Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0717959	09/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital	209 N W 8th St, Seminole, 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 onsite unannounced complaint investigation was performed September 13 - 14, 2022 to investigate allegations made for complaint TX00429186. The complaint was substantiated and the laboratory failed to meet the following conditions:The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780. 493. 1100 Condition: Facility administration; 493. 1441 Condition: Laboratory director.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of policies and procedures, laboratory records, transfusion records and interview of facility personal the laboratory failed to meet the requirements for transfusion services as specified in 493.1101 through 493.1105. (refer to D 3023 and D3025)
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:
Review of laboratory and nursing policies and procedures, transfusion records, corrective actions records and interview of facility personnel found the laboratory failed to follow their own policy for issuance of blood products and identification of recipient receiving the blood product resulting in a hemolytic transfusion reaction for one patient. The findings included: 1. Review of policies and procedures found: a. Review of the laboratory policy titled Pre-transfusion Testing of the Recipient (effective 01-01-2004, reviewed /revised 02082022) found on page 2 under the heading LABELING AND RELEASE OF CROSSMATCHED BLOOD: "4. Release forms shall be compared with the blood label and request forms. The release record shall be filled out in the Blood Bank Log by the persons issuing and receiving the unit. 5. Final identification of the recipient and the blood container rest with the transfusionist, who must positively identify the patient and compare the wristband information with the container label before infusion." b. Review of the laboratory policy titled Infusion of Blood Products (Effective Date 01-01-2004) found on page one under the heading Identification of Blood Product: "a. Check the blood compatibility label for the patient's name,hospital number, ABO type and Rh factor, blood unit number, technologist's initials, date and the Hollister number. b. Check the ABO type and Rh factor of the blood container label to be certain it agrees with the compatibility label. c. Check the unit number on the blood container to be certain it agrees with the compatibility label. " Further review found on page 2 under the heading Identification of the Patient: "a. Check the patient's name, hospital number, room number, and doctor's name on the patient's blood bank wristband against the information on the compatibility label. b. Ask the patient to identify themselves by stating their name. Never ask, "Are you Mr.____?" NOTE: DO NOT BEGIN INFUSION UNTIL ANY AND ALL DISCREPANCIES ARE RESOLVED." c. Review of the nursing policy titled Transfusion of Blood and Blood Products (APPROVED 01/20/2020 LAST REVIEWED 11/19/2020) found on page one under the heading OBTAINING BLOOD FROM BLOOD BANK: " A licensed nurse who has been in-serviced in blood procurement will pick up blood or blood product when blood bank notifies emergency department or inpatient department that it is ready. The nurse that is procuring the blood will follow this procedure: 1. Take preprinted patient identification label to blood bank and give to blood bank personnel; inform blood bank personnel of the desired component. All units of blood and blood components must be checked out by a technologist with a licensed nurse. 2. The patients name, record number, doctor, donor number, donor and patients type and Rh, and the expiration date of the blood component must be compared with that listed in the blood bank log book, the patients transfusion sheet and the unit of blood. 3. After determining that all information checks, the technologist must fill out the log with the information required and the licensed nurse must sign the blood bank log book along with date and time. 4. Receive blood bank system transfusion record for each unit." Further review found on page two under the heading PREPARING TO ADMINISTER BLOOD/BLOOD PRODUCT " Two licensed staff members, one being a registered nurse, will check blood bag id, transfusion record and patient id at the bedside" 2. Review of transfusion records found packed red cell unit W0415 22 015816 002 (A positive) was retrieved from the blood bank by nursing personnel on July 5, 2022 at 18:23. 3. Review of corrective actions records found laboratory personnel responsible for signing out the unit of packed red blood cells failed to require the nursing staff to provide the patient identification slip for the unit being signed out. Unit W0415 22 015816 002 (A positive) had been crossmatched for

	patient 46751(A positive) on July 5, 2022. This unit was infused to patient 079986 who had been typed as O positive. Patient 46751 and patient 079986 had the same last name. 4. Interview of the General supervisor conducted on September 13, 2022 at 11: 25 AM confirmed the unit crossmatched for patient 46751 had been removed from the blood bank refrigerator by nursing staff and given to laboratory staff for signing out to be transfused. Nursing staff did not provide the patient identification slip for identification of the unit and patient stating she would bring it later and the laboratory staff reviewed the unit number, type expiration date with her and they both signed the unit of blood out using the blood bank log book. He went on to say that nursing staff did not verify the identity of the patient matched the unit to be given prior to infusion.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Review of laboratory and nursing policies and procedures, transfusion records, corrective actions records and interview of facility personnel found the laboratory failed to follow their own policies for preventing transfusion reactions and investigate transfusion reactions when they occur, resulting in a hemolytic transfusion reaction in one patient. The findings included: 1. Review of policies and procedures found: a. Review of the laboratory policy titled Pre-transfusion Testing of the Recipient (effective 01-01-2004, reviewed /revised 02082022) found on page 2 under the heading LABELING AND RELEASE OF CROSSMATCHED BLOOD: "4. Release forms shall be compared with the blood label and request forms. The release record shall be filled out in the Blood Bank Log by the persons issuing and receiving the unit. 5. Final identification of the recipient and the blood container rest with the transfusionist, who must positively identify the patient and compare the wristband information with the container label before infusion." b. Review of the laboratory policy titled Infusion of Blood Products (Effective Date 01-01-2004) found on page one under the heading Identification of Blood Product: "a. Check the blood compatibility label for the patient's name,hospital number, ABO type and Rh factor, blood unit number, technologist's initials, date and the Hollister number. b. Check the ABO type and Rh factor of the blood container label to be certain it agrees with the compatibility label. c. Check the unit number on the blood container to be certain it agrees with the compatibility label. " Further review found on page 2 under the heading Identification of the Patient: "a. Check the patient's name, hospital number, room number, and doctor's name on the patient's blood bank wristband against the information on the compatibility label. b. Ask the patient to identify themselves by stating their name. Never ask, "Are you Mr.____?" NOTE: DO NOT BEGIN INFUSION UNTIL ANY AND ALL DISCREPANCIES ARE RESOLVED." c. Review of the laboratory procedure titled Investigation of Suspected Transfusion Reactions (Reviewed/ Revised 02082022) found on page 1 under the heading STATEMENT OF PURPOSE: " A reexamination of patient and donor specimens for discrepancies in the ABO type, Rh factor, Antibody Screening, Compatibility Testing and Bacterial Contamination." Further review found on pate two under the heading Investigative Procedure: " a. Clerical Error 1. Check all Laboratory- prepared blood labels for accuracy. 2. Check patient's wristband for complete information. 3.

Compare Unit information with patient's label information. b. Immediate Procedure 1. Examine patient's pre- and post transfusion specimens and post transfusion urine for visible hemolysis. Record in the blood bank log. 2. Repeat ABO and Rh typing on PATIENT'S pre- and post-transfusion specimens. 3. Repeat ABO and Rh typing on DONOR's pre- and post-transfusion specimens. 4. Repeat ABO and Rh typing on BLOOD BAG. 5. Perform Direct Antiglobulin Test on PATIENT'S pre- and post-transfusion specimens. 6. Check Urine with N-multistix for Hemoglobin. 7. Examine spun urine sediment for RBC's. c. Definitive Procedure: 1. Repeat crossmatch and antibody screening on pre- and post-transfusion specimens for both the DONOR and the PATIENT. 2. Culture the blood bag and prepare smear for gram stain using aseptic technique (hold negative culture for 5 days). 3. Perform bilirubin test on PATIENTS''S pre- and post- transfusion specimens. d. Corroborative Procedure: Identify any irregular antibodies and follow-up on any incompatibility (Antibody identities are performed by Vitalant). e. Optional procedures: 1. Haptoglobin and Methemoglobin on PATIENT'S pre- and post-transfusion specimens. 2. Urea on PATIENT'S post-transfusion specimen. 3. Hemosiderin on PATIENT'S Urine specimen. NOTE: FULLY DOCUMENT ALL FINDINGS IN THE BLOOD BANK LOG, AND ON THE TRANSFUSION REACTION FORM, REPORT ALL FINDINGS TO THE DOCTOR, AND PLACE RESULTS ON THE PATIENT'S CHART." d. Review of the nursing policy titled Transfusion of Blood and Blood Products (APPROVED 01/20/2020 LAST REVIEWED 11/19/2020) found on page one under the heading OBTAINING BLOOD FROM BLOOD BANK: " A licensed nurse who has been in-serviced in blood procurement will pick up blood or blood product when blood bank notifies emergency department or inpatient department that it is ready. The nurse that is procuring the blood will follow this procedure: 1. Take preprinted patient identification label to blood bank and give to blood bank personnel; inform blood bank personnel of the desired component. All units of blood and blood components must be checked out by a technologist with a licensed nurse. 2. The patients name, record number, doctor, donor number, donor and patients type and Rh, and the expiration date of the blood component must be compared with that listed in the blood bank log book, the patients transfusion sheet and the unit of blood. 3. After determining that all information checks, the technologist must fill out the log with the information required and the licensed nurse must sign the blood bank log book along with date and time. 4. Receive blood bank system transfusion record for each unit." Further review found on page two under the heading PREPARING TO ADMINISTER BLOOD/BLOOD PRODUCT " Two licensed staff members, one being a registered nurse, will check blood bag id, transfusion record and patient id at the bedside" 2. Review of the TRANSFUSION REACTION REPORT for patient 467629 found the record incomplete with the following fields blank: a. No documentation of unit donor number number b. No documentation of Regroup and Rh (old blood sample) c. No documentation of Regroup and Rh (new blood Sample) d. no documentation of Date of original crossmatch e. No documentation of the Original Pilot tube Group and Rh f. No documentation of the Pilot tube Regroup and Rh g. No documentation of Bag Group and Rh h. No documentation of Original blood sample drawn from patient Recrossmatch- albumin- tube i. No documentation of Recrossmatch - Coombs tube j. No documentation of Post reaction blood sample drawn from patient Recrossmatch- albumin- tube k. No documentation of Post reaction blood sample drawn from patient Coombs tube l. No documentation of DIRECT COOMBS TEST (patient) m. No documentation of culture on blood remaining in Donor Unit Blood Bag 3. Review of corrective actions records found laboratory personnel responsible for signing out the unit of packed red blood cells failed to require the nursing staff to provide the patient identification slip for the unit being signed out. Unit W0415 22 015816 002 (A positive) had been crossmatched for

	patient 46751(A positive) on July 5, 2022. This unit was infused to patient 079986 who had been typed as O positive. Patient 46751 and patient 079986 had the same last name. 4. Interview of the General supervisor conducted on September 13, 2022 at 1: 12 PM confirmed the laboratory did not complete the Transfusion reaction form because it was the wrong unit transfused and went on to say that "common sense tells us it is going to be incompatible."
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, emergency transfusion request forms, instrument results, and confirmed in interview, the laboratory failed to follow its policy for the verification of donor blood types for 17 out of 18 packed red blood cell (RBC) donor products before issuing them to patients for emergency use reviewed in January, February, and July of 2022. The findings include: 1. Review of the laboratory policy titled "Verification of Donor Type and Rh" stated the following: "All donor blood received in blood bank will be retyped before the blood is issued to the patient." 2. Review of laboratory "Emergency Transfusion Request forms" and retype records has the following 17 donor units issued to patients prior to donor type verification in January, February, March, and July of 2022: January 2022: Patient: 079485 - 3 RBC units RBC Unit W041521034542 Issued on 1/1/2022 (no time documented on form) Donor type verification performed on 1/1/2022 at 07:42 RBC Unit W041521027734 Issued on 1/1/2022 (no time documented on form) Donor type verification performed on 1/1/2022 at 07:42 RBC Unit W041521024595 Issued on 1/1 /2022 (no time documented on form) Donor type verification performed on 1/1/2022 at 07:44 Patient: 457559 - 2 RBC units RBC Unit W286821046822 Issued Donor type verification performed on 1/18/2022 at 23:23 RBC Unit W286821031537 Issued Donor type verification performed on 1/18/2022 at 23:23 February 2022: Patient: E64742 - 3 RBC units RBC Unit W041522000211 Issued on 2/7/2022 at 00:40 Donor type verification performed on 2/7/2022 at 03:01 RBC Unit W042321035675 Issued on 2/7/2022 at 00:40 Donor type verification performed on 2/7/2022 at 03:01 RBC Unit W041522000233 Issued on 2/7/2022 at 01:03 Donor type verification performed on 2/7/2022 at 03:01 Patient: 459236 - 1 RBC unit RBC Unit W041522001069 Issued 2/17/2022 at 1416 Donor type verification performed on 2/17/2022 at 15:00 Patient: 459323 - 2 RBC units RBC Unit W041522001302 - unit 1 Issued on 2/18/2022 at 12: 25 Donor type verification performed on 2/18/2022 at 13:38 RBC Unit W041522001302 - unit 2 Issued on 2/18/2022 at 12:25 Donor type verification performed on 2/18/2022 at 13:38 Patient: E64989 - 3 RBC units RBC Unit W01522001857 Issued 2/22/2022 at 1933 Donor type verification performed on 2/22 /2022 at 20:10 RBC Unit W041522007450 Issued 2/22/2022 at 1933 Donor type verification performed on 2/22/2022 at 20:10 RBC Unit W041522007437 Issued 2/22 /2022 at 12:30 Donor type verification performed not documented. March 2022: Patient: 462131 - 1 RBC units RBC Unit W041522002240 Issued 4/12/2022 at 16:55 Donor type verification performed 4/12/2022 at 17:21 July 2022: Patient: 467629- 2 RBC units RBC Unit W041522015746 Issued 7/6/22 at 15:35 Donor type verification performed on 7/6/2022 at 16:02 RBC Unit W041522019421 Issued 7/6/2022 at 15:50

	Donor type verification performed on 7/6/2022 at 16:17 Patient: 064021 - 1 RBC unit RBC Unit W041522016549 Issued 7/28/2022 at 11:15 Donor type verification performed: 7/28/2022 at 11:41 3. In an interview on 09/14/2022 at 11:08 hours, in the office, the laboratory manager confirmed that the above RBC donor units issued during an emergency release did not have their donor type verified until after it was issued to the patient.
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 laboratory operator's manual, instrument printouts, and confirmed in interview, the laboratory failed to include, in policy, the handling and specimen processing of flagged results from the Ortho Vision immunohematology analyzer for 26 of 26 patients reviewed with flags in January and July of 2022. The findings include: 1. Review of the Ortho Vision Analyzer Reference Guide, Chapter 10 "Results", Section "Flags and Codes" had the following explanation for common flags: "Result code : Acronym Definition : Colum Interpretation : Conditions : Suggested Actions WLL - Wrong liquid level - no result reported - the imaging system could not confirm that the correct volume of liquid is in the reaction chamber. One of the liquid additions may be missing. - Inspect the reaction chamber to determine if the liquid level is correct or not. A false error may be caused by a faint meniscus. If the liquid level is correct, manually read the column and edit the column results. If the liquid level is not correct, inspect the sample and reagents. Remove bubbles or foam before loading tubes and vials onto the instrument. Review the error screen for liquid flow or liquid level errors that are time-related and troubleshoot as necessary. Rerun the test. If the error persists, inspect the SYRINGE, DILUTOR VALVE, and TIP TUBING fittings for leaks. Perform the PIPETTE Volume Test to verify metering system integrity. TMC - Too many cells - no result reported - The IMAGING SYSTEM determined that there were too many cells in the column for a valid interpretation. - Reagent Red Blood Cells (RBCs) may not have been properly suspended, RBCs may have evaporated, or there was not enough sample serum /plasma and patient red blood cells were aspirated instead of plasma. If you suspect the reagent red blood cells have been compromised due to improper suspension or

	evaporation (exceeded on-board stability), discard all vials from that set and replace with a new set. Resuspend the reagents and rerun the test period if you suspect the sample is the source of the TMC code, make sure there is adequate plasma volume and re-run the test period re centrifuge the sample if needed. MF - Mixed Field - No result reported - the distribution of the cells within the column indicates that there may be a dual population of cells. - Manually interpret the reaction; follow your laboratory standard operating procedures with dual reactions. ? - Indeterminate - No result reported - the strength of the reaction or the distribution of the cells within the reaction prevented the system imaging from determining whether the reaction was positive or negative. - Rerun the test or manually interpret the reaction following your laboratory standard operating procedures. FIB - Fibrin - No result reported - The IMAGING SYSTEM saw an agglutinate distribution which may have been caused by fibrin in the sample. - manually review the card. Follow standard operating procedures for manually reviewing, reporting results, and retesting. Inspect the sample for quality issues. Follow your standard operating procedures for sample processing before testing. Adjust the centrifugation speed and time to achieve optimal cell slash plasma separation. If the problem persists, call OCD customer Technical Support." 2. Review of instrument printouts from January and July 2022 had the following 26 patient results that were flagged by the Ortho Vision analyzer and modified by the user. Patient ID - Date of Testing Test Ortho Vision result: User modified result: E63842 - 1 /1/2022 2Cell Screen, Screen cell 1 Ortho Vision Result: WLL Modified by user: 0 456696 - 1/4/2022 2Cell Screen, Screen cell 2 Ortho Vision: ? User modified result: 0 456675 - 1/4/2022 2Cell Screen, Screen cell 2 Ortho Vision: ? User modified result: 0 456804 - 1/5/2022 2Cell Screen, Screen cell 1 Ortho Vision: ? User modified result: 0 456814 - 1/5/2022 2Cell Screen, Screen cell 2 Ortho Vision: ? User modified result: 0 456786 - 1/5/2022 2Cell Screen, Screen cell 1 Ortho Vision: ? User modified result: 0 456822 - 1/5/2022 2Cell Screen, Screen cell 2 Ortho Vision:? User modified result:0 Anti-A Ortho Vision: ? User modified result:0 456760 - 1/5/2022 Anti-A Ortho Vision: ? User modified result: 0 457131 - 1/10/2022 Anti-A Ortho Vision: MF User modified result: 3+ 457771 - 1/19/2022 Anti-B Ortho Vision: ? User modified result: 0 2Cell Screen, Screen cell 1 Ortho Vision: WLL User modified result: 0 457843 - 1 /21/2022 Anti-A Ortho Vision: TMC User modified result: 0 43573 - 1/22/2022 Anti-A Ortho Vision: MF User modified result: 3+ 458003 - 1/25/2022 Anti-A Ortho Vision: FIB User modified result: 0 Anti-B Ortho Vision: MF User modified result: 3+ 44746 - 1/25/2022 Anti-B Ortho Vision: MF User modified result: 3+ 45090 - 1/25 /2022 Anti-A Ortho Vision: MF User modified result: 3+ 458345 - 1/29/2022 Anti-A Ortho Vision: MF User modified result: 3+ 467470 - 7/1/2022 A1 Cells Ortho Vision: TMC User modified result: 0 467581 - 7/05/2022 2Cell Screen, Screen Cell 2 Ortho Vision: ? User modified result: 0 467697 - 07/06/2022 IgG Ortho Vision: ? User modified result: 0 467629 - 7/6/2022 2Cell Screen, Screen cell 1 Ortho Vision: ? User modified result: 0 Anti-D Ortho Vision: MF User modified result: 4+ Crossmatch-IAT W041522019421 Ortho Vision: ? User modified result: 0 E67890 - 07/22/2022 2Cell Screen, Screen Cell 1 Ortho Vision: ? User modified result: 0 468712 - 7/22 /2022 2Cell Screen, Screen Cell 2 Ortho Vision: ? User modified result: 0 468792 - 7 /25/2022 Anti-B Ortho Vision: MF User modified result: 3+ E67984 - 7/26/2022 Anti-A Ortho Vision: ? User modified result: 0 468940 - 7/26/2022 2Cell Screen, Screen Cell 1 Ortho Vision: ? User modified result: 0 E67979 - 7/26/2022 2Cell Screen, Screen Cell 1 Ortho Vision: ? User modified result: 0 3. In an interview on 9/14/2022 at 10:05 hours, in the office, the laboratory manager stated that the laboratory did not have a policy in place for the handling and specimen processing of flagged results from the Ortho Vision immunohematology analyzer.
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 instrument user manual, laboratory policy, instrument printouts, and confirmed in an interview, the laboratory failed to have a corrective action policy in place for non-agreement results on the Ortho Vision immunohematology analyzer versus manual interpretation of the gel card by testing personnel for three out of three patients with non-conformant results reviewed in January 2022. 1. Review of the Ortho Vision operator's manual had the following result code interpretations: Result Code - Column Interpretation 0 - Negative 1+ - Positive 2+ - Positive 3+ - Positive 4+ - Positive U - No result reported 2. Review of the laboratory "Procedure 5 Antibody Detection Method - Two Cell Screen" and the laboratory policy "Procedure 13 Direct Antiglobulin Test" (DAT) had the same statement regarding test interpretation under the section titled "Interpretation of Results": "Positive result - Agglutination and/or hemolysis of the red blood cells is a positive test result. Red blood cells may remain suspended on the top of the gel or are dispersed throughout the gel in varying degrees. A few red blood cells may form a button in the bottom of the microtube in some positive reactions." 3. Review of patient records from January 2022 had the following three patients that had positive result codes reported from the Ortho Vision, to which the testing personnel modified the results without documentation of corrective actions, or steps taken that resulted in the modified results reported in the laboratory information system (LIS). Patient ID 457060 performed 1/8/2022 Test: DAT Ortho Vision: 1+ Manual DAT '0' - resulted in LIS Patient ID 457512 performed 1/17/2022 Test: DAT Ortho Vision: 1+ Manual DAT '0' - resulted in LIS Surveyor queried TPX as to why the initial result from the analyzer was questioned, and the testing was repeated manually, and it was stated that they oftentimes will wash the patient's RBCs and retest manually. Surveyor queried for the policy, and none was provided. Patient ID 458147 performed 1/26/2022 Test: 2Cell Screen Screen Cell 1 - Original result 1+, Modified by testing personnel to a 2+, resulted in LIS Surveyor queried TPC for documentation as to why the original 1+ result was modified to a 2+ before resulting in the LIS and none was provided. 4. In an interview on 9/14/2022 at 10:05, in the office, the office manager confirmed that the laboratory did not have a corrective action policy for non-agreement results from the Otho Vision immunohematology analyzer.
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: The laboratory director failed to provide overall management and direction. (see D 6079)
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: Review of facility policies and procedures, Immunohematology records, patient transfusion records, transfusion reaction records and interview of facility personnel found the laboratory director failed to provide overall direction and administration of the laboratory. (See D3023, D3025, D5401, D5403 and D5779)