| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 11D0258220 | 03/03/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Piedmont Henry Hospital, Inc | 1133 Eagle'S Landing Parkway, Stockbridge, GA | |

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 |
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| **D0000** | An unannounced onsite complaint investigation was conducted 03/01/2022 through 03 /03/2022. Allegations for intake #GA00219068 were substantiated and this facility was found NOT to be in compliance with CLIA regulations found at 42 CFR, as follows: 493.1100 Condition: Facility Administration 493.1217 Condition: Immunohematology |
| **D3000** | FACILITY ADMINISTRATION<br>CFR(s): 493.1100<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the facility records and a random review of patient transfusion records (02/2021, 05/2021, 11/2021, and 01/2022), it was revealed the facility administration failed to meet the requirements specified in 493.1101 through 493.1105, as evidenced by: 1. The facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions. Refer to D3025 |
| **D3025** | REQUIREMENTS FOR TRANSFUSION SERVICES<br>CFR(s): 493.1103(d) |

Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities.

This STANDARD is not met as evidenced by:
Based on review of the facility and laboratory blood/blood product transfusion policies, review of facility blood administration educational material, review of blood product transfusion forms, a random review of patient transfusion records (02/2021, 05 /2021, 11/2021, and 01/2022) and staff interview, it was revealed the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 9 of 12 patients that received blood products. Findings included: 1. The facility policy titled "Administration of Blood and Blood Components Procedures" (PHC-01-000127) stated the following: " ...Pre-Administration: Handling of Blood and Blood Components at the Bedside ...6. Patient vital signs are to be taken and documented prior to initiating any administration /transfusion ...9. The patient should remain under direct observation by the transfusionist for fifteen (15) minutes after the transfusion is begun. 10. After a transfusion is started, the progress of the transfusion should be monitored throughout the infusion ...12. Patients receiving blood or blood products should have vital signs monitored, including the following and at the following intervals: Temperature, Blood Pressure, Pulse, Respiration Rate, O2 saturation, Lung sounds. Intervals: No longer than 30 minutes prior to each unit being transfused according to AABB standards, Vitals are taken within the first 15 minutes of each unit being transfused, Additional vital signs are obtained each one (1) hour during the infusion, at the end of the infusion, and as warranted by the patient's condition/history or if a transfusion reaction is suspected, Complete a post transfusion lung sound assessment, A patient may be monitored up to one (1) hour following the completion of the transfusion as required to ensure patient's stability ...Transfusion reactions: Transfusion reactions can happen during and after a transfusion. They can occur with any blood component ...If a Reaction is Suspected ...2. Notify the ordering physician and the blood bank. 3. If the physician orders a transfusion reaction workup: ...b. Complete a hospital specific 'Request for Transfusion Reaction Investigation' form ...c. Have a post transfusion reaction blood sample (1 pink tube) collected ..." The facility policy, in the section titled, "Signs and Symptoms of Transfusion Reactions" referred to the following signs and symptoms of a transfusion reaction: "chills, fever, dyspnea, hemoglobinuria, back pain, loin pain, hypotension, renal failure, shock, Disseminated Intravascular Coagulation, fatigue, jaundice, temperature elevation of 1C or 2F or more, coughing, bronchospasm, respiratory distress, vascular instability, nausea, abdominal cramps, vomiting, diarrhea, loss of consciousness, erythema, hives and itching, TRALI is a well characterized clinical constellation of symptoms including dyspnea, hypotension, and fever which typically begins one to two (1-2) hours after transfusion ..." The facility policy failed to define specific criteria for blood pressure, pulse, respiration rate, and oxygen saturation as indicative of signs or symptoms of a transfusion reaction. The facility policy stated that the provider, not the transfusion service director, determined if a transfusion reaction workup was ordered. 2. The laboratory policy titled, "Transfusion Reaction Investigation" (Approved by the laboratory director 12/15/2020), stated the following: " ...Supplies: 1. Blood Product Transfusion Record-Nursing staff uses the transfusion reaction symptoms section of the Product Identification Tag form to record the transfusion symptoms and sends a copy to the blood bank. These symptoms are used by the pathologist to aid in the diagnosis ..." The laboratory policy failed to define what vital signs were to be

documented and when the vital signs were to be documented during the transfusion. The laboratory policy failed to define specific criteria for the signs and symptoms of a transfusion reaction. The laboratory policy stated that the nursing staff is to use the "Product Identification Tag" to record transfusion symptoms and send a copy to Blood Bank. The facility policy stated a "Request for Transfusion Reaction Investigation" form was to be used. 3. Review of the facility's training records for nursing personnel revealed the facility required annual review of the "Administration of Blood and Blood Components Procedures" (PHC-01-000127) by the nursing staff. Refer to #1 above. Further review of the facility's "Passport 2021" skills competency evaluation document for Labor and Delivery nurses, ICU nurses, and Emergency Room nurses revealed the facility did not include transfusion of blood/blood components or signs /symptoms of a transfusion reaction in the competency assessment. 4. A review of blood product transfusion forms revealed the following: a. "Product Identification Tag" The form included the following information: "Recipient; MRN (medical record number); Unit ABO/Rh; ... Vital Signs: PRE: Time; Temp; B/P; RESP; PULSE 15 MIN: Time; Temp; B/P; RESP; PULSE COMPLETED: Time; Temp; B/P; RESP; PULSE ... TRANSFUSION REACTION SYMPTOMS: Chills, Fever (Temp. Rise>2F or 1C); Dyspnea, Nausea, Headache, Shock, Hemoglobinuria, Urticaria, Pain, Other ..." The form failed to correspond to the facility's policy for documentation of patient vital signs at one-hour intervals during the transfusion and one-hour post transfusion. The form failed to define specific criteria for blood pressure, pulse, and respiration rate as indicative of signs or symptoms of a transfusion reaction. b. "Blood Product Transfusion Record" The form included the following information: "Vital Signs: Interval: No greater than 30 minutes before pre-transfusion: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 15 minutes after start of transfusion: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 1 hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 2-hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 3 hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 4 hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site Up to 1 hour post transfusion: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site Reaction to Blood: No; Yes, Protocol followed (refer to facility specific Blood Administration Policy: Type of Reaction ..." The form failed to define specific criteria for temperature, blood pressure, respiration rate, and oxygen saturation as indicative of signs or symptoms of a transfusion reaction. 5. In an interview on 03/02/2022 at 2: 25 pm in the conference room, the Laboratory Director was asked what patient vital sign criteria would be indicative of a transfusion reaction. He stated the most common sign was a change in temperature. The laboratory director was asked what vital sign changes would he consider significant. He stated an increase in temperature of 2 degrees (F), hypotension, a significant elevation of blood pressure and shortness of breath. The laboratory director was asked what would constitute a significant elevation of blood pressure. He stated an increase of 15 or 20 (mmHg). 6. A random review of patient transfusion records (02/2021, 05/2021, 11/2021, and 01/2022) revealed the following 9 of 12 patients in which the facility failed to ensure transfusion reactions were promptly identified, investigated and documented: a. Patient 900733870 Unit Number: W2003 21 063766 Date/Times of Transfusion: 02/22 /2021; Start time 0535; End time 0935 Vital Signs: Time: 0535; Temp-98.2F; Heart Rate (pulse)-82; Resp-18; B/P-106/67; O2 Sat-No documentation Time: 0550; Temp-97.7F; Heart Rate (pulse)-82; Resp-16; B/P-103/62; O2 Sat-No documentation Post transfusion vitals documented at 1115 (1 hour and thirty minutes post transfusion); No temperature documented Time: 1200; Temp-100.4F At this time the patient had a temperature increase of 2.7 degrees F from the temperature documented at 0550. Per facility policy, a temperature increase of 2 degrees F is a sign of a transfusion reaction. Review of facility variance reports revealed a variance report was created 02

/22/2021 for this patient with the notation, "Bld product, Adverse Rxn". In an interview on 03/03/2022 at 12:10 pm in the conference room, the blood bank manager stated that this was the first time the blood bank was aware of the variance report. She explained that the issue was reported using the facility's "Radical Logic" variance reporting system and that the laboratory was not notified of the incident. b. Patient 907853916 First Unit Number: W2003 21 088803 Dates/Times of Transfusion: 05/01 /2021; Start time 2351; 05/02/2021; End time 0059 Vital Signs: Time: 2351; Temp-100.6F; Heart Rate (pulse)-123; Resp-25; B/P-99/61; O2 Sat-No documentation Time: 0006; Temp-100.9; Heart Rate (pulse)-122; Resp-22; B/P-100/58; O2 Sat-No documentation Time: 0100; Temp-102F; Heart Rate (pulse)-124; Resp-34; B/P-No documentation; O2 Sat-100 Time: 0113 (Post transfusion); Temp-102.4F; Heart Rate (pulse)-125; Resp-30; B/P-146/95; O2 Sat-No documentation At this time the patient had an increase in systolic blood pressure of 47 mmHg from the blood pressure documented at the start of the first unit on 05/01/2021 at 2351. Second Unit Number: W2003 21 102679 Dates/Times of Transfusion: 05/02/21; Start time 0113; End time 0300 Vital Signs: Time: 0113; Temp-102.4F; Heart Rate (pulse)-125; Resp-30; B/P-146/95; O2 Sat-No documentation Time: 0128; Temp-102.5F; Heart Rate (pulse)-125; Resp-30; B/P-134/88; O2 Sat-No documentation Time: 0200; Temp-102.9F; Heart Rate (pulse)-125; Resp-31; B/P-No documentation; O2 Sat-98 Time: 0300; Temp-103.9F; Heart Rate (pulse)-125; Resp-30; B/P-No documentation; O2 Sat-98 Time: 0353; Temp- 104.4F; Heart Rate (pulse)-124; Resp-26; B/P-119/82; O2 Sat-No documentation At this time the patient had a temperature increase of 2.0 degrees F from the start of the second unit and a temperature increase of 3.8 degrees F from the start of the first unit. The patient had a systolic blood pressure decrease of 27 mmHg from the start of the second unit at 0113. Per facility policy, a temperature increase of 2 degrees F is a sign of a transfusion reaction. c. Patient 906788999 The units were given as part of a Massive Transfusion Protocol (MTP) First Unit Number: W2036 21 171950 Dates/Times of Transfusion: 05/10/2021; Start time 0530; End time 0555 Vital Signs: Time: 0530; Temp-96.7F; Heart Rate (pulse)-71; Resp-18; B/P-116/78; O2 Sat-100 Second Unit Number: W2012 21 665555 Dates/Times of Transfusion: 05 /10/2021; Start time 0536; End time 0627 Vital Signs: Time: 0542; Temp-No documentation; Heart Rate (pulse)-70; Resp-No documentation; B/P-135/80; O2 Sat-No documentation Time: 0620: Temp-97.0F; Heart Rate (pulse)-68; Resp-18; B/P-166 /80; O2 Sat-100 At this time the patient had an increase in systolic blood pressure of 50 mmHg from the start of the first unit at 0530. Third Unit Number: W2041 21 588981 Dates/Times of Transfusion: 05/10/2021; Start time 0630; End time 0700 Vital Signs: Time: 0657; Temp-97.1F; Heart Rate (pulse)-77; Resp-No documentation; B/P-184/78; O2 Sat-No documentation Time: 0705; Temp-98F; Heart Rate (pulse)-76; Resp-20; B/P-186/82; O2 Sat-98 At this time the patient had an increase in systolic blood pressure of 70 mmHg from the start of the first unit at 0530. d. Patient 908414967 Unit Number: W2003 21 106110 Dates/Times of Transfusion: 05/13/2021; Start time 1107; End time 1245 Vital Signs: Time: 1107; Temp-97.5F; Heart Rate (pulse)-64; Resp-17; B/P-121/83; O2 Sat-No documentation Time: 1122; Temp-98.5F; Heart Rate (pulse)-68; Resp-18; B/P-121/80; O2 Sat-No documentation Time: 1200; Temp-98.1F; Heart Rate (pulse)-57; Resp-18; B/P-134/83; O2 Sat-100 Time: 1245; Temp-No documentation; Heart Rate (pulse)-86; Resp-29; B/P-138/82; O2 Sat-100 Time: 1457 (2 hours post transfusion); B/P-154/93 The patient had heart rate increase of 29 from the heart rate documented at 1200 and an increase in systolic blood pressure of 33 mmHg from the start of the transfusion at 1107. e. Patient 903544881 Unit Number: W2041 21 610596 Dates/Times of Transfusion: 11/01 /2021; Start time 2128; End time 2353 Vital Signs: Time: 2128; Temp-98F; Heart Rate (pulse)-96; Resp-16; B/P-149/75; O2 Sat-No documentation Time: 2145; Temp-97.9F; Heart Rate (pulse)-89; Resp-16; B/P-142/77; O2 Sat-100 Time: 2215; Temp-

97.9F; Heart Rate (pulse)-90; Resp-16; B/P-139/76; O2 Sat-100 Time: 2322; Temp-98.1F; Heart Rate (pulse)-94; Resp-16; B/P-170/85; O2 Sat-100 At this time the patient had an increase in systolic blood pressure of 31 mmHg from the blood pressure documented at 2215. f. Patient 903589517 Unit Number: W2036 21 272717 Dates/Times of Transfusion: 11/12/2021; Start time 0954; End time 1227 Vital Signs: Time: 0954; Temp-103.3F; Heart Rate (pulse)-114; Resp-30; B/P-106/57; O2 Sat-No documentation Time: 1015; Temp-103.5F; Heart Rate (pulse)-114; Resp-30; B/P-68 /52; O2 Sat-100 At this time the patient had a decrease in systolic blood pressure of 38 mmHg from the blood pressure documented at 0954. Time: 1100; Temp-103.5F; Heart Rate (pulse)-117; Resp-30; B/P-158/62; O2 Sat-100 At this time the patient had an increase in systolic blood pressure of 90 mmHg from the blood pressure documented at 1015. g. Patient 903600764 Unit Number: W2003 21 218882 Dates /Times of Transfusion: 01/13/2022; Start time 1438; End time 1800 Vital Signs: Time: 1438; Temp-97.9F; Heart Rate (pulse)-88; Resp-23; B/P-106/64; O2 Sat-96 Time: 1530; Temp-No documentation; Heart Rate (pulse)-99; Resp-22; B/P-113/58; O2 Sat-100 Time: 1635; Temp-97.0F; Heart Rate (pulse)-76; Resp-18; B/P-110/76; O2 Sat-97 At this time the patient had a decrease in heart rate of 23 from the heart rate documented at 1530. h. Patient 903346705 Unit Number: W2003 21 206397 Dates /Times of Transfusion: 01/16/2022; Start time 1609; End time 2007 Vital Signs: Time: 1609; Temp-98.8F; Heart Rate (pulse)-110; Resp-16; B/P-111/55; O2 Sat-100 Time: 1613; Temp-97.3; Heart Rate (pulse)-100; Resp-23; B/P-112/64; O2 Sat-84 At this time the patient had a decrease in oxygen saturation of 16 from the oxygen saturation documented at 1609. Time: 1728; Temp-No documentation; Heart Rate (pulse)-125; Resp-45; B/P-114/55; O2 Sat-100 At this time the patient had an increase in respiration rate of 29 from the respiration rate documented at 1609. i. Patient 903489600 Unit Number: W2003 21 200286 Dates/Times of Transfusion: 01/17 /2022; Start time 0542; End time 0800 Vital Signs: Time: 0542; Temp-97.0F; Heart Rate (pulse)-76; Resp-32; B/P-112/62; O2 Sat-No documentation Time: 0600; Temp-97.0; Heart Rate (pulse)-103; Resp-21; B/P-172/98; O2 Sat-92 At this time the patient had an increase in systolic blood pressure of 60 mmHg and an increase in heart rate of 27 from the vital signs documented at 0542. Time: 0700; Temp-No documentation; Heart Rate (pulse)-70; Resp-12; B/P-101/60; O2 Sat-96 At this time the patient had a decrease in systolic blood pressure of 71 mmHg from the blood pressure documented at 0600. The facility policy failed to define specific blood pressure, heart rate, oxygen saturation, and respiration rate criteria for a transfusion reaction. No documentation of prompt identification or investigation of a transfusion reaction was provided for the above transfusions. 7. Review of the laboratory's blood/blood component records revealed the facility performed 5473 transfusions in 2020 with 6 reported transfusion reactions and 6459 transfusions in 2021 with 9 reported transfusion reactions. 8. In an interview on 03/02/2022 at 10:00 am in the conference room with the Chief Operating Officer, the Director of Quality and Safety Integration and the ICU charge nurse on duty, the charge nurse for ICU was asked at what time intervals are patient vital signs documented during a blood/blood component transfusion. She stated 15 minutes before transfusion, one hour after start of transfusion, 15 minutes post-transfusion, and 1-hour post-transfusion. These stated timed intervals did not correspond to the time intervals in the facility policy. She was asked what changes in vital signs would be indicative of a transfusion reaction. She stated that she did not know exact numbers and would rely on her clinical judgement or refer to the facility policy for guidance. The Chief Operating Officer (COO) stated that the facility policy, "Administration of Blood and Blood Components Procedures" (PHC-01-000127), was a general procedure purchased from Lippincott, which is a medical publisher of professional health information. The COO and Director of Quality and Safety Integration confirmed that the procedure did not define specific criteria for blood pressure, heart

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| | rate, respiration rate, and oxygen saturation for a transfusion reaction. The Director of Quality and Safety Integration was asked how the "Product Identification Tag" was utilized by the facility. She stated that form is provided by the laboratory when a blood product was sent to the transfusing unit but the form was not utilized for any purpose. She further stated that the form was scanned into the patient's medical record. This statement did not correspond to the laboratory policy titled, "Transfusion Reaction Investigation" which stated that the nursing staff uses the transfusion reaction symptoms section of the "Product Identification Tag" to record the transfusion symptoms and sends a copy to the blood bank. In an interview on 03/02 /2022 at 2:25 pm in the conference room, the laboratory director was asked if he had reviewed the facility policy, "Administration of Blood and Blood Components Procedures" (PHC-01-000127). He stated that he was not aware of the facility policy. This confirmed the above findings. Word Key: O2=Oxygen AABB= Association for the Advancement of Blood & Biotherapies TRALI=Transfusion Related Acute Lung Injury ICU=Intensive Care Unit Temp=Temperature B/P=Blood Pressure Resp=Respiration Rate O2 Sat=Oxygen saturation FiO2=Fraction of Inspired oxygen Bld=blood Rxn=Reaction F=Fahrenheit mmHg-millimeters of Mercury |
| **D5026** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1217<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's policy, emergency release/massive transfusion protocol (MTP) documentation, root cause analysis (RCA), facility's policy, patient emergency release/MTP orders, laboratory and facility blood/blood product transfusion policies, blood product transfusion forms, and patient transfusion records, the laboratory failed to meet the requirements of immunohematology, as evidenced by: 1. The laboratory failed to follow their own written policy for emergency release /MTP blood products for 1 of 1 patient reviewed on 08/01/2021. Refer to D5401. 2. The laboratory failed to ensure emergency release/MTP's of blood products were signed by the ordering physician for 10 of 19 orders in four (4) months. Refer to D5553. 3. The laboratory failed to ensure transfusion reactions were promptly identified, investigated, and documented and that recommendations were made to medical staff regarding transfusion procedure improvements for 9 of 12 patients that received blood products. Refer to D5559. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy, emergency release/massive transfusion protocol (MTP) documentation, root cause analysis (RCA), and interview with the |

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| | blood bank manager, the laboratory failed to follow their own written policy for emergency release/MTP blood products for 1 of 1 patient reviewed on 08/01/2021. Findings included: 1. The laboratory did not follow their own written policy for selecting O negative RBC units when there was no current specimen and no patient history for patient #903576877. Review of the laboratory's "Massive Transfusion (Emergency Release)" policy (last revised date 4/23/19) stated the following: "C. Select Units. 1. No current specimen available and no patient history: Four pre tagged O Rh negative red blood cells for emergency release are stored in pairs in blood bank refrigerator #1 in the right top drawer." Patient #903576877 did not have a current specimen (for ABO type) and did not have history of a blood type. On 08/01/2021, the laboratory provided three (3) units of B Positive RBCs according to what was documented on the "Emergency Release Form" and photo copies of the units: unit numbers W200321142030, W200321159962, W200321158589. (patient was transfused on 08/01/2021 at 11:10 pm) 2. The laboratory did not follow their own written policy for checking the patient's history in their system (with patient's name, medical record number, gender and age) when they obtained patient information for an emergency release/MTP order. Review of the laboratory's "Massive Transfusion (Emergency Release)" policy (last revised date 4/23/19) stated the following: "VI. EMERGENCY RELEASE PROTOCOL (Uncrossmatched provided within 2 minutes of request): A. The floor notifies Transfusion Services immediately that emergency release of uncrossmatched blood is needed. B. Obtain the following information and immediately check the patient's history in the laboratory computer system: 1. Patient's name 2. Patient's medical record number 3. Gender and age (if known) 4. Number of uncrossmatched red blood cells and other blood components needed." According to the "Safety Event Analysis Report - RCA 284" and "RCA #284 - Incorrect Blood Administered," as Testing Person (TP) #9 was preparing the emergency release cooler (for patient #903576877) she searched with the patient's first three (3) letters of the first/last name in the Hemocare Lifeline (HCLL) Transfusion system and "~60 patients" appeared in the system. TP #9 confused patient #903576877 full name with the name of patient #908540825 (different date of birth). Patient #908540825 had a history of B Positive and that type was used to give type-specific units to patient #903576877 for the emergency release. TP #9 proceeded to prepare the cooler with three (3) units of B positive RBCs. During an interview on 03/02/2022 at 1:30 pm, the blood bank manager was asked for documentation that patient #903576877 history was checked (before preparing the cooler) in the laboratory computer system with name, medical record number, gender and age for patient's emergency release/MTP as outlined in their written policy. She was unable to provide documentation. 3. The laboratory did not follow their own written policy for ensuring the transporter/runner brought a means of patient identification (patient #903576877) for picking up the emergency release/MTP cooler of units. Review of the laboratory's "Massive Transfusion (Emergency Release)" policy (last revised date 4/23/19) stated the following: "VII. MASSIVE TRANSFUSION PROTOCOL: I. Notes: 1. The transporter will bring a Blood Component Release Request or other means of identifying patient. The minimum information needed on this request is patient medical record number and patient name. Issue the blood product in the computer." Review of patient #903576877 "Massive Transfusion Protocol Worksheet" included date/time of cooler pickup "8/1/21 @ 2302," the transporter's identification number, and TP #9 documented "No chart label for pickup." The transporter did not bring a means of patient identification for pickup as required in the laboratory's policy. |
| **D5553** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(b)(f) |

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| | (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policy, facility's policy, patient emergency release /MTP orders, and in interview with the blood bank manager, the laboratory failed to ensure emergency release/MTP's of blood products were signed by the ordering physician for 10 of 19 orders in four (4) months (10/2020, 01/2021, 05/07/2021, 07 /2021). Findings included: 1. Review of the laboratory's "Massive Transfusion (Emergency Release)" policy (last revised date 4/23/19) stated, "V. EQUIPMENT AND SUPPLIES: E. After transfusion, obtain a signed copy of the Emergency Blood Release Form (See Annex A)." Review of "Annex A" was an "Emergency Blood Release Form" that included a line for the "Physician's Signature." Review of the "Mass Transfusion Protocol Worksheet" did not have a section for physician signature. During an interview on 03/03/2022 at 12:45 pm, the blood bank manager was asked where the physician was expected to sign for MTP orders. She stated an "Emergency Release Form" must also be completed (by the blood bank) and signed by the physician accompanying the "Mass Transfusion Protocol Worksheet." 2. Review of "MASSIVE TRANSFUSION PROTOCOL (MTP) - For ALL Non-Trauma Facilities" (revised 03/09/2021) stated, "BLOOD BANK ...Sends emergency release form to be signed by ordering physician/anesthesiologist if required" and "NURSING /RUNNER ...If required, has physician sign Emergency Release form & returns it to Blood Bank after transfusion complete." The facility protocol did not include that a physician signature for emergency release was required. 3. A random sampling of months in 2020 and 2021 were reviewed for emergency release/MTP transfusion orders and the following patients did not have physician's signature: 01/19/2021: patient #900490876 MTP did not include an Emergency Blood Release Form with a physician signature. 01/22/2021: patient #905982205 MTP order included an Emergency Blood Release Form without a physician signature. 05/10/2021: patient #906788999 MTP order included an Emergency Blood Release Form without a physician signature. 05/15/2021: patient #903532891 Emergency Blood Release Form did not have a physician signature. 05/20/2021: patient #900019595 MTP order included an Emergency Blood Release Form without a physician signature. 05/20 /2021: patient #903346174 had two orders of emergency release for RBCs that included two Emergency Blood Release Forms. The forms did not have a physician signature for the pick up at 5:06 pm and for the pick up at 5:25 pm. 05/25/2021: patient #907850563 MTP order included an Emergency Blood Release Form with a physician assistant (PA) signature. Documentation did not include a physician signature, as required. 07/16/2021: patient #907615985 Emergency Blood Release Form did not have a physician signature. 07/30/2021: patient #908536992 MTP order included an Emergency Blood Release Form with a PA signature. Documentation did not include a physician signature, as required. 4. During an interview on 03/03/2022 at 12:45 pm, the blood bank manager was asked for documentation of physicians' signature for the above emergency releases/MTPs, she stated she has made attempts but was not successful in obtaining the signatures. |
| **D5559** | IMMUNOHEMATOLOGY<br>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:
Based on review of the laboratory and facility blood/blood product transfusion policies, review of blood product transfusion forms, a random review of patient transfusion records (02/2021, 05/2021, 11/2021, and 01/2022) and staff interview, it was revealed the laboratory failed to ensure transfusion reactions were promptly identified, investigated, and documented and that recommendations were made to medical staff regarding transfusion procedure improvements for 9 of 12 patients that received blood products. Findings included: 1. The laboratory policy titled, "Transfusion Reaction Investigation" (Approved by the laboratory director 12/15 /2020), stated the following: " ...Supplies: 1. Blood Product Transfusion Record-Nursing staff uses the transfusion reaction symptoms section of the Product Identification Tag form to record the transfusion symptoms and sends a copy to the blood bank. These symptoms are used by the pathologist to aid in the diagnosis ..." The laboratory policy failed to define what vital signs were to be documented and when vital signs were to be documented during the transfusion. The laboratory policy failed to define specific criteria for the signs and symptoms of a transfusion reaction. 2. The facility policy titled "Administration of Blood and Blood Components Procedures" (PHC-01-000127) stated the following: " ...Pre-Administration: Handling of Blood and Blood Components at the Bedside ...6. Patient vital signs are to be taken and documented prior to initiating any administration/transfusion ...9. The patient should remain under direct observation by the transfusionist for fifteen (15) minutes after the transfusion is begun. 10. After a transfusion is started, the progress of the transfusion should be monitored throughout the infusion ...12. Patients receiving blood or blood products should have vital signs monitored, including the following and at the following intervals: Temperature, Blood Pressure, Pulse, Respiration Rate, O2 saturation, Lung sounds. Intervals: No longer than 30 minutes prior to each unit being transfused according to AABB standards, Vitals are taken within the first 15 minutes of each unit being transfused, Additional vital signs are obtained each one (1) hour during the infusion, at the end of the infusion, and as warranted by the patient's condition/history or if a transfusion reaction is suspected, Complete a post transfusion lung sound assessment, A patient may be monitored up to one (1) hour following the completion of the transfusion as required to ensure patient's stability ...Transfusion reactions: Transfusion reactions can happen during and after a transfusion. They can occur with any blood component ...If a Reaction is Suspected ...2. Notify the ordering physician and the blood bank. 3. If the physician orders a transfusion reaction workup: ...b. Complete a hospital specific 'Request for Transfusion Reaction Investigation' form ...c. Have a post transfusion reaction blood sample (1 pink tube) collected ..." The facility policy, in the section titled, "Signs and Symptoms of Transfusion Reactions" referred to the following signs and symptoms of a transfusion reaction: "chills, fever, dyspnea, hemoglobinuria, back pain, loin pain, hypotension, renal failure, shock, Disseminated Intravascular Coagulation, fatigue, jaundice, temperature

elevation of 1C or 2F or more, coughing, bronchospasm, respiratory distress, vascular instability, nausea, abdominal cramps, vomiting, diarrhea, loss of consciousness, erythema, hives and itching, TRALI is a well characterized clinical constellation of symptoms including dyspnea, hypotension, and fever which typically begins one to two (1-2) hours after transfusion ..." The facility policy failed to define specific criteria for blood pressure, pulse, respiration rate, and oxygen saturation as indicative of signs or symptoms of a transfusion reaction. The facility policy stated that the provider, not the transfusion service director, determined if a transfusion reaction workup was ordered. The facility policy stated a "Request for Transfusion Reaction Investigation" form was to be used. The laboratory policy stated that the nursing staff is to use the "Product Identification Tag" to record transfusion symptoms and send a copy to Blood Bank. 3. A review of blood product transfusion forms revealed the following: a. "Product Identification Tag" The form included the following information: "Recipient; MRN (medical record number); Unit ABO/Rh; ... Vital Signs: PRE: Time; Temp; B/P; RESP; PULSE 15 MIN: Time; Temp; B/P; RESP; PULSE COMPLETED: Time; Temp; B/P; RESP; PULSE ... TRANSFUSION REACTION SYMPTOMS: Chills, Fever (Temp. Rise>2F or 1C); Dyspnea, Nausea, Headache, Shock, Hemoglobinuria, Urticaria, Pain, Other ..." The form failed to correspond to the facility's policy for documentation of patient vital signs at one-hour intervals during the transfusion and one-hour post transfusion. The form failed to define specific criteria for blood pressure, pulse, and respiration rate as indicative of signs or symptoms of a transfusion reaction. b. "Blood Product Transfusion Record" The form included the following information: "Vital Signs: Interval: No greater than 30 minutes before pre-transfusion: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 15 minutes after start of transfusion: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 1 hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 2-hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 3 hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site 4 hour interval: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site Up to 1 hour post transfusion: Time, Temp, Pulse, Resp, O2 Sat, FiO2, BP, IV site Reaction to Blood: No; Yes, Protocol followed (refer to facility specific Blood Administration Policy: Type of Reaction ..." The form failed to define specific criteria for temperature, blood pressure, respiration rate, and oxygen saturation as indicative of signs or symptoms of a transfusion reaction. 4. In an interview on 03/02/2022 at 2:25 pm in the conference room, the Laboratory Director was asked what patient vital sign criteria would be indicative of a transfusion reaction. He stated the most common sign was a change in temperature. The laboratory director was asked what vital sign changes would he consider significant. He stated an increase in temperature of 2 degrees (F), hypotension, a significant elevation of blood pressure and shortness of breath. The laboratory director was asked what would constitute a significant elevation of blood pressure. He stated an increase of 15 or 20 (mmHg). 5. A random review of patient transfusion records (02/2021, 05/2021, 11 /2021, and 01/2022) revealed the following 9 of 12 patients in which the laboratory failed to ensure transfusion reactions were promptly identified, investigated and documented: a. Patient 900733870 Unit Number: W2003 21 063766 Date/Times of Transfusion: 02/22/2021; Start time 0535; End time 0935 Vital Signs: Time: 0535; Temp-98.2F; Heart Rate (pulse)-82; Resp-18; B/P-106/67; O2 Sat-No documentation Time: 0550; Temp-97.7F; Heart Rate (pulse)-82; Resp-16; B/P-103/62; O2 Sat-No documentation Post transfusion vitals documented at 1115 (1 hour and thirty minutes post transfusion); No temperature documented Time: 1200; Temp-100.4F At this time the patient had a temperature increase of 2.7 degrees F from the temperature documented at 0550. Per facility policy, a temperature increase of 2 degrees F is a sign of a transfusion reaction. Review of facility variance reports revealed a variance report was created 02/22/2021 for this patient with the notation, "Bld product,

Adverse Rxn". In an interview on 03/03/2022 at 12:10 pm in the conference room, the blood bank manager stated that this was the first time the blood bank was aware of the variance report. She explained that the issue was reported using the facility's "Radical Logic" variance reporting system and that the laboratory was not notified of the incident. b. Patient 907853916 First Unit Number: W2003 21 088803 Dates/Times of Transfusion: 05/01/2021; Start time 2351; 05/02/2021; End time 0059 Vital Signs: Time: 2351; Temp-100.6F; Heart Rate (pulse)-123; Resp-25; B/P-99/61; O2 Sat-No documentation Time: 0006; Temp-100.9; Heart Rate (pulse)-122; Resp-22; B/P-100 /58; O2 Sat-No documentation Time: 0100; Temp-102F; Heart Rate (pulse)-124; Resp-34; B/P-No documentation; O2 Sat-100 Time: 0113 (Post transfusion); Temp-102.4F; Heart Rate (pulse)-125; Resp-30; B/P-146/95; O2 Sat-No documentation At this time the patient had an increase in systolic blood pressure of 47 mmHg from the blood pressure documented at the start of the first unit on 05/01/2021 at 2351. Second Unit Number: W2003 21 102679 Dates/Times of Transfusion: 05/02/21; Start time 0113; End time 0300 Vital Signs: Time: 0113; Temp-102.4F; Heart Rate (pulse)-125; Resp-30; B/P-146/95; O2 Sat-No documentation Time: 0128; Temp-102.5F; Heart Rate (pulse)-125; Resp-30; B/P-134/88; O2 Sat-No documentation Time: 0200; Temp-102.9F; Heart Rate (pulse)-125; Resp-31; B/P-No documentation; O2 Sat-98 Time: 0300; Temp-103.9F; Heart Rate (pulse)-125; Resp-30; B/P-No documentation; O2 Sat-98 Time: 0353; Temp- 104.4F; Heart Rate (pulse)-124; Resp-26; B/P-119/82; O2 Sat-No documentation At this time the patient had a temperature increase of 2.0 degrees F from the start of the second unit and a temperature increase of 3.8 degrees F from the start of the first unit. The patient had a systolic blood pressure decrease of 27 mmHg from the start of the second unit at 0113. Per facility policy, a temperature increase of 2 degrees F is a sign of a transfusion reaction. c. Patient 906788999 The units were given as part of a Massive Transfusion Protocol (MTP) First Unit Number: W2036 21 171950 Dates/Times of Transfusion: 05/10/2021; Start time 0530; End time 0555 Vital Signs: Time: 0530; Temp-96.7F; Heart Rate (pulse)-71; Resp-18; B/P-116/78; O2 Sat-100 Second Unit Number: W2012 21 665555 Dates/Times of Transfusion: 05/10/2021; Start time 0536; End time 0627 Vital Signs: Time: 0542; Temp-No documentation; Heart Rate (pulse)-70; Resp-No documentation; B/P-135 /80; O2 Sat-No documentation Time: 0620: Temp-97.0F; Heart Rate (pulse)-68; Resp-18; B/P-166/80; O2 Sat-100 At this time the patient had an increase in systolic blood pressure of 50 mmHg from the start of the first unit at 0530. Third Unit Number: W2041 21 588981 Dates/Times of Transfusion: 05/10/2021; Start time 0630; End time 0700 Vital Signs: Time: 0657; Temp-97.1F; Heart Rate (pulse)-77; Resp-No documentation; B/P-184/78; O2 Sat-No documentation Time: 0705; Temp-98F; Heart Rate (pulse)-76; Resp-20; B/P-186/82; O2 Sat-98 At this time the patient had an increase in systolic blood pressure of 70 mmHg from the start of the first unit at 0530. d. Patient 908414967 Unit Number: W2003 21 106110 Dates/Times of Transfusion: 05/13/2021; Start time 1107; End time 1245 Vital Signs: Time: 1107; Temp-97.5F; Heart Rate (pulse)-64; Resp-17; B/P-121/83; O2 Sat-No documentation Time: 1122; Temp-98.5F; Heart Rate (pulse)-68; Resp-18; B/P-121/80; O2 Sat-No documentation Time: 1200; Temp-98.1F; Heart Rate (pulse)-57; Resp-18; B/P-134/83; O2 Sat-100 Time: 1245; Temp-No documentation; Heart Rate (pulse)-86; Resp-29; B/P-138/82; O2 Sat-100 Time: 1457 (2 hours post transfusion); B/P-154/93 The patient had heart rate increase of 29 from the heart rate documented at 1200 and an increase in systolic blood pressure of 33 mmHg from the start of the transfusion at 1107. e. Patient 903544881 Unit Number: W2041 21 610596 Dates/Times of Transfusion: 11/01 /2021; Start time 2128; End time 2353 Vital Signs: Time: 2128; Temp-98F; Heart Rate (pulse)-96; Resp-16; B/P-149/75; O2 Sat-No documentation Time: 2145; Temp-97.9F; Heart Rate (pulse)-89; Resp-16; B/P-142/77; O2 Sat-100 Time: 2215; Temp-97.9F; Heart Rate (pulse)-90; Resp-16; B/P-139/76; O2 Sat-100 Time: 2322; Temp-

98.1F; Heart Rate (pulse)-94; Resp-16; B/P-170/85; O2 Sat-100 At this time the patient had an increase in systolic blood pressure of 31 mmHg from the blood pressure documented at 2215. f. Patient 903589517 Unit Number: W2036 21 272717 Dates/Times of Transfusion: 11/12/2021; Start time 0954; End time 1227 Vital Signs: Time: 0954; Temp-103.3F; Heart Rate (pulse)-114; Resp-30; B/P-106/57; O2 Sat-No documentation Time: 1015; Temp-103.5F; Heart Rate (pulse)-114; Resp-30; B/P-68 /52; O2 Sat-100 At this time the patient had a decrease in systolic blood pressure of 38 mmHg from the blood pressure documented at 0954. Time: 1100; Temp-103.5F; Heart Rate (pulse)-117; Resp-30; B/P-158/62; O2 Sat-100 At this time the patient had an increase in systolic blood pressure of 90 mmHg from the blood pressure documented at 1015. g. Patient 903600764 Unit Number: W2003 21 218882 Dates /Times of Transfusion: 01/13/2022; Start time 1438; End time 1800 Vital Signs: Time: 1438; Temp-97.9F; Heart Rate (pulse)-88; Resp-23; B/P-106/64; O2 Sat-96 Time: 1530; Temp-No documentation; Heart Rate (pulse)-99; Resp-22; B/P-113/58; O2 Sat-100 Time: 1635; Temp-97.0F; Heart Rate (pulse)-76; Resp-18; B/P-110/76; O2 Sat-97 At this time the patient had a decrease in heart rate of 23 from the heart rate documented at 1530. h. Patient 903346705 Unit Number: W2003 21 206397 Dates /Times of Transfusion: 01/16/2022; Start time 1609; End time 2007 Vital Signs: Time: 1609; Temp-98.8F; Heart Rate (pulse)-110; Resp-16; B/P-111/55; O2 Sat-100 Time: 1613; Temp-97.3; Heart Rate (pulse)-100; Resp-23; B/P-112/64; O2 Sat-84 At this time the patient had a decrease in oxygen saturation of 16 from the oxygen saturation documented at 1609. Time: 1728; Temp-No documentation; Heart Rate (pulse)-125; Resp-45; B/P-114/55; O2 Sat-100 At this time the patient had an increase in respiration rate of 29 from the respiration rate documented at 1609. i. Patient 903489600 Unit Number: W2003 21 200286 Dates/Times of Transfusion: 01/17 /2022; Start time 0542; End time 0800 Vital Signs: Time: 0542; Temp-97.0F; Heart Rate (pulse)-76; Resp-32; B/P-112/62; O2 Sat-No documentation Time: 0600; Temp-97.0; Heart Rate (pulse)-103; Resp-21; B/P-172/98; O2 Sat-92 At this time the patient had an increase in systolic blood pressure of 60 mmHg and an increase in heart rate of 27 from the vital signs documented at 0542. Time: 0700; Temp-No documentation; Heart Rate (pulse)-70; Resp-12; B/P-101/60; O2 Sat-96 At this time the patient had a decrease in systolic blood pressure of 71 mmHg from the blood pressure documented at 0600. The facility policy failed to define specific blood pressure, heart rate, oxygen saturation, and respiration rate criteria for a transfusion reaction. No documentation of prompt identification or investigation of a transfusion reaction was provided for the above transfusions. 6. Review of the laboratory's blood/blood component records revealed the facility performed 5473 transfusions in 2020 with 6 reported transfusion reactions and 6459 transfusions in 2021 with 9 reported transfusion reactions. 7. In an interview on 03/02/2022 at 10:00 am in the conference room with the Chief Operating Officer, the Director of Quality and Safety Integration and the ICU charge nurse on duty, the charge nurse for ICU was asked at what time intervals are patient vital signs documented during a blood/blood component transfusion. She stated 15 minutes before transfusion, one hour after start of transfusion, 15 minutes post-transfusion, and 1-hour post-transfusion. These stated timed intervals did not correspond to the time intervals in the facility policy. She was asked what changes in vital signs would be indicative of a transfusion reaction. She stated that she did not know exact numbers and would rely on her clinical judgement or refer to the facility policy for guidance. The Chief Operating Officer (COO) stated that the facility policy, "Administration of Blood and Blood Components Procedures" (PHC-01-000127), was a general procedure purchased from Lippincott, which is a medical publisher of professional health information. The COO and Director of Quality and Safety Integration confirmed that the procedure did not define specific criteria for blood pressure, heart rate, respiration rate, and oxygen saturation for a transfusion reaction. The Director of

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| | Quality and Safety Integration was asked how the "Product Identification Tag" was utilized by the facility. She stated that form is provided by the laboratory when a blood product was sent to the transfusing unit but the form was not utilized for any purpose. She further stated that the form was scanned into the patient's medical record. This statement did not correspond to the laboratory policy titled, "Transfusion Reaction Investigation" which stated that the nursing staff uses the transfusion reaction symptoms section of the "Product Identification Tag" to record the transfusion symptoms and sends a copy to the blood bank. In an interview on 03/02 /2022 at 2:25 pm in the conference room, the laboratory director was asked if he had reviewed the facility policy, "Administration of Blood and Blood Components Procedures" (PHC-01-000127). He stated that he was not aware of the facility policy. This confirmed the above findings. |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on review of the RCA, blood utilization committee agendas, the emergency release/MTP policy, and in interview with staff, the laboratory failed to ensure all corrective actions were implemented to prevent recurrence of problems identified in their quality assessment (QA) review for emergency release/MTP of blood products. Findings included: 1. On 08/01/2021, patient #903576877 (typed as O Positive) received three (3) units of red blood cells (RBCs) with the wrong blood-type (B Positive) during an emergency release/MTP. Review of the "Safety Event Analysis Report - RCA 284" included the following corrective actions: a) "Corrective Actions and Action Steps ...Have the team members in the blood bank utilize the [sic] and complete the emergency release function in HCLL before releasing the blood/cooler to the runner; a. Upon completion of the emergency release function, print the ID tag from HCLL and utilize this information as an effective handoff tool with the runner before the cooler is taken; Due Date: 10/14/2021" During an interview on 03/03/2022 at 9:15 am, the blood bank manager was asked for documentation for the corrective action above, she stated she sat down with each of the techs on using the emergency release module around 10/2021 but did not document the training. She had documentation for TP #9 but not for the other ten (10) techs. b) "Take the details of the case to the blood utilization committee for the discussion; a. Propose a change to the process to allow the blood bankers more time to utilize HCLL and get the coolers together; Due Date: 10/14/2021" During an interview on 03/03/2022 at 9:15 am, the blood bank manager and the chief operating officer were asked whether the above corrective action was implemented, they stated they have emphasized to the techs that going beyond the 2 minutes (2 units in 2 minutes protocol) was acceptable and to use the emergency module function in the computer system even if it takes more than 2 minutes. The blood bank manager stated she was unsure if she had taken out the "2 units in 2 minutes" protocol in their revised policy. 2. Review of blood utilization committee (hospital system wide) meeting agenda from 09/21/2021 stated, "Review of the current MTP process and if it should be changed to incorporate additional time added to the current '2 units in 2 minutes' for cooler zero preparation. Consensus at |

this time is, there is inconclusive evidence to support making a change to current policy." Review of the "Massive Transfusion (and Emergency Release)" policy (revised 12/17/21) remained unchanged for the "2 units in 2 minutes" protocol, "VI. Emergency Release Protocol (Uncrossmatched provided within 2 minutes of request) ...VII. Massive Transfusion Protocol (Crossmatched except Cooler 0) ... B. Immediately issue two group O or type specific uncrossmatched red blood cells units using the Emergency Release Protocol into a validated cooler (Cooler 0, TAT is 2 minutes)." (TAT = turnaround time). The laboratory had not implemented their corrective actions in their written policy for expanding the time beyond 2 minutes when preparing emergency release/MTP orders. 3. During an interview on 03/01/2022 at 2:30 pm, the blood bank manager had stated it was impossible to prepare emergency release/MTP coolers within the "2 units in 2 minutes" protocol (implemented in 2019). She stated they had timed the process using their computer system (emergency release module in HCLL) and it was beyond the 2 minutes. The timer for 2 minutes began from the time the blood bank received the order via phone call to the time the units were picked up. She stated this was implemented for the hospital system (18 hospitals) based on an event at another facility. The laboratory did not ensure corrective actions were implemented based on their individual processes. 4. Review of blood utilization committee minutes agenda from 06/15/2021 stated, "Emergency Release Blood and MD Signatures: Dr. [name] led a discussion regarding concern for capturing MD signatures in a timely fashion for the use of emergency release blood orders. The discussion conclusions yielded further investigation into an electronic order that would be sent to the provider through epic. Further investigation will be done as follow up to discussion." During an interview on 03/03/2022 at 9:40 am, the blood bank manager was asked if any corrective actions or policy changes have been implemented to ensure physician signatures are being obtained for emergency release/MTPs. She stated no, this has been a discussion for two (2) years now and she has emails (electronic mail) with floor nurses/staff trying to get signatures but has not been successful. Review of emergency release/MTP orders from four (4) months included 10 of 19 orders without physician signatures. Refer to D5553. 46043 II. Based on review of facility and laboratory records, patient records, and staff interview, the laboratory failed to have an effective QA (quality assessment) plan to monitor, assess, and, when indicated, correct problems identified in transfusion medicine. Findings included: 1. The facility's "Quarterly System Wide Blood Utilization Committee Meeting" minutes from 09/20/2021 stated, "Today's main objective for the meeting was to host a system discussion which resolved around PHH (Piedmont Henry Hospital) Serious Safety Event, wrong blood to patient ... Discussion topics related to the case included: ...Improving nursing process within Epic and possible order sets for reporting all suspected blood transfusion workups ... The tasks requests are being monitored by the Transfusion Safety Officer ..." 2. The job description for the "Manager, Transfusion Safety" (Created 08/26/2016) stated the following: "Job Purpose: Directs, implements, and is accountable for system-wide programs related to evidenced-based patient blood management, transfusion safety and compliance ...Key Responsibilities: 1. Creates, oversees, and manages a system-wide program for blood management and transfusion ...2. Establishes and oversees robust reporting and auditing processes to monitor the program: Oversee blood usage statistics and identify/investigate trends related to transfusion practices. Reviews all requests for uncrossmatched, emergency release RBC's and massive transfusion protocol events to ensure documentation of urgent need is provided by ordering physician. Review all variances and complaints related to blood and blood component administration ...5. Brings expertise and educates/trains appropriate physicians, nurses and staff ...Drives and leads educational activities to ensure the safe use of blood products, specimen labeling requirements and recognition of transfusion reactions ..."

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| | The Transfusion Safety Officer (Transfusion Safety Manager) was identified as a hospital system employee who monitored the transfusion practices of 18 system facilities. In an interview on 03/03/2022 at 11:43am in the conference room, the Manager of Transfusion Safety was asked to provide documentation of the 2021 reviews and audits specified in her job description. No documentation was provided. The Manager of Transfusion Safety stated that hospital system utilizes the "Tableau Dashboard" data management program but that the dashboard was not functioning at the present time because errors were found in the system. The Manager of Transfusion Safety was asked how long the dashboard program had been down. She stated 3 years. She was asked if the hospital system conducted reviews or audits using an alternative method. She stated the hospital system had not used an alternative method to perform reviews and audits. 3. The facility policy titled, "Administration of Blood and Blood Components Policy" (Revised 01/20/2020) stated, " ...4.2 Guidelines for Consideration when Transfusing Blood and Blood Components and Products: Transfusion guidelines are developed by the Blood Utilization Committee and approved by the Medical Executive Committee at each hospital. The auditing process is overseen by the individual hospital ..." A review of the facility "Blood Administration Audits" report (02/09/2022) revealed the facility collected data sample sizes of greater than 100 transfusions per month from May 2021 through December 2021. The data collected included documentation of vital signs (temperature, blood pressure, pulse, respiration rate, and oxygen saturation) prior to blood transfusion, within 15 minutes of blood transfusion start, and every hour of transfusion. In an interview of 03/03/2022 at 12:26 pm in the conference room, the Director of Inpatient Nursing was asked to describe the facility's transfusion auditing process. She stated that nursing personnel from each unit compiled data from at least 10 transfusions a month. She stated that this number could be less based on the hospital unit's transfusion rate. She further stated that nursing then provided her a form that included the patient medical record number, the date of transfusion, and a yes or no answer to documentation of patient vital signs pre-transfusion, within 15 minutes of each unit transfused, and every hour of the transfusion. The data from 05/2021 through 10/2021 was compiled for the blood administration audit report. The Director of Inpatient Nursing was asked if the vitals were evaluated for signs and symptoms of a transfusion reaction. She stated that the audit was only for documentation of patient vital signs at the specified times. 4. A random review of patient transfusion records (02 /2021, 05/2021, 11/2021, and 01/2022) revealed 9 of 12 patients in which the facility failed to document all the required patient vital signs at the specified times and/or failed to ensure transfusion reactions were promptly identified, investigated and documented. Refer to D5559, #5 This confirmed the above findings. Word Key: RBC-Red Blood Cells |
| **D6120** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(7)(8)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on record review and interview with general supervisor, the laboratory failed to |

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| | complete Re-training for a transfusion related death for 3 of 11 testing personnel (TP). Findings include: 1. Record review revealed a transfusion related death occurred on August 1, 2021. Review of the laboratory Root Cause Analysis (RCA) (Line Item 1.) "Safety Event Analysis Report-RCA 284, Corrective Actions and Action Steps stated, "Department Manager/Director will share outcome with staff within 30 days, determine lessons learned and report feedback to the RCA facilitator/Project Manager." The laboratory's deadline for the action was not met for 4 TP. 2. Review of the Re-training records found the laboratory did not complete training titled "2021 Annual CGMP Training" for 4 of the testing personnel working in the Blood Bank by October 14, 2021. The laboratory failed to provide completed training documents for TP#1, TP #2, TP3# and TP#11. 3. The General Supervisor confirmed on 3/2/2022 at 10:00am, the Blood Bank re-training was not completed for all TP. |
| **D6127** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(9)<br><br>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedure, administrative competency evaluation and staff interview, the technical supervisor failed to evaluate and document the semi-annual competency for 1 of 12 Testing Personnel (TP). Findings include: 1. Review of Blood Bank competency records revealed the Technical Supervisor failed to review and document the semi- annual competency for 1 of 12 testing personnel. The laboratory assigned the general supervisor the responsibility to perform semi-annual competency. 2. The laboratory Procedure "Laboratory Competency Assessment" does not state the Technical Supervisor signs/reviews the competency assessment during the first year. 3. Review of the"Administrative Competency Evaluation policy" found the general supervisor assigned the responsibility for semi-annual and annual competency assessment. The general supervisor did not qualify to serve as a technical supervisor for the specialty of immunohematology and therefore should not assess semi-annual competency. 4. During an interview in the conference room with the technical supervisor confirmed on 3/02/22 at 1:15 pm, that he did not review and sign semi-annual competency assessment. |
| **D6151** | GENERAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1463(b)(3)(4)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Blood Bank competency records and interview with the general supervisor, the general supervisor failed to evaluate and document the annual competency for 11 of 12 testing personnel (TP) in 2021. Findings include: 1. Review of competency records revealed the last competency for 11 of 12 of the Blood Bank employees was performed in August 2020. One new TP was hired in February 2022. 2. Review of the general supervisor Administrative Checklist, dated 6/30/3021 states; |

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| | "Personnel: ....Assures testing personnel competency assessed using appropriate measures at required intervals. Ensures that all personnel records are up to date and complete." The general supervisor failed to perform and document annual competency in 2021 for 11 of 12 TP. 3. The general supervisor failed to update the annual competency checklist needed to perform the 2021 annual competency. 4. The general supervisor confirmed on 3/2/2022 at 10:15 am, the Blood Bank annual competency was not completed in 2021. |