Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0052671	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hamilton Hospital Laboratory	901 W Hamilton Po Box 158, Olney, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties/subspecialties surveyed for 45 CFR 493.1101 Facility Administration 493.1217 Immunohematology 493.1441 Laboratory Director, (high complexity) Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the hospital transfusion services, the facility administration failed to meet the requirements specified in 493.1101 through 493.1105. Refer to D3025

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 the facility's blood and blood product transfusion policies, patient transfusion records, and staff interview, the facility failed to ensure end user nursing personnel were adequately trained on Blood Product Administration to ensure prompt identification, reporting, and investigation of blood and blood product transfusion reactions to the laboratory. Findings included: 1. Review facility's policy titled "Blood Transfusion" (Departments Affected: Nursing, Emergency, Laboratory; Effective date 11/1/2012) stated the following in the section titled "Suspected Transfusion Reaction": "1. Discontinue blood immediately. 2. The I.V. will be kept open with 0.9% Normal Saline utilizing an IV set other than the transfusion blood administration set. 3. Document signs and symptoms observed. 4. Take vitals and continue to monitor. 5. Notify physician and Blood Bank immediately. 6. Follow physician orders related to the care of the patient having the reaction. 7. Return remaining unit of blood and tubing in a biohazard bag to Blood Bank. 8. Obtain a patient urine sample and send it to the Lab alone with the completed Blood Transfusion Reaction Report. 9. The Blood Transfusion Reaction Report can be obtained from the Lab and will be completed by an RN. 10. Monitor and document Vital Signs and urine output every hour for the first 24 hours. 11. Send a urine sample to the Lab 24 hours after the onset of the initial reaction." The policy failed to define signs and symptoms of a possible transfusion reaction. 2. Review of an additional facility policy titled "Blood Administration" (Departments Affected: Nursing, Emergency, Laboratory; Effective date 11/1/2012; Reviewed date 07/28/2016) stated the following: "Transfusion: ....3. Obtain baseline vital signs immediately before transfusion and document on the Transfusion form prior to spiking the unit. 4. Do not administer any medications through blood tubing. The only fluid compatible with blood is 0.9% Normal Saline. 5. Initiate the blood transfusion at 100 cc/hr for the first 15 minutes and evaluate for a transfusion reaction. If no evidence of a reaction, increase the flow at a rate that is compatible with the patient's condition and following physician orders. 6. An RN will remain at bedside to closely monitor the patient and evaluate and record the follow-up vital signs at the 15 minute interval after the transfusion start time, and document on the Transfusion form. Observe for any temperature fluctuations above baseline that is one degree above Centigrade or two degrees Fahrenheit. 7. Monitor and document vital signs hourly after the initial 15 minute check until the transfusion is completed and record results on the Transfusion Form. Possible Signs and Symptoms of a Transfusion Reaction: General: Fever (Rise of 1 degree C or 2 degrees F), Chills, Muscle aches/pain, Headache, Heat at the site of infusion or along vein Nervous System: Apprehension/impending sense of doom, Tingling/numbness Respiration System: Respiration rate/Tachypnea/apnea, Cough, Wheezing, Rales Gastrointestinal System: Nausea, Vomiting, Pain/Abdominal cramping, Diarrhea (may be bloody) Integumentary System: Rashes/hives (urticaria) /swelling, Itching, Diaphoresis Cardiovascular System: Heart rate/bradycardia /tachycardia, Blood pressure/hypertension/hypotension/shock, Peripheral circulation /color-cyanosis-facial flushing/ temperature-cool-clammy-not-flushed-dry/edema, Bleeding/generalized (DIC)/oozing of surgical wounds Renal System: Dyspnea

/changes in urine volume/oliguria/anuria/renal failure, Changes in urine color/dark-concentrated/shades of red, brown, amber (may indicate presence of RBC's/hematuria /or free hemoglobin/hemoglobinuria in urine) Unconscious Patient: Weak pulse, Fever, Hypotension, Visible hemoglobinuria, Increased blood oozing at surgical site, Vasomotor instability/tachycardia-bradycardia-hypotension, Oliguria/anuria" The policy failed to specifically define what changes in blood pressure, respiration rate, heart rate, pulse constitute a possible transfusion reaction. The policy failed to address signs and symptoms of Transfusion Related Acute Lung Injury (TRALI) or Transfusion Associated Circulatory Overload (TACO). 3. Review of patient transfusion records from 01/2019 through 07/04/2019 revealed the following 7 of 30 transfusions in which a possible transfusion reaction was NOT identified, reported or investigated and/or vital signs were NOT monitored and documented per facility policy: a. Patient 00498917; Unit# W035218639661; Transfusion 01/10/2019 Start Time/1600 hours; Blood Pressure 123/53 15 minute/1615 hours; Blood Pressure 124 /51 60 minute/1630 hours; Blood Pressure 126/53 120 minute/1700 hours; Blood Pressure 133/48 180 minute/1800 hours; Blood Pressure 102/26 240 minute/1900 hours; Blood Pressure 103/38 1-hour Post Completion/2000 hours; Blood Pressure 92 /41 This patient's blood pressure had a 31-point drop in systolic pressure. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". b. Patient 00503374; Unit# W035219777510; Transfusion 02/25/2019 Start Time/1740 hours; Temperature 97.7 15 minute/1755; Temperature 97.4 60 minute/1840 hours; Temperature 97 120 minute/1940 hours; Temperature 99.2 AT THIS TIME, the patient had a 2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. 240 minute/2040 hours; Temperature 99.2 1-hour Post Completion/2145 hours; Temperature 99.3 At 1- hours post completion of the transfusion, the patient maintained a 2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". c. Patient 00502644; Unit# W035219776414; Transfusion 02/18/2019 Start Time/1800 hours; Blood Pressure 124/79 15 minute /1815 hours; Blood Pressure 133/81 60 minute/1900 hours; Blood Pressure 119/76 120 minute/2000 hours; Blood Pressure 110/58 AT THIS TIME, the patient's blood pressure had a 23-point drop in systolic pressure. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". 180 minute; NO vitals (Temperature, Pulse, Blood Pressure, or Respiration) documented 240 minute; NO vitals (Temperature, Pulse, Blood Pressure, or Respiration) documented d. Patient 00508020; Unit# W035219828149; Transfusion 04/16/2019 Start Time/1635 hours; Temperature 97.2 15 minute/1650; Temperature 98.1 60 minute/1750 hours; Temperature 99.4 AT THIS TIME, the patient had a 2.2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. 120 minute/1850 hours; Temperature 97.1 240 minute/1930 hours; Temperature 98.4 1-hour Post Completion/2030 hours; Temperature 99.8 At this time, the patient had a 2.7 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". e. Patient 00509175; Unit# W035219791715; Transfusion 05/01/2019 Start Time/0633 hours; Temperature 99.4; Pulse 85; Blood Pressure 125/71; Respiration 24 No other vital signs were documented during the transfusion. If vital signs are not taken, a possible transfusion reaction CANNOT be identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was NOT answered. f. Patient 00509980; Unit# W035219833058; Transfusion 05/08/2019 Start Time

/2335 hours; Temperature 98.4 15 minute/2354; Temperature 98.6 60 minute/0036 hours; Temperature 100.7 AT THIS TIME, the patient had a 2.3 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". g. Patient 00514514; Unit# W035219832521; Transfusion 07/04/2019 Start Time/1310 hours; Temperature 101.4 15 minute/1325; Temperature 103.3 AT THIS TIME, the patient had a 1.9 degree Fahrenheit temperature increase. The transfusion nurse contacted the provider at 1330 hours after the temperature increase. The provider instructed the nurse to continue with the transfusion. The laboratory was called to draw blood cultures and the increase in temperature was not communicated to the laboratory. The transfusion nurse failed to follow facility policy to "Notify physician and Blood Bank immediately." The question on the patient's transfusion record, "Was there a reaction to blood?", answered "No". The Technical Supervisor initiated a transfusion reaction workup after conducting a "Transfusion Tag" review. 4. In an interview on 07/10/2019 at 1145 hours in the hospital chapel, the Technical Supervisor (TS) was asked to provide documentation of nurse training/competency for blood product administration and the identification, reporting, and investigating of blood and blood product transfusion reactions. The TS stated that the facility had NO nursing education and/or training related to blood product administration or signs and symptoms of a transfusion reaction. This confirmed the findings that the facility failed to ensure end user nursing personnel were adequately trained on Blood Product Administration to ensure prompt identification, reporting, and investigation of blood and blood product transfusion reactions to the laboratory. II. Based on review of the facility's blood and blood product transfusion policies, blood product administration training records, patient transfusion records, and confirmed in staff interview, the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Findings included: 1. Review facility's policy titled "Blood Transfusion" (Departments Affected: Nursing, Emergency, Laboratory; Effective date 11/1/2012) stated the following in the section titled "Suspected Transfusion Reaction": "1. Discontinue blood immediately. 2. The I.V. will be kept open with 0.9% Normal Saline utilizing an IV set other than the transfusion blood administration set. 3. Document signs and symptoms observed. 4. Take vitals and continue to monitor. 5. Notify physician and Blood Bank immediately. 6. Follow physician orders related to the care of the patient having the reaction. 7. Return remaining unit of blood and tubing in a biohazard bag to Blood Bank. 8. Obtain a patient urine sample and send it to the Lab alone with the completed Blood Transfusion Reaction Report. 9. The Blood Transfusion Reaction Report can be obtained from the Lab and will be completed by an RN. 10. Monitor and document Vital Signs and urine output every hour for the first 24 hours. 11. Send a urine sample to the Lab 24 hours after the onset of the initial reaction." The policy failed to define signs and symptoms of a possible transfusion reaction. 2. Review of an additional facility policy titled "Blood Administration" (Departments Affected: Nursing, Emergency, Laboratory; Effective date 11/1/2012; Reviewed date 07/28/2016) stated the following: "Transfusion: ....3. Obtain baseline vital signs immediately before transfusion and document on the Transfusion form prior to spiking the unit. 4. Do not administer any medications through blood tubing. The only fluid compatible with blood is 0.9% Normal Saline. 5. Initiate the blood transfusion at 100 cc/hr for the first 15 minutes and evaluate for a transfusion reaction. If no evidence of a reaction, increase the flow at a rate that is compatible with the patient's condition and following physician orders. 6. An RN will remain at bedside to closely monitor the patient and evaluate and record the follow-up vital signs at the 15 minute interval after the transfusion start time, and document on the Transfusion form. Observe for any

temperature fluctuations above baseline that is one degree above Centigrade or two degrees Fahrenheit. 7. Monitor and document vital signs hourly after the initial 15 minute check until the transfusion is completed and record results on the Transfusion Form. "Possible Signs and Symptoms of a Transfusion Reaction: General: Fever (Rise of 1 degree C or 2 degrees F), Chills, Muscle aches/pain, Headache, Heat at the site of infusion or along vein Nervous System: Apprehension/impending sense of doom, Tingling/numbness Respiration System: Respiration rate/Tachypnea/apnea, Cough, Wheezing, Rales Gastrointestinal System: Nausea, Vomiting, Pain/Abdominal cramping, Diarrhea (may be bloody) Integumentary System: Rashes/hives (urticaria) /swelling, Itching, Diaphoresis Cardiovascular System: Heart rate/bradycardia /tachycardia, Blood pressure/hypertension/hypotension/shock, Peripheral circulation /color-cyanosis-facial flushing/temperature-cool-clammy-not-flushed-dry/edema, Bleeding/generalized (DIC)/oozing of surgical wounds Renal System: Dyspnea /changes in urine volume/oliguria/anuria/renal failure, Changes in urine color/dark-concentrated/shades of red, brown, amber (may indicate presence of RBC's/hematuria /or free hemoglobin/hemoglobinuria in urine) Unconscious Patient: Weak pulse, Fever, Hypotension, Visible hemoglobinuria, Increased blood oozing at surgical site, Vasomotor instability/tachycardia-bradycardia-hypotension, Oliguria/anuria" The policy failed to specifically define what changes in blood pressure, respiration rate, heart rate, pulse constitute a possible transfusion reaction. The policy failed to address signs and symptoms of Transfusion Related Acute Lung Injury (TRALI) or Transfusion Associated Circulatory Overload (TACO). 3. The facility was asked to provide documentation of nurse training/competency for blood product administration and the identification, reporting, and investigating of blood and blood product transfusion reactions. No documentation was provided. 4. Review of patient transfusion records from 01/2019 through 07/04/2019 revealed the following 7 of 30 transfusions in which a possible transfusion reaction was NOT identified, reported or investigated and/or vital signs were NOT monitored and documented per facility policy: a. Patient 00498917; Unit# W035218639661; Transfusion 01/10/2019 Start Time/1600 hours; Blood Pressure 123/53 15 minute/1615 hours; Blood Pressure 124 /51 60 minute/1630 hours; Blood Pressure 126/53 120 minute/1700 hours; Blood Pressure 133/48 180 minute/1800 hours; Blood Pressure 102/26 240 minute/1900 hours; Blood Pressure 103/38 1-hour Post Completion/2000 hours; Blood Pressure 92 /41 This patient's blood pressure had a 31-point drop in systolic pressure. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". b. Patient 00503374; Unit# W035219777510; Transfusion 02/25/2019 Start Time/1740 hours; Temperature 97.7 15 minute/1755; Temperature 97.4 60 minute/1840 hours; Temperature 97 120 minute/1940 hours; Temperature 99.2 AT THIS TIME, the patient had a 2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. 240 minute/2040 hours; Temperature 99.2 1-hour Post Completion/2145 hours; Temperature 99.3 At 1- hours post completion of the transfusion, the patient maintained a 2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". c. Patient 00502644; Unit# W035219776414; Transfusion 02/18/2019 Start Time/1800 hours; Blood Pressure 124/79 15 minute /1815 hours; Blood Pressure 133/81 60 minute/1900 hours; Blood Pressure 119/76 120 minute/2000 hours; Blood Pressure 110/58 AT THIS TIME, the patient's blood pressure had a 23-point drop in systolic pressure. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". 180 minute; NO vitals (Temperature, Pulse, Blood Pressure, or Respiration) documented 240 minute; NO

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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 surveyor's review of the Immunohematology records, patient records, and staff interviews the laboratory failed to meet applicable requirements in the specialty of Immunohematology. Refer to D5559.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory policy for the Coulter DxH600 hematology analyzer (Serial Number AZ24840), laboratory maintenance records (01/2018 through 06/2019)) and staff interview, the laboratory failed to have documentation of performing monthly maintenance for 4 of 18 months. Findings included: 1. The laboratory policy titled "DxH600 Start up and Quality Control" (# HM-S&QC; Approved by the Laboratory Director on 01/12/2018), stated the following: "Maintenance, Monthly: Each technologist should be familiar with the monthly cleaning of air filter -Pneumatic Supply. Currently performed by an assigned technologist." 2. Review of laboratory maintenance records (01/2018 through 06 /2019) titled "Beckman Coulter DxH600 Daily Worksheet" revealed the laboratory failed to have documentation of performing monthly maintenance for the following 4 of 18 months: March 2019 April 2019 May 2019 June 2019 3. The above findings were confirmed by Technical Supervisor on 07/09/2019 at 1540 hours in the hospital chapel.
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: Based on review of the laboratory's blood and blood product transfusion policies, facility blood and blood product transfusion policy, blood product administration training records, patient transfusion records, and confirmed in staff interview, the laboratory failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Findings included: 1. Review of the laboratory's policy titled "Transfusion Reaction Investigation" (Sisgned by the laboratory director 01/21/2019) stated the following: "Procedure: 1. Nursing service is responsible for notification to the patient's physician and the laboratory blood bank department. The laboratory employee or lab manager will notify the pathologist ... ...3. The laboratory will contact the pathologist ASAP. 4. If the physician or the pathologist is concerned about a possible transfusion reaction, the laboratory will perform a transfusion reaction investigation." 2. Review of the laboratory policy titled "Blood Bank Transfusion Tag Review" stated the following:

"Purpose: To ensure pertinent information is provided on the Transfusion Tag pre and post transfusion. Procedure: 1. Verify BB Number is in right hand corner of the Tag. 2. Verify Patient Name. 3. Verify Medical Record Number. 4. Verify Doctor. 5. Verify transfusionist and 2nd identifier. 6. Verify Product. 7 ... .11. Date and time started and beginning vital signs. 12. 15 minute vital signs. 13. Date and time completed and vital signs .....15. Reaction or No Reaction, with a transfusion reaction report if Yes ... .21. Check beginning and ending temperature rise of >2 degrees for PRBC. Review: 1. Review the blood tag upon return of the unit. Making sure all information is filled out correctly. Immediately check with nursing service for correction is any section is not filled out." This review did NOT include a check for documentation of vital signs hourly after the initial 15 minute check until the transfusion is completed. This review ONLY referred to a change in temperature as a possible sign of a transfusion reaction with packed Red Blood Cells (PRBC). 3. Review of the facility policy titled "Blood Administration" (Departments Affected: Nursing, Emergency, Laboratory; Effective date 11/1/2012; Reviewed date 07/28 /2016) stated the following: "Transfusion: ....3. Obtain baseline vital signs immediately before transfusion and document on the Transfusion form prior to spiking the unit. 4. Do not administer any medications through blood tubing. The only fluid compatible with blood is 0.9% Normal Saline. 5. Initiate the blood transfusion at 100 cc/hr for the first 15 minutes and evaluate for a transfusion reaction. If no evidence of a reaction, increase the flow at a rate that is compatible with the patient's condition and following physician orders. 6. An RN will remain at bedside to closely monitor the patient and evaluate and record the follow-up vital signs at the 15 minute interval after the transfusion start time, and document on the Transfusion form. Observe for any temperature fluctuations above baseline that is one degree above Centigrade or two degrees Fahrenheit. 7. Monitor and document vital signs hourly after the initial 15 minute check until the transfusion is completed and record results on the Transfusion Form. "Possible Signs and Symptoms of a Transfusion Reaction: General: Fever (Rise of 1 degree C or 2 degrees F), Chills, Muscle aches/pain, Headache, Heat at the site of infusion or along vein Nervous System: Apprehension /impending sense of doom, Tingling/numbness Respiration System: Respiration rate /Tachypnea/apnea, Cough, Wheezing, Rales Gastrointestinal System: Nausea, Vomiting, Pain/Abdominal cramping, Diarrhea (may be bloody) Integumentary System: Rashes/hives (urticaria)/swelling, Itching, Diaphoresis Cardiovascular System: Heart rate/bradycardia/tachycardia, Blood pressure/hypertension/hypotension /shock, Peripheral circulation/color-cyanosis-facial flushing/temperature-cool-clammy-not-flushed-dry/edema, Bleeding/generalized (DIC)/oozing of surgical wounds Renal System: Dyspnea/changes in urine volume/oliguria/anuria/renal failure, Changes in urine color/dark-concentrated/shades of red, brown, amber (may indicate presence of RBC's/hematuria/or free hemoglobin/hemoglobinuria in urine) Unconscious Patient: Weak pulse, Fever, Hypotension, Visible hemoglobinuria, Increased blood oozing at surgical site, Vasomotor instability/tachycardia-bradycardia-hypotension, Oliguria/anuria" The policy failed to specifically define what changes in blood pressure, respiration rate, heart rate, pulse constitute a possible transfusion reaction. The policy failed to address signs and symptoms of Transfusion Related Acute Lung Injury (TRALI) or Transfusion Associated Circulatory Overload (TACO). 4. The laboratory was asked to provide documentation of nurse training /competency for blood product administration and the identification, reporting, and investigating of blood and blood product transfusion reactions. No documentation was provided 5. Review of patient transfusion records from 01/2019 through 07/04/2019 revealed the following 7 of 30 transfusions in which a possible transfusion reaction was NOT identified, reported or investigated and/or vital signs were NOT monitored and documented per facility policy: a. Patient 00498917; Unit# W035218639661;

Transfusion 01/10/2019 Start Time/1600 hours; Blood Pressure 123/53 15 minute /1615 hours; Blood Pressure 124/51 60 minute/1630 hours; Blood Pressure 126/53 120 minute/1700 hours; Blood Pressure 133/48 180 minute/1800 hours; Blood Pressure 102/26 240 minute/1900 hours; Blood Pressure 103/38 1-hour Post Completion/2000 hours; Blood Pressure 92/41 This patient's blood pressure had a 31-point drop in systolic pressure. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". b. Patient 00503374; Unit# W035219777510; Transfusion 02/25/2019 Start Time/1740 hours; Temperature 97.7 15 minute/1755; Temperature 97.4 60 minute/1840 hours; Temperature 97 120 minute /1940 hours; Temperature 99.2 AT THIS TIME, the patient had a 2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. 240 minute/2040 hours; Temperature 99.2 1-hour Post Completion/2145 hours; Temperature 99.3 At 1- hours post completion of the transfusion, the patient maintained a 2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". c. Patient 00502644; Unit# W035219776414; Transfusion 02/18/2019 Start Time/1800 hours; Blood Pressure 124/79 15 minute/1815 hours; Blood Pressure 133/81 60 minute/1900 hours; Blood Pressure 119/76 120 minute/2000 hours; Blood Pressure 110/58 AT THIS TIME, the patient's blood pressure had a 23-point drop in systolic pressure. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". 180 minute; NO vitals (Temperature, Pulse, Blood Pressure, or Respiration) documented 240 minute; NO vitals (Temperature, Pulse, Blood Pressure, or Respiration) documented d. Patient 00508020; Unit# W035219828149; Transfusion 04/16/2019 Start Time/1635 hours; Temperature 97.2 15 minute/1650; Temperature 98.1 60 minute/1750 hours; Temperature 99.4 AT THIS TIME, the patient had a 2.2 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. 120 minute/1850 hours; Temperature 97.1 240 minute/1930 hours; Temperature 98.4 1-hour Post Completion /2030 hours; Temperature 99.8 At this time, the patient had a 2.7 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". e. Patient 00509175; Unit# W035219791715; Transfusion 05/01/2019 Start Time/0633 hours; Temperature 99.4; Pulse 85; Blood Pressure 125/71; Respiration 24 No other vital signs were documented during the transfusion. If vital signs are not taken, a possible transfusion reaction CANNOT be identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was NOT answered. f. Patient 00509980; Unit# W035219833058; Transfusion 05/08/2019 Start Time/2335 hours; Temperature 98.4 15 minute/2354; Temperature 98.6 60 minute/0036 hours; Temperature 100.7 AT THIS TIME, the patient had a 2.3 degree Fahrenheit temperature increase. A possible transfusion reaction was NOT identified, reported or investigated. The question on the patient's transfusion record, "Was there a reaction to blood?", was answered "No". g. Patient 00514514; Unit# W035219832521; Transfusion 07/04/2019 Start Time/1310 hours; Temperature 101.4 15 minute/1325; Temperature 103.3 AT THIS TIME, the patient had a 1.9 degree Fahrenheit temperature increase. The transfusion nurse contacted the provider at 1330 hours after the temperature increase. The provider instructed the nurse to continue with the transfusion. The laboratory was called to draw blood cultures and the increase in temperature was not communicated to the laboratory. The transfusion nurse failed to follow facility policy to "Notify physician and Blood Bank immediately." The question on the patient's transfusion record, "Was

	there a reaction to blood?", answered "No". The Technical Supervisor initiated a transfusion reaction workup after conducting a "Transfusion (form) Tag" review. 6. In an interview on 07/10/2019 at 1145 hours in the hospital chapel, the Technical Supervisor (TS) was asked to provide all transfusion reaction investigation documents for 2017 through 2019. She provided 2 investigations (05/24/2017 and 07/04/2019). The TS was asked if the facility conducted blood product administration training /competency for nursing. The TS stated that the facility had NO nursing education training related to blood product administration or signs and symptoms of a transfusion reaction. The TS was shown the above findings (#3) from the Transfusion Forms. She confirmed the findings that the laboratory failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for all blood products. Word Key: BB=Blood Bank RN=Registered Nurse ASAP=As Soon As Possible PRBC=Packed Red Blood Cells
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policies, patient transfusion records, and interview with staff, the laboratory failed to ensure quality assessment activities included an effective review process to monitor, assess and, when indicated, correct problems identified in transfusion medicine. Findings included: 1. The laboratory did not have an effective mechanism in place to monitor, assess and, when indicated, correct problems, such as: a. Underreporting of transfusion reactions by the facility. b. Ensuring all information was documented for patient transfusions, in order to promptly identify and report transfusion reactions. c. Policies included the definition of vital signs to be obtained prior, during, and after a transfusion. d. Routine blood product administration education and/or competency to include identification of the signs and symptoms of a possible transfusion reaction and the steps to follow to report a possible transfusion reaction. Refer to D5559 2. The laboratory did not have an effective transfusion review committee composed of representatives from all departments responsible for the collection, preparation, and administration of blood products. In an interview on 07 /10/2019 at 1145 hours in the chapel, the laboratory manager stated that the facility did NOT have a blood review committee and that the Laboratory Director was the only person who reviewed blood utilization. She also stated that there was NO nursing review of the blood administration flowsheet.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by:

	Based on review of the laboratory records and staff interview, it was revealed the laboratory director failed to provide overall management for the laboratory. Refer to D6094
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 review of the facility records and staff interview, it was revealed the laboratory failed director to ensure a quality assessment plan identified and corrected problems. Refer to D5793
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) 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. This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid (CMS) 209 form, personnel records, and interview with staff, the Technical Supervisor (TS) failed to evaluate and document performance of 1 of 13 Testing Persons responsible for high complexity testing at least semiannually during the first year testing persons analyze patient specimens in 2018. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person #13 listed to perform high complexity testing. 2. Review of personnel records from 2017 through 2019 revealed the following: Testing Person #13; Date of hire-12/13/2017 Training documentation 01/2018 Competency Evaluation 06/20/2018 No other documentation of competency from 06/20/2018 through 07/11/2019. The TS failed to evaluate and document performance at least semiannually during the first year of patient testing. 3. In an interview on 07/09/2019 at 1230 hours in the hospital chapel, the TS was asked to provide documentation of semiannual competency assessment for Testing Person #13. No documentation was provided. This confirmed the above findings.