Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0668484	**(X3) Date Survey Completed** 04/28/2023
Name of Provider or Supplier Md Anderson Cancer Center	**Street Address, City, State** 1515 Holcombe Blvd, Unit 0085, Houston, 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	Complaint Intake: TX00449886 The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D5026 - 42 C.F.R. 493.1217 Condition: Immunohematology; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
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: Based on a review of laboratory records, Food and Drug Administration (FDA) incident reports, transfusion incident reports, and confirmed in an interview the laboratory failed to report one of 40 patients, reviewed in 2021 and 2022, who had undergone an allogeneic bone marrow transplant (ALLO BMT) and received red blood cells (RBCs) that were transfused inconsistent with their current blood type (ABO). The findings included: 1. In a record review of 40 random ALLO BMT patients that had immunohematology testing performed in 2021 and 2022 the following patient ALLO BMT patient was transfused inconsistent with their current blood type (ABO) and was not reported as an incident to the FDA: Patient MRN 2611155 On June 21, 2022 a "Blood Bank Comment" was placed in the BBLIS (Blood Bank Laboratory Information System) that stated the following: "Original Type: Apos BMT transplant at Texas Children's Hospital (West Tower), in Houston, Texas on 4/20/2022. Donor Type: Opos" On 8/17/2022, accession number 22-229-04524, the patient's blood type was verified as follows: Procedure - Result Current

	ABORh - O POS On 8/19/2022, accession number 22-229-04524, the patient was crossmatched with 2 A POS RBC's, Unit numbers W044622281701 and W044622346456. Unit W044622281701 was then dispensed to hospital staff for transfusion on 8/19/2022 at 15:07 hours. Unit W044622346456 was then dispensed to hospital staff for transfusion on 8/20/2022 at 01:38 hours. On 8/20/2022, accession number 22-229-04524, the patient was crossmatched with an additional 2 A POS RBCs, unit numbers W0226122006329 and W221622351328. Unit W221622351328 was then dispensed to hospital staff for transfusion on 8/20/2022 at 17:00 hours. Unit W226122006329 was then dispensed to hospital staff for transfusion on 8/20/2022 at 22:23 hours. 2. Review of the SI-144337 Transfusion Event Report submitted by hospital staff on 8/29/2022, section "Event Detail" stated the following concerning patient MRN2611155, above, which was not reported to the FDA: "Patient received a stem cell transplant in an outside facility 04/2022. original bood type A pos, donor blood type O pos. on 08/19/2022 the patient was forwarding O and reversing A and received A RBCs SOP-2676 establishes that Group O RBCs of the apporptiate Rh type should be given only after consultation with a supervisor or the TMP on call." 3. Review of the laboratory FDA incident reports from 2021 and 2022 had the following three patients with similar circumstances in which the patient was issued blood products for transfusion that were inconsistent with their blood type and was reported to the FDA: 2021: Patient MRN 1088196 Original ABO: A Pos Donor Type: O Pos ALLO BMT date - 1/7/2021 On 1/21/2021, Accession 21-019-04916, the patient was crossmatched with an A POS RBC, unit number W044620455837. Unit W044620455837 was then dispensed to hospital staff for transfusion on 1/21/2021 at 10:00 hours. Patient MRN 243663 Original ABO: B Pos Donor Type: O Pos ALLO BMT date - 7/29/2021 On 8/10/2021, Accession 21-220-03169, the patient was crossmatched with a B POS RBC, unit number W226121034268. Unit W226121034268 was then dispensed to hospital staff for transfusion on 8/10/2021 at 11:19 hours. Patient MRN 2596756 Original ABO: A Pos Donor Type: B Pos & A Pos ALLO BMT date - 11/1/2021 On 11/15/2021, accession 21-318-02264, the patient was crossmatched with an A POS RBC, unit number W226121007933. Unit W226121007933 was then dispensed to hospital staff for transfusion on 11/16/2021 at 09:46 hours. On 12/19/2021, accession 21-353-00262, the patient was crossmatched with an A POS RBC, unit number W226121018845. Unit W226121018845 was then dispensed to hospital staff for transfusion on 12/19/2021 at 22:07 hours. 4. In an interview on 4/27/2023 at 11:20 hours, in the hallway, the Director of Donor Operations and Transfusion Medicine stated that Patient MRN 2611155 had not been reported to the FDA for receiving and being transfused four A Pos RBC units inconsistent with his current blood type of O Pos. Key: TMP: Transfusion Medicine Physician
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, laboratory documents, and confirmed in interview, the laboratory failed to retain a record of testing personnel worksheets printed on "Transfusion Medicine Request" forms for 10 months and 29

days of 15 months requested from January 2022 to March 2023. The findings included: 1. During a tour of the laboratory on 4/25/2023 at 15:50 hours, surveyor noted the form titled "Transfusion Medicine Request Form" which included a blue pre-printed box with the following information to be filled out by testing personnel at the times of serological crossmatch, or the assignment of blood products: "BMT Patient: __ YES __ NO Transfusion Requirements: _____ Antibodies: _____ Current Type & Screen ACC #/ Date: ____ Confirm Type Completed: __ YES ___ NO 1st Review Tech Initials ____ Date: ____ 2nd Review Tech Initials: ____ Date: ____ XM Tag Reviewer Initials: ____ Date: ____ 3rd Dispense Reviewer: _____ Date: _____ ** This Section for PLT/FFP/CRYO order use only ** Blood Type: _____ __SDP __ACR __RDP __FFP __CRYO Unit # _____ Tech Initials: _____ " 2. Review of the laboratory policy titled "SOP-2678 Serological Crossmatch", section "Procedure", had the following instructions: "Note: Crossmatch test should be added to patient's type and screen specimen at time of order review, Initial reviewer (filling the stamp) is responsible for adding the XM orderable in BBIS. Crossmatch test will only need to be ordered once per accession. o Stamp is now Preprinted on the paper BEFORE it is loaded in the Crossmatch AND the Platelet/Plasma/Cryo Printers. For instructions on how to load the paper, refer to SOP-4512: Loading Printer with Preprinted Documents. o Ensure that the stamp is filled out accurately and completely. First reviewer will initial and date the stamp in the space provided. o Do not write additional blood types on the stamp. o Ensure that the transfusion requirement documented on the stamp corresponds to the correct product (RBC, FFB, PLT. Cryo). Highlight the transfusion requirement once it is verified. Ensure it is highlighted. o If more than one blood type is listed in the Transfusion Requirements, circle the one that will be given. o Write down the accession number of the sample that will be used. Ensure that this sample includes all required testing completed (ABORH, ABSC, ABID (if needed). By writing the accession number, you are confirming that you, as a reviewer, have ensured the sample is appropriate for use. o CONFIRM all of this by opening Order Result Viewer and reviewing all tests on this accession. o Make sure that if patient had a transfusion reaction, that the sample you are documenting is the POST sample. o If someone else completed the stamp, review all information against BBIS and initial/date the stamp as well to confirm the 2nd tech review, document in spaces provided. o 1st Reviewer: MT doing the initial Review. o 2nd Reviewer: MT performing XM AFTER it has been reviewed by another. IF 1st reviewer is also the XM MT, "NA" each field. o XM Tag Reviewer: IF Allo BMT patient requires an A, B, or AB RBC. If O is given, "NA" each field." o 3rd Dispense Reviewer: Distribution Tech (LT/MT), ensuring requirements are reviewed if patient is Allo." Surveyor queried for the 2022 records of the "Transfusion Medicine Request" forms, to include the 'stamp' portion that techs filled out, as part of their review and patient workup. On 4/26/2023 at 14:25, the Director of Donor Operations and Transfusion Medicine alerted the surveyor that the records from January to November 29, 2022, were not available for review, and that they had not been retained. 3. In an interview on 4/26/2023 at 14:30 hours, in the conference room, the Director of Donor Operations and Transfusion Medicine stated that the "Transfusion Medicine Request" form had not been retained prior to 11/30/2022 and that the laboratory had not been aware that those documents were being disposed of. This confirmed the finding. Word Key: ABID - Antibody Identification ABSC - Antibody Screen ACC# - Account Number ACR - (undefined in policies obtained) ALLO BMT - Allogenic Bone Marrow Transplant BBIS - Blood Bank Information System BMT - Bone Marrow Transplant CRY - Cryoprecipitate FFP - Fresh Frozen Plasma LT - Laboratory Technician MT - Medical Technician NA - Not applicable PLT - Platelet RBC - Red Blood Cells RDP - Random donor platelet SDP - Single donor platelet XM - Crossmatch

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 the laboratory's policies, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to meet the requirements for Immunohematology. The finding include: 1. The laboratory failed to follow its own policies for review of blood products prior to dispense (refer to D 5401 I). 2. The laboratory failed to follow its own policy for transfusion requirements for blood and blood products for patients who had undergone an allogeneic bone marrow transplant (refer to D5401 II). 3. The laboratory failed to follow its own policy to obtain approval for the crossmatching and issuing of Rh-positive (Rh +) red blood cell (RBC) units to patients who require Rh-negative (Rh -) RBCs (refer to D5401 III). 4. The laboratory failed to follow its own policies for obtaining a Transfusion Medicine Consultation for ALLO Bone Marrow Transplant patients (refer to D5401 IV).
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: I. Based on review of laboratory policies, Transfusion Medicine Request Forms (TMRF) and confirmed in interview, the laboratory failed to follow their own written policies for review of blood products prior to dispense for 31 of 31 blood products randomly reviewed in March 2023. Findings Included: 1. Review of laboratory policy, "SOP-3728: Reviewing and Approving Blood Products for Transfusion" (Effective Date: 12/05/2022), revealed the following: "Procedure 1.0 Order Review: All Orders 1.1 Receive computer requisition from the clinic or floor, or a verbal requisition from the OR. 1.2 Evaluate patient's lab results and reason for transfusion (indication). ..1.4 Order will print with the stamp template at the bottom of the request form. 1.5 Fill in all required information. If field is not needed, enter "NA". Tech reviewing order must initial/date. All product orders must be stamped. ..1.7 For Bone Marrow patients: Double check that you are documenting the transfusion requirement for the product type being ordered. This is crucial in ensuring that the correct product is being approved/crossmatched/assigned to the patient. ..1.10 3rd Dispense Reviewer section should be filled for any Allo patient (regardless of blood type) by the dispensing tech (any job title)." Further review revealed the following: "2.0 Order Review: RBC Orders For all ALLO BMT Patients, the blood order must travel with the unit and placed on the unit holder for a final review to be done prior to dispensing. This review will be completed by whoever is dispensing the RBC product." 2. Review of laboratory policy, "SOP-2707: Dispensing Blood Products and Tissue" (Effective Date: 12/05/2022) revealed the following: "Final Inspection of Blood, Blood Components, and Administration Supplies at B2.4400 The dispensing personnel will:

Match the TRANSFUSION REQUIREMENTS with the information in the computer and initial/date as the 3rd reviewer on the order stamp. A. All blood products must be reviewed by the dispensing tech at dispense. B. RBC: Allo patient will have transfusion requirements added. The blood crossmatch/dispense should always match the requirements." 3. Review of the laboratory blood product order forms, Transfusion Medicine Request Forms (TMRF) revealed a pre-stamped box located at the bottom of the form. In the box contained a location for documentation of BMT history, transfusion requirements, antibodies, current type and screen, account number and date, 2 locations to document crossmatch reviews by technologists and a location to document a 3rd review by the dispensing technologist. Further review of the order forms revealed the following randomly reviewed blood products dispensed in March 2023 that did NOT have a 3rd review by the dispensing tech and/or any BMT documentation, prior to dispensing the blood product to hospital staff: a. Patient MRN: 878622 Date Time Requested: 03/03/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation b. Patient MRN:878622 Date Time Requested: 03/04/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation c. Patient MRN:2616157 Date Time Requested: 03/05/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation d. Patient MRN: 1025847 Date Time Requested: 03/05/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation e. Patient MRN:2675403 Date Time Requested: 03/05/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation f. Patient MRN:2277177 Date Time Requested: 03/05/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation g. Patient MRN:875851 Date Time Requested: 03/27/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation h. Patient MRN:2564608 Date Time Requested: 03/27/2023 Component: PRBC Unit: 1 of 2 BMT Patient: Yes 3rd Dispense Reviewer: No documentation i. Patient MRN: 2564608 Date Time Requested: 03/27/2023 Component: PRBC Unit: 2 of 2 BMT Patient: Yes 3rd Dispense Reviewer: No documentation j. Patient MRN:2704915 Date Time Requested: 03/27/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation k. Patient MRN:2683552 Date Time Requested: 03/27 /2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation l. Patient MRN:2133879 Date Time Requested: 03/27/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation m. Patient MRN:2712036 Date Time Requested: 03/27/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation n. Patient MRN:2662682 Date Time Requested: 03/27/2023 Component: PRBC BMT Patient: No documentation 3rd Dispense Reviewer: No documentation o. Patient MRN:2683552 Date Time Requested: 03/27/2023 Component: PRBC BMT Patient: No documentation 3rd Dispense Reviewer: No documentation p. Patient MRN:2732180 Date Time Requested: 03/27/2023 Component: PRBC BMT Patient: No documentation 3rd Dispense Reviewer: No documentation q. Patient MRN:2717639 Date Time Requested: 03/28/2023 Component: PRBC BMT Patient: No documentation 3rd Dispense Reviewer: No documentation r. Patient MRN:2066180 Date Time Requested: 03/28/2023 Component: PRBC BMT Patient: No documentation 3rd Dispense Reviewer: No documentation s. Patient MRN:2513145 Date Time Requested: 03/28/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation t. Patient MRN:2714994 Date Time Requested: 03/28/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation u. Patient MRN:2675008 Date Time Requested: 03/28/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation v. Patient MRN:2616157 Date Time Requested: 03/28/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation w. Patient MRN:2454677

Date Time Requested: 03/29/2023 Component: PRBC BMT Patient: No documentation 3rd Dispense Reviewer: No documentation x. Patient MRN:2726325 Date Time Requested: 03/29/2023 Component: PRBC BMT Patient: No documentation 3rd Dispense Reviewer: No documentation y. Patient MRN:2549706 Date Time Requested: 03/29/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation z. Patient MRN:2701056 Date Time Requested: 03/29/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation aa. Patient MRN:2613560 Date Time Requested: 03/29/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation bb. Patient MRN:2549706 Date Time Requested: 03/29/2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation cc. Patient MRN:2564608 Date Time Requested: 03/29/2023 Component: PLT-Concentrate BMT Patient: Yes 3rd Dispense Reviewer: No documentation dd. Patient MRN:2386988 Date Time Requested: 03/29/2023 Component: PLT-Concentrate BMT Patient: Yes 3rd Dispense Reviewer: No documentation ee. Patient MRN:2603600 Date Time Requested: 03/29 /2023 Component: PRBC BMT Patient: Yes 3rd Dispense Reviewer: No documentation The laboratory failed to follow their own written policies for review of blood products prior to dispense for 31 of 31 blood products randomly reviewed in March 2023. 4. During an interview on 04/26/2023 with Testing Person 21 (TP-21) at 09:44 hours, TP-21 was asked to describe the procedure once the Transfusion Medicine Request Form was received in the laboratory for patient analyses. TP-21 stated the patient history would be reviewed for a BMT and documented on the TMRF. If the patient did have a history of Allo BMT, a 3rd review would be completed by the dispensing tech and documented on the Transfusion Medicine Request Form under 3rd Dispense Reviewer. This confirmed the above findings. Word Key Allo BMT-Allogeneic Bone Marrow Transplant RBC- Red Blood Cell OR- Operating Room PRBC- Packed Red Blood Cells MRN- Medical Record Number PLT- Platelet 45469 II. Based on a review of laboratory policy, patient records, laboratory documents, laboratory dispense records, and confirmed in interview, the laboratory failed to follow its own policy for transfusion requirements for blood and blood products for patients who had undergone an allogeneic bone marrow transplant (ALLO BMT) for 7 out of 45 patients who had Food and Drug Administration (FDA) reportable events reviewed in 2021 and 2022. The findings included: 1. Review of the laboratory policy titled "Reviewing and Approving Blood Products for Transfusion" , section 1.0 "Order Review: All Orders" had the following instruction: "Review patient's record for sample availability, transfusion requirements and most recent product distributions. For Bone Marrow patients: Double check that you are documenting the transfusion requirement for the product type being ordered. This is crucial in ensuring that the correct product is being approved/crossmatched /assigned to the patient." Section 3.0 "Instructions: 2nd review for ALLO-BMT patient receiving NON-GROUP O RBC products" had the following instructions: "3.3 Verify that the information in the BBIS matches that documented in the order stamp: A. Review original blood type, BMT Type, antibodies, and all transfusion requirements in the BBIS are documented properly on the stamp. - NOTE: It is important to ensure that the transfusion requirement documented on the stamp matches that of the product being ordered (i.e. RBC transfusion requirements in BBIS documented in the RBC order). B. Verify that the patient's transfusion requirement in BBIS state it is acceptable to give a non-group O RBC unit to the patient and that the unit(s) crossmatched match it. C. Place your initials and date on the stamp to document that a 2nd review of the stamp is complete. 3.4 Verify that the unit(s) crossmatched are the blood type approved in transfusion requirements." 2. Review of the laboratory FDA reportable events of 2021 and 2022 had the following seven documented ALLO BMT patients that had blood or blood products dispensed for

transfusion against their transfusion requirements. 2021: Patient MRN 1088196 ALLO BMT date - 1/7/2021 The transfusion requirement placed on 1/7/2021 stated: "Transfuse O RBCs" On 1/21/2021, Accession 21-019-04916, the patient was crossmatched with an A POS RBC, unit number W044620455837. Unit W044620455837 was then dispensed to hospital staff for transfusion on 1/21/2021 at 10:00 hours. Patient MRN 243663 ALLO BMT date - 7/29/2021 The transfusion requirement placed on 7/29/2021 stated: "Transfuse O RBCs" On 8/10/2021, Accession 21-220-03169, the patient was crossmatched with a B POS RBC, unit number W226121034268. Unit W226121034268 was then dispensed to hospital staff for transfusion on 8/10/2021 at 11:19 hours. Patient MRN 2596756 ALLO BMT date - 11/1/2021 The transfusion requirement placed on 11/1/2021 stated: "Transfuse O RBCs" On 11/15/2021, accession 21-318-02264, the patient was crossmatched with an A POS RBC, unit number W226121007933. Unit W226121007933 was then dispensed to hospital staff for transfusion on 11/16/2021 at 09:46 hours. On 12/19 /2021, accession 21-353-00262, the patient was crossmatched with an A POS RBC, unit number W226121018845. Unit W226121018845 was then dispensed to hospital staff for transfusion on 12/19/2021 at 22:07 hours. Patient MRN 1200233 ALLO BMT dates: 8/13/2019, and 9/1/2020 The transfusion requirement placed on 9/2/2020 stated: "Transfuse A, O PLTs" A review of the laboratory information system (LIS) CERNER blood bank comments had the following additional statement: "SEP/02/20 10:57:00 Platelets: A, O (determined due to Fwd/Rev typing: Plasma reduction will occur if necessary)" On 1/20/2021, the patient was assigned a non-plasma reduced, pooled O POS platelet with unit number W411021000965. Unit W411021000965 was then dispensed to hospital staff for transfusion on 1/20/2021 at 01:26 hours, without documented approval to assign non-plasma reduced platelets for transfusion. 2022: Patient MRN 2586355 ALLO BMT date: 12/07/2021 The transfusion requirement placed on 12/6/2021 stated "Transfuse O, A, AB PLTs" On 2/1/2022, the patient was assigned an apheresed B POS platelet with unit number W044621441845. Unit W044621441845 was then dispensed to hospital staff for transfusion on 2/1/2022 at 20:28 hours. Patient MRN 2160881 ALLO BMT date: 9/12/2017 The transfusion requirement placed on 9/11/2017 stated "Transfuse O, A, AB PLTs" On 6/8/2022, the patient was assigned a single donor B POS platelet with unit number W036522055838. Unit W036522055838 was then dispensed to hospital staff for transfusion on 6/8/2022 at 15:11 hours. 4. Through record review and interviews on 4 /27/2023 at 10:40 hours, in the conference room with the Director of Donor Operations and Transfusion Medicine and the general supervisor (GS) 2, it was confirmed that the laboratory failed to follow its policy to follow transfusion requirements for the above patients. This confirmed the findings. III. Based on a review of laboratory policy, patient results, laboratory documentation, and interviews, the laboratory failed to follow its own policy to obtain approval for the crossmatching and issuing of Rh-positive (Rh +) red blood cell (RBC) units to patients who require Rh-negative (Rh -) RBCs for 1 of 45 patients who had Food and Drug Administration (FDA) reportable events reviewed in 2021 and 2022. The findings included: 1. Review of the laboratory policy titled "SOP-2678 Seriological Crossmatch", revision 07, section "General Guideline/Definitions", subsection "Transfusion of non-group specific PRBCs" stated the following: "Rh-positive blood may be crossmatched for Rh-negative recipients only with the approval of a TMP and the recipient is lacking anti-D. These Medical Exceptions must be documented." 2. On 4/5/2021, accession 21-095-02872, patient with the MRN2438691 had the following ABORh documented: B (Rh -) On 4/08/2021, accession 21-095-02872, the patient was crossmatched with an O (Rh +) RBC, unit number W221621250853. Unit W221621250853 was then dispensed to hospital staff for transfusion on 4/8/2021 at 11:36 hours. 3. Review of the laboratory document titled "Deviation Report", deviation log number 043020211300,

stated the following: "On 04/08/2021, O+ RBC was crossmatched and transfused for a patient whose requirements state to give Rh Negative RBC .... Tech does not remember if she received approval from TMP to crossmatch O+ RBC." 4. Through record review and interviews on 4/27/2023 at 10:40 hours, in the conference room with the Director of Donor Operations and Transfusion Medicine and the general supervisor (GS) 2 it was confirmed that the laboratory failed to follow its policy and issued and transfused Rh (+) RBCs to a patient who required Rh (-) RBCs. This confirmed the findings. 31968 IV. Based on review of the laboratory's policies, and review of nursing policies, review of a sampling of patient records from June 2022 to March 2023 and staff interview, it was revealed the laboratory failed to follow its policies to ensure that pathologists' instructions for transfusion requirements were provided to nurse's for 2 of 10 patients who had bone marrow transplants performed at another facility. The findings include: 1. A review of the laboratory's policy titled "SOP-3728: Reviewing and Approving Blood Products for Transfusion" (effective date: 08 Dec 2021) under the section titled "Allo Bone Marrow Transplant Transfusions" revealed: "Patients receiving Allo BMT Transfusions will get a TMP Consult prior to or on the transplant date. This Consult will include the Transfusion Requirement that the patient will follow. The transfusion requirement in the BBIS will be updated to match the TMP Consult on the date of transplant. Refer to SOP-1156 Transfusion Medicine Consultation..." 2. A review of the laboratory's policy titled "SOP-1156: Transfusion Medicine Consultation" (effective date: 19 Oct 2020) under the section titled "TMP Consultation" revealed: "- Patients receiving ALLO BMT transplants will require a TMP Consultation. - TMP will review Requests for TMP Consultation and will define the patient's Transfusion Requirements. - The TMP Consult will guide the ABO of products that can be assigned and dispensed to the patient. - The patient's Transfusion Requirements will be updated prior to or on the transplant day." and, Under the section titled "Communication" revealed: "- Requests for TMP Consultation are ordered by the nursing unit and received at Transfusion Services prior to transplantation. - A phone call can also be received to notify the need for a TMP Consultation , use FORM-0374 Transfusion Medicine Consultation Form to record the information. - The patient's Blood Bank Comments is updated with the information provided." 3. A review of the nursing policy titled "Blood Component Transfusion Administration Procedure - Attachment #ATT1711" under the section titled "4.0 Stem Cell Transplant and Cellular Therapy" revealed: "4.1 In allogeneic Stem Cell Transplant and Cellular Therapy (SCTCT) patients who have had allogeneic transplants at MDAnderson, each time a blood component is to be transfused, the RN will verify that a Transfusion Medicine consult has been completed and the recommendations for compatible Blood Components have been documented. As the patient is changing to the donor's blood type, check for update in the electronic health records (EHR), transfusion medicine consult, and follow the guidelines. 4.2 The two LHPs performing the Blood Component verification procedure will confirm the Blood Component compatibility is in accordance with the recommendations on the most current transfusion medicine note in the EHR." 3. A sampling of 40 patient transfusion records from June 2022 to March 2023 identified 10 patients who received Bone Marrow Transplants at other facilities. Of these 10, one was determined to have not had a TMP Consult ordered at all and one was determined to have had a TMP Consult ordered after the patient had already received 5 units of red blood cells. They were: a) TMP not ordered Medical Record: 272801 17 units of product (Red Blood Cells, Platelets) administered from January 2023 to March 2023. b) TMP ordered after transfusions Medical Record: 2611155 4 units of product (Red Blood Cells) administered from August 18 - 20, 2023. TMP entered August 22, 2023. TMP stated only O red blood cells were to be transfused. The four units transfused were A red blood cells. 4. An interview with the transfusion safety

	officer on 04/26/2023 at 1530 hours in the office - after her review of the records- confirmed the findings. Key BMT - bone marrow transplant RN - registered nurse