 & 3 QC, ran-OK" 10/06/2018 Problem: "PTT level 3 out" Action: "Rpt out" 10/08 /2018 Problem: "PT level 3 out low" Action: "reran low, rerun w/fresh innovin low; made up new innovin & QC reran, OK" 10/08/2018 Problem: "Level 3 PTT high" Action: "reran w/new action FSL high; Let reagent sit out a few minutes (3 min) then reran -high; made new QC reagent reran, OK" 10/09/2018 Problem: "PTT level 1 & 3 high" Action: "reran level one OK; level three high; added new actin FSL, reran OK" 10/10/2018 Problem: "PTT level 3 low" Action: "reran (on level one-out, mistake caught); then reran w/new innovin. OK" 10/11/2018 Problem: "PT level 1 out" Action: "Reran OK" 10/11/2018 Problem: "Level 1 & 3 PTT out" Action: "add New (open bottle) of actin, reran level one in, level 3 out; Mixed QC a little, reran, QC" 10 /14/2018 Problem: "Level 3 PTT high" Action: "Rpt ? , rpt w/new level 3, OK" 10/14 /2018 Problem: "Level 3 PTT high" Action: "Rpt after bleaching DI water tank, high, rpt w/fresh CaCl & Actin FSL high, rpt w/new level 3-OK" 10/15/2018 Problem: "Level 3 PTT high" Action: "opened new actin, added, reran-OK" 10/16/2018 Problem: "Level 1 & 3 PTT out" Action: "reran, out, added Actin from new bottle, level 3 in, level 1 out, No specimen received. No test performed. 10/17/2018 Problem: "Recalibrated LED due to high PTT QC" Action: 10/25/2018 Problem: "PTT level 1 high" Action: "reran out; added new actin, rerun OK" 10/28/2018 Problem: "PT level 3 out" Action: "new innovin, reran QC Okay" 11/06/2018 Problem: "PT on levels 1 & 3 high" Action: "reran, OK" 11/06/2018 Problem: "PTT level 1 high" Action: "added fresh actin FSL, still out, reran, out, made new level 1 QC, reran OK 11/07/2018 Problem: "PTT level 3 high" Action: "opened new actin FSL, added & reran OK" The laboratory did not have an effective Quality Assessment system in place to identify and the correct coagulation analytical system problems that contributed to excessive quality control out of range values. 2. During an interview on 11/16/2018 at 1300 hours in the conference room, the laboratory manager was asked if any other corrective actions were performed other than utilizing fresh reagents or quality control material with a rerun for the numerous out of range coagulation quality control values. She replied that no other methods for out of range coagulation quality control material were attempted. The laboratory manager was asked if the laboratory attempted to determine the root cause of the numerous coagulation quality control failures. She replied that Siemens technical support had been contacted but they were not much help. This confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures

	necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, calibration reports, quality control (QC) data, corrective action log, patient test reports, and in interview with staff, the laboratory failed to ensure quality assessment activities included a review of effectiveness of corrective actions taken to resolve problems, revision of policies /procedures necessary to prevent recurrence of problems in analytic systems. Findings included: 1. The laboratory failed to evaluate and document evaluation of all patient sodium test results affected by new lot of sodium (Na+) reagent on the Ortho Vitros 5600 from 03/18/2018 through 03/30/2018. Refer to D5783.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of calibration reports, quality control (QC) data, corrective action log, patient test reports, and in interview with staff, the laboratory failed to document notification to the authorized person who ordered the test of corrected reports for 6 of 6 patients with corrected sodium (Na+) levels on 03/30/2018. Findings included: 1. Review of calibration reports for Orthos Vitros 5600 Sodium reagent revealed a new lot (Lot #42113760) was loaded for use on 03/18/2018 6:54 am. Review of calibration reports for Orthos Vitros 5600 Sodium reagent (Lot #42113760) included the following documentation, "Patient result running low on this particular lot of reagent. See Action Log. [Technical Consultant signature] 3/30/18." 2. Review of the Ortho Vitros 5600 analyzer "Instrumentation/Control Corrective Action Log" for 03/30/2018 stated, "PROBLEM: Patient Na+ Results running low on lot #42113760; CORRECTIVE ACTION: Calibrated and QC - ok. Patient reports were corrected." 3. Review of patients instrument data, final reports, and corrected reports from 03/30 /2018 for sodium levels (reference range for Na+: 137 - 145 mEq/L), revealed the following: Patient 24609 initial sodium analysis was on 03/30/2018 at 12:22 am: 135 mEq/L (reflected on final test report); repeat sodium analysis was on 03/30/2018 at 9: 53 am: 143 mEq/L; corrected report included previous and corrected result. Patient 24574 initial sodium analysis was on 03/30/2018 at 5:23 am: 133 mEq/L (reflected on final test report); repeat sodium analysis was on 03/30/2018 at 9:53 am: 142 mEq/L; corrected report included previous and corrected result. Patient 24600 initial sodium analysis was on 03/30/2018 at 5:26 am: 131 mEq/L (reflected on final test report); repeat sodium analysis was on 03/30/2018 at 9:53 am: 138 mEq/L; corrected report included previous and corrected result. Patient 24586 initial sodium analysis was on 03 /30/2018 at 5:28 am: 129 mEq/L (reflected on final test report); repeat sodium analysis was on 03/30/2018 at 9:52 am: 138 mEq/L; corrected report included previous and corrected result. Patient 24632 initial sodium analysis was on 03/30

	/2018 at 7:11 am: 130 mEq/L (reflected on final test report); repeat sodium analysis was on 03/30/2018 at 9:52 am: 138 mEq/L; corrected report included previous and corrected result. Patient 24643 initial sodium analysis was on 03/30/2018 at 8:27 am: 133 mEq/L (reflected on final test report); repeat sodium analysis was on 03/30/2018 at 9:52 am: 143 mEq/L; corrected report included previous and corrected result. The above initial sodium test results were all flagged as "LO" (low) and repeat analysis revealed sodium levels within normal reference range post-calibration. There was no documentation of the authorized person who ordered the above tests being notified of the corrected reports. 4. During an interview on 11/15/2018 at 5:08 pm, the Technical Consultant (TC) and Director of Quality/Compliance were asked whether the authorized person who ordered the tests was promptly notified and documentation of notification, they stated they would look in the patients charts. Documentation was never provided for notification of corrected patient sodium test results.The TC and Director of Quality/Compliance stated the Nurse Manager had notified the authorized person at "daily huddle."
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, calibration reports, quality control (QC) data, corrective action log, patient test reports, and in interview with staff, the technical consultant failed to ensure that remedial actions were taken whenever test systems deviated front he laboratory's established and defined performance specifications. The laboratory failed to evaluate and document evaluation of all patient sodium test results affected by new lot of sodium (Na+) reagent on the Ortho Vitros 5600 from 03/18/2018 through 03/30/2018. Refer to D5783.
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 facility/laboratory policy, laboratory records, patient records, and staff interview, the laboratory director failed to provide overall management. Refer to D6082, D6094, and D6096.
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 facility/laboratory policy, laboratory records, patient records, and staff interview, the laboratory director failed to ensure transfusion medicine systems provided quality laboratory services for analytic phase of testing. Refer to D5417.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on facility/laboratory policy, laboratory records, patient records, and staff interview, the laboratory director failed to have an effective Quality Assessment system in place to monitor, assess and correct problems identified in the Blood Bank analytical system. Refer to D5791
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on facility/laboratory policy, laboratory records, patient records, and staff interview, the laboratory director failed to ensure all remedial actions that were part of an immunohematology patient testing error were taken and documented. Refer to D5551.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of facility/laboratory policy, laboratory records, patient records, and staff interview, the general supervisor failed to provide general supervision as evidenced by: 1. The general supervisor failed to monitor immunohematology testing to ensure acceptable levels of analytic performance. Refer to D6148.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen

	examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of facility/laboratory policy, laboratory records, patient records, and staff interview, the general supervisor failed to monitor immunohematology testing to ensure acceptable levels of analytic performance. Refer to D5417 and D5551.