Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0464490	02/10/2023
Name of Provider or Supplier	**Street Address, City, State**	
Madison Parish Hospital	900 Johnson Street, Tallulah, LA	

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 performed at Madison Parish Hospital, CLIA ID # 19D0464490, on February 9, 2023 through February 10, 2023. Madison Parish Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1100 CONDITION: Facility Administration 42 CFR 493.1217 CONDITION: Immunohematology 42 CFR 493.1441 CONDITION: Laboratories Performing High Complexity Testing, Laboratory Director 42 CFR 493.1459 CONDITION: Laboratories Performing High Complexity Testing, General Supervisor
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation, record review and interview with personnel, the facility failed to ensure that procedures are established to provide quality services to the facility and the patients served by the facility. Findings include: 1. The facility failed to document complete transfusion related investigation for Patient MR#1044441. Refer to D3015. 2. The facility failed to have a procedure to report transfusion reactions to Federal and

	State authorities. Refer to D3025 I. 3. The facility failed to establish a procedure to identify and investigate transfusion reactions for all blood products. Refer to D3025 II.
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy and patient records, the facility failed to document complete transfusion related investigation for Patient MR#1044441. Findings: 1. Review of the laboratory records revealed Patient MR# 1044441 received five (5) units of Packed Red Blood Cells (PRBCs) from October 25, 2021 through October 28, 2021. 2. Review of written email communication between laboratory staff, nursing staff, laboratory director and ordering physician revealed the fifth (5th) unit of Packed Red Blood Cells (PRBCs) was ordered in error, resulting in patient distress. Concern for circulatory overload was noted by the laboratory director. 3. Review of the laboratory policy revealed circulatory shock and/or circulatory collapse as well as respiratory distress listed as indicators of transfusion reactions. 4. Further review of laboratory records, patient chart review and medical staff meetings revealed no documentation for investigation of transfusion error and patient outcome.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: I. Based on review of hospital policies and interview with personnel, the facility failed to have a procedure to report transfusion reactions to Federal and State authorities. Findings: 1. Review of the hospital policies regarding transfusion reactions and transfusion servicies, to include "Blood/Blood Components-Transfusion Reactions" and "Blood/Blood Components-Transfusion" revealed no instructions or requirements to notifiy the Food and Drug Administration (FDA), or any state or federal regulatory authority. 2. Further review of patient transfusion records revealed the following patient with negative outcome related to transfusion of blood products: Patient MR# 1044441: patient chart and laboratory records revealed the patient received four (4) units of Packed Red Blood Cells (PRBC) between October 25, 2021 through October 27, 2021 as ordered by physician. Upon patient rounding on October 28, 2021 at 16: 55 pm, an additional unit of PRBCs was ordered by the physician on written chart order. Nursing servicies processed the order through electronic medical record (EMR) to the laboratory. The additional unit was transfused October 28, 2021 at 19:55 pm. Following transfusion, patient observed and documented in respiratory distress and placed on bi-pap. Patient expired on October 31, 2021. 3. In interview with ordering physician, director of nursing and laboratory general supervisor confirmed there was no report to FDA or any other state or federal authority. In interview on February 10,

2023 at 1pm, the Director of Nursing stated she was not aware any transfusion reactions or fatalities needed to be reported to the laboratory or any outside agency. II. Based on review of hospital policies and interview with personnel, the facility failed to establish a procedure to identify and investigate transfusion reactions for all blood products. Findings: 1. Review of nursing services policy and annual nursing training revealed the following two (2) different policies for transfusion reaction identification: a) Blood/Blood Components-Transfusion Reactions (adopted 04/18/2019) b) Blood /Blood Components-Transfusion (adopted 01/19/2023) 2. Further review of the identified hospital policies revealed the following: a) Blood/Blood Components-Transfusion Reactions (adopted 04/18/2019): Notification of the physician must take place for the following: Hemolytic - chills, fever, backache, restlessness, anxiety, nausea, vomiting, chest pain, tachycardia, dyspnea, hypotension, cyanosis, hemoglobinuria, hemoglobinuria, oliguria, anuria, juandice, vascular collapse; Allergic - uticaria, puritis, chills, nausea, vomiting, headache, nasal congestion, wheezing, bronchospasm, severe dyspnea, laryngeal edema, circulatory overload; Febrile - fever, chills, flushing, back pain, malaise, tachycardia, headache, confusion, nausea, vomiting; Bacterial - fever, chills, abdominal and extremity pain, vomiting, hypotension, bloody diarrhea; Circulatory Overload - cough, chest pain, dyspnea, distended neck veins, tachycardia, cyanosis, frothy sputum, pleural rales, hemoptysis b) Blood/Blood Components-Transfusion (adopted 01/19/2023): Observe for transfusion reactions up to one (1) hour after infusion of blood/blood component for the following: Rash, Flushed feeling (hot), Chills, Shortness of breath, Headache, Fever, Anxiety, Urticaria, Decreased Blood Pressure, Hematuria, Pharyngeal edema, Wheezing, Pain in lower back and legs, or other reactions. 3. Review of all laboratory records from January 2021 through December 2022 as well as chart reviews with nursing staff on February 10, 2023 revealed the following twelve (12) of seventy one (71) patients with indicators of transfusion reactions based on hospital policies with no transfusion workup: a) MR #52707 * Unit Number W069121131481 Transfusion Begin Date/Time 07/26/2021 16:40 pm Transfusion End Date/Time 07/26/2021 19:40 pm Pre-Transfusion Vital Signs documented 16:30 pm Blood Pressure 132/86; Pulse 111; Respirations 20; Temperature 97.7; SAT O2: NO ENTRY; Pain Level 0/10 1 hour Vital Signs documented at 19:30 pm Blood Pressure 126/84; Pulse 109; Respirations 20; Temperature 100.6; SAT O2: NO ENTRY; Pain Level 6/10 The patient had an increase in temperature of 2.9 degrees fahrenheit and pain level of 6/10. The facility did not define specific criteria for temperature and pain level changes. b) MR #52707 * Unit Number W069121131484 Transfusion Begin Date/Time 07/27 /2021 10:25 am Transfusion End Date/Time 07/27/2021 13:45 pm Pre-Transfusion Vital Signs documented at 10:25 am Blood Pressure 138/91; Pulse 90; Respirations 18; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 Post-Transfusion Vital Signs documented at 14:45 pm Blood Pressure 133/94; Pulse 104; Respirations 18; Temperature 100.4; O2 SAT 98%; Pain Level 0/10 The patient had an increase in temperature of 2.4 degrees fahrenheit from the start of the transfusion to the end of the transfusion. The facility did not define specific criteria for temperature changes. c) MR #7882 * Unit Number W036522011990 Transfusion Begin Date/Time 03/14 /2022 16:30 pm Transfusion End Date/Time 03/14/2022 20:15 pm Pre-Transfusion Vital Signs documented at 16:15 pm Blood Pressure 130/72; Pulse 100; Respirations 20; Temperature 97.8; O2 SAT 96%; Pain Level 0/10 15 minute Vital Signs documented at 17:00 pm Blood Pressure 164/67; Pulse 101; Respirations 20; Temperature 97.8; O2 SAT 97%; Pain Level 0/10 The patient had a noted increase in Blood Pressure; however, the facility did not define specific criteria for Blood Pressure changes. 15 minute Vital Signs documented at 17:15 pm Blood Pressure 177 /80; Pulse 116; Respirations 20; Temperature 97.7; O2 SAT 98%; Pain Level 0/10 The patient had a noted increase in Blood Pressure and an increase in pulse from the

start of the transfusion and previous vital sign check. The facility did not define specific criteria for Blood Pressure and Pulse changes. d) MR #7882 * Unit Number W036522033384 Transfusion Begin Date/Time 03/15/2022 17:30 pm Transfusion End Date/Time 03/15/2022 Pre-Transfusion Vital Signs documented at 17:15 pm Blood Pressure 132/76; Pulse 112; Respirations 20; Temperature 97.3; O2 SAT 97%; Pain Level 0/10 5 minute (after start of Transfusion) Vital Signs documented at 17:20 pm Blood Pressure 153/77; Pulse 115; Respirations 22; Temperature 98.1; O2 SAT 98%; Pain Level: NO ENTRY The patient had an increase in Blood Pressure from the start of the transfusion; however, the facility did not define specific criteria for Blood Pressure changes. e) MR #7882 * Unit Number W036522033384 Transfusion Begin Date/Time 03/15/2022 17:30 pm Transfusion End Date/Time 03/15/2022 20:50 pm Pre-Transfusion Vital Signs documented at 17:15 pm Blood Pressure 132/76; Pulse 112; Respirations 20; Temperature 97.3; O2 SAT 97%; Pain Level 0/10 15 minute Vital Signs documented at 17:45 pm Blood Pressure 156/93; Pulse 113; Respirations 20; Temperature 97.4; O2 SAT 97%; Pain Level 0/10 The patient had an increase in Blood Pressure of 156/93 from the start of the transfusion. The facility did not define specific criteria for Blood Pressure changes. Post-Transfusion Vital Signs documented at 21:50 pm Blood Pressure 107/63; Pulse 117; Respirations 20; Temperature 97.8; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Blood Pressure from the previous vital sign as well as start of the transfusion. The facility did not define specific criteria for Blood Pressure changes. f) MR #17075 * Unit Number W036522087283 Transfusion Begin Date/Time 10/08/2022 11:15 am Transfusion End Date/Time 10/08/2022 14:05 pm Pre-Transfusion Vital Signs documented at 11: 10 am Blood Pressure 112/56; Pulse 93; Respirations 22; Temperature 98.6; O2 SAT 100%; Pain Level 1/10 1 hour Vital Signs documented at 14:05 pm Blood Pressure 117/63; Pulse 108; Respirations 20; Temperature 100.7; O2 SAT 100%; Pain Level 1 /10 The patient had an increase in temperature of 2.1 degrees fahrenheit and increase pulse from the start of the transfusion. The facility did not define specific criteria for temperature and pulse changes. Post-Transfusion Vital Signs documented at 15:05 pm Blood Pressure 140/52; Pulse 98; Respirations 22; Temperature 102.4; O2 SAT 100%; Pain Level 1/10 The patient had an increase in temperature of 3.8 degrees fahrenheit from the start of the transfusion and increase blood pressure. The facility did not define specific criteria for temperature and Blood Pressure changes. g) MR #54111 * Unit Number W036522048784 Transfusion Begin 07/21/2022 00:48 am Transfusion End 07/21/2022 04:30 am Pre-Transfusion Vital Signs documented at 00: 24 am Blood Pressure 130/77; Pulse 84; Respirations 22; Temperature 97.2; O2 SAT 100%; Pain Level 0/10 15 minute Vital Signs documented at 01:38 am Blood Pressure 120/66; Pulse 61; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Blood Pressure of 120/66 from start of transfusion. The facility did not define specific criteria for Blood Pressure changes. 30 minute Vital Signs documented at 02:08 am Blood Pressure 135/69; Pulse 62; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 The patient had an increase in Blood Pressure of 135/69 and decrease in Respirations of 16 from last documentation of vital signs. The facility did not define specific criteria for Blood Pressure and Respiration changes. 30 minute Vital Signs documented at 02:38 am Blood Pressure 148/76; Pulse 91; Respirations 18; Temperature 97.8; O2 SAT 100%; Pain Level 0/10 The patient had an increase in Blood Pressure of 148/76 and an increase in Pulse of 91 from last documentation of vital signs. The facility did not define specific criteria for Blood Pressure and Pulse changes. 1 hour Vital Signs documented at 03:38 am Blood Pressure 135/75; Pulse 60; Respirations 18; Temperature 97.8; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Pulse of 60 from last documentation of vital signs. The facility did not define specific criteria for Pulse changes. h) MR #54111 * Unit Number W036522061302 Transfusion Begin 07/21/2022 05:50 am Transfusion

End 07/21/2022 09:40 am Pre-Transfusion Vital Signs documented at 05:24 am Blood Pressure 163/86; Pulse 94; Respirations 18; Temperature 97.6; O2 SAT 100%; Pain Level 0/10 5 minutes (after start of transfusion) Vital Signs documented at 05:55 am Blood Pressure 138/83; Pulse 89; Respirations 18; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Blood Pressure and Pulse from the start of the transfusion. The facility did not define specific criteria for Blood Pressure and Pulse changes. 15 minutes Vital Signs documented at 06:10 am Blood Pressure 120 /69; Pulse 73; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 The patient had a continued decrease in Blood Pressure and Pulse from the start of the transfusion. The facility did not define specific criteria for Blood Pressure and Pulse changes. 1 hour Vital Signs documented at 9:40 am Blood Pressure 112/66; Pulse 95; Respirations 16; Temperature 98.0; O2 SAT 100%; Pain Level 0/10 The patient had a continued decrease in Blood Pressure from the start of the transfusion. The facility did not define specific criteria for Blood Pressure changes. Post-Transfusion Vital Signs documented at 10:40 am Blood Pressure 104/68; Pulse 83; Respirations 17; Temperature 97.9; O2 SAT 100%; Pain Level 0/10 The patient had a continued decrease in Blood Pressure from the start of the transfusion. The facility did not define specific criteria for Blood Pressure changes. i) MR #54111 * Unit Number W036522060578 Transfusion Begin 07/21/2022 16:50 Transfusion End 07/21/2022 20:00 Pre-Transfusion Vital Signs documented at 16:25 pm Blood Pressure 128/78; Pulse 76; Respirations 16; Temperature 98.0; O2 SAT 100%; Pain Level 0/10 15 minute Vital Signs documented at 17:40 pm Blood Pressure 138/77; Pulse 76; Respirations 18; Temperature 97.5; O2 SAT 100%; Pain Level 0/10 30 minute Vital Signs documented at 18:10 pm Blood Pressure 118/68; Pulse 88; Respirations 16; Temperature 98.3; O2 SAT 99%; Pain Level 0/10 The patient had a decrease in Blood Pressure and an increase in Pulse from start of transfusion. The facillity did not define specific criteria for Blood Pressure and Pulse changes. 30 minute Vital Signs documented at 18:40 pm Blood Pressure 110/78; Pulse 85; Respirations 18; Temperature 97.5; O2 SAT 100%; Pain Level 0/10 The patient had a continued decrease in Blood Pressure from start of transfusion. The facillity did not define specific criteria for Blood Pressure changes. 1 hour Vital Signs documented at 19:40 pm Blood Pressure 129/71; Pulse 63; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Pulse. The facillity did not define specific criteria for Pulse changes. j) MR# 14112 Unit Number W036522053628 Transfusion Begin 09/26/2022 14:00 pm Transfusion End 09/26 /2022 17:40 pm Pre-Transfusion Vital Signs documented at 13:45 pm Blood Pressure 141/77; Pulse 104; Respirations 20; Temperature 98.2; O2 SAT 96%; Pain Level 0/10 5 minute (after start of transfusion) Vital Signs documented at 14:05 pm Blood Pressure 141/77; Pulse 96; Respirations 20; Temperature 101.8; O2 SAT 96%; Pain Level 0/10 The patient had an increase in temperature of 3.6 degrees fahrenheit . The facility did not define specific criteria for temperature changes. k) MR# 1044113 Unit Number W069121114512 Transfusion Begin 05/07/2021 14:35 pm Transfusion End 05/07/2021 18:15 pm Pre-Transfusion Vital Signs documented at 14:15 pm Blood Pressure 120/60; Pulse 97; Respirations 24; Temperature 97.9; O2 SAT 95%; Pain Level 0/10 15 minute Vital Signs documented at 15:25 pm Blood Pressure 128/60; Pulse 79; Respirations 18; Temperature 98.0; O2 SAT: NO ENTRY; Pain Level: NO ENTRY The patient had a decrease in pulse of 79 from the start of the transfusion. The facility did not define specific criteria for pulse changes. Missing documentation of vital signs from 15:25pm - 19:15pm. Post-Transfusion Vital Signs documented at 19:15 pm Blood Pressure 120/62; Pulse 96; Respirations 30; Temperature 100.3; O2 SAT 85%; Pain Level 0/10 The patient had an increase in temperature of 2.4 degrees fahrenheit and a decrease in O2 Sat of 85% from the start of the transfusion. The facility did not define specific criteria for temperature and O2 SAT changes. l) MR#

	49786 Unit Number W069121135687 Transfusion Begin 08/28/2021 21:10 pm Transfusion End 08/29/2021 0059 am Pre-Transfusion Vital Signs documented at 21: 04 pm Blood Pressure 128/78; Pulse 84; Respirations 18; Temperature 100.6; O2 SAT: NO ENTRY; Pain Level 0/10 5 minute vital signs documented at 21:15 pm Blood Pressure 118/73; Pulse 83; Respirations 18; Temperature 99.8; O2 SAT: NO ENTRY; Pain Level 0/10 Missing vital sign documentation throughout transfusion. 1 hour Vital Signs documented at 19:40 pm Blood Pressure 130/89; Pulse 106; Respirations 20; Temperature 101.1; SAT O2: NO ENTRY; Pain Level 6/10 The patient had an increase in temperature, increase pulse and increase pain level of 6/10. The facility did not define specific criteria for temperature, pulse or pain changes. 4. In interview with Director of Nursing on February 10, 2023 at time of chart reviews revealed nursing services uses their own transfusion reaction policy (Blood Transfusion Record) and notifies the physician when a sign or symptom of transfusion reaction is identified. The Director of Nursing further stated that ordering physician would determine whether to treat the patient, for example with Tylenol, Benadryl, or pause the transfusion, but the laboratory was not notified or involved. She further stated she was not aware the laboratory should be notified. The Director of Nursing confirmed the transfusion policy does not specify the changes in vital signs that would indicate transfusion reactions, it is at the discretion of the nursing and physicians treating the patients.
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 observation by surveyors, review of laboratory policy, patient records, and interview with personnel, the laboratory failed to provide quality services for the specialty of Immunohematology. Findings: 1. The laboratory failed to have a system in place to identify problems that occurred as a result of breakdown in communication between the laboratory and nursing personnel responsible for transfusion services within the hospital. Refer to D5207. 2. The laboratory failed to ensure that transfusion reactions according to the laboratory policy were investigated for twelve (12) of seventy one (71) blood products issued in the facility from January 2021 through December 2022. Refer to D5559 I. 3. The laboratory failed to make recommendations to the medical staff regarding improvements in transfusion procedures. Refer to D5559 II. 4. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
D5207	COMMUNICATIONS CFR(s): 493.1234 The laboratory must have a system in place to identify and document problems that occur as a result of a breakdown in communication between the laboratory and an authorized person who orders or receives test results. This STANDARD is not met as evidenced by: Based on review of laboratory and hospital policies, patient records, documentation

provided by the laboratory and interview with laboratory and hospital personnel, the laboratory failed to have a system in place to identify problems that occurred as a result of breakdown in communication between the laboratory and nursing personnel responsible for transfusion services within the hospital. Findings: 1. Review of the "Blood Transfusion Records" policy provided by nursing services, implemented on April 15, 2021, revealed the following as the only instruction to nursing personnel monitoring patients during transfusion regarding communication with the laboratory: "Procedure: Observation of adverse effects during administration with appropriate actions if such effects should occur (i.e., stopping of administration, notification of physician and the Blood Bank). A transfusion reaction record shall be completed." 2. In interview on February 9, 2023 at 11:28 am, the Director of Nursing stated nursing would only notify the laboratory if the ordering physician initiated a transfusion reaction. 3. Review of the laboratory "Blood Bank Transfusion Criteria Policy" revealed "At MPH, if a patient experiences signs and/or symptoms during a transfusion of blood or blood products that are unrelated to their present illnesses, a transfusion reaction workup is initiated by the nursing services utilizing the "Nursing Services Transfusion Reaction Form". The laboratory is notified by the nursing services or physician to perform the laboratory portion of the workup using the "Lab Transfusion Reaction Form". Most suspected transfusion reaction workups are intiated by the nursing services with communication with the attending physician. Laboratory personnel may initiate a transfusion reaction workup if indicated by suspected hemolysis within the unit or subsequent lab test results, including possible infection or sepsis." 4. In inteview on February 9, 2023 at 10:30 am, the laboratory general supervisors confirmed there were no specific processes in place for nursing services and laboratory communication during transfusion of blood products. 5. Review of patient transfusion records from January 2021 through December 2022 revealed the following patient with identified negative outcome due to communication breakdown between ordering physician, nursing services, and the laboratory: Patient MR #1044441 6. Further review of Patient MR #1044441 chart and laboratory records revealed the patient received four (4) units of Packed Red Blood Cells (PRBCS) between October 25, 2021 through October 27, 2021 as ordered by physician. Upon Patient rounding on October 28, 2021 at 16:55 pm an additional - fifth (5) unit of PRBC was ordered by physician. Nursing services processed order to laboratory. The additional unit was transfused October 28, 2021 at 19:55 pm. Following transfusion, patient observed and documented in respiratory distress and placed on bi-pap. 7. Review of laboratory email correspondance between the laboratory director and general supervisor on November 1, 2021 at 11:22 am provided to surveyors revealed the laboratory phlebotomist upon morning blood collection on Friday, October 29, 2021 noticed Patient MR# 1044441 had difficulty breathing, wheezing, and flushed face. The phlebotomist reported patient condition to the nursing station along with notification to laboratory general supervisor. 8. Further review of laboratory email correspondance between the laboratory director and general supervisor on November 1, 2021 at 1:35 pm revealed general supervisor received a phone call from the attending physician concerning Patient MR# 1044441. The attending physician questioned why the laboratory director was notified about Patient MR# 1044441 condition. General supervisor informed the attending physician that Patient MR# 1044441 received five (5) units of PRBCs and that the patient was placed on bi-pap following transfusions. The general supervisor informed the attending physician that this was something that the laboratory reports to the laboratory director. The attending physician said that the patient only received three (3) units of PRBCs and that he did not order five (5) units. General supervisor referred the attending physician to speak with the nursing staff responsible for processing transfusion orders. 9. In interview on February 10, 2023 at 2:02 pm with the ordering physician confirmed that Patient MR#

	1044441 was transfused with more units of PRBCs than intended and the breakdown between laboratory and nursing contributed to this error. Ordering physician further stated nursing should have known his order was meant for the fourth unit of PRBCs, not for an additional fifth unit of PRBC. 10. Interview with laboratory general supervisors and director of nursing confirmed no changes to processes or communication had been implemented after the incident with Patient MR# 1044441.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy and blood bank records, patient transfusion records as well as interview with personnel, the laboratory failed to ensure that transfusion reactions according to the laboratory policy were investigated for twelve (12) of seventy one (71) blood products issued in the facility from January 2021 through December 2022. Findings: 1. Review of the laboratory blood bank records revealed the zero (0) transfusion reaction workups were initiated in 2021 and 2022. 2. Review of the laboratory policy "Evaluation of a Suspected Acute Transfusion Reaction" revealed the following indicators determined by the laboratory as indicators of transfusion reaction: a) Fever with or without body chills (2 degrees fahrenheit increase in body temperature) b) Shaking chills (rigors) with or without fever c) Pain at infusion siteor in chest, abdomen, or flanks d) Blood pressure changes, usually acute, either hypertension or hypotension e) Respiratory distress including dyspnea, tachypnea, wheezing, or hypoxemia f) Skin changes including uticaria, puritis (itching), flushing or localized edema (angioedemia) g) Nausea with or without vomiting h) Darkened urine or jaundice i) Bleeding or other manisfestations of a consumptive coagulopathy 3. Review of all laboratory records as well as chart reviews with nursing staff on February 10, 2023 revealed the following twelve (12) of seventy one (71) patients with indicators of transfusion reactions: a) MR #52707 * Unit Number W069121131481 Transfusion Begin Date/Time 07/26/2021 16:40 pm Transfusion End Date/Time 07/26/2021 19:40 pm Pre-Transfusion Vital Signs documented 16:30 pm Blood Pressure 132/86; Pulse 111; Respirations 20; Temperature 97.7; SAT O2: NO ENTRY; Pain Level 0/10 1 hour Vital Signs documented at 19:30 pm Blood Pressure 126/84; Pulse 109; Respirations 20; Temperature 100.6; SAT O2: NO ENTRY; Pain Level 6/10 The patient had an increase in temperature of 2.9 degrees fahrenheit and increase pain level of 6/10. The facility did not define specific criteria for pain level changes. b) MR #52707 * Unit Number W069121131484 Transfusion Begin Date/Time 07/27/2021 10:25 am Transfusion End Date/Time 07/27/2021 13:45 pm Pre-Transfusion Vital Signs documented at 10:25 am Blood Pressure 138/91; Pulse 90; Respirations 18; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 Post-Transfusion Vital Signs

documented at 14:45 pm Blood Pressure 133/94; Pulse 104; Respirations 18; Temperature 100.4; O2 SAT 98%; Pain Level 0/10 The patient had an increase in temperature of 2.4 degrees fahrenheit from the start of the transfusion to the end of the transfusion. c) MR #7882 * Unit Number W036522011990 Transfusion Begin Date /Time 03/14/2022 16:30 pm Transfusion End Date/Time 03/14/2022 20:15 pm Pre-Transfusion Vital Signs documented at 16:15 pm Blood Pressure 130/72; Pulse 100; Respirations 20; Temperature 97.8; O2 SAT 96%; Pain Level 0/10 15 minute Vital Signs documented at 17:00 pm Blood Pressure 164/67; Pulse 101; Respirations 20; Temperature 97.8; O2 SAT 97%; Pain Level 0/10 The patient had an increase in Blood Pressure of 164/67. The facility did not define specific criteria for Blood Pressure changes. 15 minute Vital Signs documented at 17:15 pm Blood Pressure 177 /80; Pulse 116; Respirations 20; Temperature 97.7; O2 SAT 98%; Pain Level 0/10 The patient had an increase in Blood Pressure and an increase in Pulse from the start of the transfusion. The facility did not define specific criteria for Blood Pressure and Pulse changes. d) MR #7882 * Unit Number W036522033384 Transfusion Begin Date /Time 03/15/2022 17:30 pm Transfusion End Date/Time 03/15/2022 Pre-Transfusion Vital Signs documented at 17:15 pm Blood Pressure 132/76; Pulse 112; Respirations 20; Temperature 97.3; O2 SAT 97%; Pain Level 0/10 5 minute (after start of Transfusion) Vital Signs documented at 17:20 pm Blood Pressure 153/77; Pulse 115; Respirations 22; Temperature 98.1; O2 SAT 98%; Pain Level: NO ENTRY The patient had an increase in Blood Pressure from the start of the transfusion. The facility did not define specific criteria for Blood Pressure changes. e) MR #7882 * Unit Number W036522033384 Transfusion Begin Date/Time 03/15/2022 17:30 pm Transfusion End Date/Time 03/15/2022 20:50 pm Pre-Transfusion Vital Signs documented at 17:15 pm Blood Pressure 132/76; Pulse 112; Respirations 20; Temperature 97.3; O2 SAT 97%; Pain Level 0/10 15 minute Vital Signs documented at 17:45 pm Blood Pressure 156/93; Pulse 113; Respirations 20; Temperature 97.4; O2 SAT 97%; Pain Level 0/10 Post-Transfusion Vital Signs documented at 21:50 pm Blood Pressure 107/63; Pulse 117; Respirations 20; Temperature 97.8; O2 SAT 100%; Pain Level 0/10 The patient had both an increase and decrease in Blood Pressure from the start of the transfusion. The facility did not define specific criteria for Blood Pressure changes. f) MR #17075 * Unit Number W036522087283 Transfusion Begin Date/Time 10/08/2022 11:15 am Transfusion End Date/Time 10/08 /2022 14:05 pm Pre-Transfusion Vital Signs documented at 11:10 am Blood Pressure 112/56; Pulse 93; Respirations 22; Temperature 98.6; O2 SAT 100%; Pain Level 1/10 1 hour Vital Signs documented at 14:05 pm Blood Pressure 117/63; Pulse 108; Respirations 20; Temperature 100.7; O2 SAT 100%; Pain Level 1/10 The patient had an increase in temperature of 2.1 degrees fahrenheit and increase pulse from the start of the transfusion. The facility did not define specific criteria for pulse changes. Post-Transfusion Vital Signs documented at 15:05 pm Blood Pressure 140/52; Pulse 98; Respirations 22; Temperature 102.4; O2 SAT 100%; Pain Level 1/10 The patient had an increase in temperature of 3.8 degrees fahrenheit and increase Blood Pressure from the start of the transfusion. The facility did not define specific criteria Blood Pressure changes. g) MR #54111 * Unit Number W036522048784 Transfusion Begin 07/21 /2022 00:48 am Transfusion End 07/21/2022 04:30 am Pre-Transfusion Vital Signs documented at 00:24 am Blood Pressure 130/77; Pulse 84; Respirations 22; Temperature 97.2; O2 SAT 100%; Pain Level 0/10 15 minute Vital Signs documented at 01:38 am Blood Pressure 120/66; Pulse 61; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 30 minute Vital Signs documented at 02:08 am Blood Pressure 135/69; Pulse 62; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 30 minute Vital Signs documented at 02:38 am Blood Pressure 148/76; Pulse 91; Respirations 18; Temperature 97.8; O2 SAT 100%; Pain Level 0/10 1 hour Vital Signs documented at 03:38 am Blood Pressure 135/75; Pulse 60; Respirations

18; Temperature 97.8; O2 SAT 100%; Pain Level 0/10 The patient had changes in Blood Pressure, Pulse, and respiration throughout transfusion. The facility did not define specific criteria for Blood Pressure, Pulse or respiration changes. h) MR #54111 * Unit Number W036522061302 Transfusion Begin 07/21/2022 05:50 am Transfusion End 07/21/2022 09:40 am Pre-Transfusion Vital Signs documented at 05: 24 am Blood Pressure 163/86; Pulse 94; Respirations 18; Temperature 97.6; O2 SAT 100%; Pain Level 0/10 5 minutes (after start of transfusion) Vital Signs documented at 05:55 am Blood Pressure 138/83; Pulse 89; Respirations 18; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 15 minutes Vital Signs documented at 06:10 am Blood Pressure 120/69; Pulse 73; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 1 hour Vital Signs documented at 9:40 am Blood Pressure 112/66; Pulse 95; Respirations 16; Temperature 98.0; O2 SAT 100%; Pain Level 0/10 Post-Transfusion Vital Signs documented at 10:40 am Blood Pressure 104/68; Pulse 83; Respirations 17; Temperature 97.9; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Blood Pressure from the start of the transfusion, and changes in pulse throughout the transfusion. The facility did not define specific criteria for Blood Pressure or pulse changes. i) MR #54111 * Unit Number W036522060578 Transfusion Begin 07/21/2022 16:50 Transfusion End 07/21/2022 20:00 Pre-Transfusion Vital Signs documented at 16:25 pm Blood Pressure 128/78; Pulse 76; Respirations 16; Temperature 98.0; O2 SAT 100%; Pain Level 0/10 15 minute Vital Signs documented at 17:40 pm Blood Pressure 138/77; Pulse 76; Respirations 18; Temperature 97.5; O2 SAT 100%; Pain Level 0/10 30 minute Vital Signs documented at 18:10 pm Blood Pressure 118/68; Pulse 88; Respirations 16; Temperature 98.3; O2 SAT 99%; Pain Level 0/10 30 minute Vital Signs documented at 18:40 pm Blood Pressure 110/78; Pulse 85; Respirations 18; Temperature 97.5; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Blood Pressure from start of transfusion. The facillity did not define specific criteria for Blood Pressure changes. 1 hour Vital Signs documented at 19:40 pm Blood Pressure 129/71; Pulse 63; Respirations 16; Temperature 97.7; O2 SAT 100%; Pain Level 0/10 The patient had a decrease in Pulse from start of transfusion. The facillity did not define specific criteria for Pulse changes. j) MR# 14112 Unit Number W036522053628 Transfusion Begin 09/26/2022 14:00 pm Transfusion End 09/26/2022 17:40 pm Pre-Transfusion Vital Signs documented at 13:45 pm Blood Pressure 141/77; Pulse 104; Respirations 20; Temperature 98.2; O2 SAT 96%; Pain Level 0/10 5 minute (after start of transfusion) Vital Signs documented at 14:05 pm Blood Pressure 141/77; Pulse 96; Respirations 20; Temperature 101.8; O2 SAT 96%; Pain Level 0/10 The patient had an increase in temperature of 3.6 degrees fahrenheit. k) MR# 1044113 Unit Number W069121114512 Transfusion Begin 05/07/2021 14:35 pm Transfusion End 05/07 /2021 18:15 pm Pre-Transfusion Vital Signs documented at 14:15 pm Blood Pressure 120/60; Pulse 97; Respirations 24; Temperature 97.9; O2 SAT 95%; Pain Level 0/10 15 minute Vital Signs documented at 15:25 pm Blood Pressure 128/60; Pulse 79; Respirations 18; Temperature 98.0; O2 SAT: NO ENTRY; Pain Level: NO ENTRY The patient had a decrease in pulse from the start of the transfusion. The facility did not define specific criteria for pulse changes. Post-Transfusion Vital Signs documented at 19:15 pm Blood Pressure 120/62; Pulse 96; Respirations 30; Temperature 100.3; O2 SAT 85%; Pain Level 0/10 The patient had an increase in temperature of 2.4 degrees fahrenheit and a decrease in O2 Sat from the start of the transfusion. The facility did not define specific criteria O2 SAT changes. l) MR# 49786 Unit Number W069121135687 Transfusion Begin 08/28/2021 21:10 pm Transfusion End 08/29/2021 0059 am Pre-Transfusion Vital Signs documented at 21: 04 pm Blood Pressure 128/78; Pulse 84; Respirations 18; Temperature 100.6; O2 SAT: NO ENTRY; Pain Level 0/10 5 minute vital signs documented at 21:15 pm Blood Pressure 118/73; Pulse 83; Respirations 18; Temperature 99.8; O2 SAT: NO

	ENTRY; Pain Level 0/10 1 hour Vital Signs documented at 19:40 pm Blood Pressure 130/89; Pulse 106; Respirations 20; Temperature 101.1; SAT O2: NO ENTRY; Pain Level 6/10 The patient had changes in Blood Pressure throughout the transfusion, and increase of pulse, respiration and pain level. The facility did not define specific criteria for Blood Pressure, pulse, respiration or pain level changes. 4. In interview with Director of Nursing on February 10, 2023 at time of chart reviews revealed nursing services uses their own transfusion reaction policy (Blood Transfusion Record) and notifies the physician when a sign or symptom of transfusion reaction is identified. The Director of Nursing further stated that ordering physician would determine whether to treat the patient, for example with Tylenol, Benadryl, or pause the transfusion, but the laboratory was not notified or involved. She further stated she was not aware the laboratory should be notified. 5. In interview with General Supervisor 1&2 on February 9, 2023 revealed the laboratory reviews all blood products transfused, but the laboratory does not access nursing charts for full transfusion records. II. Based on review of laboratory and nursing policies as well as interview with personnel, the laboratory failed to make recommendations to the medical staff regarding improvements in transfusion procedures. Findings: 1. Review of three (3) different hospital procedures (Evaluation of a Suspected Acute Transfusion Reaction, Blood/Blood Components - Transfusion Reactions, Blood /Blood Components - Transfusion) revealed separate parameters for identification of indicators of transfusion reactions. 2. Review of email communications between laboratory staff and director of nursing revealed notification of different policies on November 9, 2022 by email. 3. In interview on February 10, 2023 the laboratory general supervisors and director of nursing confirmed there were different policies throughout the facility, expectations for identification of transfusion reactions, and how to communicate these indicators between laboratory and transfusion servicies.
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 observation by surveyors, review of laboratory policy, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to have a system in place to identify problems that occurred as a result of breakdown in communication between the laboratory and nursing personnel responsible for transfusion services within the hospital. Refer to D5207. 2. The laboratory failed to ensure that transfusion reactions according to the laboratory policy were investigated for twelve (12) of seventy one (71) blood products issued in the facility from January 2021 through December 2022. Refer to D5559 I. 3. The laboratory failed to make recommendations to the medical staff regarding improvements in transfusion procedures. Refer to D5559 II.
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 observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D6079. 2. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6094.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient test records and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The laboratory failed to have a system in place to identify problems that occurred as a result of breakdown in communication between the laboratory and nursing personnel responsible for transfusion services within the hospital. Refer to D5207. 2. The laboratory failed to make recommendations to the medical staff regarding improvements in transfusion procedures. Refer to D5559 II.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Findings: 1. The laboratory failed to ensure that transfusion reactions according to the laboratory policy were investigated for twelve (12) of seventy one (71) blood products issued in the facility from January 2021 through December 2022. Refer to D5559 I. 2.

	The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with laboratory personnel, the General Supervisor failed to provide day to day supervision or oversight to ensure accurate and reliable patient test results. Refer to D6144.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on review of laboratory policy and records as well as interview with personnel, the General Supervisor failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. The laboratory failed to ensure that transfusion reactions according to the laboratory policy were investigated for twelve (12) of seventy one (71) blood products issued in the facility from January 2021 through December 2022. Refer to D5559 I. 2. The laboratory failed to make recommendations to the medical staff regarding improvements in transfusion procedures. Refer to D5559 II.