Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0506590	03/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
Memorial Hospital Lab	224 East 2nd Street, Dumas, 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 onsite validation survey conducted on March 20-23, 2023, found the laboratory out of compliance with the CLIA regulations. The condition not met was: D3000 - 42 C.F.R. 493.1100 Condition: Facilities Administration Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
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 a review of laboratory and nursing policies, review of patient transfusion records, and confirmed in interview of facility and laboratory personnel, the facility failed to follow its policy to investigate and report potential transfusion reactions to the laboratory for 2 of 25 occurrences from June 2022 to December 2022 (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:
Based on a review of laboratory and nursing policies, review of patient transfusion records, and confirmed in interview of facility and laboratory personnel, the facility failed to follow its policy to investigate and report potential transfusion reactions to the laboratory for 2 of 25 occurrences from June 2022 to December 2022. The findings included: 1. A review of the laboratory's policy titled "Transfusion Reactions," (Laboratory Director approval date not available on copy provided by the laboratory on the day of the survey, March 22, 2023) stated: "Principle: Whenever blood component or products are being transfused, the recipient is to be monitored carefully for signs of a transfusion reaction. Any adverse symptoms or physical signs during transfusion of blood or its components should initially be considered as a potentially life-threatening reaction. A transfusion reaction work up is performed to determine if a life-threatening hemolytic transfusion reaction has occurred." and; Step 1 in the Procedure's Flowchart stated: "When an indicator of reaction occurs, the unit is immediately discontinued and the physician and lab are immediately notified. The IV line is kept open with an infusion of normal saline." and; under, "Transfusion Reaction Report Form" the laboratory's policy included "Criteria for Reaction" as follows: "Chills, Headache, Backache, Fever, Shock, Urticaria (hives), Dyspnea, Cyanosis, Abnormal Oozing or Bleeding, Nausea or Vomiting, Hematuria, Chest Pain, Tachycardia" 2. A review of General Nursing policy titled, "Procedure for Transfusion Reactions" (Section: Meds, IV Therapy & Blood Prod., Number 6105, Revised Date: 04/09)", no Laboratory Director approval date available on copy provided by laboratory on the day of the survey, March 22, 2023) it stated: "1. If any indicators of transfusion reaction are observed STOP the transfusion immediately. Infuse Normal Saline to maintain patent [SIC] intravenous line. Notify blood bank and the physician immediately. Symptoms of Reactions Include: 1.Chills 2.Headache 3.Backache 4.Shock 5.Dyspnea 6.Cyanosis 7.Abnormal oozing or bleeding 8.Nausea and / or Vomiting 9.Hematuria 10.Chest Pain 11.Tachycardia 12.*Fever (temp increases > 2 degrees Fahrenheit or 1 degrees Celsius) 13.*Urticaria / Hives "2. Following the AABB Standards for Blood Banking the transfusion must be STOPPED. The IV line should be kept open with the infusion of normal saline. The physician may give orders for patient symptoms at this time but the transfusion MUST stop awaiting the DAT result." "IMPORTANT - IT IS NOT ACCEPTABLE TO GIVE MEDICATION AND CONTINUE THE BLOOD/BLOOD PRODUCT. THE TRANSFUSION REACTION WORK-UP MUST BE COMPLETED BEFORE ANYMORE BLOOD/BLOOD PRODUCT IS TRANSFUSED!!!!!!!!!!!!!!!!!!!!!!!!!!!!" "3. Notify the blood bank / physician of patient's possible transfusion reaction and present physician assessment findings. *Monitor patient vitals every 15 minutes or more frequently if deemed necessary." "4. Complete the "Transfusion Reaction Report Form". This form MUST be completely filled in. The time is the time you called a possible reaction (not the time the report is filled out)." "5. The transfusion MUST BE DISCONTINUED until a NEGATIVE DAT result is reported from the transfusion work-up, and this has been communicated to the physician. The communication of the DAT results and Physicians order to continue or discontinue the blood transfusion must be documented on the patients [SIC] chart. The laboratory staff will send the DAT work-up to the pathologist for review via FAX ..." 3. A random sampling of 25

	patient records from June 2022 to December 2022 found the following 2 patients reported an indicator according to the laboratory's and facility's policies after their transfusion began: Specimen Identification: 0601:BB1R Date: 06/02/2022 Unit W091022236287 Notes: -Transfusion started at 0732 -0745 patient reports feeling heaviness on chest and shortness of breath, blood infusion stopped and LR bolus started -0750 notified [physician name redacted] of patients [SIC] reactions -0800 [physician name redacted] at bedside for assessment and discuss plan of care -0801 Benadryl 25 mg given IV per verbal order -1045 blood transfusion complete. Patient remains resting with eyes closed. Respirations non labored with equal rise and fall of chest observed. Husband remains at bedside, encouraged to call for any needs. a. The transfusion was stopped, but the facility failed to follow its policy to notify the laboratory. b. Interview with the Director of Women's Services on March 22, 2023, at 15:45 hours in the conference room confirmed there was no documentation of the facility contacting the laboratory. Specimen Identification: 1109:BB6R Date: 11-09-2022 Unit W091022163292 Notes: -Transfusion started on 11-10-2022 at 0035 baseline pain level 0 -0050 pain level 2 -0115 patient reports mild headache rated 2 /10, SN attempted to call physician, message left -0117 [physician name redacted] returned phone call, it was reported to him that patient was experiencing a mild headache after beginning blood, PRN Tylenol ordered at this time -0124 patient states she has a headache, PRN PO Tylenol administered per MAR. Patient denies any other needs at this time. Side rails up x2 and call light left within reach, will continue to monitor -0135 pain level 3 -0212 pain level 0, transfusion ended a. The facility failed to follow its policy to stop the transfusion when the patient reported a headache which is an indicator for a potential transfusion reaction according to its own policy. 4. An interview with the laboratory manager and technical supervisor #2 (as listed on Form CMS 209) on March 22, 2023, at 16:45 hours in the conference room confirmed that there was no documentation to review that the laboratory was contacted to perform a potential transfusion reaction workup. Key: Mg - milligrams IV - intravenous AABB - Association for the Association for the Advancement of Blood & Biotherapies DAT - Direct Antiglobulin Test LR - Lactated Ringer PO - by mouth PRN - as needed CMS - Centers for Medicare and Medicaid Services
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory policy titled Laboratory competency Assessment Plan, the CMS 209 Laboratory Personnel report, personnel records, and interview of facility personnel, the laboratory failed to assess the competency of one of two technical consultants and one of one general supervisor. The findings included: 1. Review of the policy titled Laboratory Competency Plan (dated 2/08) found on page one: "The Laboratory Director/Manager, Pathologist-Medical Director, and the Senior Technologists are responsible for the review and documentation of competencies for all laboratory personnel." 2. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory listed two technical consultants and one general supervisor. 3. Review of personnel records found no assessment of competency for technical consultant two (hire date 04/29/2002) or the general supervisor (hire date 03 /17/2017). 4. During interview of Technical Consultant two conducted March 20,

	2023 at 3:04 PM she confirmed that she did not have a competency assessment for duties of the Technical Consultant, only as a testing personnel. During interview of the General Supervisor conducted March 20, 2023 at 3:33 PM, she confirmed that their was no competency assessment of her duties as General supervisor.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on observation, review of patient test counts and interview of facility personnel, the laboratory failed to verify the accuracy of their results for serum Ketones at least twice annually when using the Germaine AimTab Ketone Tablets to test patient specimens. The laboratory tested 59 patient specimens for serum Ketones between February 2022 and January 2023. The findings included: 1. Observations made during the tour of the laboratory conducted March 20, 2023 at 4:22 PM found the laboratory used the Germaine AimTab Ketone Tablets to test patient specimens for Ketones. 2. Review of patient test counts found the laboratory tested 59 patient specimens for serum Ketones between February 2022 and January 2023. 2. During interview of technical consultant 2 on the CMS- 209 conducted March 20, 2023 at 4:50 PM, she confirmed the laboratory did not participate in a proficiency testing program for serum Ketone or have another means of verifying the accuracy of results at least twice annually.
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: Based on review of manufacturer's instructions, laboratory policies, the laboratory's previous Innovin lot roll over study, and confirmed in interview of laboratory personnel, the laboratory failed to follow the manufacturer's instructions for how to complete an MNPT (Mean Normal Prothrombin Time) study for 1 of 1 lot of Innovin performed in February 2022. The findings included: 1. Review of the Sysmex CS-2500 manufacturer's instructions (2500 Reference Guide: RG_36_EN-U Rev.2.11) under "Remarks" it stated, "The mean normal PT (MNPT) is defined as the mean value of the normal range. Follow the appropriate CLSI guideline for establishing an MNPT." 2. Review of the Sysmex CA-600 manufacturer's instructions (CA-600 Reference Guide: RG_31_EN-U_4-10) under "Remarks" it stated, "The mean normal PT (MNPT) is defined as the mean value of the normal range. Follow the appropriate CLSI guideline for establishing an MNPT." 3. Review of the laboratory's policy titled "Prothrombin Time" approved by the laboratory director November 2019 found the policy failed to include instructions on how to complete an MNPT study as required by the manufacturer. 4. Review of CLSI document H54-A, "Procedures for Validation of INR and Local Calibration of PT/INR Systems; Approved Guideline" it stated:

	"Determining the correct mean normal Prothrombin time (MNPT) is vital to reporting accurate INR results, because INR is determined based on the following equation: INR = (Plasma PT / MNPT)^ISI. Using an inappropriate MNPT can have a clinically significant and systematic effect on the INR and can either inappropriately increase or decrease the results. The MNPT is defined as the geometric mean of the prothrombin times of the healthy adult population and can be approximated by the geometric mean of the prothrombin time calculated from at least 20 fresh samples from healthy individuals, including those of both sexes. Arithmetic mean should not be used. Many laboratories still utilize the arithmetic mean; however, since a healthy population is considered to be lognormally distributed, the geometric mean is a more accurate value and is the value used in the establishment of the INR of the certified plasmas. The method for calculating the geometric mean is included in Appendix A. Individual samples used to determine MNPT are best tested over several days to take account of day-to-day variation in the measurement system. It is recommended that each laboratory should determine MNPT using its own thromboplastin/instrument combination, and its own blood collection system." 5. Review of the laboratory's MNPT study performed in February 2022 (Innovin lot number: 549796, expiration date: 05/28/2023) found the following: a. The laboratory did not calculate and use the geometric mean. b. The laboratory did not have a system in place to screen donors to ensure they were healthy. 6. The laboratory performed approximately 1,728 PTs with INR in 2022. 7. An interview with the Hematology Technical Supervisor on March 22, 2023 at 11:00 hours confirmed the laboratory's policy did not include instructions on how to perform an Innovin lot roll over that included the calculation of the geometric mean. Key: PT - Prothrombin Time INR - International Normalized Ratio ISI - International Sensitivity Index CLSI - Clinical and Laboratory Standards Institute
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of manufacturer's instructions, review of laboratory quality control records, review of patient final reports, and confirmed in interview with laboratory personnel, the laboratory failed to perform graded quality control for 9 reactive RPRs (Rapid Plasma Reagin) with reflex to titer from April 2022 to December 2022. The findings included: 1. Review of the manufacturer's instructions for the Sure-Vue RPR test kit (document number: 6004-900SV Rev. 09-2021) under "Quality Control", it stated, "Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control Procedures. Controls with graded reactivity should be included ..." 2. Review of the laboratory's quality control records from April 2022 to December 2022 found no documentation of controls with graded reactivity. 3. A random sampling of patient final reports from April 2022 to December 2022 found the following 9 patients with a reactive RPR that reflexed to an RPR Titer: Specimen Number: 0405:S22R Date & Time Verified: 04/05

	/2022 @ 2159 Result:1:1 Specimen Number: 0509:S34R Date & Time Verified: 05/11 /2022 @ 1537 Result: 1:2 Specimen Number: 0913:S9R Date & Time Verified: 09/16 /2022 @ 0337 Result: 1:1 Specimen Number: 0926:S18R Date & Time Verified: 09 /26/2022 @ 2221 Result: 1:4 Specimen Number: 1022:S7R Date & Time Verified: 10 /23/2022 @ 0931 Result: 1:8 Specimen Number: 1024:S13R Date & Time Verified: 10/26/2022 @ 1558 Result: 1:4 Specimen Number: 1101:S1R Date & Time Verified: 11/01/2022 @ 2208 Result: 1:4 Specimen Number: 1120:S9R Date & Time Verified: 11/21/2022 @ 1513 Result: 1:2 Specimen Number: 1213:S26R Date & Time Verified: 12/14/2022 @ 1512 Result: 1:32 4. An interview with the laboratory manager on March 21, 2023 at 10:15 hours in the laboratory confirmed the laboratory did not perform quantitative quality control for reactive RPRs.