Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0883999	07/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Texoma Urology Center	5500 Kell West Blvd Suite 200, Wichita Falls, 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 routine recertification survey of the laboratory was completed on 07/17/2026. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, and confirmed in interview, the laboratory failed to ensure one of one laboratory policies was approved, signed, and dated by the laboratory director. Findings include: 1. Review of the laboratory's policies determined the laboratory failed to have a written policy for the Sciteck AUA-450 urinalysis analyzer, approved, signed, and dated by the laboratory director prior to patient use. The surveyor requested documentation of a policy for the Sciteck AUA-450 urinalysis analyzer that was approved, signed, and dated by the laboratory director prior to patient use. No documentation was provided. 2. The laboratory director confirmed findings during an interview on 07/17/2026 at 0940 hours in the office.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)

	(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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: I. Based on review of the laboratory's verification records for the Sciteck AUA-450 urinalysis analyzer, review of the laboratory's submitted CMS-116 form, and confirmed in interview, the laboratory failed to ensure one of one verification studies was approved, signed, and dated by the laboratory director prior to patient use. Findings include: 1. A review of the laboratory's verification records for the Sciteck AUA-450 urinalysis analyzer (serial number 7257-0018) performed in March 2025 determined the laboratory failed to ensure one of one verification studies was approved, signed, and dated by the laboratory director prior to patient use. 2. A review of the laboratory's submitted form CMS-116 determined the laboratory performed 49,742 non-waived urinalysis tests annually. 3. The laboratory director confirmed the findings during an interview on 07/24/2026 at 0950 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services II. Based on review of the laboratory's verification records for the Sciteck AUA-450 urinalysis analyzer in March 2025, review of patient test reports, review of the laboratory's submitted CMS-116 form, and confirmed in interview, the laboratory failed to have documentation of verifying one of one set of patient normal ranges. Findings include: 1. A review of the laboratory's verification records for the Sciteck AUA-450 urinalysis analyzer (serial number 7257-0018) performed in March 2025 determined the laboratory failed to have documentation of verifying one of one set of patient normal ranges. 2. A review of patient test reports from July 2026 determined the laboratory had the following set of patient normal ranges: a. Albumin 0.0 - 1.9 mg/dL b. Creatinine, Urine 20.0 - 500.0 mg/dL c. Urine Specific Gravity 1.002 - 1.035 d. Urine pH 6.0 - 10.0 e. Urine Glucose 0.0 - 15.0 mg/dL f. Urine Ketones 0.0 - 9.9 mg/dL g. Urine Hemoglobin 0.0 - 500.0 ug /dL h. Urobilinogen 0.1 - 1.9 mg/dL i. Urine Bilirubin 0.0 - 1.4 mg/dL j. Urine Leukocyte Esterase 0.0 - 3.0 LEU/L k. Urine Nitrite 0.0 - 0.10 mg/dL l. Non-Albumin Proteins 0.0 - 2.0 mg/dL m. Normalized Non-Albumin Proteins 0.0 - 2.0 mg/dL n. Total Urine Protein:Creatinine Ratio 0.0 - 150.0 mg/g o. Normalized Total Urine Protein:Creatinine Ratio 0.0 - 150.0 mg/g p. Albumin:Creatinine Ratio 0.0 - 30.0 mg /g q. Normalized Albumin:Creatinine Ratio 0.0 - 30.0 mg/g r. Non-Albumin Protein (NAP) Creatinine Ratio 0.0 - 120.0 mg/g s. Normalized Non-Albumin Protein (NAP) Creatinine Ratio 0.0 - 120.0 mg/g t. Estimated 24 Hour Urine Protein Excretion 0.0 - 0.2 g/day u. Normalized Estimated 24 Hour Urine Protein Excretion 0.0 - 0.2 g/day 3. A review of the laboratory's submitted CMS-116 form determined the laboratory performed 49,742 non-wiaved urinalysis tests annually. 4. The laboratory director confirmed the findings during an interview on 07/17/2026 at 1110 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services mg/dL - milligrams per deciliter ug/dL - micrograms per deciliter LEU/L - Leukocytes per liter mg/g - milligrams per gram g/day - grams per day
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical

	consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, review of verification studies, review of laboratory policies, and confirmed in interview, the laboratory director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in moderate complexity for one of two specialties reviewed in 2026, as evidenced by: 1. The laboratory director failed to ensure one of one policies was approved, signed, and dated prior to patient testing. Refer to D5407. 2. The laboratory director failed to ensure one of one verification studies was approved, signed, and dated prior to patient testing. Refer to D5421-I. 3. The laboratory director failed to ensure one of one patient normal ranges was verified prior to patient testing. Refer to D5421-II. 4. The laboratory director failed to ensure five of seven testing persons received the appropriate training in moderate complexity testing prior to patient testing. Refer to D6029.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted form CMS-209, review of the laboratory's personnel records, review of the laboratory's submitted form CMS-116, and confirmed in interview, the laboratory director failed to ensure training was documented prior to patient testing for the Sciteck AUA-450 urinalysis analyzer for five of seven testing personnel. Findings include: 1. Review of the laboratory's submitted form CMS-209 determined the laboratory had seven testing persons performing non-waived testing on the Sciteck AUA-450 urinalysis analyzer. 2. Review of the laboratory's personnel records determined five of seven testing persons did not have documentation of training prior to patient use: a. TP-2 b. TP-4 c. TP-5 d. TP-6 e. TP-7 The surveyor requested documentation of initial training for the Sciteck AUA-450 analyzer for six of seven testing persons. No documentation was provided. 3. A review of the laboratory's submitted form CMS-116 determined the laboratory performed 49,742 non-waived Urinalysis tests annually. 4. The laboratory director confirmed the findings in an interview on 07/17/2026 at 0930 hours in the office. Key: TP - Testing Person CMS - Centers for Medicare and Medicaid Services
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

	This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted form CMS-209, review of personnel records, review of the laboratory's submitted form CMS-116, and confirmed in interview, the technical consultant failed to ensure competency assessments were documented for seven of seven testing personnel in 2025 and 2026. Findings include: 1. Review of the laboratory's submitted form CMS-209 determined the laboratory had seven testing persons performing non-waived testing on the Sciteck AUA-450 urinalysis analyzer. 2. Review of the laboratory's personnel records determined the laboratory failed to have documentation of assessing competency for seven of seven testing persons in 2025 and 2026. The surveyor requested documentation of performing competency assessments for seven of seven testing persons performing non-waived testing on the Sciteck AUA-450 urinalysis analyzer. No documentation was provided. 3. A review of the laboratory's submitted form CMS-116 form determined the laboratory performed 49,742 non-waived urinalysis tests annually. 4. The laboratory director confirmed the findings in an interview on 04/17/2026 at 0930 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services