Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0680542	(X3) Date Survey Completed 01/10/2024
Name of Provider or Supplier Ennis Regional Medical Center	**Street Address, City, State** 2201 West Lampasas, Ennis, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on review of laboratory and facility policies, patient transfusion records, and confirmed in interview, the facility failed to ensure all transfusion related activities were documented for administration of blood products to be able to identify and promptly investigate transfusion reactions for 1 of 4 patients in 2022 (random review January, February and May) and 1 of 3 patients in 2023 (random review February and May). Findings included: 1. Review of the laboratory and facility's policy "Blood Administration" revealed: "Procedure ... D. Patient Monitoring: 1. Only an RN or LIP may initiate the blood product, an LVN may monitor a patient receiving blood. An RN /LIP will remain with patient for the first 15 minutes after the transfusion is initiated. Take base line vital signs upon initiation of transfusion. Afterward take vital signs after first 15 minutes x 1, then every 1-hour until complete. Then take one set at the time of completion and 1-hour post transfusion. Vital signs will be documented by nursing staff or LIP in the appropriate transfusion record. 2. Assess patient for sign [sic] and symptoms of transfusion reaction: If transfusion reaction suspected, Refer to Laboratory Policy and Procedure LB B12 - Transfusion Reaction Workup. a. Fever- chills, shaking or rigors, an increase in 2 degrees F must be reported to the lab for a transfusion reaction investigation and to the physician. b. Pain- Chest, abdomen or flank, IV site and along venous track, acute leg pain, muscle aches/pain, headache must be reported to the lab for a transfusion reaction investigation and to the physician. c. B/P Changes- Usually acute, hypotensive or hypertensive, progressive

signs of shock, anaphylaxis. Any unexplained / unexpected changes [increase] or [decrease] of 30mm HG in diastolic or systolic must be reported to the lab for transfusion reaction investigation, and to the physician. Any [sic] such changes occurring in the 1st 15 minutes of the transfusion must be reported for investigation, regardless of circumstances. d. Heart - tachycardia, bradycardia, cardiac arrhythmia, and sensation of tightness of the chest, possible cardiac arrest. Heart rate change of 40 beats per minute must be reported as a possible reaction. e. Respiratory Changes - Shortness of breath, respiratory distress, including dyspnea, tachypnea, wheezing, or hypoxemia, respirator failure, or difficulty breathing while lying down, cough, cyanosis, pulmonary edema or rales. f. Skin Changes - including urticaria, itching, flushing, ot [sic] localized edema, rashes, hives, swelling g. Nausea - with or without vomiting, diarrhea, abdominal cramping h. Renal - -Darkened urine may be the earliest indication of an acute hemolytic reaction in anesthetized patients. Reddish, amber, brown, black, dark concentrated urine, renal failure with oliguria or anuria i. Mental Changes -Anxiety, felling of impending doom j. Death-During transfusion or within 3 hours post transfusion. Any unexplained death should be reported immediately to the lab so that an attempt to collect blood may be made to rule out an adverse reaction ... 5. One hour after the blood is infused, document post transfusion vital signs on the blood administration flow sheet." The policy did not define the criteria for "respiratory distress including dyspnea, tachypnea, or hypoxemia". Refer to D3025. Review of the facility and laboratory policy titled "Transfusion Reaction Workup Lbb12" revealed: "POLICY ... Every patient recognized as having an adverse sign or symptom associated with the transfusion of a blood product should be reported immediately to the Blood Bank. Signs and symptoms of transfusion reaction include: Fever (a rise >/= 1 degree C or 2 degrees from pre-transfusion value), chills, hemoglobinuria, hysteria, shock, hypotension, generalized bleeding, nausea, oliguria or anuria, flushing, back, flank, or chest pain, itching or pain at the infusion site, uticaria [sic] (rash), jaundice, dyspnea, (shortness of breath), tachycardia, hives or cyanosis. NOTE: NURSING If any of these signs or symptoms occurs, the below stated actions should immediately be followed: 1. Stop the transfusion immediately 2. Maintain the intravenous line with 0.9% saline 3. Notify the attending physician and the Blood Bank for further instructions 4. Record the symptoms observed 5. Retain all containers and tubing for possible analysis" The policy did not specify if a rise of 2 degrees from pre-transfusion was in degrees Fahrenheit or Celsius. The policy did not define the criteria for "hypotension" or "tachycardia". Refer to D3025. Transfusion reactions were identified by symptoms and patient vital signs taken which were documented by the staff administering the blood products. 2. In a random review, 1 of 4 patients in 2022 (January, February and May) and 1 of 3 patients in 2023 (February and May) revealed the following incomplete documentation: Patient Number: 7218204 was administered PRBC, Unit #W200922677826n on 02/05/2022 at 17:45 hours. Patient temperature, pulse, respirations, O2 saturation, and blood pressure were not taken or documented 1-hour post transfusion. The transfusion was completed at 20: 30 hours. The above incomplete documentation could not properly identify transfusion reactions. Patient Number: 7241330 was administered PRBC, Unit #W200222237915U on 02/07/2023 at 21:00 hours. Patient temperature, pulse, respirations, O2 saturation, and blood pressure were not taken or documented at baseline and 1-hour post transfusion. The transfusion was completed at 23:48 hours. On 02/08/2023 at 00:11 hours the patient was administered PRBC, Unit #204922850393Q. Patient temperature, pulse, respirations, O2 saturation, and blood pressure were not taken or documented at baseline and 1-hour post transfusion. The transfusion was completed at 02:58 hours. The above incomplete documentation could not properly identify transfusion reactions. 3. During an interview on 01/09 /2024 at 2:28 pm, the Quality Manager, stated that audits of transfusion records were

	not performed by the facility and after a review of records confirmed the above findings. During an interview on 01/09/2024 at 3:15 pm, the Laboratory Supervisor, stated that audits of transfusion records were not performed by the laboratory and after a review of records confirmed the above findings. Word Key: mmHg- millimeters of mercury F- Fahrenheit C- Celsius PRBC- packed red blood cells O2- oxygen
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 laboratory and facility policies, patient transfusion records, and confirmed in interview, the facility failed to ensure transfusion reaction procedures included defined criteria to promptly identify, investigate and document blood product transfusion reactions and the facility failed to promptly identify, investigate, and document blood product transfusion reactions for 1 of 4 patients in 2022 (random review January, February and May) and 1 of 3 patients in 2023 (random review February and May). Findings included: 1. Review of the laboratory and facility's policy "Blood Administration" revealed: "Procedure ... D. Patient Monitoring: 1. Only an RN or LIP may initiate the blood product, an LVN may monitor a patient receiving blood. An RN/LIP will remain with patient for the first 15 minutes after the transfusion is initiated. Take base line vital signs upon initiation of transfusion. Afterward take vital signs after first 15 minutes x 1, then every 1-hour until complete. Then take one set at the time of completion and 1-hour post transfusion. Vital signs will be documented by nursing staff or LIP in the appropriate transfusion record. 2. Assess patient for sign[sic] and symptoms of transfusion reaction: If transfusion reaction suspected, Refer to Laboratory Policy and Procedure LB B12 - Transfusion Reaction Workup. a. Fever- chills, shaking or rigors, an increase in 2 degrees F must be reported to the lab for a transfusion reaction investigation and to the physician. b. Pain- Chest, abdomen or flank, IV site and along venous track, acute leg pain, muscle aches/pain, headache must be reported to the lab for a transfusion reaction investigation and to the physician. c. B/P Changes- Usually acute, hypotensive or hypertensive, progressive signs of shock, anaphylaxis. Any unexplained / unexpected changes [increase] or [decrease] of 30mm HG in diastolic or systolic must be reported to the lab for transfusion reaction investigation, and to the physician. Any [sic] such changes occurring in the 1st 15 minutes of the transfusion must be reported for investigation, regardless of circumstances. d. Heart - tachycardia, bradycardia, cardiac arrhythmia, and sensation of tightness of the chest, possible cardiac arrest. Heart rate change of 40 beats per minute must be reported as a possible reaction. e. Respiratory Changes - Shortness of breath, respiratory distress, including dyspnea, tachypnea, wheezing, or hypoxemia, respirator failure, or difficulty breathing while lying down, cough, cyanosis, pulmonary edema or rales. f. Skin Changes - including urticaria, itching, flushing, ot [sic] localized edema, rashes, hives, swelling g. Nausea - with or without vomiting, diarrhea, abdominal cramping h. Renal - -Darkened urine may be the earliest indication of an acute hemolytic reaction in anesthetized patients. Reddish, amber, brown, black, dark concentrated urine, renal failure with oliguria or anuria i. Mental Changes -Anxiety, felling of impending doom j. Death-During transfusion or

within 3 hours post transfusion. Any unexplained death should be reported immediately to the lab so that an attempt to collect blood may be made to rule out an adverse reaction ... 5. One hour after the blood is infused, document post transfusion vital signs on the blood administration flow sheet." The policy did not define the criteria for "respiratory distress including dyspnea, tachypnea, or hypoxemia". Review of the facility and laboratory policy titled "Transfusion Reaction Workup Lbb12" revealed: "POLICY ... Every patient recognized as having an adverse sign or symptom associated with the transfusion of a blood product should be reported immediately to the Blood Bank. Signs and symptoms of transfusion reaction include: Fever (a rise >/= 1 degree C or 2 degrees from pre-transfusion value), chills, hemoglobinuria, hysteria, shock, hypotension, generalized bleeding, nausea, oliguria or anuria, flushing, back, flank, or chest pain, itching or pain at the infusion site, uticaria [sic] (rash), jaundice, dyspnea, (shortness of breath), tachycardia, hives or cyanosis. NOTE: NURSING If any of these signs or symptoms occurs, the below stated actions should immediately be followed: 1. Stop the transfusion immediately 2. Maintain the intravenous line with 0.9% saline 3. Notify the attending physician and the Blood Bank for further instructions 4. Record the symptoms observed 5. Retain all containers and tubing for possible analysis" The policy did not specify if a rise of 2 degrees from pre-transfusion was in degrees Fahrenheit or Celsius. The policy did not define the criteria for "hypotension" or "tachycardia". Transfusion reactions were identified by symptoms and patient vital signs taken which were documented by the staff administering the blood products. The above procedures were not consistent with one another. The facility did not ensure transfusion reaction procedures included defined criteria to promptly identify, investigate and document blood product transfusion reactions. 2. A random review of blood and blood component transfusion patient records from 2022 (January, February, and May) and 2023 (February and May) revealed the following patient transfusions with signs/symptoms of a transfusion reaction: 02/09/2022 Patient Number: 7218493 PRBC Unit #: W200922682062C Baseline Assessment at 21:59 hours Temp: 99.3 Pulse: 108 Resp: 20 SBP: 146 DBP: 62 O2Sat: 96 Pain: 0 Transfusion started: 22:01 hours 15 Minutes Post Start Assessment at 22:20 hours Temp: 100.4 Pulse: 104 Resp: 20 SBP: 124 DBP: 60 O2Sat:93 Pain: not performed/no documentation Did patient have a reaction to blood administration: No 30 Minutes Assessment at 22:35 hours Temp: 100.2 Pulse: 103 Resp: 20 SBP: 117 DBP: 59 O2Sat: 93 Pain: not performed/no documentation Did patient have a reaction to blood administration: No 1 Hour Assessment at 23:00 hours Temp: 100.0 Pulse: 105 Resp: 16 SBP: 112 DBP: 65 O2Sat: 93 Pain: 0 Did patient have a reaction to blood administration: No 1 Hour 30 Minute Assessment at 23:30 hours Temp: 99.1 Pulse: 103 Resp: 18 SBP: 119 DBP: 69 O2Sat: 92 Pain: 0 Did patient have a reaction to blood administration: No 2 Hour Assessment at 00:00 hours on 02/10/2022 Temp: 98.9 Pulse: 99 Resp: 18 SBP: 128 DBP: 69 O2Sat: 94 Pain: 0 Did patient have a reaction to blood administration: No 2 Hour 30 Minute Assessment at 00:30 hours Temp: 98.9 Pulse: 95 Resp: 16 SBP: 128 DBP: 69 O2Sat: 92 Pain: 0 Did patient have a reaction to blood administration: No 3 Hour Assessment at 01:26 hours Temp: 98.9 Pulse: 92 Resp: 16 SBP: 117 DBP: 65 O2Sat:92 Pain: 0 Did patient have a reaction to blood administration: No Assessment when Unit of Blood Stopped or Completed at 01:45 hours Temp: 98.7 Pulse: 92 Resp: 18 SBP: 133 DBP: 68 O2Sat: 92 Pain: 0 Did patient have a reaction to blood administration: No 1 Hour Post Infusion Assessment at 02:25 hours Temp: 98.7 Pulse: 95 Resp: 16 SBP: 122 DBP: 67 O2Sat: 93 Pain: 0 Did patient have a reaction to blood administration: not performed /no documentation The patient had a decrease in systolic blood pressure of 34 mmHg from baseline at 23:00 hours Per facility policy, a systolic blood pressure decrease of 30 mmHg was a sign of a transfusion reaction. NO documentation of prompt identification or investigation of a transfusion reaction was provided. 05/12/2023

	Patient Number: 7247204 PRBC Unit #: W204923681839 Baseline Assessment at 13:00 hours Temp: 98.1 Pulse: 92 Resp: 16 SBP: 89 DBP: 45 O2Sat: 94 Transfusion started: 13:00 hours 15 Minutes Post Start Assessment at 13:15 hours Temp: 98.1 Pulse: 91 Resp: 16 SBP: 93 DBP: 49 O2Sat: 94 Pain: not performed/no documentation Did patient have a reaction to blood administration: No 30 Minutes Assessment at 13:35 hours Temp: 97.4 Pulse: 104 Resp: 16 SBP: 133 DBP: 71 O2Sat: 96 Pain: not performed/no documentation Did patient have a reaction to blood administration: No 1 Hour Assessment at 14:00 hours Temp: 97.2 Pulse: 86 Resp: 17 SBP: 105 DBP: 61 O2Sat: 93 Pain: not performed/no documentation Did patient have a reaction to blood administration: No 2 Hour Assessment at 15:00 hours Temp: 97.5 Pulse: 86 Resp: 16 SBP: 108 DBP: 61 O2Sat: 94 Pain: not performed/no documentation Did patient have a reaction to blood administration: No Assessment when Unit of Blood Stopped or Completed at 15:45 hours Temp: 97.2 Pulse: 91 Resp: 17 SBP: 107 DBP: 59 O2Sat: 94 Pain: not performed/no documentation Did patient have a reaction to blood administration: not performed/no documentation 1 Hour Post Infusion Assessment at 16:45 hours Temp: 98.9 Pulse: 91 Resp: 16 SBP: 110 DBP: 57 O2Sat: 97 Pain: not performed/no documentation Did patient have a reaction to blood administration: not performed/no documentation The patient had an increase in systolic blood pressure of 44 mmHg from baseline at 13:35 hours. Per facility policy, a systolic blood pressure increase of 30 mmHg was a sign of a transfusion reaction. NO documentation of prompt identification or investigation of a transfusion reaction was provided. THE FACILITY FAILED TO ENSURE TRANSFUSION REACTIONS WERE PROMPTLY IDENTIFIED, INVESTIGATED AND DOCUMENTED FOR ALL BLOOD PRODUCTS. 3. During an interview on 01/09/2024 at 2:28 pm, the Quality Manager, stated that audits of transfusion records were not performed by the facility and after a review of records confirmed the above findings. During an interview on 01/09/2024 at 3:15 pm, the Laboratory Supervisor, stated that audits of transfusion records were not performed by the laboratory and after a review of records confirmed the above findings. Word Key: mmHg- millimeters of mercury F- Fahrenheit C- Celsius PRBC- packed red blood cells Temp- temperature Resp- respiration SBP- systolic blood pressure DBP- diastolic blood pressure O2SAT- oxygen saturation
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of Quality Control (QC) records and confirmed in interview, the laboratory failed to retain all package inserts for complete blood count (CDB) QC material tested on the Sysmex XP 2000 hematology analyzer for 6 of 6 lot numbers in June 2022 and 9 of 9 lot numbers in July through August 2023 and failed to retain all package inserts for body fluid cell count QC material performed on a hemacytometer for 2 of 2 lots in 2022 (October) and 8 of 8 lots in 2023 (March, July and October). Findings included: 1. Review of CBC QC records tested on the Sysmex XP 2000 hematology analyzer in June 2022 and July through August 2023 revealed the laboratory failed to retain the e-CHECK package insert for the following QC lots: June 2022 Lot#: QC-21030801 (level 1); QC-21030802 (level 2); QC-21030803 (level 3) Lot#: QC-21590801 (level 1); QC-21590802 (level 2); QC-21590803 (level

	3) July 2023: Lot#: QC-31300801 (level 1); QC-31300802 (level 2); QC-31300803 (level 3) Lot#: QC-31860801; QC-31860802 (level 2); QC-31860803 (level 3) August 2023: Lot#: QC-31860801 (level 1); QC-31860802 (level 2); QC-31860803 (level 3) Lot#: QC-32420801 (level 1); QC-32420802(level 2); QC-32420803 (level 3) The laboratory was asked to provide the above package inserts, and none were provided. The laboratory did not establish their own QC ranges and used the QC ranges from the manufacture's package insert for acceptability. Without the package inserts QC ranges could not be verified. 2. Review of body fluid cell count QC records performed on a hemacytometer in October 2022 and in March, July and October 2023 revealed the laboratory failed to retain the Cell-Chex package insert for the following QC lots: October 2022 QC Level 1 Lot#: 23340412 QC Level 2 Lot #: 22340413 March 2023 QC Level 1 Lot#: 23460412 QC Level 2 Lot #: 23460413 July 2023 QC Level 1 Lot#: 30930411 QC Level 2 Lot #: 30930413 October 2023 QC Level 1 Lot#: 32610412 QC Level 2 Lot #: 32610413 The laboratory was asked to provide the above package inserts, and none were provided. The laboratory did not establish their own QC ranges and used the QC ranges from the manufacture's package insert for acceptability. Without the package inserts QC ranges could not be verified. 3. During an interview on 01/10/2024 at 10:40 am, the Laboratory Supervisor stated that the package inserts for old lots of CBC QC material were not retained. During an interview on 01/10 /2024 at 1:00pm, Testing Person #2 stated that the package inserts for old lots of body fluid cell count QC material were not retained. The above interviews confirmed the laboratory failed to retain all QC material package inserts tested on the Sysmex 2000 hematology analyzer and body fluid cell counts performed on a hemacytometer.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, patient test reports, laboratory records, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing confirmatory testing for positive results on the Siemens Dimension EXL for 5 of 10 patients in 2023 (random review 01/2023 through 10 /2023). Findings included: 1. Review of manufacturer's instructions for the Siemens Dimension EXL Urine Drugs of Abuse Supplement page 1 revealed: "Overview ... The urine drugs of abuse methods provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to results from any drug of abuse test, particularly when preliminary positive results are obtained." 2. Random review of patient test records from 01/2023 through 10/2023 revealed the laboratory failed to follow manufacturer's instructions for performing confirmatory testing on the following 5 patients: 01/01/2023 Patient # 7239104; positive for THC 02/03/2023 Patient # 7241123; positive for THC 03/03 /2023 Patient # 7242971; positive for THC 04/02/2023 Patient # 7244725; positive for THC 05/01/2023 Patient # 7246603; positive for THC 3. Review of laboratory records revealed the laboratory had annual volume of 1,500 toxicology tests. 4. During an interview on 01/09/2024 at 3:15 pm, the Laboratory Supervisor stated that the

laboratory did no send positive toxicology results for confirmatory testing, confirming the above findings. Word Key: THC- tetrahydrocannabinol II. Based on direct observation, review of manufacturer's instructions, laboratory policy, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for the use of one of one Hema 3 Stain reagent kits used for peripheral blood smears in 2023. Findings included: 1. During a tour of the hematology area of the laboratory on 01/10 /2024 at 12:15 pm, the surveyor observed the Hema 3 Stain reagents (Fixative, Solution I and Solution II) poured into secondary containers on the counter next to the sink. 2. Review of HEMA 3 STAIN instructions for use revealed: "Procedure: 1. Transfer each solution into coplin jar or staining dish. keep covered when not in use. 2. Prepare slides as instructed under Specimen Preparation. 3. Dip slide five times for one second each in Hema 3 Fixative Solution. Allow excess to drain. 4. Dip slide three to five times for one second each in Hema 3 Solution I. Allow excess to drain. 5. Dip slide three to five times for one second each in Hema 3 solution II. Allow excess to drain. 6. Rinse slide with deionized water. 7. Allow to dry. Examine under oil immersion lens. NOTE: An important advantage of the Hema 3 method is the flexibility to produce desirable results for varied applications. Staining intensity may be varied by increasing or decreasing the number of dips in Solutions I and II. Eosinophilic staining may be Intensified by increasing dips in Solution I. Basophilic staining may be intensified by increasing dips in Solution II. Two to six dips in Hema 3 Solution I and II will provide desirable results for most staining applications. Any variation of the procedure described above may adversely affect results." 3. Review of the laboratory's policy titled "Blood Smear/Differential Lbh 08" revealed: "Procedure: Staining Slide: 1. Place a medium size drop of blood on the end of the slide. 2. Using another clean slide, make a wedge smear of moderate thickness that covers no more than of the glass length of the slide. Smear should have a good feather edge. The angle of the smearing slide should be approximately 45%. The smear should be made in one smooth flowing motion. Decreasing the angle will increase the length of the smear and make the smear thinner. 3. Label the frosted end of the slide with the patient name, identifying number and date. Allow to air dry. 4. Dip the slide into the Fixative 5 times. 5. Dip the slide into the Solution I 5 times. 6. Dip the slide into Solution II 10 times. 7. Rinse slide with tap water to remove excess stains. Blot excess water and place on a paper towel to drain [sic] 8. Allow the slide to air dry or use the hand drier." The written laboratory policy failed to follow manufacturer's instructions. 4. During an interview on 01/10/2024 at 12:15 pm, Testing Person-2 stated that the staining procedure for making peripheral blood smears was to dip the slide five times in the Fixative Solution, dip five times in Hema 3 Solution I, dip ten times in Hema 3 Solution II and rinse with tap water. This confirmed the above findings. 44278 III. Based on surveyor observation, review of manufacturer's instructions, laboratory policy, CLSI Document C28-A3c, current PT (Prothrombin Time) thromboplastin (Dade Innovin) lot roll over, patient final reports, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for determining MNPT (Mean Normal Prothrombin Time) for 1 of 1 lot used in 2022 and 2023 (December 2022-October 2023). Findings Included: 1. During a tour of the facility on 01/10/2024 at 11: 14 a.m., the surveyor observed 1 Siemens Sysmex CA-600 coagulation analyzer in the patient testing area (Serial Number: 25320). The MNPT listed in the coagulation analyzer for the current lot of thromboplastin reagent (Lot Number: 564616A) was 10.7. 2. Review of thromboplastin reagent manufacturer's instructions, "Siemens Dade Innovin" (Revision 2018-08) revealed the following: "The mean normal PT (MNPT) is defined as the mean value of the normal range. It must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples and, where appropriate, using the coagulation analyzer used for the analysis. Follow appropriate laboratory guidelines for establishing an MNPT ... The geometric mean

(MNPT) is an average that multiplies all values and finds a root of the number ..." 3. Review of manufacturer's instructions (also used as the laboratory policy), "Siemens Healthcare Diagnostics Sysmex CA-600 System" (Revision 08/2018; Approved by the Laboratory Director on: 10/2019) revealed the following: "XIV. Lot Roll Over Procedures Verification of Reference Range: A. 20 Normal Individuals: 10 males; 10 females representing reference population. 20 is the minimum requirement for a statistically valid study. Fresh samples preferred but frozen platelet poor plasma may be used if preferred and thawed per CLSI Guidelines. Note medication history. After review, history may be used for excluding aberrant results. B. Assay samples on current and new lot number reagents simultaneously or within 1 hour of each other. C. Calculate mean and 2SD range ... ...A skewed data pool is most likely the result of improper specimen type and additional samples may be required. Reference: CLSI C28-A3c, Defining, Establishing and Verifying Reference Intervals in the Laboratory." 4. Review of referenced document, "CLSI C28-A3c, Defining, Establishing and Verifying Reference Intervals in the Laboratory", revealed the following: "Section 4.2 ...Verifying (or validating) a reference interval- the process by which one ensures, with reasonable confidence, using a relatively small number of reference individuals (be, n=20), that a reference interval established elsewhere, or transferred from another study, can be used locally ... Section 7.1 ... The designation of good health for a candidate reference individual may involve a variety of examinations, such as history and physical and/or certain laboratory tests. The criteria used for any reference value study should be described and documented so others can evaluate the health status of that reference sample group ... 7.2 Exclusion and Partitioning Exclusion criteria are details about the candidate reference individual that, if present, serve to keep that person from being included in the reference sample ...certain items may need to be controlled when selecting persons for a reference sample for health-related reference intervals... Partitioning criteria are characteristics of the selected reference individual that divide the reference sample into significant subclasses. Two of the most common partitioning criteria are age and sex... Section 11.1 Validation: Subjective The acceptability of the transfer may be rather subjectively assessed by a careful inspection of the pertinent factors of the original appropriate reference value study. To be able to do this, all of the reference population demographic variables and geographic locations must be adequately described and be available for review... Section 11.2 Validation: Using Small Number of Reference Individuals ... For the transference validation study, the reference individuals are selected and the reference values are obtained in accordance with the previously discussed guidelines. These 20 persons should reasonably represent the receiving laboratory's healthy population and satisfy the exclusion and partition criteria appropriately. After testing these 20 specimens according to the appropriate specifications, the test results should be examined to make sure they represent a statistically homogenous group of results, i.e., that none of the results appears to be an outlier." 5. Review of laboratory thromboplastin lot roll over raw data in October 2022 (Approved by the Laboratory Director on 12/08/2022), revealed the laboratory failed to document the correct data for the MNPT calculation on the Lot Roll Over Documentation Form, resulting in an incorrect MNPT value. The following was documented: Dade Innovin New Lot Number: 564616A Expiration Date: 03/20/2024 (NOTE: Previous Innovin lot number and expiration not documented.) Sample ID; PT Result MNPT Raw Data Lot Roll Over Documentation Form 1: 10.6 sec 1: 10.6 sec 2: 11.0 sec 2: 11.0 sec 3: 10.5 sec 3: 10.5 sec 4: 10.4 sec 4: 10.4 sec 5: 11.1 sec 5: 11.1 sec 6: 12.3 sec 6: 12.3 sec 7: 10.7 sec 7: 10.7 sec 8: 9.8 sec 8: 11.0 sec 9: 11.4 sec 9: 11.4 sec 10: 9.9 sec 10: 10.8 sec 11: 9.6 sec 11: 9.9 sec 12: 10.4 sec 12: 10.3 sec 13: 9.6 sec 13: 12.1 sec 14: 10.9 sec 14: 10.7 sec 15: 12.1 sec 15: 10.4 sec 16: 10.7 sec 16: 11.2 sec 17: 10.4 sec 17: 10.1 sec 18: 14.5 sec 18: 10.2 sec 19: 10.1 sec 19: 10.1 sec

	20: 10.2 sec 20: 10.2 sec 21: 10.0 sec 21: 9.9 sec 22: 9.9 sec 22: 10.3 sec 23: 10.3 sec 23: 11.3 sec 24: 11.3 sec 24: 11.6 sec 25: 9.5 sec 25: 10.4 sec 26: 9.8 sec 26: 10.8 sec 27: 9.7 sec 27: 11.2 sec 28: 10.2 sec 28: 10.2 sec 29: No documentation 29: 10.1 sec 30: 10.0 sec 30: 10.0 sec 31: 9.9 sec 31: 11.0 sec 32: 9.9 sec 32: 10.5 sec 33: 9.9 sec 33: 10.4 sec 34: 9.4 sec 34: 10.8 sec 35: 10.9 sec 35: 10.8 sec 36: 13.2 sec 36: 11.0 sec 37: 10.2 sec 37: 11.0 sec 38: 11.2 sec 38: 11.2 sec 39: 11.0 sec 39: 11.0 sec 40: No documentation 40: 11.0 sec The surveyor requested the above missing raw data documentation, to include the previous Innovin lot results ran simultaneously or within 1 hour of the new lot, and none were provided. The MNPT calculation for the above listed raw data is 10.5 seconds. The MNPT calculation for the above documentation listed on the Lot Rollover Documentation form and in the coagulation analyzer was 10.7 seconds. Further review of the lot rollover revealed the laboratory failed to document exclusion or partition criteria for the reference individuals used in the study (i.e., sex, geographical location, age, medical history, etc.). 6. Review of patient final reports revealed the laboratory performed 756 PT patient tests from 12/08 /2022-10/31/2023. 7. During an interview on 01/10/2024 with GS-1 at 12:31 p.m., in the laboratory, GS-1 confirmed the laboratory failed to define exclusion and partition criteria for reference individuals used in the lot roll over study. GS-1 stated the previous laboratory manager performed the lot rollover in October 2022, and she could not provide the supporting raw data for the MNPT documented. This confirmed the laboratory failed to follow manufacturer's instructions for determining MNPT (Mean Normal Prothrombin Time) for 1 of 1 lot used in 2022 and 2023 (December 2022-October 2023). Word Key: CLSI- Clinical & Laboratory Standards Institute SD- Standard Deviation Sec- Seconds N- Number of reference individuals GS- General Supervisor
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, review of the manufacturer's package inserts, and confirmed in interview, the laboratory failed to ensure proper storage of 6 of 6 boxes of quality control materials . Findings include: 1. During a tour of the laboratory on 01/10/2024 at 1128 hours, the surveyor observed a thermometer reading of -16C in a frost-free freezer storing quality control materials. 4 boxes of Liquicheck Cardiac Markers Plus Control LT: Lot# 67660 2 boxes of Liquicheck Immunology Control: Lot# 85710 2. A review of the laboratory's policy titled "Quality Control for Chemistry Analyzers Lbch 12" revealed: "Stability: All control material is stored frozen at -20C to -70C except the Ethanol/Ammonia, Spinal Fluid, Urine chemistry and DOA controls which are stored at 2-8C." 3. A review of the manufacturer's package insert for the Bio-Rad Liquicheck Cardiac Markers Plus Control LT revealed: "STORAGE AND STABILITY This product will be stable until the expiration date when stored unopened at -20 to -70C. Do not store this product in a frost-free freezer." Review of the manufacturer's package inset for the Bio-Rad

	Liquicheck Immunology Control revealed: "STORAGE AND STABILITY This product will be stable until the expiration date when stored unopened at -20 to -70C." 4. During an interview with Testing Person-4 (as listed in the CMS-209 form) on 01 /10/2024 at 1203 hours in the conference room, Testing Person-4 stated the laboratory was aware the controls were stored improperly due to the lack of a suitable freezer.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on surveyor observation, review of the manufacturer's package insert and confirmed in interview, the laboratory failed to label in-use stains with preparation date, expiration date, and lot# for 3 of 3 reagents. Findings include: 1. During a tour of the laboratory on 01/10/2024 the surveyor observed on the counter next to the sink in the hematology section of the laboratory three Hema 3 Hematology stains in staining jars labeled as follows: "Fixative" "Solution 1" "Solution 2" The laboratory failed to label the secondary containers with the lot numbers, preparation, and expiration dates. Without proper labeling, the reagents could not be linked to an original container and therefore the expiration dates could not be determined. 2. An interview with Testing Person-1 on 01/10/2024 at 1215 hours in the laboratory confirmed the above findings. II. Based on surveyor observation, and confirmed in interview, the laboratory failed to label in-use stains with preparation date, expiration date, and lot# for 5 of 5 reagents. Findings include: 1. During a tour of the laboratory on 01/10/2024 at 1126 hours, the surveyor observed on the counter in the histology section of the laboratory the following reagents: 1 staining jar labeled "Hematoxalin" 1 staining jar labeled "Eosin" 1 staining jar labeled "Alcohol" 1 staining jar labeled "Water" 1 staining jar labeled "Toluidine Blue" The laboratory failed to label the secondary containers with the lot numbers, preparation, and expiration dates. Without proper labeling, the reagents could not be linked to an original container and therefore the expiration dates could not be determined. 2. An interview with the laboratory director on 01/10/2024 at 1218 hours in the conference room confirmed the findings.
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 surveyor observation, review of manufacturer's instructions, laboratory policy, Siemens Sysmex CA-600 maintenance records (2022), and confirmed in interview, the laboratory failed to follow manufacturer's instructions for performing yearly maintenance for 1 of 1 year (January-December) in 2022. Findings Included: 1. During a tour of the facility on 01/10/2024 at 11:14 a.m., the surveyor observed 1

	Siemens Sysmex CA-600 coagulation analyzer in the patient testing area (Serial Number: 25320). 2. Review of manufacturer's instructions, ""Siemens Healthcare Diagnostics Sysmex CA-600 System" (Revision 08/2018) revealed the following: "To ensure the instrument will serve you in the optimal operating condition, it requires periodic maintenance. Follow the maintenance schedule as described below and keep the result in the Maintenance Checklist. ...11.7 Replace Rinse Filter The Rinse Filter is placed in the tubing between the Rinse Bottle and the instrument rear panel nipple. Replace the Rinse Filter once every year." 3. Review of laboratory policy, "Maintenance Sysmex 600 Series Lbco 09" (Approved by the Laboratory Director on: 03/2023) revealed the following: "Principle Routine maintenance is performed to insure proper operation of the CA 600. ...Yearly Maintenance 1. Replace Rinse Filter" 4. Review of laboratory CA-600 monthly maintenance records in 2022, revealed yearly maintenance was not documented in 2022 (January-December). 5. During an interview on 01/10/2024 with General Supervisor-1 (GS-1)at 02:34 p.m., in laboratory, GS-1 confirmed the laboratory failed to follow manufacturer's instructions for performing yearly maintenance for 1 of 1 year (January-December) in 2022.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of calibration records, and confirmed in interview, the laboratory failed to perform calibration verification for the i-STAT analyzers for 2 of 2 events in 2022 and 1 of 2 events in 2023. Findings include: 1. A review of the laboratory's policy titled "I-Stat System Blood Gas Procedure" revealed: "Calibration Calibration verification will be performed yearly or when any of the following occur: Replacement of critical parts If controls reflect an unusual shift or trend or fall outside acceptable limits and other means of correcting unacceptable control values has failed to correct the problem " 2. Review of calibration records in 2022 and 2023 revealed the laboratory failed to perform 2 of 2 calibrations in 2022 and 1 of 2 calibrations in 2023 on the i-STAT analyzer. The laboratory was asked to provide calibration records, and none were provided. 3. An interview with Testing

	Person-1 on 1/09/2024 at 1504 hours in the conference room revealed the laboratory did not perform calibration verification in 2022 and for 1 event of 2023.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, quality control (QC) records from December 2022, August 2023 and September 2023, review of patient test records from December 2022, August 2023 and September 2023, and staff interview, it was revealed the laboratory failed to perform two acceptable levels of quality control each day of patient testing for 16 of 16 patients tested on the Siemens Dimension EXL chemistry analyzer. The findings include: 1. Review of laboratory policy titled "Quality Control for Chemistry Analyzers Lbch 12" revealed: "REVIEW OF QC: The performing tech reviews the data. Results are evaluated in Unity Real Time to determine acceptability of controls. When to accept the QC: 1.Both levels of control are within +/-2 SD of established mean. 2.One control is within +/-2 SD of the mean and the second control is between 2 and 3 SD of the mean and the previous control was within +/-2 SD." 2.A random review of quality control records from 12/01/2022 - 13/31/2022, 08/01/2023 - 8/31/2023, and 09/01/2023 - 09/30/2023 revealed the following days of patient testing in which the laboratory failed to perform two acceptable levels of quality control. ALT (Alanine aminotransferase): a) 12/05/2022 Patient ID:7237309 b) 12/08/2022 Patient ID: 7237600 c) 12/19/2022 Patient ID: 7238257 d) 12/26/2022 Patient ID: 7238269 e) 12/27/2022 Patient ID: 7238676 f) 08 /29/2023 Patient ID: 7254088 g) 09/07/2023 Patient ID: 7254735 h) 09/08/2023 Patient ID: 7254829 Lactic Acid: a) 8/20/2023 Patient ID: 7229891 Patient ID: 7230150 b) 09/13/2023 Patient ID: 7231720 Potassium: a) 09/12/2023 Patient ID: 7254795 HCG (Human chorionic gonadotropin): a) 12/07/2022 Patient ID: 7237498 b) 12/08/2022 Patient ID: 7237614 T4, Free (thyroxine): a) 08/02/2023 Patient ID: 7252429 Ammonia: a) 08/26/2023 Patient ID: 7253948 3. An interview with Testing Person-1 (as listed in the CMS-209 form) on 01/09/2024 at 1315 hours in the conference room, confirmed the laboratory did not perform two acceptable levels of quality control on patient testing days. Word Key: CMS- Center for Medicare & Medicaid Services
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the

	laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions for Cell-Chex Body Fluid Cell Count Control, quality control (QC) records, and confirmed in interview, the laboratory failed to establish its own mean and acceptability ranges for body fluid controls used for monitoring the performance of manual counts of patient body fluids on a hemocytometer for 2 of 2 lots in 2022 (October) and 8 of 8 lots in 2023 (March, July and October). Findings: 1. Review of the laboratory's policy "Body Fluid Cell Count LBH 14" page 4 revealed: "QUALITY CONTROL ... 1. Expected results are listed on QC sheets." 2. Review of Cell-Chex Instructions for Use revealed: "EXPECTED RESULTS ... Assay range values were established based on+/- 3SD for WBC differential parameters and+/- 2SD for the RBC and WBC parameters. Upon receipt of a new control lot, it is good laboratory practice that an individual laboratory establish its own mean and limits for each parameter. However, the control means established by the laboratory should fall within the expected range specified for the control." 3. Review of body fluid cell count QC records performed on a hemacytometer in October 2022 and in March, July and October 2023 revealed the laboratory failed to retain the Cell-Chex package insert for the following QC lots: October 2022 QC Level 1 Lot#: 23340412 QC Level 2 Lot #: 22340413 March 2023 QC Level 1 Lot#: 23460412 QC Level 2 Lot #: 23460413 July 2023 QC Level 1 Lot#: 30930411 QC Level 2 Lot #: 30930413 October 2023 QC Level 1 Lot#: 32610412 QC Level 2 Lot #: 32610413 Refer to D3031-I. Further review of the above QC records revealed means and limits for each parameter were documented on the Body Fluid Cell Count QC Log. 4. During an interview on 01/10/2024 at 1:00 pm, Testing Person-2 stated that the laboratory did not establish its own mean and ranges for manual body fluid cell counts and the package inserts were used for QC acceptability.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on review of laboratory and facility policies, patient transfusion records, and confirmed in interview, the laboratory failed to ensure all transfusion related activities were documented for administration of blood products to be able to identify and promptly investigate transfusion reactions for 1 of 4 patients in 2022 (random review January, February and May) and 1 of 3 patients in 2023 (random review February and

May). Findings included: 1. Review of the laboratory and facility's policy "Blood Administration" revealed: "Procedure ... D. Patient Monitoring: 1. Only an RN or LIP may initiate the blood product, an LVN may monitor a patient receiving blood. An RN /LIP will remain with patient for the first 15 minutes after the transfusion is initiated. Take base line vital signs upon initiation of transfusion. Afterward take vital signs after first 15 minutes x 1, then every 1-hour until complete. Then take one set at the time of completion and 1-hour post transfusion. Vital signs will be documented by nursing staff or LIP in the appropriate transfusion record. 2. Assess patient for sign [sic] and symptoms of transfusion reaction: If transfusion reaction suspected, Refer to Laboratory Policy and Procedure LB B12 - Transfusion Reaction Workup. a. Fever- chills, shaking or rigors, an increase in 2 degrees F must be reported to the lab for a transfusion reaction investigation and to the physician. b. Pain- Chest, abdomen or flank, IV site and along venous track, acute leg pain, muscle aches/pain, headache must be reported to the lab for a transfusion reaction investigation and to the physician. c. B/P Changes- Usually acute, hypotensive or hypertensive, progressive signs of shock, anaphylaxis. Any unexplained / unexpected changes [increase] or [decrease] of 30mm HG in diastolic or systolic must be reported to the lab for transfusion reaction investigation, and to the physician. Any [sic] such changes occurring in the 1st 15 minutes of the transfusion must be reported for investigation, regardless of circumstances. d. Heart - tachycardia, bradycardia, cardiac arrhythmia, and sensation of tightness of the chest, possible cardiac arrest. Heart rate change of 40 beats per minute must be reported as a possible reaction. e. Respiratory Changes - Shortness of breath, respiratory distress, including dyspnea, tachypnea, wheezing, or hypoxemia, respirator failure, or difficulty breathing while lying down, cough, cyanosis, pulmonary edema or rales. f. Skin Changes - including urticaria, itching, flushing, ot [sic] localized edema, rashes, hives, swelling g. Nausea - with or without vomiting, diarrhea, abdominal cramping h. Renal - -Darkened urine may be the earliest indication of an acute hemolytic reaction in anesthetized patients. Reddish, amber, brown, black, dark concentrated urine, renal failure with oliguria or anuria i. Mental Changes -Anxiety, felling of impending doom j. Death-During transfusion or within 3 hours post transfusion. Any unexplained death should be reported immediately to the lab so that an attempt to collect blood may be made to rule out an adverse reaction ... 5. One hour after the blood is infused, document post transfusion vital signs on the blood administration flow sheet." The policy did not define the criteria for "respiratory distress including dyspnea, tachypnea, or hypoxemia". Refer to D5559-II. Review of the facility and laboratory policy titled "Transfusion Reaction Workup Lbb12" revealed: "POLICY ... Every patient recognized as having an adverse sign or symptom associated with the transfusion of a blood product should be reported immediately to the Blood Bank. Signs and symptoms of transfusion reaction include: Fever (a rise >/= 1 degree C or 2 degrees from pre-transfusion value), chills, hemoglobinuria, hysteria, shock, hypotension, generalized bleeding, nausea, oliguria or anuria, flushing, back, flank, or chest pain, itching or pain at the infusion site, uticaria [sic] (rash), jaundice, dyspnea, (shortness of breath), tachycardia, hives or cyanosis. NOTE: NURSING If any of these signs or symptoms occurs, the below stated actions should immediately be followed: 1. Stop the transfusion immediately 2. Maintain the intravenous line with 0.9% saline 3. Notify the attending physician and the Blood Bank for further instructions 4. Record the symptoms observed 5. Retain all containers and tubing for possible analysis" The policy did not specify if a rise of 2 degrees from pre-transfusion was in degrees Fahrenheit or Celsius. The policy did not define the criteria for "hypotension" or "tachycardia". Refer to D5559 II. Transfusion reactions were identified by symptoms and patient vital signs taken which were documented by the staff administering the blood products. 2. In a random review, 1 of 4 patients in 2022 (January, February and May) and 1 of 3 patients in 2023 (February

and May) revealed the following incomplete documentation: Patient Number: 7218204 was administered PRBC, Unit #W200922677826n on 02/05/2022 at 17:45 hours. Patient temperature, pulse, respirations, O2 saturation, and blood pressure were not taken or documented 1-hour post transfusion. The transfusion was completed at 20: 30 hours. The above incomplete documentation could not properly identify transfusion reactions. Patient Number: 7241330 was administered PRBC, Unit #W200222237915U on 02/07/2023 at 21:00 hours. Patient temperature, pulse, respirations, O2 saturation, and blood pressure were not taken or documented at baseline and 1-hour post transfusion. The transfusion was completed at 23:48 hours. On 02/08/2023 at 00:11 hours the patient was administered PRBC, Unit #204922850393Q. Patient temperature, pulse, respirations, O2 saturation, and blood pressure were not taken or documented at baseline and 1-hour post transfusion. The transfusion was completed at 02:58 hours. The above incomplete documentation could not properly identify transfusion reactions. 3. During an interview on 01/09 /2024 at 2:28 pm, the Quality Manager, stated that audits of transfusion records were not performed by the facility and after a review of records confirmed the above findings. During an interview on 01/09/2024 at 3:15 pm, the Laboratory Supervisor, stated that audits of transfusion records were not performed by the laboratory and after a review of records confirmed the above findings. Word Key: mmHg- millimeters of mercury F- Fahrenheit C- Celsius PRBC- packed red blood cells O2- oxygen II. Based on review of laboratory and facility policies, patient transfusion records, and confirmed in interview, the laboratory failed to ensure transfusion reaction procedures included defined criteria to promptly identify, investigate and document blood product transfusion reactions and the facility failed to promptly identify, investigate, and document blood product transfusion reactions for 1 of 4 patients in 2022 (random review January, February and May) and 1 of 3 patients in 2023 (random review February and May). Findings included: 1. Review of the laboratory and facility's policy "Blood Administration" revealed: "Procedure ... D. Patient Monitoring: 1. Only an RN or LIP may initiate the blood product, an LVN may monitor a patient receiving blood. An RN/LIP will remain with patient for the first 15 minutes after the transfusion is initiated. Take base line vital signs upon initiation of transfusion. Afterward take vital signs after first 15 minutes x 1, then every 1-hour until complete. Then take one set at the time of completion and 1-hour post transfusion. Vital signs will be documented by nursing staff or LIP in the appropriate transfusion record. 2. Assess patient for sign[sic] and symptoms of transfusion reaction: If transfusion reaction suspected, Refer to Laboratory Policy and Procedure LB B12 - Transfusion Reaction Workup. a. Fever- chills, shaking or rigors, an increase in 2 degrees F must be reported to the lab for a transfusion reaction investigation and to the physician. b. Pain- Chest, abdomen or flank, IV site and along venous track, acute leg pain, muscle aches/pain, headache must be reported to the lab for a transfusion reaction investigation and to the physician. c. B/P Changes- Usually acute, hypotensive or hypertensive, progressive signs of shock, anaphylaxis. Any unexplained / unexpected changes [increase] or [decrease] of 30mm HG in diastolic or systolic must be reported to the lab for transfusion reaction investigation, and to the physician. Any [sic] such changes occurring in the 1st 15 minutes of the transfusion must be reported for investigation, regardless of circumstances. d. Heart - tachycardia, bradycardia, cardiac arrhythmia, and sensation of tightness of the chest, possible cardiac arrest. Heart rate change of 40 beats per minute must be reported as a possible reaction. e. Respiratory Changes - Shortness of breath, respiratory distress, including dyspnea, tachypnea, wheezing, or hypoxemia, respirator failure, or difficulty breathing while lying down, cough, cyanosis, pulmonary edema or rales. f. Skin Changes - including urticaria, itching, flushing, ot [sic] localized edema, rashes, hives, swelling g. Nausea - with or without vomiting, diarrhea, abdominal cramping h. Renal

- -Darkened urine may be the earliest indication of an acute hemolytic reaction in anesthetized patients. Reddish, amber, brown, black, dark concentrated urine, renal failure with oliguria or anuria i. Mental Changes -Anxiety, felling of impending doom j. Death-During transfusion or within 3 hours post transfusion. Any unexplained death should be reported immediately to the lab so that an attempt to collect blood may be made to rule out an adverse reaction ... 5. One hour after the blood is infused, document post transfusion vital signs on the blood administration flow sheet." The policy did not define the criteria for "respiratory distress including dyspnea, tachypnea, or hypoxemia". Review of the facility and laboratory policy titled "Transfusion Reaction Workup Lbb12" revealed: "POLICY ... Every patient recognized as having an adverse sign or symptom associated with the transfusion of a blood product should be reported immediately to the Blood Bank. Signs and symptoms of transfusion reaction include: Fever (a rise >/= 1 degree C or 2 degrees from pre-transfusion value), chills, hemoglobinuria, hysteria, shock, hypotension, generalized bleeding, nausea, oliguria or anuria, flushing, back, flank, or chest pain, itching or pain at the infusion site, uticaria [sic] (rash), jaundice, dyspnea, (shortness of breath), tachycardia, hives or cyanosis. NOTE: NURSING If any of these signs or symptoms occurs, the below stated actions should immediately be followed: 1. Stop the transfusion immediately 2. Maintain the intravenous line with 0.9% saline 3. Notify the attending physician and the Blood Bank for further instructions 4. Record the symptoms observed 5. Retain all containers and tubing for possible analysis" The policy did not specify if a rise of 2 degrees from pre-transfusion was in degrees Fahrenheit or Celsius. The policy did not define the criteria for "hypotension" or "tachycardia". Transfusion reactions were identified by symptoms and patient vital signs taken which were documented by the staff administering the blood products. The above procedures were not consistent with one another. The facility did not ensure transfusion reaction procedures included defined criteria to promptly identify, investigate and document blood product transfusion reactions. 2. A random review of blood and blood component transfusion patient records from 2022 (January, February, and May) and 2023 (February and May) revealed the following patient transfusions with signs/symptoms of a transfusion reaction: 02/09/2022 Patient Number: 7218493 PRBC Unit #: W200922682062C Baseline Assessment at 21:59 hours Temp: 99.3 Pulse: 108 Resp: 20 SBP: 146 DBP: 62 O2Sat: 96 Pain: 0 Transfusion started: 22:01 hours 15 Minutes Post Start Assessment at 22:20 hours Temp: 100.4 Pulse: 104 Resp: 20 SBP: 124 DBP: 60 O2Sat:93 Pain: not performed/no documentation Did patient have a reaction to blood administration: No 30 Minutes Assessment at 22:35 hours Temp: 100.2 Pulse: 103 Resp: 20 SBP: 117 DBP: 59 O2Sat: 93 Pain: not performed /no documentation Did patient have a reaction to blood administration: No 1 Hour Assessment at 23:00 hours Temp: 100.0 Pulse: 105 Resp: 16 SBP: 112 DBP: 65 O2Sat: 93 Pain: 0 Did patient have a reaction to blood administration: No 1 Hour 30 Minute Assessment at 23:30 hours Temp: 99.1 Pulse: 103 Resp: 18 SBP: 119 DBP: 69 O2Sat: 92 Pain: 0 Did patient have a reaction to blood administration: No 2 Hour Assessment at 00:00 hours on 02/10/2022 Temp: 98.9 Pulse: 99 Resp: 18 SBP: 128 DBP: 69 O2Sat: 94 Pain: 0 Did patient have a reaction to blood administration: No 2 Hour 30 Minute Assessment at 00:30 hours Temp: 98.9 Pulse: 95 Resp: 16 SBP: 128 DBP: 69 O2Sat: 92 Pain: 0 Did patient have a reaction to blood administration: No 3 Hour Assessment at 01:26 hours Temp: 98.9 Pulse: 92 Resp: 16 SBP: 117 DBP: 65 O2Sat:92 Pain: 0 Did patient have a reaction to blood administration: No Assessment when Unit of Blood Stopped or Completed at 01:45 hours Temp: 98.7 Pulse: 92 Resp: 18 SBP: 133 DBP: 68 O2Sat: 92 Pain: 0 Did patient have a reaction to blood administration: No 1 Hour Post Infusion Assessment at 02:25 hours Temp: 98.7 Pulse: 95 Resp: 16 SBP: 122 DBP: 67 O2Sat: 93 Pain: 0 Did patient have a reaction to blood administration: no documentation The patient had a decrease in systolic blood

	pressure of 34 mmHg from baseline at 23:00 hours Per facility policy, a systolic blood pressure decrease of 30 mmHg was a sign of a transfusion reaction. NO documentation of prompt identification or investigation of a transfusion reaction was provided. 05/12/2023 Patient Number: 7247204 PRBC Unit #: W204923681839 Baseline Assessment at 13:00 hours Temp: 98.1 Pulse: 92 Resp: 16 SBP: 89 DBP: 45 O2Sat: 94 Transfusion started: 13:00 hours 15 Minutes Post Start Assessment at 13:15 hours Temp: 98.1 Pulse: 91 Resp: 16 SBP: 93 DBP: 49 O2Sat: 94 Pain: not performed /no documentation Did patient have a reaction to blood administration: No 30 Minutes Assessment at 13:35 hours Temp: 97.4 Pulse: 104 Resp: 16 SBP: 133 DBP: 71 O2Sat: 96 Pain: no documentation Did patient have a reaction to blood administration: No 1 Hour Assessment at 14:00 hours Temp: 97.2 Pulse: 86 Resp: 17 SBP: 105 DBP: 61 O2Sat: 93 Pain: not performed/no documentation Did patient have a reaction to blood administration: No 2 Hour Assessment at 15:00 hours Temp: 97.5 Pulse: 86 Resp: 16 SBP: 108 DBP: 61 O2Sat: 94 Pain: not performed/no documentation Did patient have a reaction to blood administration: No Assessment when Unit of Blood Stopped or Completed at 15:45 hours Temp: 97.2 Pulse: 91 Resp: 17 SBP: 107 DBP: 59 O2Sat: 94 Pain: not performed/no documentation Did patient have a reaction to blood administration: not performed/no documentation 1 Hour Post Infusion Assessment at 16:45 hours Temp: 98.9 Pulse: 91 Resp: 16 SBP: 110 DBP: 57 O2Sat: 97 Pain: not performed/no documentation Did patient have a reaction to blood administration: not performed/no documentation The patient had an increase in systolic blood pressure of 44 mmHg from baseline at 13:35 hours. Per facility policy, a systolic blood pressure increase of 30 mmHg was a sign of a transfusion reaction. NO documentation of prompt identification or investigation of a transfusion reaction was provided. THE FACILITY FAILED TO ENSURE TRANSFUSION REACTIONS WERE PROMPTLY IDENTIFIED, INVESTIGATED AND DOCUMENTED FOR ALL BLOOD PRODUCTS. 3. During an interview on 01/09/2024 at 2:28 pm, the Quality Manager, stated that audits of transfusion records were not performed by the facility and after a review of records confirmed the above findings. During an interview on 01 /09/2024 at 3:15 pm, the Laboratory Supervisor, stated that audits of transfusion records were not performed by the laboratory and after a review of records confirmed the above findings. Word Key: mmHg- millimeters of mercury F- Fahrenheit C- Celsius PRBC- packed red blood cells Temp- temperature Resp- respiration SBP- systolic blood pressure DBP- diastolic blood pressure O2SAT- oxygen saturation