Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0446923	07/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Texas County Memorial Hospital	1333 S Sam Houston Blvd, Houston, MO	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of blood bank procedures, Community Blood Center of the Ozarks (CBCO) patient reports, blood bank patient file cards, and interview with the technical supervisor (TS) #2, the laboratory failed to follow procedure for cross match of blood products. Findings: 1. Review of "Cross-Match Procedure and Antibody Screen (Indirect Coombs)" procedure states, "If there is not already a file card on patient, fill one out including full name, date of birth, medical record #, group/type and AB screen results, with today's date and your initials. Also include the number and type of any compatible/incompatible units. File alphabetically." 2. Review of CBCO patient reports showed an immunohematology consultation report for patient AA for a positive antibody screen and an Anti- M antibody identified on July 12, 2021. 3. Review of blood bank patient file cards showed no file card for patient AA. 4. Interview with the TS # 2 on July 6, 2022 at 10:00 AM confirmed the laboratory failed to follow procedure for cross match of blood products by not documenting patient results on a patient file card.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Sysmex XN-550 hematology analyzer and interview with the technical supervisor (TS) #2, the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Sysmex XN-550 hematology analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in May 2020. 2. Interview with the TS #2 on July 6, 2022 at 10:30 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.
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 2020, 2021, and to date July 6, 2022 calibration records for the Ortho Diagnostics Vitros 5600 chemistry analyzer and interview with the technical supervisor (TS) #2, the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range. Findings: 1. Review of Vitros 5600 calibration records for 2020, 2021, and to date July 6, 2022 showed no calibration every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for the analytes: total iron-binding capacity (TIBC),

	vitamin D, vitamin B12 and procalcitonin. 2. Interview with the TS #2 on July 6, 2022 at 10:00 AM confirmed the laboratory failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range for TIBC, vitamin D, vitamin B12 and procalcitonin.
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 procedures, chemistry control package inserts, Vitros 5600 quality control (QC) and interview with technical supervisor (TS) #2, the laboratory failed to follow procedure and ensure two levels of chemistry QC were performed each day. Findings: 1. Review of "Quality Control Program-Chemistry" procedure states "Two levels of control must be run each day". 2. Review of MAS Omni CORE liquid assayed chemistry controls package insert for showed level 1 total bilirubin range is . 89-1.37. 3. Review of total bilirubin QC showed on June 22, June 23 and June 24 level 1 QC was not within acceptable limits. 4. Interview with the TS #2 on July 6, 2022 at 11:00 AM confirmed the laboratory failed to follow procedure and ensure two levels of acceptable QC was performed each day for total bilirubin testing.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual, blood bank alarm test log, and interview with the technical supervisor (TS) #2, the laboratory failed to perform refrigerator alarm inspections according to the laboratory's established procedure. Findings: 1. Review of blood bank procedure "Testing Blood Bank Refrigerator Alarms" states, "There are two alarm systems connected to blood bank refrigerators. These must both be tested quarterly. Results should be documented on chart posted in blood bank." 2. Review of blood bank alarm test log showed refrigerator alarm inspections for 2020, 2021 and to date July 6, 2022 were not performed quarterly according to procedure. 3. Interview with the TS #2 on July 6, 2022 at 10:00 AM confirmed, the laboratory failed to perform blood bank refrigerator alarm inspections according to the laboratory's established procedure.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of ACL Elite analyzer quality control (QC) and interview with technical supervisor (TS) #2, the TS failed to ensure prothrombin time (PT), partial thromboplastin time (PTT) QC program was appropriate for the testing performed. Findings: 1. Review of the PT, PTT QC showed no documentation could be provided for time and data points for QC from January 2020 to June 30, 2022. 2. Interview with the TS #2 on July 6, 2022 at 11:00 AM confirmed the TS failed to ensure PT and PTT QC was stored and retrievable for review.