Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0660706	03/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hardeman County Memorial Hospital	402 Mercer St, Quanah, TX	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced recertification survey conducted 03/20/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the facility blood/blood product transfusion policies, a random review of patient transfusion records (01/2022-12/2022), and confirmed in staff interview, it was revealed the facility failed to ensure possible transfusion reactions were promptly identified, investigated, and documented for 3 of 12 patients that received blood products in 2022. Findings Included: 1. Review of facility policy, "Blood Transfusion Policy" (Effective: 03/01/2010) revealed the following: "Management of Suspected Transfusion Reaction 1. If a reaction occurs, it usually manifests with in the first fifteen minutes of the transfusion. However, transfusion related adverse events can occur hour after the transfusion is complete. 2. Some common signs and symptoms associated with transfusion reactions are: Fever (increase in temperature (100.4) from baseline) Skin manifestations - Urticaria Hemoglobinuria Oliguria- decreased urine output Anuria- absence of urine output Nausea/Vomiting- sweating, weakness, increase saliva, urge to vomit Pain- back, muscle, flank Chills/rigors with or without fever Abnormal bleeding- any new onset or unsuspected bleeding occurrence. Oozing blood at IV site. Respiratory distress /Shortness of breath Hypotension- clinically significant decrease in blood pressure (30 mmHg fall in systolic) Hypertension- clinically significant decrease in blood pressure

	(30 mmHg rise in systolic) TRALI (Transfusion Related Lung Injury) TACO (Transfusion Associated Circulatory Overload) 3. Stop transfusion 4. Two licensed nursing staff, one must be an RN, will check the blood bag identification against the patient identification. 5. Notify physician and Lab. Lab will provide a transfusion reaction investigation form to the RN to fill out. The Lab will notify the blood bank. 6. Get order for UA- Collect urine specimen for examination, send blood bag with completed transfusion reaction investigation for to the Lab. 7. Take any measurements to stabilize/support the patient throughout the event." 2. Random review of patient transfusion records in 2022, revealed the following 3 of 12 patients in which the facility did not follow its own policy to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products: a. 02/20/2022-02/21 /2023 Patient ID: 54659 Product: Unit Number W091022129966; Packed Red Blood Cells Transfusion start time: 23:30 Blood Pressure at 23:30: 108/60 mmHg Blood Pressure at 01:55: 161/87 mmHg The rise in systolic pressure was 53 mmHg. Per facility policy, an increase in blood pressure by 30 mmHg indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. b. 03 /12/2022 Patient ID: 6892 Product: Unit Number W091022128672; Packed Red Blood Cells Transfusion start time: 16:00 Blood Pressure at 16:00: 118/67 mmHg Blood Pressure at 18:00: 169/69 mmHg Review of laboratory transfusion form completeted by nursing staff revealed the following: "Transfusion reaction: No" The rise in systolic pressure was 51 mmHg. Per facility policy, an increase in blood pressure by 30 mmHg indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. c. 04/02/2022 Patient ID: 7138 Product: Unit Number W091022146646; Packed Red Blood Cells Transfusion start time: 21:20 Blood Pressure at 21:05 (baseline): 121/62mmHg Blood Pressure at 18: 00: 159/85 mmHg Review of laboratory transfusion form completeted by nursing staff revealed the following: "Transfusion reaction: No" The rise in systolic pressure was 38 mmHg from baseline. Per facility policy, an increase in blood pressure by 30 mmHg indicated a transfusion reaction. No documentation of a transfusion reaction investigation was provided. 3. During an interview with the general supervisor (GS-1) on 03/20/2023, at 12:35 p.m. in the laboratory, GS-1 stated the laboratory performed audits and discovered the above possible transfusion reactions. These transfusion reactions were not communicated to the laboratory by the facility. This confirmed the facility failed to ensure possible transfusion reactions were promptly identified, investigated, and documented for 3 of 12 patients that received blood products in 2022. Word Key RN- Registered Nurse mmHg-millimeter of mercury
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

	This STANDARD is not met as evidenced by: Based on review of the laboratory policy, patient test requisitions, and confirmed in interview, the laboratory failed to ensure patient test requisitions solicited date and/or time of specimen collection for Complete Blood Count (CBC) specimens collected from outside facilities for 12 of 12 patients from March 2023 (random sampling). The findings include: 1. Review of the laboratory policy for pre-analytic systems revealed: "PREANALYSIS Preanalysis refers to all complex steps that must take place before a sample can be analyzed. Preanalytic factors include patient related variable such as diet, age, sex, specimen collection and labeling techniques, specimen preservatives and anticoagulants, specimen transport and processing and storage. Specimen Collection a. The Test Order In order for the laboratory personnel to begin the process, a written order from the doctor or an electronic request through the laboratory information system is needed. Verbal orders are accepted in emergency situations and are documented on a standard form. However, an official laboratory request or computerized order should be received within 72 hours of verbal order. b. Time of Collection Specimen collected and submitted to the laboratory must have time of collection at all times. c. Specimen Rejection All Specimens must be collected, labeled, transported and processed according to established procedures. The following are the criteria for rejecting specimens: i. Unlabeled or mislabeled ii. Discrepancies between requisition and specimen label iii. Specimen type unsuitable for the test ordered iv. Hemolyzed and lipemic specimens v. Clots present in anticoagulated sample vi. Nonfasting specimen when the test requires fasting vii. Short draws, wrong volume viii. Improper blood collection tube ix. Inadequate specimen-anticoagulant ratio x. Improper transport conditions xi. Specimen too old for testing xii. Contaminated specimen/leaking container" The policy did not specify date of collection as a required element for test requisitions. 2. A random review of patient test requisitions revealed the following 12 patients whose requisitions did not include a collection date and/or time: Patient IDs: 10063734, 10063735, 10063927, 10063937, 10063954, 10063984, 10064064, 10064096, 10064117, 10064131, 10064183, 10064208 3. During the exit conference on 03/20/2023 at 6:00 p.m., the Laboratory Manager confirmed the above findings.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, manufacturer's instructions, patient test records, and confirmed in interview, the laboratory failed to ensure patient complete blood count (CBC) specimens were not analyzed beyond the manufacturers stability requirements prior to testing on the Sysmex XN-L 550 hematology analyzer for 3 of 11 specimens in March 2023 (random sampling). The findings include: 1. Review of the laboratory policy titled "COMPLETE BLOOD COUNT USING SYSMEX XN 550" revealed: "Specimen Collection, Preservation, and Transport: Unhemolysed [sic]

	whole blood collected on a lavender top K2 EDTA. Sample is stable for 24 hours after collection at room temperature." 2. Review of the Sysmex Basic Operation guide revealed: "Chapter 4 Analyzing Samples ... 4.3 Preparing Samples ... Handling whole blood Mix the venous blood with an anticoagulant (EDTA-2K or EDTA-3K). Draw the amount of venous blood that is specified for the amount of EDTA anticoagulant. The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2 to 8C until it can be analyzed ..." 3. Review of the Sysmex Method Verification Manual revealed: "Section 3 Method Verification Protocols ... It is the customer's responsibility to perform additional studies, following the requirements of their accrediting agency. The following protocols are provided: Correlation Studies (CAS assists) Sensitivity Studies (See Resource Manual) Reference Range Verification (See Resource Manual) Stability Study (See Resource Manual) Mixing Study (See Resource Manual) Typically, method verification studies are performed on new analyzers to verify and document satisfactory analyzer performance according to the manufacturer's specifications. It is up to the laboratory to perform more extensive studies if they deem it necessary to satisfy requirements over and above what is contained in these protocols." 4. During an interview on 03/20/2023 at 12:44 p.m., the surveyor asked the Laboratory Manager if stability studies were performed for the Sysmex XN-L 550 hematology analyzer. The Laboratory Manager stated that the laboratory did not perform any stability studies. 5. A random review of patient test records from March 2023 revealed the following patients whose CBCs were performed beyond the manufacturer's 4-hour stability requirement: Patient ID: 10063734 Collection date /time: 03/01/2023 at 10:50 hours Analysis date/time: 03/01/2023 at 16:47 hours Elapsed time from collection to analysis: 5 hours and 57 minutes Patient ID: 10063927 Collection date/time: 03/06/2023 at 10:30 hours Analysis date/time: 03/06 /2023 at 15:17 hours Elapsed time from collection to analysis: 4 hours and 47 minutes Patient ID: 10064131 Collection date/time: 03/15/2023 at 09:00 hours Analysis date /time: 03/15/2023 at 13:04 hours Elapsed time from collection to analysis: 4 hours and 4 minutes The laboratory did not ensure their written preanalytical requirements were consistent with manufacturer's preanalytical requirements. The laboratory extended the specimen stability beyond manufacturer's instructions for the above CBC specimens and could not provide studies to support the extended stability. 6. During an exit conference on 03/20/2023 at 06:00 p.m., the Laboratory Manager confirmed the above findings. II. Based on laboratory policy, patient test records, and confirmed in interview, the laboratory failed to ensure patient slides for manual differentials were labeled with at least 2 unique patient identifiers for 5 of 7 slides in March of 2023 (random sampling). The findings include: 1. Review of the laboratory policy titled "BLOOD SMEAR PREPARTION" revealed: "Procedure: 1. Prepare a thing film of blood from EDTA tube. 2. Label slide in pensil [sic] with patients last name /date and order number (at least 2 patient identifier) ..." The laboratory policy did not include labeling instructions to reliably identify patients using at least 2 unique patient identifiers to distinguish between specimens. 2. A random review of patient slides from March 2023 revealed 5 of 7 slides labeled with only a patient last name and order number. The laboratory failed to ensure patient slides for manual differentials were labeled with at least 2 unique patient identifiers. 3. During an interview on 03/20 /2023 at 1:37 p.m., the Laboratory Manager confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's

	verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of laboratory policies, quality control (QC) records, and confirmed in interview, the laboratory failed to document corrective actions taken when QC did not meet acceptability criteria for 9 of 110 QC runs from January to February 2023 on the Sysmex XN-L 550 hematology analyzer. The findings include: 1. Review of the laboratory QC policy revealed: "H. Westgard rules of Quality Control will be observed in this lab. Control procedure (13s/22s/R4s/41s) ... 3. Require additional data inspection when one control observation exceeds n +- 2s. a. Apply 13s rule b. Apply 22s rule, within run. c. Apply R4s rule, within run. d. Apply 22s rule, across runs and materials. e. Apply 41s rule, across runs and materials. f. Reject the run when any one-control rule is violated. Do not report data. Go to step 4 ... 4. When the run is rejected because the method is out-of-control: a. Determine the type of error occurring ... b. Refer to troubleshooting guides and inspect the analytical method ..." 2. Review of the laboratory's troubleshooting guide revealed: "Class II QC Failure Trouble Shooting Steps After repeating QC, preparing/thawing/opening a new QC vial, is QC acceptable? | Yes | Review the Class I failure troubleshooting guide, document, and proceed with testing." 3. Review of Sysmex XN-L 550 QC records revealed the laboratory failed to document corrective actions for CBC QC failures in 2023 (January and February) on the following dates and times: XN-L Control Level 1 lot#23231401; expiration: 2/28/2023 XN-L Control Level 3 lot#23231403; expiration: 2/28/2023 01/02/2023 01:01 hours- QC level 1 failed for WBC-C 01:08 hours- QC was repeated and passed 02/01/2023 04:06 hours- QC level 3 failed for HCT 04:13 hours- QC was repeated and passed 02/20/2023 10:46 hours- QC level 3 failed for RDW-CV 10:55 hours- QC was repeated and passed 02/25/2023 01:48 hours- QC level 3 failed for RDW-CV 02:41 hours- QC was repeated and failed 03:02 hours- QC was repeated and failed 03:09 hours- QC was repeated and passed 12:33 hours- QC level 3 failed for HCT 12:43 hours- QC was repeated and passed 02/26/2023 02:24 hours- QC level 3 failed for HCT 02:33 hours- QC was repeated and passed 02/27 /2023 15:40 hours- QC level 3 failed for HCT 15:48 hours- QC was repeated and passed The surveyor requested documentation of corrective action for the above QC failures. None was provided. The laboratory failed to document corrective actions. 4. During an interview on 03/20/2023 at 12:44 p.m., the Laboratory Manager confirmed the above findings. Key: CBC-complete blood count WBC-C-white blood cell count HCT-hematocrit RDW-CV- red cell distribution width coefficient of variation
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically

	transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's specimen drop off log, patient final reports, and confirmed in interview, the laboratory failed to ensure that the collection time was accurately transcribed into the laboratory information system (LIS) for 8 of 11 complete blood count (CBC) specimens in March 2023 (random sampling). The findings include: 1. A random review of the laboratory's "SPECIMEN DROP OFF LOG IN SHEET" and final patient test reports from March 2023 revealed the following: Patient ID: 10063734 Log in sheet collection date/time: 03/01/2023 at 10: 50 hours Final report collection date/time: 03/01/2023 at 11:55 hours Patient ID: 10063735 Log in sheet collection date/time: 03/01/2023 at 13:00 hours Final report collection date/time: 03/01/2023 at 13:34 hours Patient ID: 10063927 Log in sheet collection date/time: 03/06/2023 at 10:30 hours Final report collection date/time: 03/06 /2023 at 14:53 hours Patient ID: 10063984 Log in sheet collection date/time: 03/08 /2023 at 08:45 hours Final report collection date/time: 03/08/2023 at 09:25 hours Patient ID: 10064064 Log in sheet collection date/time: 03/10/2023 at 14:15 hours Final report collection date/time: 03/10/2023 at 15:21 hours Patient ID: 10064131 Log in sheet collection date/time: 03/15/2023 at 09:00 hours Final report collection date /time: 03/15/2023 at 10:02 hours Patient ID: 10064183 Log in sheet collection date /time: 03/17/2023 at 15:00 hours Final report collection date/time: 03/17/2023 at 16: 13 hours Patient ID: 10064208 Log in sheet collection date/time: 03/20/2023 at 10:20 hours Final report collection date/time: 03/20/2023 at 11:20 hours The final report collection times did not reflect the collection times in the specimen log for the above patients. The laboratory failed to ensure collection times were accurately transcribed into the LIS. 2. During the exit conference on 03/20/2023 at 6:00 p.m., the Laboratory Manager confirmed the above findings.