

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0446923	(X3) Date Survey Completed 08/18/2026
Name of Provider or Supplier Texas County Memorial Hospital	Street Address, City, State 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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 review of the Siemens Healthineers RAPIDPoint 500 system operator's guide, arterial blood gas (ABG) laboratory temperature logs for 2025 to date August 18, 2026, and patient results and interview with the testing personnel (TP) #11, the laboratory failed to ensure the room temperature and humidity was monitored and documented as required by the manufacturer for 18 of 595 days. Findings: 1. Review of the Siemens Healthineers RAPIDPoint 500 system operator's guide states "ambient operating temperature 15-30 degrees Celsius, and ambient operating relative humidity 5-85% noncondensing". 2. Review of the ABG laboratory temperature logs where the Siemens Healthineers RAPIDPoint 500 is located showed no documentation of room temperature for 18 of 595 days in 2025 to date August 18, 2026. 3. Review of the ABG laboratory temperature logs where the Siemens Healthineers RAPIDPoint 500 is located showed no documentation of humidity for 18 of 595 days in 2025 to date August 18, 2026. 4. Review of patient results showed the ABG laboratory performs approximately 477 ABG patient tests per year. 5. Interview with the TP #11 on August 18, 2026 at 2:00 PM confirmed the laboratory failed to ensure the room temperature and humidity was monitored and documented as required by the manufacturer for 18 days.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

A.) Based on review of the HemosIL D-Dimer HS 500 Controls package insert, observation of open HemosIL D-Dimer HS 500 Control vials, review of HemosIL Q.F.A Thrombin (Bovine) package insert, observation of an open HemosIL Q.F.A Thrombin (Bovine) vial, review of patient results, and interview with the general supervisor (GS) #2, the laboratory failed to document correct expiration dates on open d-dimer control vials and on an open thrombin vial. Findings: 1. Review of the HemosIL D-Dimer HS 500 Controls package insert states "up to 5 days when controls are on-board for 1 hour each time, twice daily and the vials are returned well capped to 2-8C between sessions." 2. Observation of open HemosIL D-Dimer HS 500 Controls level one and level 3 vials lot # B37786 showed an open date of August 13, 2026, and expiration date of September 14, 2026. 3. Review of HemosIL Q.F.A Thrombin (Bovine) package insert states "Stability after reconstitution: 7 days at 2-8C in closed original vials." 4. Observation of an open HemosIL Q.F.A Thrombin (Bovine) vial lot # M158382 showed an open date of August 14 and no expiration date. 5. Review of patient results showed the laboratory performs approximately 468 d-dimer tests and 28 fibrinogen tests per year. 6. Interview with the GS #2 on August 18, 2026, at 1:00 PM confirmed the laboratory failed to document correct expiration dates on open d-dimer control vials and on a thrombin vial. 52867 B.) Based on review of the Abbott i-STAT CG8+ Cartridge package insert, and Abbott i-STAT CG8+ Cartridge box, observation of i-STAT testing area and interview with the general supervisor (GS) #2, the laboratory failed to document revised expiration dates on one of one i-STAT CG8+ cartridge. Findings: 1. Review of the Abbott i-STAT CG8+ Cartridge package insert states "Storage Conditions: Refrigerated at 2-8C (35-46F) until expiration date. Room Temperature at 18-30C (64-86F). Cartridges may be stored at room temperature for the time frame indicated on the cartridge box". 2. Review of the Abbott i-STAT CG8+ Cartridge box showed "Store at room temperature for 14 days". 3. Observation of Abbott i-STAT testing area in the main laboratory showed one i-STAT CG8+ cartridge Lot H26066 exp 09/03/2026 stored at room temperature with no revised expiration date on package. 4. Interview with the GS #2 on August 18, 2026 at 1:30 PM confirmed the laboratory failed to document revised expiration dates on one i-STAT CG8+ cartridge.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based on observation of laboratory supplies during the laboratory tour, review of

	patient results and interview with the general supervisor (GS) #1, the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date. Findings: 1. Observation of laboratory supplies during the laboratory tour on August 18, 2026 showed the following still in use: 1 box of Vitros Immunodiagnostic Total Triiodothyronine (T3) II Calibrator Lot 0390 exp 07/27/2026 1 each of Remel Potassium Hydroxide (KOH) Lot 231606 exp 08/05/2026 2. Review of patient results showed the laboratory performs approximately 215 Total T3 and 2 KOH patient tests annually. 3. Interview with the GS #1 on August 18, 2026, at 1:00 PM confirmed the laboratory failed to ensure laboratory supplies were not used when they had exceeded their expiration date.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 2025, and to date August 18, 2026 Vitros XT 7600 chemistry calibration records and interview with the general supervisor (GS) #1, 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 in 2025 and date August 18, 2026 for 1 of 64 analytes. Findings: 1. Review of the Vitros XT 7600 chemistry analyzer calibration records for 2025 and to date August 18, 2026 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 hemoglobin A1C. 2. The laboratory performs 5,323 hemoglobin A1C chemistry patient tests annually. 3. Interview with the GS #1 on August 18, 2026 at 11:00 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 hemoglobin A1C.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the

manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of June 2026 to date August 18, 2026 Vitros XT 7600 chemistry analyzer quality control (QC), patient results and interview with the general supervisor (GS) #1, the laboratory failed to ensure QC was acceptable before reporting patients results for the analyte direct bilirubin for 61 of 79 days. Findings: 1. Review of June 2026 to date August 18, 2026 Vitros XT 7600 chemistry QC showed the laboratory could not provide documentation for direct bilirubin QC from June 5, 2026 through July 31, 2026, could not provide QC for August 2, 2026 through August 6, 2026 and could not provide QC for August 13, 2026 through August 16, 2026. 2. The laboratory performed approximately 13 direct bilirubin tests from June 2026 to date August 18, 2026. 3. Interview with the GS #1 on August 18, 2026 at 1:30 PM confirmed the laboratory failed to ensure QC was acceptable before reporting direct bilirubin patient results.