Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0487752	03/21/2023
Name of Provider or Supplier	**Street Address, City, State**	
Clay County Memorial Hospital Lab	310 W South St, Henrietta, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced recertification survey conducted 03/21/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of facility policies, laboratory policy, patient transfusion records, and confirmed in interview, the facility failed to promptly identify, investigate, document and report transfusion reactions to the laboratory for 4 of 11 transfusions in 2021 (December), 2022 (January and September), and 2023 (March). The findings include: 1. Review of the facility transfusion policy titled "11.01 Admin Blood&Products.2011. doc" in the "CCMH Nursing Service P&P" manual revealed: "GUIDLEINES A. This procedure is appropriate for transfusion of whole blood, packed red blood cells, fresh frozen plasma, and leukocyte-free or poor red blood cells ... L. The nurse must be aware of the clinical manifestations of transfusion reactions of complication so that there is no delay in diagnosis and intervention. Types of transfusion reactions and complications are described below ... M. Whenever a blood transfusion reaction or complication is suspected, the following measures should be implemented: 1. Immediately stop the transfusion by closing the roller clamp; prime new intravenous tubing with the normal saline; disconnect the blood tubing at the connector; open the clamp and infuse the normal saline to maintain the patency of the line. 2. Monitor the patient closely and provide emergency treatment as necessary. 3. Notify the physician immediately. 4. Save the blood and the tubing and notify the blood bank personnel of

the possible reaction. 5. Send the first voided specimen of the patient following the reaction to the laboratory for analysis. Following a hemolytic reaction, red cells are found in urine ... DOCUMENTATION A. Date, time transfusion was started and discontinued, blood component administered, donor numbers, and approximate volume B. Any medication administered. C. All parameters of assessment. D. Any reactions, interventions, and results. E. All patient teaching done and the level of understanding." 2. Review of the facility policy titled "10.06 Administering Blood Transfusion.doc" in the "CCMH Laboratory Technical Procedure Manual #10.06" and "CCMH Nursing Service Administration Procedure #11.02" last edited "07/2022" revealed: "Administering Blood ... 4. Responsibility during administration of blood - Before beginning transfusion, it is important to have an understanding of the patient's medical history and baseline vital signs. -Record temperature, pulse, respiration and blood pressure five minutes before administering blood, and five minutes after transfusion is started. Then vital signs are to be taken every fifteen (15) minutes X 4, then every thirty (30) minutes X 4, then every hour until transfusion is complete. - Observe the patient at frequent intervals for: -Proper infusion solution -Infiltration - Fever, >/= 1C, with or without chills from baseline) -Chills/rigors, with or without fever -Respiratory Distress (Respiratory Rate >28, dyspnea, wheezing, coughing, hypoxemia) -Blood pressure changes from baseline (acute hypertension or hypotension, 30 mmHg rise or fall in systolic) -Abdominal, chest, flank or back pain - Pain at the infusion site -Skin changes including urticaria, pruritus (itching), flushing or localized edema) -Jaundice or darkened red urine -Nausea with or without vomiting -Bleeding or other manifestations of a consumption coagulopathy -Decreased/no urination -Anaphylaxis -Blood oozing from the intravenous or surgical site may be in the first indication of an acute hemolytic reaction in anesthetized patients - Tachycardia or Bradycardia 5. Instruct patient to report any of the above to the nurse ... 7. The transfusionist completes the vital signs, volume TX, and check "were noted" or "were not noted" under the signs and symptoms of a transfusion reaction statement in the Product ID tag. 8. In case of reaction a. STOP the transfusion immediately. Leave needle in place. The IV line should be kept open with a slow infusion of 0.9% normal saline until additional orders are received by a physician. b. Immediately notify the charge nurse on duty c. Immediately notify the physician d. Immediately notify laboratory; laboratory will immediately notify reference laboratory and pathologist on-call e. Record temperature, pulse, respiration, and blood pressure f. Check the patient's identification band, all labels on the blood component, and forms for the transfusion, to determine if the transfused component was intended for the recipient. g. The responsible attending physician should evaluate the patient to determine if a transfusion reaction is a possibility, what kind it might be, and what immediate medical actions should be undertaken. h. Fill out sections 1-9 of Form 255 Investigation of Suspected Transfusion Reaction Form i. Complete the post transfusion data information located on the lower section of the Product ID tag if the unit is permanently discontinued j. Return remaining blood and Form 255 to lab k. Send first urine passed after reaction to laboratory. Mark request "for transfusion workup"." 3. Review of the laboratory policy titled "10.14 Transfusion Reaction Procedure-URHCS.doc URHCS" revealed: "Transfusions [sic] Reaction Procedure-URHCS Purpose: To outline Laboratory procedures in the case of transfusion reactions to blood or blood products. All transfusion reactions must be reported to the laboratory and be evaluated to the extent considered appropriate by the Medical Director. Major adverse effects, e.g., hemolytic transfusion reactions and disease transmission, must be reported to the Bureau of Biologics, Food and Drug Administration ... Preliminary Steps: Whenever a transfusion reaction involving more than just hives is suspected, the transfusion should be immediately discontinued, but the intravenous line kept open. The remaining blood, a new sample from the recipient,

and a reaction report will be sent to the laboratory for prompt investigation." 4. A random review of blood infusion records and progress notes from patient charts from 2021 (December), 2022 (January and September), and 2023 (March) revealed the following 4 transfusions in which transfusion reactions were NOT identified, investigated, documented, and reported to the laboratory: A. Patient Hospital Number: 10085273 Transfusion of unit 1 of 2 packed Red Blood Cells (Label number: W091021402915) initiated on 12/10/2021 at 04:40 hours and completed at 06:45 hours. The following were the patient vitals documented on the Blood Infusion Record: TIME: 04:40 hours BP before infusion started: 143/50 TIME: 05:15 hours BP: 177/81 At 05:15 hours the patient's blood pressure increased >30 mmHg from the baseline which was 1 of 16 criteria defined by the facility as signs of a transfusion reaction. There were no patient progress notes charted for this time. TIME: 05:45 hours BP: 173/79 At 05:45 hours the patient's blood pressure increased >30 mmHg from the baseline which was 1 of 16 criteria defined by the facility as signs of a transfusion reaction. Patient progress notes at 06:00 noted "1st unit PRBCs infusing without difficulty. No s/s of reaction at this time. V/S stable. IV site to left ac healthy. No signs of infiltration". TIME: 06:15 hours BP: 177/82 At 06:15 hours the patient's blood pressure increased >30 mmHg from the baseline which was 1 of 16 criteria defined by the facility as signs of a transfusion reaction. TIME: 06:45 hours BP: 186 /64 At 06:45 hours the patient's blood pressure remained increased >30 mmHg from the baseline which was 1 of 16 criteria defined by the facility as signs of a transfusion reaction. The following was noted in the "REACTION: Please circle YES OR NO" section of the infusion record: Blood pressure change from baseline (acute hyper or hypotension of 30 mmHg rise or fall in systolic)- "NO" The nurse who completed the reaction section did NOT indicate the >30 mmHg blood pressure changes from the baseline as a possible transfusion reaction. The facility failed to identify and report to the laboratory the increases in blood pressure as a possible transfusion reaction. B. Patient Hospital Number: 10086152 Transfusion of unit 2 of 2 packed Red Blood Cells (Label number: W090121437294) initiated on 01/05/2022 at 13:45 hours and completed at 16:45 hours. The following were the patient vitals documented on the Blood Infusion Record: TIME: 13:40 hours BP before infusion started: 181/66 TIME: 14:15 hours BP: 144/60 At 14:15 hours the patient experienced a blood pressure decrease >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. There were no patient progress notes charted for this time. TIME: 14:45 hours BP: 148/54 At 14:45 hours the patient experienced a blood pressure decrease >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. There were no patient progress notes charted for this time. TIME: 15:15 hours BP: 146/55 Patient progress notes at 15:15 noted "IV infiltration and bleeding. Blood transfusion stopped. Notified ...RN. IV removed from rt hand and pressure dressing applied with coban ...IV reinserted in lt wrist with 20G angiocath x 1 attempt ...Flushed with NS and patent. Blood transfusion resumed at 15:10". At 15:15 hours the patient experienced a blood pressure decrease >30 mmHg from the baseline and infiltration which were 2 of the 16 criteria defined by the facility as signs of a transfusion reaction. TIME: 15:45 hours BP: 164/70 Patient progress notes at 15:49 noted "During blood transfusion monitoring for adverse reactions, writer noticed BP change from baseline of >30 mmHG at 1415 during 2nd unit of blood transfusion that started at 1345. Baseline BP 181/96 at 13:40. BP 144/60 at 1415. However, patient has had increased confusion and restlessness intermittent throughout the day causing BP readings to flucuate [sic] as she isn't keeping still. No other reactions observed during transfusion. Will continue to monitor for adverse reactions. The following was noted in the "COMMENTS" section of the infusion record: "Blood pressure changes from baseline related to increased confusion and restlessness that has come and gone throughout the

day." The following was noted in the "REACTION: Please circle YES OR NO" section of the infusion record: Infiltration- "NO" Blood pressure change from baseline (acute hyper or hypotension of 30 mmHg rise or fall in systolic)- "YES" The nurse who completed the reaction section did NOT indicate infiltration as a possible transfusion reaction. The facility failed to identify and report the decreases in blood pressure and infiltration to the laboratory as a possible transfusion reaction. C. Patient Hospital Number: 10095035 Transfusion of unit 1 of 2 packed Red Blood Cells (Label number: W091022302826) initiated on 09/10/2022 at 01:02 hours and completed at 03:27 hours. The following were the patient vitals documented on the Blood Infusion Record:. TIME: 01:02 hours Resp before infusion started: 24 BP before infusion started: 159/79 TIME: 02:07 hours Resp: 36 BP: 200/100 At 02:07 the blood transfusion was stopped. The patient's respiration rate was >28 and their systolic pressure had increased by >30 mmHg from the baseline, which were 2 of the 16 criteria defined by the facility as signs of a possible transfusion reaction. Patient Progress notes at 02:10 noted: "Blood stopped at 0207 due to s/s overload. Patient began to have increased breathing and labored respirations with a decrease in O2 sats going into the high 87%. Pt was placed on a simple face mask at 6L and had labored respirations and using abdominal muscles. MD called and orders to give 40 MG of Lasix IVP was ordered and if Patient returned to normal then to restart the blood due to no rash, no itching, no redness, no rise in temp" Note: Lasix is a loop diuretic used to treat fluid retention and swelling. The following was noted in the "COMMENTS" section of the infusion record: "Blood was stopped at 0207 d/t s/s of overload and restarted at 120 mL/hr at 0257" The following was noted in the "REACTION: Please circle YES OR NO" section of the infusion record: Respiratory distress (rate greater than 28, dyspnea, wheezing, coughing, hypoxemia)- "YES" Blood pressure change from baseline (acute hyper or hypotension of 30 mmHg rise or fall in systolic)- "YES" Abdominal, chest, flank, or back pain- "YES" Nausea with or without vomiting- "YES" Decreased/No urination- "YES" The nurse who completed the above section indicated the patient experienced respiratory distress, blood pressure changes from the baseline, abdominal, chest, flank, or back pain, nausea with or without vomiting, and decreased/no urination which were 5 of 16 criteria defined by the facility as signs of a transfusion reaction. The facility failed to report the respiratory distress, increase in blood pressure, pain, nausea, or decreased/no urination to the laboratory as a possible transfusion reaction. D. Patient Hospital Number: 10101209 1. Transfusion of unit 1 of 2 packed Red Blood Cells (Label number: W091032138149) initiated on 03/09 /2023 at 10:00 hours and completed at 00:25 hours. The following were the patient vitals documented on the Blood Infusion Record: TIME: 10:00 hours BP before infusion: 169/79 TIME: 10:20 hours BP: 133/83 At 10:20 hours the patient's blood pressure decreased >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. TIME: 10:35 hours BP: 131 /80 At 10:35 hours the patient's blood pressure remained decreased >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. TIME: 10:50 hours BP: 124/78 At 10:50 hours the patient's blood pressure remained decreased >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. TIME: 11:35 hours BP: 129/80 At 11:35 hours the patient's blood pressure remained decreased >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. TIME: 00:05 hours BP: 117/76 At 00:05 hours the patient's blood pressure remained decreased >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. TIME: 00:25 hours BP: 116/70 At 00:25 hours the patient's blood pressure remained decreased >30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. The following was noted in the "COMMENTS" section of

	the infusion record: "11:02 PM given Tylenol 650 mg PO for c/o H/A. Spoke with [Attending Physician] to report change of more than 30 mmHg in SBP. Believed not a reaction to blood but due to blood pressure med administered in ER. Patient reports BP usually in 120s". The following was noted in the "REACTION: Please circle YES OR NO" section of the infusion record: Blood pressure change from baseline (acute hyper or hypotension of 30 mmHg rise or fall in systolic)- "NO" The nurse who completed the above section did NOT identify the >30 mmHg blood pressure decreases from the baseline as a possible transfusion reaction. 2. Transfusion of unit 2 of 2 packed Red Blood Cells (Label number: W091023156256) initiated on 03/10 /2023 at 00:38 hours and completed at 04:00 hours. The following were the patient vitals documented on the Blood Infusion Record: TIME: 00:38 hours BP before infusion started:130/70 TIME: 02:13 hours BP: 110/68 At 02:13 hours the patient's blood pressure remained decreased 30 mmHg from the baseline which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. The following was noted in the "COMMENTS" section of the infusion record: "Zofran 4 mg IVP administered @ 0053 d/t c/o nausea after ambulating to bathroom." At 00:53 hours the patient experienced nausea with or without vomiting which was 1 of the 16 criteria defined by the facility as signs of a transfusion reaction. Note: Zofran is an antiemetic drug. The following was noted in the "REACTION: Please circle YES OR NO" section of the infusion record: Blood pressure change from baseline (acute hyper or hypotension of 30 mmHg rise or fall in systolic)- "NO" Nausea with or without vomiting- "YES" The nurse who completed the above section did NOT identify the 30 mmHg blood pressure decrease from the baseline as a possible transfusion reaction. The facility failed to identify and report the decreases in blood pressure from the baseline and nausea to the laboratory as a possible transfusion reaction. 5. During an interview on 03/21/2023 at 11:49 a.m., the Laboratory Manager confirmed the above findings. Key: temp-temperature resp-respirations BP-blood pressure min-minute mm Hg-millimeters mercury s/s-signs and symptoms d/t-due to sats-saturation pt-patient MD-medical doctor mg-milligram IVP-intravenous push mL/hr-milliliters per hours F-Fahrenheit c/o-complaints of O2-oxygen L-liter IV-intravenous Rt-right Lt-left G-gauge NS-normal saline pRBCS-packed red blood cells V/S-vital signs ac-antecubital SBP-systolic blood pressure ER-emergency room