Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0491588	12/16/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ut Md Anderson Clinical	1515 Holcombe Blvd Unit 24, 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	A complaint survey was completed on 12/16/2024. Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1217 Immunohematology 42 C.F.R. 493.1441 Laboratory Director, High Complexity 42 C.F.R. 493.1453 Clinical Consultant
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 written procedures, patient records, SafeTrace reports, direct observation, verification studies, corrective actions, quality control records, and interview with staff, the laboratory failed to meet the requirements of immunohematology specialty, as evidenced by: 1. The laboratory failed to have written policies and procedures for the collection of patient confirmatory ABO/Rh specimens. Refer to D5311. 2. The laboratory failed to establish written patient specimen processing policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 42 CFR 493.1241 through 493.1242. Refer to 5391. 3. The laboratory failed to have documentation of following its procedure to perform PGD testing on units received outside the laboratory's acceptable shipping temperature for 11 of 12 shipments. Refer to D5401, I. 4. The laboratory failed to follow their own written policy for resolving one of one ABO/Rh discrepancy in 2024. Refer to D5401, II. 5. The laboratory failed to follow their own policy on performing blood bank inventory for two of two days observed in December 2024 (12/11-12/2024). Refer to D5401, III. 6. The laboratory failed to follow their own policy for massive transfusion protocol (MTP) deactivation, for 22 of 22 blood products returned to the laboratory in August

	2024. Refer to D5401, IV. 7. The laboratory failed to follow laboratory policy for the selection and issuing of blood and blood products for patients that had undergone bone marrow transplants (BMT) for 4 of 18 BMT patients randomly reviewed in 2023 and January through December 10th, 2024. Refer to D5401, V. 8. The laboratory failed to ensure changes to the MTP standard operating procedure (SOP) were completed and approved by the laboratory director before use. Refer to D5407. 9. The laboratory failed to use gel cards following the manufacturer's instructions and have documentation indicating that the gel cards were used in a manner that provided patient test results within the laboratory's performance specifications. Refer to D5411, I. 10. The laboratory failed to have documentation of performing each of the required steps for Anti-E testing on 2 of 9 patients. Refer to D5411, II. 11. The laboratory failed to have documentation of performing each of the required steps for Anti-c testing on 4 of 7 patients. Refer to D5411, III. 12. The laboratory failed to ensure that immunohematology reagents met the manufacturer's instructions for proper temperature storage. Refer to D5413. 13. The laboratory failed to establish test performance specifications before reporting patient test results for each test performance characteristics listed at 42 CFR 493.1253(b)(2). Refer to D5423. 14. The laboratory failed to maintain documentation to indicate that quality control procedures were performed before resuming patient testing when a change of reagents were introduced. Refer to D5461. 15. The laboratory, which used the stated values of commercially assayed quality control materials, failed to verify the criteria for acceptability of all quality control materials used to monitor patient testing using the Grifols Erytra instrument. Refer to D5469. 16. The laboratory failed to confirm patient ABO group by testing the patient unknown serum with known A1 and B red cells. Refer to D5551. 17. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the immunohematology analytic systems specified in 42 CFR 493.1251 through 493.1283. Refer to D5791, I & II. 18. The laboratory failed to ensure that testing personnel overrides and exceptions to standard operating procedures were reviewed daily by approved staff members, for three of twelve months reviewed from January 2024 to December 1, 2024. Refer to D5791, III. 19. The laboratory failed to ensure their quality assurance (QA) included a review of effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems. Refer to D5793.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on general supervisor (GS) 1, GS2, and phlebotomy supervisor interviews and phlebotomy specimen collection policies and procedures record review on December 10, 2024 at 11:00 am and December 12, 2024 at 09:15 am, the laboratory failed to have a written policy and procedure for the collection of patient confirmatory ABO /Rh specimens. Findings included: a. In the immunohematology protocol titled "Blood Component Administration and Transfusion Reaction Policy" at "2.0 Type and

	Screen," it states that "a confirmatory sample to determine [a patient's ABO/Rh] must be collected if the patient has never had a previous Type and screen (ABO RH) performed at MD Anderson," and that "the blood collection for the Type and Screen (ABO RH) and the confirmatory [ABO/Rh] must be drawn by two different phlebotomists or LHPs." b. On December 12, 2024 at 09:15 am, GS1, GS2, and the phlebotomy supervisor confirmed that there was no written patient specimen collection policy and procedure detailing the laboratory's immunohematology patient confirmatory ABO/Rh specimen collection requirements stated the above. c. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on direct observation, general supervisor (GS) 2 and laboratory personnel interviews, and immunohematology patient specimen processing record review on December 10, 2024 at 02:30 pm, the laboratory failed to establish written patient specimen processing policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 42 CFR 493.1241 through 493.1242. Findings included: a. In the immunohematology section, whenever the laboratory received a patient specimen in which the barcode on the specimen label was unclear or unreadable, laboratory personnel would reprint the specimen label, verify that the reprinted label corresponded to the patient specimen by obtaining a second laboratory personal review, and attach the reprinted label to the patient specimen as to not completely obscure the original label. b. In addition to not having a written protocol detailing this patient specimen relabeling process, the laboratory failed to establish any mechanism to monitor, assess, and when indicated, correct potential patient specimen labeling problems. c. These findings were confirmed by GS2 and laboratory personnel on December 10, 2024 at 02:30 pm. d. According to laboratory personnel, the laboratory received and processed approximately 1200 patient type and screen tests weekly.
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 the laboratory's procedure titled "Receiving Products", review of the laboratory's procedure titled "Verax Biomedical Platelet PGD Test", review of the laboratory's platelet packing lists from June 2024 to July 2024, and staff interview, the laboratory failed to have documentation of following its procedure to perform PGD testing on units received outside the laboratory's acceptable shipping

temperature for 11 of 12 shipments. The findings included: 1. A review of the laboratory's procedure titled "Receiving Products" (SOP 2699) under the section titled "Acceptable Temps" identified the acceptable criteria for the shipment of platelets was a temperature of 20 - 24C. In addition, the section titled "Platelet Temp Deviation" stated: "Platelets received greater than 24C and up to 27C must be Quarantined and platelet PGD tested within 24 hours of use. - PGD test must be non-reactive to remove from quarantine. - Refer to SOP-3669 Verax Biomedical Platelet PGD Test." 2. A review of the laboratory's procedure titled "Verax Biomedical Platelet PGD Test" (SOP 3669) under the section titled "Indications for Use" determined: "PGD testing should be performed: - Any platelet arriving in the blood bank at 24.1 to 26.9C. - As directed by a TMP" 3. A review of the laboratory's platelet packing lists from June 2024 to July 2024 identified 11 shipments of platelets where the temperature of the platelets at receipt by the laboratory was within 24.1 to 26.9C, however PGD testing was not performed. They were: a) Pack List #SH060724SQ0118 Receipt Date: 06/07/2024 Temperature at arrival: 25.0C Number of units: 19 b) Transaction Number: STA562114 Receipt Date: 06/15/2024 Temperature at arrival: 24.5C Number of units: 6 c) Pack List #SH061824SO0083 Receipt Date: 06/18/2024 Temperature at arrival: 24.5C Number of units: 40 d) Transaction Number: STA564116 Receipt Date: 06/25/2024 Temperature at arrival: 24.8C Number of units: 30 e) Transaction Number: STA565145 Receipt Date: 07/01 /2024 Temperature at arrival: 25.2C Number of units: 8 f) Transaction Number: STA565149 Receipt Date: 07/012024 Temperature at arrival: 25.0C Number of units: 8 g) Transaction Number: STA565144 Receipt Date: 06/30/2024 Temperature at arrival: 25.0C Number of units: 2 h) Transaction Number: STA565147 Receipt Date: 07/01/2024 Temperature at arrival: 25.8C Number of units: 8 i) Transaction Number: STA565344 Transaction Number: STA565347 Transaction Number: STA565346 Transaction Number: STA565349 Receipt Date: 07/01/2024 Temperature at arrival: 24.9C Number of units: 32 j) Transaction Number: STA566768 Receipt Date: 07/09 /2024 Temperature at arrival: 24.7C Number of units: 8 k) Transaction Number: STA567087 Transaction Number: STA567088 Transaction Number: STA567089 Transaction Number: STA567090 Transaction Number: STA567091 Transaction Number: STA567092 Transaction Number: STA567093 Transaction Number: STA567097 Transaction Number: STA567100 Transaction Number: STA567113 Transaction Number: STA567116 Transaction Number: STA567119 Transaction Number: STA567128 Transaction Number: STA567131 Transaction Number: STA567132 Transaction Number: STA567133 Receipt Date: 07/11/2024 Temperature at arrival: 25.4C Number of units: 125 l) Transaction Number: STA569343 Receipt Date: 07/21/2024 Temperature at arrival: 24.4C Number of units: 8 4. General Supervisor number 2 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 12/11/2024 at 1500 in the laboratory. Key PGD - Pan Genera Detection 43232 II. Based on review of SafeTrace reports and results, Erytra analyzer printouts, standard operating procedures (SOP), interviews with staff, ABO testing worksheet, and electronic mail (email) communications, the laboratory failed to follow their own written policy for resolving one of one ABO/Rh discrepancy in 2024. Findings included: 1. Review of a SafeTrace ABO/Rh discrepancy report included patient #2800161 with comments on 12/02/2024 "POSSIBLE TRANSFUSED CELLS, TMP INVESTIGATING" and "SUB A BLOOD TYPE" by testing person-28 (TP-28, as listed in the CMS-209 form). (TMP - transfusion medicine physician) Review of the patient's specimens 24B-337T0466 and 24B-337T0453 Erytra analyzer results tested on 12/02/2024 included the interpretation "Fwd Gr: A Rh: Pos" and "Rev Gr: O" invalidating the results in the SafeTrace system. (Fwd Gr - forward group, Rev Gr - reverse group) According to the SafeTrace system, patient #2800161 did not have a history with the facility and

required two specimens be collected for ABO/Rh and antibody screen testing (per SOP-2676 and policy #CLN1115). Specimen 24B-337T0453 was the "Type and Screen" and specimen 24B-337T0466 was the "confirmatory Type and Screen." 2. Review of SafeTrace results included repeated ABO/Rh forward and reverse testing via tube method by two testing persons (TP-7 and TP-28) on 12/02/2024. One performed on specimen 24B-337T0453 and the other performed on specimen 24B-337T0466 with the following results (immediate spin) Anti-A: 4MF (mixed field), Anti-B: 0, Anti-D: 4, Rh Con: 0, A1 cells: 2, A2 cells: 0, B cells: 4 (the discrepancy persisted). During an interview on 12/11/2024 at 3:30 pm, TP-7 stated the patient was in surgery and could not obtain a transfusion history and contacted clinical consultant # 1 (CC-1) (a transfusion medicine physician - TMP) to follow-up about the patient's history and TP-7 and TP-28 suspected a subgroup. TP-7 sent an email to CC-1 as a follow-up to their conversation on 12/02/2024 at 6:24 pm. TP-28 added "Group O RBC's only" requirement and "Sub A Blood Type" comment in the patient's SafeTrace file. 3. A continued review of patient #2800161 SafeTrace results included (both specimens 24B-337T0453 and 24B-337T0466) SR A1 Cells: 0 and SR B Cells: 4 (immediate spin) with the interpretation as "A" type on 12/05/2024 by TP-27 /Dayshift Lead Technologist (SR- saline replacement). On 12/05/2024 at 3:37 pm, the "Group O RBC's only" requirement was removed by TP-27. The extra red cell and mixed-field reactivity was not investigated by TP-27 as required by the procedure and there was no documentation of the TMP requesting the "Group O RBC's only" requirement be removed. 4. Review of the "Resolution of ABORH Discrepancy" SOP-2679 stated the following: On page 2, "ABO interpretation must be delayed until an unexplained discrepancy is resolved. If the patient has order for transfusion notify the TMPs; Group O RBCs of the appropriate Rh type should be given until ABO discrepancy is resolved." On page 6, after the ABORH is repeated via tube method (per the "Initial Investagation" steps, page 6) it stated, "Step 4 If the discrepancy persists, continue to 'evaluating the discrepancy' section." The "Evaluating the Discrepancy" section included a step-by-step procedure for reverse and forward tube testing, "Note-Anti-A1 Lectin and Anti-H Lectin may be added for additional investigation", immediate spin and incubation at room temperature steps. Pages 7 through 8 included interpreting red cell and plasma reactions, and ABO Subgroups. On page 4, "Extra Red Cell Reactivity - Requires workup to confirm/resolve, Auto-agglutinins/excess protein coating red cells, Unwashed red-cells; plasma proteins, Unwashed red cells; antibody in patient's serum to reagent constituent; Requires confirmation of patient history. No serological resolution." On page 9 Common Resolution Methods, "Commonly Used Methods ...If the discrepancy is ...Extra Red Cell Reactivity, Then the following may be performed to resolve ...Wash red cells, Warm wash red cells (Cold Ab), Perform ABO subgroup testing." On Page 4, "Mixed-field Red Cell Reactivity - Requires workup to confirm/resolve, ABO subgroup, Requires confirmation of patient history. No serological resolution." On page 9 Common Resolution Methods, "Commonly Used Methods ...If the discrepancy is ... Mixed-field Red Cell Reactivity, Then the following may be performed to resolve ... Perform ABO subgroup testing (possible A3)." On page 5, "Extra Serum Reactivity - Requires workup to confirm/resolve, Cold autoantibody, Cold-reactive alloantibody, Serum antibody to reagent constituent, Excess serum protein." On page 9 Common Resolution Methods, "Commonly Used Methods ...If the discrepancy is ... Extra Serum Reactivity, Then the following may be performed to resolve ...Saline replacement, Antibody ID (then select cells that are negative for the alloantibody), Wash reagent red cells, Dry Cell Button." Review of the Saline Replacement SOP-2673 page 4 stated, "Required: ...Must be performed when all reactions in the phase of testing being tested are positive." 4. During an interview on 12/12/2024 at 9:23 am, TP-27 was asked about the testing performed on patient #2800161 to resolve the ABO

discrepancy (on 12/05/2024). TP-27 stated general supervisor-1 (GS-1) asked them to do the saline replacement and they completed it, the ABO discrepancy was resolved, and they removed the "Group O RBC's only" requirement. TP-27 stated the repeated results via tube method on 12/02/2024 were showing mixed-field and extra red cell reactivity (not all reactions were positive) and TP-27 was instructed to do a saline replacement. No additional testing was documented. TP-27 stated they added the comment "Patient had Rouleaux/RVS type discrepancy solved by Saline Replacement Method" on 12/05/2024 as reviewed on the "Patient Snapshot Report." TP-27 did not "workup to confirm/resolve" for the mixed-field red cell reactivity and extra red cell reactivity as outlined in the laboratory's SOP-2679 (ABO subgroup testing, Lectin testing, washing red cells, warm red cells). 5. During an interview on 12/12/2024 at 10:00 am, CC-1 was asked whether they approved the "Group O RBC's only" requirement being removed from patient #2800161 file on 12/05/2024. CC-1 stated no and received an email on 12/05/2024 at 11:20 am from GS-1 stating the discrepancy was resolved, the mixed field was due to a high WBC, the extra reactivity was rouleaux and "The instructions for give [sic] group O POS was removed from the patient's file." CC-1 replied to GS-1 stating, "Please let Dr. [CC-4] review the case before the RBC transfusion requirements are changed in SafeTrace." CC-1 stated TP-21 did additional testing and discussed with CC-4. The "Group O RBC's only" requirement was added back on 12/05/2025 at 3:37 pm by TP-21. On 12/05/2024 at 4:05 pm, the laboratory director provided a peripheral smear image to CC-2, TP-21, GS-1, and TP-7 stating there was no rouleaux and "let the TMPs make the final determination and don't change anything in terms of the typing and requirements until they review the case and the studies." On 12/05/2024 at 4:26 pm, CC-2 asked whether a direct antiglobulin test (DAT) was performed, and GS-1 responded stating one would be performed (12/05/2024 at 4:32 pm). According to SafeTrace and the one "Manual Testing Worksheet" provided, a DAT was not performed. On 12/05/2024 at 6:05 pm, CC-4 in an email to CC-2, the laboratory director, TP-21, GS-1, and TP-7 asking why the Lectin test was not performed and to not remove the "O RBC's only" requirement. 6. During an interview on 12/12/2024 at 11:00 am, the laboratory director reviewed patient #2800161 testing performed and the SOP-2679 and confirmed the SOP should have been followed which was approved by them. The laboratory director stated "Group O RBC's only" requirements should only be removed by TMPs and was not sure whether the requirement was still present on the patient's file in SafeTrace. 7. During an interview on 12/12/2024 at 12:11 pm, TP-21 was asked whether additional testing was performed for patient #2800161. TP-21 stated they performed a lectin test (per SOP) on 12/05/2024 and it was negative. TP-21 stated they also performed a crossmatch with the patient's specimen (24B-337T0466) and an A pos RBC unit (W0244624321059) which was incompatible and with an O pos RBC unit (W035224299358) which was compatible (per Erytra analyzer results on 12/09/2024). TP-21 presented this information to GS-1 and GS-1 stated it was rouleaux, not an ABO subgroup. 8. During an interview on 12/12/2024 at 2:56 pm, GS-1 was asked for additional documentation regarding the testing for patient #2800161 ABO discrepancy issue, GS-1 stated there was one downtime worksheet for repeat testing. GS-1 stated it was rouleaux and a high WBC caused the mixed-field reaction and other patients with high WBCs have also had mixed-field reactions. GS-1 stated they did not suspect an ABO subgroup, and it was not investigated. During an interview on 12/12/2024 at 3:02 pm, GS-1 provided a "Manual Testing Worksheet" from 12/04/2024 at 6:35 pm for patient #2800161 specimen 24B-337T0466 resulted by TP-18. The tube method results were Anti-A: 4MF, Anti-B: = (negative), Anti-D: 4, Mono Clt.: =, A1 Cells: 1, B Cells: 4. The repeat testing was not performed on specimen 24B-337T0453, which is required per SOP-2676 and #CLN1115. The repeat testing did not align with the SOP (five test

tubes for reverse and four test tubes for forward testing). GS-1 stated the high WBC and rouleaux were causing the reactions and these results showed it was not an ABO discrepancy, a special requirement for transfusion was not required and a crossmatch was not performed. GS-1 stated CC-2 called the patient and the patient had not been transfused, there was no documentation of this information. 9. Review of patient #2800161 SafeTrace file under special requirements included the following information, "Group ORBCs only Start Date & Time 12/05/2024 - 3:37 pm; End Date & Time 12/06/2024 - 8:58 am." The group O only requirements had been removed. According to the "Activity" tab under the patient's file in SafeTrace, the requirement was removed on 12/07/2024 at 8:58 am by GS-1. During an interview on 12/12/2024 at 11:25 am with the laboratory's SafeTrace IT contact, when asked why the dates were different for the requirement removal (12/6 and 12/7), the IT contact stated the removal occurred on 12/07/2024 at 8:58 am but was backdated to 12/06/2024 at 8:58 am. The IT contact stated SafeTrace has the capability of backdating by selecting a date from a calendar pop-up. The laboratory failed to follow their own SOPs for complete testing of investigating an ABO discrepancy; the laboratory failed to test both type and screen and confirmatory specimens for ABO repeat testing; the laboratory failed to accurately enter dates for requirement removals; and failed to ensure documentation of transfusion history and TMP approval of RBC requirement. Word Key: RBCs - red blood cells product Ab - Antibody IT - information technology 44278 III. Based on review of laboratory policy, daily blood bank inventory reports in 2024, surveyor observation, and confirmed in interview, the laboratory failed to follow their own policy on performing blood bank inventory for two of two days observed in December 2024 (12/11-12/2024). Findings Included: 1. Review of laboratory policy, "Inventory Control" (Procedure: SOP-1098) (Approved by the laboratory director on 09/23/2022) revealed the following: " ...Day Shift Inventory Responsibilities ...Irradiates and transforms all products as needed into inventory. ... Evening Shift Inventory Responsibilities ...Irradiates and transforms all products as needed into inventory. ... Night Shift Inventory Responsibilities ...Irradiates and transforms all products as needed into inventory." 2. Review of daily blood bank inventory report emails in December 2024 revealed the following: a. Daily Inventory 12/11/2024 B= (negative) Units Minimum Normal Levels: 5 Minimum Critical Level: 2 RBC's in inventory: 7 b. 12/12/2024 B= (negative) Units Minimum Normal Levels: 5 Minimum Critical Level: 2 RBC's in inventory: 5 c. B+ (positive) Units Minimum Normal Levels: 50 Minimum Critical Level: 30 RBC's in inventory: 59 3. During a tour of the laboratory on 12/11/2024 at 02:25 PM, the surveyor observed four RBC B= units in the blood bank inventory ready to be transfused. On 12/12/2024 at 09:24 AM, the surveyor observed three RBC B= units, and 20 RBC B+ units in the blood bank inventory ready to be transfused. The surveyor requested documentation for the discrepancy in inventory in the blood bank, and the number of units from the daily inventory report, and no documentation was provided. 4. In an interview on 12/11 /2024 at 02:30 PM with the technical supervisor (TS-1) in the laboratory, TS-1 stated all units, including ones not irradiated or transformed, were included in the daily blood bank inventory report to providers. This confirmed the laboratory failed to follow their own policy on performing blood bank inventory for two of two days observed in December 2024 (12/11-12/2024). Word Key RBC's- Red Blood Cells IV. Based on review of laboratory policy, patient massive transfusion protocol (MTP) reports in 2024, and confirmed in interview, the laboratory failed to follow their own policy for MTP deactivation, for 22 of 22 blood products returned to the laboratory in August 2024. Findings Included: 1. Review of laboratory policy, "Massive Transfusion Protocol" (Procedure: SOP-3320) (Approved by the laboratory director on 11/23/2023) revealed the following: "MTP Deactivation ...2. Record return of coolers and any unused RBC and/or thawed FFP products on Form-3714 MTP Verbal

Request and Tracking Form." 2. Review of patient MTP reports in August 2024 (08/27 /2024), revealed an MTP event involving 22 unused blood products returned to the laboratory following the event in August 2024. Random review of blood products returned revealed the following RBC unit numbers: a. W2232 24 959800 2 b. W2232 24 959605 8 c. W0352 24 159928 R d. W2232 24 957509 3 e. W0352 24 244291 6 The facility was asked to provide Form-3714 (referenced above), documenting the returned units and temperatures recorded. No documentation was provided for the above MTP deactivation in August 2024. 3. In an interview with the transfusion safety officer on 12/12/2024 at 01:15 PM in the facility office, the safety officer confirmed Form-3714 was not documented following the above MTP event. This confirmed the laboratory failed to follow their own policy for MTP deactivation, for 22 of 22 blood products returned to the laboratory in August 2024. Word Key: RBC- Red Blood Cells FFP- Fresh Frozen Plasma 45469 V. Based on review of laboratory policies, laboratory patient transfusion records, patient history, and confirmed in interview, the laboratory failed to follow laboratory policy for the selection and issuing of blood and blood products for patients that had undergone bone marrow transplants (BMT) for 4 of 18 BMT patients randomly reviewed in 2023 and January through December 10th, 2024. The findings included: 1. Review of the 2024 and 2023 policies in place for the reviewing and approving of blood products for transfusion included the following information: a. The laboratory procedure titled "SOP-3728/REV 11" (in use from 10 /20/2023 to current) "Reviewing and Approving Blood Products for Transfusion", section "Transfusion Guidelines", subsection "Transfusion guidelines for Allo BMT Patients" included the following instructions: "Select products for BMT patients based on Figure A below. Do NOT select products based on forward and/or reverse type. Patients receiving Allo BMT transfusions will have a TMP Consult prior to or on the transplant date. The consult will reflect transfusion requirements found in Figure A below ..." b. Review of the laboratory policy number "SOP-3728" (in use from 6/5 /2023 - 10/20/2023), titled "Reviewing and Approving Blood Products for Transfusion", section "3. Policy Statements", subsection "3.4 Transfusion Guidelines: Allogeneic Bone Marrow Transplant" included the following instructions: "3.4.1 The patient should receive the below mentioned ABO types for each blood product from the date of transplant until engraftment has been confirmed. A. Engraftment or graft failure will be determined by a TMP consensus. B. TMP will update documentation with new transfusion requirements based on TMP group decision. C. Transfusion recommendation will be entered in BBIS according to SOP-1156 Transfusion Medicine Consultation ..." 2. Review of patient records, Transfusion Medicine Provider (TMP) requirements, and transfusion records included the following two bone marrow transplant (BMT) patients who were crossmatched and issued red blood cells (RBCs) against the TMP requirements: August 2023 Patient 2765049 Original Blood Type: O Pos BMT Donor Blood Type: A Pos on 2/14/2014 On 8/9/2023 the TMP requirements stated the following: "The patient should receive the below mentioned ABO types for each blood product from the date of transplant (listed above) until engraftment has been confirmed. RBC: O Platelets: A, B PLTs; Plasma reduced B, O PLTs FFP/Cryoprecipitate: A, AB" On Unit W035223506055, A Pos, was crossmatched and issued for transfusion to patient MRN 2765049 on 8/15/2023. January 2024 Patient: MRN 2182382 Original blood type: A Pos BMT Donor blood Type: O Pos on 12/14/2017 On 12/30/2023 the TMP requirements stated the following: "Transfuse RBCs: Group O; PLTS: A, AB/Plasma reduce B, O (okay to override plasma reduced B, O platelets); FFP/CRYO: A, AB" On 1/23/2024 an A Pos RBC, unit number W035223657359, was crossmatched to the patient. On 1/25/2024 the unit was marked as transfused to patient MRN 2182382. 3.Review of the laboratory policy titled "SOP-2707 revision 16, Issue of Blood and Products" in use from 10/20/2023 to 6/17/2024, section "Performing Readback Steps" included the

	following instructions: "The BBIS will check: - The intended recipient's scanned identifier (MRN) pulls up the appropriate patient electronic file. - The unit being issues is assigned or crossmatched appropriately to the identified recipient. - Blood type compatibility is acceptable with product being issued. - Crossmatch expiration date and time is acceptable. - Blood and product expiration date and time is acceptable. The dispensing personnel will: - Verify the blood product matches the patient's transfusion requirements ..." 4. Review of patient records, Transfusion Medicine Provider (TMP) requirements, and transfusion records included the following two bone marrow transplant (BMT) patients who were crossmatched and issued red blood cells (RBCs) with a crossmatch status of "incompatible": March 2024: Patient: 2734065 Original Blood Type: A Neg BMT Donor Blood Type: O Pos on 3/5/2024 On 3/5/2024 TMP stated the following: "The patient should receive the below mentioned ABO types for each blood product from the date of transplant (03/05 /2024) until engraftment has been confirmed. Please transfuse the following products: RBC: O Platelets: A or AB PLTs. Plasma reduce: B, O PLTs FFP / Cryoprecipitate: A, AB" An O+ RBC, unit W226124001584, was crossmatched and issued to the patient on 3/17/2024 with a crossmatch status of "incompatible" on the product ID tag. May 2024: Patient: 2638109 Original Blood Type: AB Neg BMT Donor Blood Type: O Pos received on 5/11/2022 (second transplant patient received) O Pos received on 3/20/2023 (first transplant patient received) On 7/11/2023 the TMP stated the following: "The patient should receive the below mentioned ABO types for each blood product from the date of transplant (listed above) until engraftment has been confirmed. Please transfuse the following blood groups: RBC: O Platelets: AB PLTs; Plasma reduce: A, B, O PLTs FFP/Cryoprecipitate: AB" An O Pos RBC, unit W223224935045, was crossmatched and transfused to the patient on 5/21/2024 with a crossmatch status of "incompatible" on the product ID tag. 5. In an interview on 12/12 /2024 at 15:15 hours, in the hallway, GS1 stated that not all laboratory dispensing personnel would confirm patient and unit requirements for the issuing and dispensing of blood products.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of an SOP, interview with TP-1, and direct observation, the laboratory failed to ensure changes to the massive transfusion protocol (MTP) SOP were completed and approved by the laboratory director before use. Findings included: 1. Review of Massive Transfusion Protocol SOP-3320 (revision 7) was approved by the laboratory director 11/20/2023 and the origin date was 03/27/2018. During an interview on 12/11/2024 at 10:29 am, TP-1 was asked for a walk-through for preparing an MTP. In review of SOP-3320 on page 9, TP-1 stated those were not the coolers they used for MTPs. The coolers in the SOP were white 16 quart "playmate" brand coolers with a lid that slid open and close. During an observation in transfusion medicine department on 12/11/2024 at 10:45 am, TP-1 presented the coolers that are used for MTPs. They were red "MaxPlus MTP Cooler with Maxify Technology Max Q Value Value in Motion" portable coolers with a yellow attachment for storing platelets and cryoprecipitate products at room temperature. The coolers included wheels and a handle for portability out of the transfusion medicine department during an MTP. 2. During an interview on 12/11/2024 at 10:45 am, TP-1

	confirmed staff were trained a few months ago with the new coolers. 3. The Massive Transfusion Protocol SOP-3320 did not include instructions for packing the current in-use observed coolers. The laboratory failed to ensure changes to the MTP SOP were completed and approved by the laboratory director before use.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on general supervisor (GS) 2 and testing personnel interviews and immunohematology supplies protocol record review on December 11, 2024 at 10:45 am, for patient tests performed using the Grifols Erytra instruments, the laboratory failed to use gel cards following the manufacturer's instructions and have documentation indicating that the gel cards were used in a manner that provided patient test results within the laboratory's performance specifications. Findings included: a. In the immunohematology section, the laboratory performed patient type and screen testing, antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. b. According to testing personnel, the Grifols Erytra instruments could recognize that a gel card used on the instruments had air pockets (i.e., bubbles) within the gel on a card, and only use gel cards without these air pockets. The instruments would alert the instrument user of the air pockets and not use the questionable gel card. c. According to GS2 and testing personnel, the gel cards with air pockets would be centrifuged to remove any air pockets and reloaded on the Grifols Erytra instruments to be used for patient specimen testing. d. The laboratory's immunohematology section maintained no written policies and procedures detailing the centrifugation of gel cards containing air pockets and the use of the centrifuged gel card on the Grifols Erytra instruments for patient specimen testing. e. GS2 could not verify whether the gel card manufacturer had instructions for centrifuging gel cards with air pockets and the use of centrifuged gel cards that had contained air pockets for patient specimen testing, and could not provide documentation indicating that the laboratory had established test performance specifications for the use of centrifuged gel cards that had contained air pockets for patient specimen testing using the Grifols Erytra instruments . f. Testing personnel could not provide any information as to whether patient specimen testing using the Grifols Erytra instruments had been completed using gels cards that had been centrifuged or uncentrifuged prior to being used for patient specimen testing. g. These findings were confirmed by GS2 and testing personnel on December 11, 2024 at 10:45 am. h. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly. 31968 II. Based on review of the manufacturer's instructions for the Immucor Anti-E (Monoclonal) Gamma-clone reagent, review of the patient test records from February 1, 2024 to November 12, 2024, staff interview, the laboratory failed to have documentation of performing each of the required steps for Anti-E testing on 2 of 9 patients. The findings included: 1. A review of the manufacturer's instructions for the Immucor Anti-E (Monoclonal) Gamma-clone reagent (Insert Code: 3009-2, Revised: 02/2013) under the section titled "Tube Method" determined the manufacturer's procedure for performing the test included two steps: a) Immediate Spin b) Room Temperature Incubation (if Immediate Spin was negative). 2. A review

	of patient test records from February 1, 2024 to November 2024 identified 2 of 9 patients tested did not have documentation of the laboratory performing each of the required steps. They were: a) Medical Record Number: 2261985 Test Date: 2/1/2024 Missing test result: Room Temperature Incubation b) Medical Record Number: 2273001 Test Date: 11/2/2024 Missing test result: Immediate Spin 3. General Supervisor number 2 confirmed the findings in an interview conducted on 12/12/2024 at 1348 hours in the hallway outside the conference room. III. Based on review of the manufacturer's instructions for the Immucor Blood Grouping Reagents Anti-C, Anti-E, Anti-c, Anti-e Series 1 (Monoclonal Reagents), review of the patient test records from February 1, 2024 to November 12, 2024, staff interview, the laboratory failed to have documentation of performing each of the required steps for Anti-c testing on 4 of 7 patients. The findings included: 1. A review of the manufacturer's instructions for the Immucor Blood Grouping Reagents Anti-C, Anti-E, Anti-c, Anti-e Series 1 (Monoclonal Reagents) (Insert Code: 365-9, Revised: 2/13) under the section titled "Tube Method" determined the manufacturer's procedure for performing the test included two steps: a) Incubation at 36-38 for 5 minutes, c) Incubation at 36-38 for 10 minutes (if negative after first 5 minute incubation). 2. A review of patient test records from February 1, 2024 to November 2024 identified 4 of 7 patients tested did not have documentation of the laboratory performing each of the required steps. They were: a) Medical Record Number: 2261985 Test Date: 2/1/2024 Missing test results: 5 minute incubation - Test was positive (No 10 minute incubation needed) - An immediate spin test was documented as being performed b) Medical Record Number: 2717816 Test Date: 2/6/2024 Missing test results: 5 minute incubation - Test was positive (No 10 minute incubation needed) - An immediate spin test was documented as being performed c) Medical Record Number: 2220474 Test Date: 2/27/2024 Missing test results: 5 minute incubation - Test was positive (No 10 minute incubation needed) - An immediate spin test was documented as being performed d) Medical Record Number: 2816056 Test Date: 3/21/2024 Missing test results: 5 minute incubation - Test was positive (No 10 minute incubation needed) - An immediate spin test was documented as being performed 3. General Supervisor number 2 confirmed the findings in an interview conducted on 12/12/2024 at 1348 hours in the hallway outside the conference room.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, general supervisor (GS) 2 and testing personnel interviews, and immunohematology reagent record review on December 11, 2024 at 11:00 am, the laboratory failed to ensure that immunohematology reagents met the manufacturer's instructions for proper temperature storage. Findings included: a. In the immunohematology section, the laboratory performed patient type and screen testing, antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. In addition, the laboratory used the following Grifols

	reagents on the three Grifols Erytra instruments: Reagent Red Blood Cells Search-Cyte I, II, III, Reagent Red Blood Cells Reverse-Cyte A1, B, and Grifols Diluent. b. On December 10, 2024 at 02:30 pm, the following Grifols reagents were observed being stored at room temperature (20.20 degrees C to 23.80 degrees C): i. Grifols Reagent Red Blood Cells Search-Cyte I, II, III, lot number 644724024, expiration date 01-04-2025. ii. Grifols Reagent RBC Reverse-Cyte A1, B, lot number 64124045, expiration date 12-21-2024. iii. Grifols Diluent, lot number 24014.01, expiration date 10-31-2025. c. Pursuant to manufacturer's instructions, Grifols Reagent Red Blood Cells Search-Cyte I, II, III, Grifols Reagent RBC Reverse-Cyte A1, B, and Grifols Diluent are to be stored at 2 to 8 degrees C. d. According to testing personnel, when the vials of reagents, used to test patient specimens, were emptied, they were replaced with the vials of reagents stored at room temperature. e. These findings were confirmed by GS2 and testing personnel on December 11, 2024 at 11:00 am. f. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on general supervisor (GS) 1 interview and immunohematology established test method performance specifications record review on December 11, 2024 at 2:50 pm, for the laboratory's manual patient antibody screening test using modified DTT (dithiothreitol) treated Immucor antibody screening cells, the laboratory failed to establish test performance specifications before reporting patient test results for each test performance characteristics listed at 42 CFR 493.1253(b)(2). Findings included: a. In the immunohematology section, the laboratory performed manual patient antibody screening tests using modified DTT treated antibody screening cells. The laboratory's modified DTT treated antibody screening cells was made in-house using commercially purchased antibody screening cells and treating these antibody screening cells with DTT. b. The laboratory's documented established test performance specifications for the use of DTT treated antibody screening cells for manual patient antibody screening tests was based on the use of Quotient ALBAcyte Antibody Screening Cells for Tube Techniques antibody screening cells. c. According to GS1, from November 4, 2024 to November 10, 2024, the laboratory used in-house made DTT treated Immucor antibody screening cells, not Quotient ALBAcyte Antibody Screening Cells for Tube Techniques antibody screening cells, for manual patient antibody screening test. The laboratory maintained no documentation to indicate that test performance specifications had been established pursuant to 42 CFR 493.1253(b)(2) for manual patient antibody screening tests using modified DTT treated Immucor antibody screening cells before reporting patient manual antibody

	screening tests. d. GS1 provided a laboratory document titled "Medical Exception Documentation Form" indicating that the change of antibody screening cells from Quotient to Immucor was significant to warrant an authorization from the "Transfusion Medicine Physician" on November 5, 2024. e. These findings were confirmed by GS1 on December 11, 2024 at 14:50 pm. f. According to GS1, the laboratory performs and reports approximately 50 manual patient antibody screening test weekly.
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on general supervisor (GS) 2 and testing personnel interviews and immunohematology instrument protocol record review on December 11, 2024 at 10: 00 am and at 11:15 am, for patient tests performed using the Grifols Erytra instruments, the laboratory failed to maintain documentation to indicate that quality control procedures were performed before resuming patient testing when a change of reagents were introduced. Findings included: a. In the immunohematology section, the laboratory performed patient type and screen testing, antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. b. According to testing personnel, quality control procedures were performed on each of the three Grifols Erytra instruments during each of the three work shifts every day. However, when there was a change to a new lot of reagents, which could include, but not limited to, anti-A, anti-B, A1 cells, B cells, anti-D, and screening cells, on any of the Grifols Erytra instruments during a work shift and after quality control procedures were performed, the laboratory maintained no documentation to indicate that quality control procedures were again performed before resuming patient testing. c. The immunohematology section maintained no written policies and procedures detailing a protocol for when a new lot of reagents are changed on the Grifols Erytra instruments. d. GS2 could not verify whether the Grifols Erytra instruments in use prevented the resumption of patient testing when new lots of reagents were changed if quality control procedures were not performed. e. These findings were confirmed by GS2 on December 11, 2024 at 10:00 am and at 11:15 am. f. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value

	of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on general supervisor (GS) 2 and testing personnel interviews and immunohematology quality control record review on December 11, 2024 at 10:30 am, the laboratory, which used the stated values of commercially assayed quality control materials, failed to verify the criteria for acceptability of all quality control materials used to monitor patient testing using the Grifols Erytra instrument. Findings included: a. In the immunohematology section, the laboratory performed patient type and screen testing, antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. b. According to testing personnel, quality control procedures were performed on each of the three Grifols Erytra instruments during each of the three work shifts every day. When there was a change to a new lot of quality control materials, the laboratory maintained no documentation to indicate that the criteria for acceptability of the new lot of quality control materials had been verified by the laboratory before being used to monitor patient specimen testing. c. In addition, the immunohematology section maintained no written policies and procedures detailing a protocol for when new lots of quality control materials are used on the Grifols Erytra instruments. d. These findings were confirmed by GS2 and testing personnel on December 11, 2024 at 10:30 am. e. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly.
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 general supervisor (GS) 1, GS2, and laboratory personnel interviews and immunohematology patient ABO discrepancies record review on December 12, 2024 at 09:00 am and 04:30 pm, the laboratory failed to confirm patient ABO group by testing the patient unknown serum with known A1 and B red cells. Findings included: a. In the immunohematology section, the laboratory performed patient type and screen testing (including patient ABO group testing), antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. If patient ABO group testing using the Grifols Erytra instruments yielded patient test results in which

the ABO group by concurrently testing the unknown patient red cells with anti-A and anti-B grouping reagents did not confirm with and/or correspond to the ABO group testing of the patient's unknown serum tested with known A1 and B red cells, the Grifols Erytra instruments would not report the patient ABO group and would flag the patient's specimen for further review. These unconfirmed patient ABO group test results were consider ABO discrepancies by the laboratory. b. Testing personnel would review all patient Grifols Erytra instrument ABO discrepant results. If after testing personnel review and possible further testing a patient's ABO discrepant test result could not be resolved, the Grifols Erytra instrument ABO group test result would be marked as "INV [invalid]" and the laboratory would perform additional manual testing. c. According to GS1 and GS2 on December 11, 2024 at 03:00 pm and December 12, 2024 at 09:30 am, the immunohematology section's informations system, SafeTrace Tx, would consider a patient record "invalid" if: i. A patient's ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents did not confirm with and/or correspond to the ABO group testing of the patient's unknown serum tested with known A1 and B red cells; or ii. The test result of a patient's ABO group by concurrently testing unknown red cells with anti-A and anti-B grouping reagents and/or a patient's ABO group of the patient's unknown serum tested with known A1 and B red cells was not entered into SafeTrace Tx. d. On December 11, 2024 at 03:00 pm and December 12, 2024 at 09:30 am, GS1 and GS2 stated that testing personnel could not enter pRBC (packed red blood cell) crossmatch information into SafeTrace Tx if a patient's SafeTrace Tx record was "invalid," thereby preventing the transfusion of blood products when patient specimen testing records were incomplete and/or yielded ABO discrepant test results. When testing personnel resolved patient ABO discrepant results and properly entered all applicable information into SafeTrace Tx, SafeTrace Tx would allow the entry of pRBC crossmatch information by testing personnel so that blood products could be issued to hospital staff for transfusion to patients. e. To confirm GS1's and GS2's representation of the laboratory's SafeTrace Tx system, on December 12, 2024 at 09:30 am, an example from January 2024 of a patient specimen with ABO discrepant test results was requested. Using the laboratory's SafeTrace Tx system, GS1 showed an example in which a patient's ABO discrepant test result was resolved. The laboratory's SafeTrace Tx record showed the Grifols Erytra instrument ABO group test result as "INV," and showed the test results of the resolved patient ABO group by concurrently testing unknown patient's red cells with anti-A and anti-B grouping reagents and the test result of the resolved confirmation of ABO group by testing the patient's unknown serum with known A1 and B red cells. This patient SafeTrace Tx record also showed that one unit of pRBC had been crossmatched and issued to hospital staff for transfusion to the patient. f. To further confirm GS1's and GS2's representation of the laboratory's SafeTrace Tx system made on December 12, 2024 at 09:30 am, a list of all patient ABO discrepant test results for December 2023, January 2024, and February 2024 was requested and provided by the laboratory's IT (information technology) personnel on December 12, 2024 at 04:30 pm. Included on this list was at least two patient records in which there was an initial determination of an ABO discrepancy. However, only the test results of the resolved patient ABO group by concurrently testing unknown patient's red cells with anti-A and anti-B grouping reagents was documented. There was no documentation of the test results of the resolved confirmation of ABO group by testing the patient's unknown serum with known A1 and B red cells. In both cases, there was documentation indicating that pRBC units were crossmatched and issued to hospital staff for transfusion to the patient. Information regarding these two cases are as follows: i. The laboratory's SafeTrace Tx record showed that on January 3, 2024 test results for patient MRN 2791232, specimen ID 24B-002T0827, was documented for the resolved patient ABO

	group by concurrently testing unknown patient's red cells with anti-A and anti-B grouping reagents only and that the patient's specimen was crossmatched and transfused with pRBC unit number W1216 23 338179 1. There was no documentation of the test results of the resolved confirmation of ABO group by testing the patient's unknown serum with known A1 and B red cells. ii. The laboratory's SafeTrace Tx record showed that on January 26, 2024 test results for patient MRN 2784109, specimen ID 24B-026T0136, was documented for the resolved patient ABO group by concurrently testing unknown patient's red cells with anti-A and anti-B grouping reagents only and that the patient's specimen was crossmatched and transfused with pRBC unit number W2261 23 026983 K. There was no documentation of the test results of the resolved confirmation of ABO group by testing the patient's unknown serum with known A1 and B red cells. g. The SafeTrace Tx records for patient MRN 2791232, (specimen ID 24B-002T0827) and patient MRN 2784109 (specimen ID 24B-026T0136) on December 11, 2024 at 03:00 pm and December 12, 2024 at 09:30 am, contradicted the explanation from GS1 and GS2 about the functions of the immunohematology section's informations system, SafeTrace Tx. h. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly for possible blood product transfusion.
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 general supervisor (GS) 2 interview and immunohematology quality assessment policies and procedures record review on December 10, 2024 at 02:45 pm and on December 11, 2024 at 09:00 am, the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the immunohematology analytic systems specified in 42 CFR 493.1251 through 493.1283. Findings included: a. In the immunohematology section, the laboratory maintained a record titled "Transfusion Service Lead MLS Daily Checklist" in which the "Lead" for each of the three work shifts would document with a check that specific tasks were accomplished. These tasks included "short date inventory review and tagging with short date tags," "review /investigate quarantine shelf," "printing final culture result for transfusion reaction," "DT viewer check," "monitor outstanding list," "discard eluates," "MTP assistance," and "[review] emergency crates." b. The laboratory established no written policies and procedures detailing the use of the form titled "Transfusion Service Lead MLS Daily Checklist," and limited written policies and procedures detailing the protocols for conducting the tasks listed. c. These findings were confirmed by GS2 on December 10, 2024 at 02:45 pm and on December 11, 2024 at 09:00 am.. d. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly II. Based on general supervisor (GS) 1 and GS2 interviews and immunohematology quality assessment policies and procedures record review on December 11, 2024 at 01:15 pm, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the immunohematology analytic systems specified in 42 CFR 493.1251 through 493.1283. Findings included: a. In the

	immunohematology section, the laboratory performed patient type and screen testing, antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. According to testing personnel, quality control procedures were performed on each of the three Grifols Erytra instruments during each of the three work shifts every day. b. According to the immunohematology written protocol titled "Quality System Overview [SOP-1038]," "laboratory manager and coordinator for Quality Assurance reviews the quality control process." According to the immunohematology written protocol titled "Quality Manual [SOP-1074]," "quality control is reviewed regularly by each section's management team and the Medical Director/Lab Director." c. The laboratory maintained no documentation to indicate that all documented quality control processes and procedures performed using the three Grifols Erytra instruments had been reviewed by the "laboratory manager and coordinator for Quality Assurance" or the "section's management team and the Medical Director/Lab Director" as required by the laboratory's written protocols. d. These findings were confirmed by GS1 and GS2 on December 11, 2024 at 01:15 pm. e. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly. 45469 III. Based on review of laboratory daily work forms and confirmed in interview the laboratory failed to ensure that testing personnel overrides and exceptions to standard operating procedures were reviewed daily by approved staff members, for three of twelve months reviewed from January 2024 to December 1, 2024. The findings included: 1. Review of the laboratory form titled "FORM-1840 REV/6, Daily Reports Review Form" included the following SafeTrace Tx (the laboratory blood bank information system) reports to be reviewed daily by supervisory staff: "Review Factors Review Factor Overrides Supervisor Reports-Exception Dashboard Corrected Tests Pt Blood Type Changes Issued Units No Type Specific Emergency Units Issued to Pts with No Blood Type Activity Reports Emergency Release Inventory Reports Current Inventory-Autologous Units Wasted Inventory - Quarantined by date Epic Beaker MDA Lab CP Blood Bank OR Inventory Reservation" 2. Surveyor asked for documentation for the daily reports for January 2024 to December 1, 2024, to ensure the overrides and exceptions performed by testing personnel were reviewed by the appropriate personnel. The general supervisor (GS) 1 provided January through August 31, 2024. Surveyor asked for documentation for the months of September, October, and November 2024. On 12/12/2024 at 14:19, in the hallway, GS 1 stated they could not locate the forms for September, October, and November 2024. 3. In an interview on 12/12/2024 at 15:20 hours, in the hallway, GS 1 stated that the use of the form was being phased out due to a department realignment of supervisors who were previously responsible for the daily reports review. GS 2 stated they were actively working with the laboratory information technology (IT) personnel to review the factory overrides and exception reports, but it was more involved than previously considered, and that it was an ongoing work in process.
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 laboratory policy, laboratory records, patient records, and staff interview, the laboratory failed to ensure their quality assurance (QA) included a review of effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, as evidenced by: A. The laboratory failed to ensure temperature storage and transport requirements for eight of ten blood and blood products for transfusion were maintained for suitability of blood for reissuance. Findings included: 1. The laboratory policy titled "SOP-2705 Return of Blood Products" stated, " ...Blood that has been removed from storage controlled by a licensed establishment shall not be reissued per regulations unless the following conditions are observed ...2. The blood has either been stored continuously at 1 to 6 C in a monitored Blood Bank refrigerator and/or returned with a temperature between 1 and 10 C ...Immediately take the temperature of ALL unopened products being returned ..." The laboratory policy titled "SOP-2699 Receiving Products" stated, " ...Receiving All RBCs ...1 Take the temperature of the product storage container using a NIST thermometer 2 Record the temperature on the packing slip 3 Sign and date the shipment form ..." 2. Review of laboratory records revealed the following: 01 /11/2023 Blood Product Deviation Report (Confirmation #854323) RBC Unit W226122028354 returned to laboratory in a cooler. The laboratory failed to obtain documentation of the person who received the unit, date and time of receipt, and temperature upon arrival. The unit was placed back into inventory and transfused on 01/15/2023. 05/05/2023 Blood Product Deviation Report (Confirmation #859754) RBC Unit W035223485651 returned to laboratory in a cooler. The laboratory failed to obtain documentation of the person who received the unit, date and time of receipt, and temperature upon arrival. The unit was placed back into inventory and transfused on 05/10/2023. 10/25/2023 Blood Product Deviation Report (Confirmation #868686) RBC Unit W140923093653 returned to laboratory in a cooler. The laboratory failed to obtain documentation of the person who received the unit, date and time of receipt, and temperature upon arrival. The unit was placed back into inventory and transfused on 10/27/2023. 07/25/2024 Medical Exception Documentation Form RBC Unit W044624330882 received at a temperature of 11.8 C. Unit was transfused on 07/30 /2024 with a medical exception for receipt temperature. 10/03/2024 Medical Exception Documentation Form RBC Units W044624311726 and W044624379344 received at a temperature of 12.9 C. Unit W044624311726 was transfused on 10/09 /2024 and W04462437934 was transfused on 10/14/2024 with a medical exception for receipt temperature. 10/14/2024 Medical Exception Documentation Form RBC Unit W044624379296 received at a temperature of 10.5 C. Unit was transfused on 10/14 /2024 with a medical exception for receipt temperature. 11/26/2024 Medical Exception Documentation Form RBC Unit W044624354593 received at a temperature of 11.0 C. Unit was transfused on 11/27/2024 with a medical exception for receipt temperature. 11/29/2024 Medical Exception Documentation Form RBC Units W044624397858 and W044624402776 received at a temperature of 11.1 C. Units were discarded "due to over temperature". The "Follow-Up" (corrective action) on the deviation report revealed the laboratory retrained staff, improved workflow in the receiving area, adjusted staff responsibilities, and edited procedures. 3. In an interview of 12/12/2024 at 09:30 am, a Quality Assessment officer confirmed that the units had been transfused. When asked why so many medical exceptions were made for temperatures outside of the acceptable transport range, the Quality Assessment officer could not explain the reason. B. The laboratory failed to ensure transport requirements for twelve of twelve apheresis platelets were maintained for suitability of transfusion. Findings included: 1. Review of the Blood Product Deviation Report (Confirmation #860588) revealed the following: 05/08/2023 Blood product supplier packed and shipped 12 apheresis platelet units to the laboratory. 05/10/2023 Apheresis platelets were received at the laboratory on 05/10/2023. The incident report stated, " ...

the receiving tech did not notice that the platelets were in transit for 48 hours instead of the 30-hour maximum allowable transit time and received the platelets in the BBIS ..." 05/29/2023 Date Biological Product Deviation (BPD) discovered. The "Follow-Up" (corrective action) on the deviation report revealed the laboratory emailed staff to reinforce requirements for platelet transport, reorganized the workflow, and updated procedures 2. Review of patient report revealed the 12 apheresis platelets were transfused: W142823016988 transfused on 05/10/2023. W142823016996 transfused on 05/11/2023. W142823021239 E2987V00 transfused on 05/10/2023. W142823021239 E5035V00 transfused on 05/10/2023. W142823021241 transfused on 05/11/2023. W142823022228 transfused on 05/11/2023. W142823022244 E53036V00 transfused on 05/11/2023. W142823022244 E53035V00 transfused on 05 /11/2023. W142823022249 transfused on 05/11/2023. W142823022250 transfused on 05/11/2023. W142823022262 transfused on 05/11/2023. W142823022281 transfused on 05/10/2023. 3. In an interview of 12/12/2024 at 09:30 am, a Quality Assessment officer confirmed that the apheresis units had been transfused. C. The laboratory failed to ensure blood products were stored under appropriate conditions with a temperature alarm system for 584 of 584 units of red blood cells (02/06/2023 through 02/10/2023). Findings included: 1. The Blood Product Deviation Report (Confirmation #855157) stated, "On Friday, 2/10/23, it was noted that blood products were being stored in refrigerator, SN 212186, that had not yet been qualified to store blood products ...root cause analysis and investigation identified the failure to place a visible 'Do not use' sign on the refrigerator ...the review found that a total of 584 units modified during the time of 2/6/23 through 2/10/23, 505 were transfused, 76 quarantined, 3 destroyed for other reasons ..." The deviation report stated that the laboratory placed an internal temperature probe in the refrigerator on 02/10/2023 to determine if the temperature data from the internal refrigerator probe could be used for acceptance. Per the incident report, "the internal refrigerator probe readings showed that on 2/10/23 from 2:59 am to 3:11 am, there was an 11-minute time frame in which the refrigerator temperature exceeded 6C to a maximum temperature of 6.6C ..." The "Follow-Up" (corrective action) on the deviation report revealed the laboratory removed the units from the refrigerator, put a "Do not Use" sign on the refrigerator, and revised procedure for new equipment. 2. A random sampling of patient records revealed the following units were transfused: W044622417865; W044622417930; W044622418306; W044622418696; W044622418718 W044622418719; W044622425960; W044622426297; W044622427436; W044622435192; W044622435926; W044622443755; W044622445325; W044622445744; W044622447691 3. In an interview of 12/12/2024 at 09:30 am, a Quality Assessment officer confirmed the findings and that the red blood cells had been transfused. D. The laboratory failed to ensure that unexpected antibody identification and compatibility testing was completed before red blood cells units were issued and transfused for three of three patients. Findings included: 1. The laboratory policy titled "SOP-2677 Antibody Identification" stated, " ...All samples with a positive antibody screen must have an antibody identification performed. All antibody identification testing must be completed BEFORE blood is issued ...It is very important to review all previous records for patient phenotyping and/or genotyping Reactivity of previously identified antibody (ies) to determine what method was used in the identification ..." The laboratory policy titled "SOP-2678 Serological Crossmatch" stated, " ...Incompatible crossmatch needs MUST be investigated and require TMP approval if clinical team cannot wait for blood ..." 2. Laboratory records revealed the following: a. The Blood Product Deviation Report (Confirmation #857251) revealed the following: On 02/26/2023, a unit of RBCs (Unit #W044623215682) was crossmatched for patient 267929 with a history of anti-Lu a (Lutheran a). The crossmatch testing was performed at immediate spin (IS) and anti-

human globulin (AHG) phases. The IS result was negative and the AHG result was positive indicating an incompatible unit. The technologist released the unit for transfusion as least incompatible and it was transfused. The "Follow-Up" (corrective action) on the deviation report revealed the laboratory updated procedure, retrained the testing person, and assigned a supervisor to review override reports. b. The Blood Product Deviation Report (Confirmation #857504) revealed the following: On 03/23 /2023, a unit of RBCs (Unit #W044623222716) was crossmatched to patient 0637710. Per the report, "The unit W044623222716 was dispensed and transfused before the ABID for the TS was completed ...ABID was completed on 03/25/2023 when it was discovered that it was not done ..." The "Follow-Up" (corrective action) on the deviation report revealed the laboratory coached, counseled and retrained the testing person. c. The Blood Product Deviation Report (Confirmation #863748) revealed the following: On 08/03/2023, a unit of RBCs (Unit #W223223848393) was crossmatched, dispensed, and transfused before the antibody identification was completed. The technologist indicated with a checkmark that the antibody screen was negative and did not check the computer for results. The unit was transfused to patient 2741222 on 08/03/2023 at 3:43 pm. Per the report, "Antibody screen was positive, and the antibody was identified as Anti-Jka, unit was Jka positive, extended crossmatch was 1+ incompatible". This testing was initiated on 08/03/2023 at 4:00 pm, after the unit had been transfused. The "Follow-Up" (corrective action) on the deviation report revealed the laboratory modified procedures and retrained staff. Further review of laboratory transfusion reaction investigation records from 08/04 /2023 revealed the patient was diagnosed with a delayed hemolytic transfusion reaction as the result of the transfusion. 3. In an interview on 12/13/2024 at 12:00 pm, a Transfusion Medicine Physician verified the findings. E. The laboratory failed to follow their own policy for the plasma reduction of apheresis platelets for six of six patients. Findings included: 1. The laboratory policy titled "SOP-4704 Selection and Assignment of Blood and Blood Components" stated, " ...Selection of platelets: For adults, select platelets to minimize exposure to passive ABO antibodies from the donor. See table below for platelet (non-Allo BMT patients) ... Adult Type O O PLTS 1st choice; A PLTS Compatible; B PLTS Compatible; AB PLTS Compatible Adult Type A O PLTS Plasma Reduce; A PLTS 1st choice; B PLTS Plasma Reduce; AB PLTS 2nd choice Adult Type B O PLTS Plasma Reduce; A PLTS Plasma Reduce; B PLTS 1st choice; AB PLTS 2nd choice Adult Type AB O PLTS Plasma Reduce; A PLTS Plasma Reduce; B PLTS Plasma Reduce; AB PLTS 1st choice ... Selection of Platelets for Allo BMT Patients: Patients receiving Allo BMt transfusions will get a TMP Consult prior to or on the transplant date. Consult will include the Transfusion Requirements that the patient will follow. Transfusion requirement in the BBIS will be updated to match the TMP consult on the date of the transplant ..." 2. Review of laboratory records revealed the following: a. The Blood Product Deviation Report (Confirmation #856638) revealed the following: Date of occurrence: 03/09/2023 Date of Discovery: 03/13/2023 "Patient 2626692 received an A Pos apheresis platelet that was not plasma reduced ...The patient's transfusion requirements indicate 'Platelets AB is preferred but all ABO types are acceptable as plasma reduction will occur is clinically necessary' ...Employee failed to indicate plasma reduction of platelets was required ..." Apheresis Platelet W035223530134 was transfused 03/09/2023. b. The Blood Product Deviation Report (Confirmation #857585) revealed the following: Date of occurrence: 03/29/2023 Date of Discovery: 03/30/2023 "Allo BMT Patient 2675008 ...TMP consult stated that all platelets given should be AB or plasma reduced A, B, O platelets. B pos platelet was assigned, released, and transfused to the patient without being plasma reduced ..." Apheresis Platelet W226123006412 was transfused 03/09/2023. c. The Blood Product Deviation Report (Confirmation #858273) revealed the following: Date of occurrence: 04/07/2023 Date of Discovery: 05/11/2023 "The

transfusion requirements for patient 2664807 state 'Transfuse AB platelets', any other type should be plasma reduced ...A pooled platelet B positive unit was assigned and dispensed ..." The nursing unit reviewed the transfusion requirements and returned the pooled platelets. d. The Blood Product Deviation Report (Confirmation #871424) revealed the following: Date of occurrence: 01/03/2024 Date of Discovery: 01/03 /2024 "A product order for platelets for patient 2798327 was received 01/03/2024. The supervisor approved an order for type A platelets. The laboratory technician assigned and dispensed an O platelet unit that was not plasma reduced. According to SOP-4704, if a type O is dispensed, the unit must be plasma reduced." The nursing unit noticed the discrepancy before it was transfused and returned the platelet. e. The Blood Product Deviation Report (Confirmation #878717) revealed the following: Date of occurrence: 05/22/2024 Date of Discovery: 05/22/2024 "During the Blood Bank computer system factor override supervisory review on May 22, 2024, it was discovered that the unit W121624985426 (A+ apheresis platelet) was dispensed and transfused to patient 2769577 ...The patient has instructions to plasma reduce all platelet products since May 16, 2024. The A pos apheresis platelet given to the patient was not plasma reduced as the patient instruction stated ..." Apheresis Platelet W121624985426 was transfused 05/22/2024. f. The Blood Product Deviation Report (Confirmation #887005) revealed the following: Date of occurrence: 10/11/2024 Date of Discovery: 10/11/2024 "A non-plasma reduced pooled O negative platelet unit was assigned and dispensed to a group O positive patient with no hematopoietic stem cell transplant history. In accordance with special instructions for this patient ...only plasma reduced platelets should have been assigned and dispensed ...." Platelet W035224282553 was dispensed, and transfusion had begun before the discrepancy was detected. The infusion was stopped after 10 minutes. The "Follow-Up" (corrective actions) on the incident reports revealed the laboratory developed a more detailed training checklist and competency assessment, retrained staff, required only Medical Laboratory Scientists to assign platelets to patients, and added a platelet assignment algorithm in the laboratory information system. 3. During an interview on 12/12/2024 at 12:00 pm, a Transfusion Medicine Physician confirmed orders for plasma reduction were missed and the laboratory failed to follow their own policy to identify patients requiring plasma reduced platelets. F. The laboratory failed to implement a system to identify and correct problems that occurred when a breakdown in communication occurred within the laboratory's transfusion services department for three of three apheresis platelet units. Findings included: 1. The laboratory policy titled "SOP-2697 Product Status Change" stated " ...Quarantine Guidelines Recalls /Market Withdrawals The supervisor/designee is responsible for documenting the response to other blood banks that request quarantine, market withdrawals, or recalls of blood products. Electronic Quarantine: The Blood Bank Information System (BBIS) can automatically and/or manually change the status of a blood product to Quarantine. Physical Quarantine: Quarantine blood products as required by a procedure or supervisor. Label units with a biohazard label and record the reason for quarantine on the label .... Do not label or issue a blood produces [SIC] labeled with a biohazard label without the approval of a supervisor/designee ...Positive Bacterial Cultures: ...When a positive gram stain is reported from Microbiology on a positive platelet bacterial culture, quarantine all units physically and in the BBIS ..." 2. Review of the laboratory's Blood Product Deviation Report (Confirmation #871314) revealed the following: 02/01/2024 The facility transfusion service received a phone call from one of its blood product suppliers that an apheresis platelet unit, W12162305022, was in transit to the facility and had tested positive for bacterial contamination and the gram stain showed gram positive cocci. The technician who recorded the information on a Post-It note, gave it to the technician in the receiving area, and sent an email to the transfusion medicine physicians group. 02/02/2024 07:27 am The blood supplier

	sent a fax to the facility with the same information that was communicated by phone. 02/02/2024 11:26am The apheresis platelet arrived at the laboratory and was entered into the BBIS at 11:30am. At this time, the information from the blood product supplier was not communicated. The apheresis unit was not quarantined in the BBIS system and was not labeled with a biohazard label. 02/02/2024 2:43pm The apheresis platelet was irradiated and released into the laboratory's inventory. The apheresis platelet remained in inventory until 02/05/2024. 02/05/2024 1:57 pm The apheresis platelet was issued and transfused to Patient 2748001. 02/05/2024 3:30 pm During a review of recall faxes, the fax notification from the blood product supplier was discovered. The "Follow-Up" (corrective action) on the incident report revealed the laboratory updated their procedure, created a new workflow for quarantining blood products and retrained the staff. 3. Further review of the laboratory's Blood Product Deviation Report (Confirmation #877127) revealed another breakdown in communication: 04/19/2024 The laboratory received a fax notification from a blood product supplier of a market withdrawal of fifty-six platelet products sent to the facility. Forty-six of the fifty-six platelets had been transfused prior to the notification. The remaining ten had not been transfused. Eight of the remaining ten were quarantined and discarded. Two of the platelet products were NOT identified and were transfused to patients. W035224089275 was transfused on 04/20/2024. W035224099001 was transfused 04/21/2024. The "Follow-Up" (corrective action) on the incident report revealed the laboratory conducted an in-service for all personnel and counseled individuals involved. 4. In an interview on 12/12/2024 at 09:22 am in the Hemovigilance Unit (HVU), after review of the laboratory reports, the Transfusion Safety Officer verified that the apheresis platelets had been transfused. Word Key: RBC=Red Blood Cells NIST=National Institute of Standards and Technology C=Celsius SN=Serial Number ABID=antibody identification TS=Type and Screen TMP=Transfusion Medicine Physician BMT=Bone Marrow Transplant TMP=Transfusion Medicine Physician
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of procedures, patient records, SafeTrace reports, direct observation, and interviews with staff, the laboratory director failed to provide overall management and direction of transfusion medicine, as evidenced by: 1. The laboratory director, high complexity testing, failed to ensure that testing systems used for each of the patient tests performed in the laboratory provided quality laboratory services for all aspects of test performance. Refer to D6082, I. 2. The laboratory director, high complexity testing, failed to ensure the immunohematology's TraceSafeTx systems used to ensure the safe and accurate transfusion of blood product to patients provided quality laboratory services for all aspects of test performance. Refer to D6082, II. 3. The laboratory director failed to ensure policies and manufacturer's instructions were followed. Refer to 6082, III. 4. The laboratory director, high complexity testing, failed to ensure that laboratory personnel were performing bi-annual Grifols Erytra instrument correlation testing as required for accurate and reliable results. Refer to D6087, I. 5. The laboratory director failed to ensure personnel followed procedures for accurate and reliable test results. Refer to D6087, II. 6. The laboratory director,

	high complexity testing, failed to ensure that quality control programs were established to assure the quality of laboratory immunohematology services provided and to identify failure in quality as they occur. Refer to D6093. 7. The laboratory director, high complexity testing, failed to ensure that quality assessment programs were established to assure the quality of laboratory services provided and to identify failures in quality as they occur. Refer to D6094, I. 8. The laboratory director failed to ensure QA was maintained and effective. Refer to D6094 II. 9. The laboratory director failed to ensure staff performing clinical consultant duties were qualified. Refer to D6101. 10. The laboratory director failed to ensure training was documented prior to testing for seven of seven technical supervisors in 2024. Refer to D6102.
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: I. Based on general supervisro (GS) 1 personnel interviews and immunohematology established test method performance specifications record review on December 11, 2024 at 14:50 pm, the laboratory director, high complexity testing, failed to ensure that testing systems used for each of the patient tests performed in the laboratory provided quality laboratory services for all aspects of test performance. Findings included: In the immunohematology section, the laboratory performed manual patient antibody screening tests using modified DTT treated antibody screening cells. The laboratory's modified DTT treated antibody screening cells was made in-house using commercially purchased antibody screening cells and treating these antibody screening cells with DTT. The laboratory maintained no documentation to indicate that test performance specifications had been established pursuant to 42 CFR 493.1253(b)(2) for manual patient antibody screening tests using modified DTT treated Immucor antibody screening cells before reporting patient manual antibody screening tests. See D5423. II. Based on general supervisor (GS) 1, GS2, and laboratory personnel interviews and immunohematology patient ABO discrepancies record review on December 12, 2024 at 09:00 am and 04:30 pm, the laboratory director, high complexity testing, failed to ensure the immunohematology's TraceSafeTx systems used to ensure the safe and accurate transfusion of blood product to patients provided quality laboratory services for all aspects of test performance. Findings included: In the immunohematology section, the laboratory performed patient type and screen testing (including patient ABO group testing), antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. If patient ABO group testing using the Grifols Erytra instruments yielded patient test results in which the ABO group by concurrently testing the unknown patient red cells with anti-A and anti-B grouping reagents did not confirm with and/or correspond to the ABO group testing of the patient's unknown serum tested with known A1 and B red cells, the Grifols Erytra instruments would not report the patient ABO group and would flag the patient's specimen for further review. These unconfirmed patient ABO group test results were consider ABO discrepancies by the laboratory. On December 11, 2024 at 03:00 pm and December 12, 2024 at 09: 30 am, GS1 and GS2 stated that testing personnel could not enter pRBC (packed red blood cell) crossmatch information into the immunohematology section's informations

	system, SafeTrace Tx, if a patient's SafeTrace Tx record was incomplete, as in the cases of unresolved patient ABO discrepancies, thereby preventing the transfusion of blood products to patients. However, at least two patient records were found in which there was an initial determination of an ABO discrepancy and the patient's SafeTrace Tx record was incomplete. In both cases, there was documentation indicating that pRBC units were crossmatched and issued to hospital staff for transfusion to the patients. See D5551. 43232 III. Based on review of records, procedures, direct observations, and interview with staff, the laboratory director failed to ensure policies and manufacturer's instructions were followed, as evidenced by: 1. The laboratory failed to have written policy and procedure for the collection of patient confirmatory ABO/Rh specimens. Refer to D5311. 2. The laboratory failed to use gel cards following the manufacturer's instructions and have documentation indicating that the gel cards were used in a manner that provided patient test results within the laboratory's performance specifications. Refer to D5411, I 3. The laboratory failed to have documentation of performing each of the required steps for Anti-E testing on 2 of 9 patients. Refer to D5411, II. 4. The laboratory failed to have documentation of performing each of the required steps for Anti-c testing on 4 of 7 patients. Refer to D5411, III. 5. The laboratory failed to ensure that immunohematology reagents met the manufacturer's instructions for proper temperature storage. Refer to D5413.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: I. Based on general supervisor (GS) 1 interview and immunohematology instrument comparison record review on December 11, 2024 at 10:55 am, the laboratory director, high complexity testing, failed to ensure that laboratory personnel were performing bi-annual Grifols Erytra instrument correlation testing as required for accurate and reliable results. Findings included: a. In the immunohematology section, the laboratory performed patient type and screen testing, antibody identification testing, and compatibility testing using one of three Grifols Erytra instruments. b. To meet the requirement at 42 CFR 493.1281(a), according to the immunohematology written protocol titled "Bi-Annual Correlation Testing [SOP-2255]," "specimens with known but different results are to be tested for each. . .assays on the [Grifols Erytra] analyzers. . ." c. Laboratory records indicate that on June 27, 2024 a "Bi-Annual Correlation Testing" was performed to compare test results using the laboratory's three Grifols Erytra instruments. The records for this June 27, 2024 "Bi-Annual Correlation Testing" do not indicate that the laboratory used "specimens with known but different results" pursuant to the laboratory's written protocol. d. These findings were confirmed by GS1 on December 11, 2024 at 10:55 am. e. According to laboratory personnel, the laboratory performs and reports approximately 1200 patient type and screen tests weekly. 43232 II. Based on review of SafeTrace reports and results, Erytra analyzer printouts, standard operating procedures (SOP), interviews with staff, ABO testing worksheet, and electronic mail (email) communications, the laboratory director failed to ensure personnel followed procedures for accurate and reliable test results, as evidenced by: 1. The laboratory failed to have documentation of following its procedure to perform PGD testing on units received outside the laboratory's acceptable shipping temperature for 11 of 12 shipments. Refer to D5401, I. 2. The laboratory failed to follow their own written policy for resolving one of one

	ABO/Rh discrepancy in 2024. Refer to D5401, II. 3. The laboratory failed to follow their own policy on performing blood bank inventory for two of two days observed in December 2024 (12/11-12/2024). Refer to D5401, III. 4. The laboratory failed to follow their own policy for MTP deactivation, for 22 of 22 blood products returned to the laboratory in August 2024. Refer to D5401, IV. 5. The laboratory failed to follow laboratory policy for the selection and issuing of blood and blood products for patients that had undergone bone marrow transplants (BMT) for 4 of 18 BMT patients randomly reviewed in 2023 and January through December 10th, 2024. Refer to D5401, V.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on general supervisor (GS) 2 and testing personnel interviews and immunohematology quality control record review, the laboratory director, high complexity testing, failed to ensure that quality control programs were established to assure the qualify of laboratory immunohematology services provided and to identify failure in quality as they occur. Findings included: a. For patient tests performed using the Grifols Erytra instruments, the laboratory failed to maintain documentation to indicate that quality control procedures were performed before resuming patient testing when a change of reagents were introduced. See D5461. b. The laboratory, which used the stated values of commercially assayed quality control materials, failed to verify the criteria for acceptability of all quality control materials used to monitor patient testing using the Grifols Erytra instrument. See D5469.
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: I. Based on direct observation, general supervisor (GS) 1 and GS2 interview and immunohematology quality assessment policies and procedures record review on December 10, 2024 at 02:45 pm and on December 11, 2024 at 09:00 am, the laboratory director, high complexity testing, failed to ensure that quality assessment programs were established to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings included: a. The laboratory failed to establish written patient specimen processing policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 42 CFR 493.1241 through 493.1242. See D5391. b. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the immunohematology analytic systems specified in 42 CFR 493.1251 through 493.1283. See D5791. 43232 II. Based on review of procedures, override reports,

	incident reports, corrective actions, and interview with staff, the laboratory director failed to ensure QA was maintained and effective, as evidenced by: 1. The laboratory failed to ensure that testing personnel overrides and exceptions to standard operating procedures were reviewed daily by approved staff members, for three of twelve months reviewed from January 2024 to December 1, 2024. Refer to D5791, III. 2. The laboratory failed to ensure their quality assurance (QA) included a review of effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems. Refer to D5793.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on review of safety reports, MTP documents, SafeTrace documents, override reports, SOPs, personnel credentials, job descriptions, and interviews with staff, the laboratory director failed to ensure staff performing clinical consultant duties were qualified. The laboratory failed to ensure GS-1 was qualified as a clinical consultant to perform those responsibilities in diagnosis, treatment, and management of patient care in transfusion medicine for three of three events (08/2024 through 12/2024). Refer to D6135.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of CMS (Center for Medicare and Medicaid Services) 209 Personnel Form, laboratory policy, SafeTrace Immunohematology information system personnel training documentation in 2024, and confirmed in interview, the laboratory director failed to ensure training was documented prior to testing for seven of seven technical supervisors in 2024. Findings Included: 1. Review of CMS-209 Form submitted at time of survey (12/10/2024) revealed seven technical supervisors currently performing patient testing in immunohematology. 2. Review of laboratory policy, "Competency and Performance Assessment Policy" (Policy: POL-0037) (Approved by the Laboratory Director on 09/27/2023) revealed the following: " ...4. Policy Statement: ...4.2.2 For testing personnel, prior to starting patient/client testing and prior to reporting patient/client results for new methods or instruments, each individual must have training and be evaluated for demonstration of the skills required for proper test performance of all applicable phases of testing and their ability to work under the expected oversight during routine patient testing. The records must cover all testing performed by each individual." 3. Review of personnel training documentation

	for the SafeTrace Immunohematology information system (implemented in October 2023), revealed seven of seven technical supervisors with no documentation of training, currently testing patients with the SafeTrace system in 2024. Technical Supervisor (TS): TS-1 (Hire date: 9/1/2011) TS-2 (Hire date: 01/01/2024) TS-3 (Hire date: 02/01/2020) TS-4 (Hire date: 11/01/2018) TS-5 (Hire date: 09/01/2008) TS-6 (Hire date: 07/01/2024) TS-7 (Hire date: 08/01/2024) The facility was asked to provide documentation of training for the above technical supervisors on the SafeTrace system. No documentation was provided. 4. In an interview with TS-1 in the laboratory on 12/11/2024 at 10:20 AM, TS-1 stated training was requested on multiple occasions by the above technical supervisors on the SafeTrace system in 2024 from the laboratory director, and no training was provided. This confirmed the laboratory director failed to ensure training was documented prior to testing for seven of seven technical supervisors in 2024.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of CMS (Center for Medicare and Medicaid Services) 209 Personnel Form, laboratory policy, SafeTrace Immunohematology information system personnel training documentation in 2024, and confirmed in interview, the technical supervisor failed to ensure training was documented prior to testing for 2 of 38 high complexity testing personnel in 2024. Findings Included: 1. Review of CMS-209 Form submitted at time of survey (12/10/2024) revealed 38 testing persons performing high complexity testing in immunohematology. 2. Review of laboratory policy, "Competency and Performance Assessment Policy" (Policy: POL-0037) (Approved by the Laboratory Director on 09/27/2023) revealed the following: " ...4. Policy Statement: ...4.2.2 For testing personnel, prior to starting patient/client testing and prior to reporting patient/client results for new methods or instruments, each individual must have training and be evaluated for demonstration of the skills required for proper test performance of all applicable phases of testing and their ability to work under the expected oversight during routine patient testing. The records must cover all testing performed by each individual." 3. Review of employee training documentation for the SafeTrace Immunohematology information system (implemented in October 2023), revealed 2 of 38 testing persons with no documentation of training, currently testing and resulting patients with the SafeTrace system. Testing Personnel (TP): a. TP-9 (Hire date: 08/26/2024) b. TP-16 (Hire date: 12/18/2023) The facility was asked to provide documentation of training for the above testing persons on the SafeTrace system. No documentation was provided. 4. In an interview on 12/11/2024 with the General Supervisor (GS-2) in the laboratory at 11:16 AM, GS-2 confirmed the technical supervisor failed to ensure training was documented prior to testing for 2 of 38 high complexity testing personnel in 2024.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453

	The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: Based on review of safety reports, MTP documents, SafeTrace documents, override reports, SOPs, personnel credentials, job descriptions, and interviews with staff, the laboratory failed to ensure general supervisor -1 (GS-1) was qualified as a clinical consultant. The laboratory failed to ensure GS-1 was qualified as a clinical consultant to perform those responsibilities in diagnosis, treatment, and management of patient care in transfusion medicine. Refer to D6135.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: Based on review of safety reports, MTP documents, SafeTrace documents, override reports, SOPs, personnel credentials, job descriptions, and interviews with staff, the laboratory failed to ensure GS-1 was qualified as a clinical consultant to perform those responsibilities in diagnosis, treatment, and management of patient care in transfusion medicine for three of three events (08/2024 through 12/2024). Findings included: 1. According to a "QAPI/GB Safety Report" for "RCA 19 MTP Event", an MTP was initiated for a patient on 08/27/2024 and a deviation from the MTP protocol was noted. MTP protocol specifies utilization Type O RBC's and Type A Plasma (per SOP-3320) and Type B+ RBC units were issued during the process after receiving Type O RBC's and A FFP's. Under "Proximate Causes" it stated, "The MLS did not scan units in safe trace and issue Product ID-tags because she lacked experience with MTP activation and was advised to deviate from the required documentation process steps of the protocol in the system by the Blood bank supervisor because there was inadequate reinforcement of departmental policies and procedures regarding the MTP process as it relates to their role." (blood bank supervisor was GS-1) Deviation from protocols as instructed by GS-1 (a non-clinical consultant and transfusion medicine physician -TMP) continued in 11/2024 and 12/2024, see below. 2. Review of the Massive Transfusion Protocol SOP-3320 page 3 stated, "Prohibited: Do NOT issue RBCs based on historical information. All emergency units will be issued as Emergency Uncrossmatched Blood." Review of a SafeTrace factory override report from 11/11/2024 through 11/15/2024 included three blood product units for patient #2760126 on 11/14/2024 with an "Activity Comment Approved per [GS-1 name]." Review of this patient's MTP documentation (FORM-3714) included "Patient ABORH: A neg" on 11/14/2024 at 8:30 am (MTP initiated) and the MTP stop time was 10:20 am. Two Uncrossmatched O Pos RBC units were dispensed and transfused during the MTP. SafeTrace Factory Overrides from 11/14/2024 at 8:30 am for patient

#2760126 included three A negative RBC units with the comment "Approved per [GS-1 name]" entered by TP-1. During an interview on 12/11/2024 at 3:15 pm, TP-1 was asked about the type-specific units approved by GS-1, TP-1 stated they were in OR satellite preparing units (O pos RBCs and A FFPs) and received a call from TP-27 in the transfusion medicine department and instructed TP-1 to prepare and dispense A neg RBC units to patient #2760126 for the MTP per GS-1. TP-1 stated a Factor Override populated in SafeTrace and TP-1 asked TP-27 what should be put in the comments section, TP-27 stated to put "Approved by [GS-1 name]." This was based on the patient's ABO/Rh history in SafeTrace from 02/12/2024. TP-1 issued the labels for the type-specific units but then immediately released them back into inventory because it was not per their SOP to give type-specific. During an interview on 12/11 /2024 at 3:26 pm, TP-27 was asked about the SafeTrace Factory Overrides from 11/14 /2024 at 8:30 am for patient #2760126 that included A negative RBC units with the comment "Approved per [GS-1 name]." TP-27 stated the request was for two units and it was not an MTP at first, but an emergency release. TP-27 was asked what the emergency release and MTP protocol was for the type of blood products, TP-27 stated Type O RBCs and Type A FFP. Tp-27 stated for any deviation, they must refer to a TMP. During an interview on 12/12/2024 at 9:30 am, TP-27 stated if the comment in SafeTrace stated "Approved per [GS-1 name]" then those type-specific units were approved by GS-1. A type and screen for this patient, including a history check, was completed on 11/14/2024 between 9:23 am through at 11:15 am (after the MTP was stopped). There was no documentation of a qualified clinical consultant/TMP approving of the above deviation. 3. Review of the "Resolution of ABORH Discrepancy" SOP-2679 on page 2 stated, "ABO interpretation must be delayed until an unexplained discrepancy is resolved. If the patient has order [sic] for transfusion notify the TMPs; Group O RBCs of the appropriate Rh type should be given until ABO discrepancy is resolved." On 12/02/2024 part of the testing for resolving an ABO discrepancy was completed and communicated to a TMP (CC-1) for further investigation. During that time "Group O RBC's only" requirement was entered in the patient's file, but then removed per GS-1 direction to TP-27 on 12/05/2024. An email was sent to the TMP on 12/05/2024 at 11:20 am from GS-1 stating the discrepancy was resolved, the mixed field was due to a high WBC, the extra reactivity was rouleaux and "The instructions for give [sic] group O POS was removed from the patient's file." CC-1 replied to GS-1 stating, "Please let Dr. [CC-4] review the case before the RBC transfusion requirements are changed in SafeTrace." Refer to D5401. On 12/05/2024 at 4:05 pm, the laboratory director provided a peripheral smear image to CC-2, TP-21, GS-1, and TP-7 stating there was no rouleaux and "let the TMPs make the final determination and don't change anything in terms of the typing and requirements until they review the case and the studies." On 12/05/2024 at 6:05 pm, CC-4 in an email to CC-2, the laboratory director, TP-21, GS-1, and TP-7 asking why the Lectin test was not performed and to not remove the "O RBC's only" requirement. During an interview on 12/12/2024 at 11:00 am, the laboratory director stated "Group O RBC's only" requirements should only be removed by TMPs and was not sure whether the requirement was still present on the patient's file in SafeTrace. Review of patient #2800161 SafeTrace file under special requirements included the following information, "Group O RBCs only Start Date & Time 12/05/2024 - 3:37 pm; End Date & Time 12/06/2024 - 8:58 am." The group O only requirements had been removed. According to the "Activity" tab under the patient's file in SafeTrace, the requirement was removed on 12/07/2024 at 8:58 am by GS-1. During an interview on 12/12/2024 at 11:25 am with the laboratory's SafeTrace IT contact, when asked why the dates were different for the requirement removal (12/6 and 12/7), the IT contact stated the removal occurred on 12/07/2024 at 8:58 am but was backdated to 12/06 /2024 at 8:58 am by GS-1. The IT contact stated SafeTrace has the capability of

	backdating by selecting a date from a calendar pop-up. There was no documentation of a medical exception documented by a qualified clinical consultant/TMP. Note: the SOP for resolving an ABO discrepancy was not followed. Refer to D5401. 4. Review of Medical Exception SOP-1129 on page 2 stated, "Any deviation from established procedures, policies, practices, and regulations/guidelines must be approved by a transfusion medicine physician and appropriately documented using the Form-0356 Exception to Standard Procedure. The form should be completed any times an override will be needed at dispense. Form should travel with the order/product." Review of documentation accompanied with the events listed above did not include medical exception forms. 5. Review of GS-1 credentials did not include the minimum requirements of a clinical consultant as outlined in 493.1455 (a) or (b). Review of GS-1 FORM-1753 Delegation Letter to General Supervisor High Complexity did not include clinical consultant responsibilities as outlined in CFR 493.1455 and 493.1457 (a) through (d). And did not include TMP responsibilities. This was signed and dated by the laboratory director on 10/22/2024. Review of one of the clinical consultant (CC-4)/TMP "Clinical Activities" included (a sampling), "Must be able to visually review, evaluate and correctly interpret medical records, patient data, patient specimens, blood and blood products, and test results based on previous training, experience and knowledge" and "Must be able to visually identify specimen constituents, contents and/or component directly or viewed through a microscope, and integrate observations into diagnostic and biologically relevant information." These "Clinical Activities" were not listed in GS-1 delegation of duties.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of CMS (Center for Medicare and Medicaid Services) 209 Personnel Form, laboratory policy, immunohematology personnel annual competency assessments in 2024, and confirmed in interview, the general supervisor failed to ensure annual competency was documented for 3 of 38 high complexity testing people currently performing patient testing in 2024. Findings Included: 1. Review of CMS-209 Form submitted at time of survey (12/10/2024) revealed 38 testing persons performing high complexity testing in immunohematology. 2. Review of laboratory policy, "Competency and Performance Assessment Policy" (Procedure: SOP-4484) (Approved by the Laboratory Director on 09/27/2023) revealed the following: " ...4.4 Competency Assessment ...4.4.2 For nonwaived testing personnel: ...B. At least annually after an individual has performed assigned duties for one year." 3. Review of laboratory testing personnel (TP) annual competency assessment documentation, revealed the following testing persons with no annual competency documentation in 2024: a. TP-11 Previous immunohematology competency documented: 09/2023 b. TP-6 Previous immunohematology competency documented: 01/2019 c. TP-26 Previous immunohematology competency documented: 09/2023 The facility was asked to provide documentation of annual competencies in immunohematology for the above testing personnel. No documentation was provided. 4. In an interview on 12/11/2024 with the General Supervisor (GS-2) in the laboratory at 11:16 AM, GS-2 confirmed the general supervisor failed to ensure annual competency was documented for 3 of 38 high complexity testing people currently performing patient testing in 2024.