

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2322497	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Texas Regional Urology - Kingwood	Street Address, City, State 201 Kingwood Medical Dr Suite B300, Kingwood, 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	The Texas Regional Urology- Kingwood laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of an initial survey on August 26, 2026 and certification is recommended. Standard level deficiencies were cited.
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 a review of the laboratory's verification studies, the laboratory's records, and staff interview, the laboratory failed to have documentation of performing an accuracy study for two of twelve analytes, included in the AutoUA 12-Panel Urine test, run on the Scitek AUA-450 urinalysis analyzer in May 2026. Findings include: 1. A review of the laboratory's AutoUA Relocation, Reference Interval Range, and Comparison Verification Studies revealed an accuracy study was completed on the following analyzer in May 2026: - Scitek AUA-450 urinalysis analyzer (Serial number: AUA-450-7257-0024) 2. Further review of the laboratory's verification studies revealed the laboratory failed to have documentation of verifying the accuracy for Creatinine and Albumin, included in the AutoUA 12-Panel Urine test, run on the Scitek AUA-450 urinalysis analyzer. 3. A review of the laboratory's records revealed

the laboratory estimated performing 6,000 urinalysis tests annually. 4. In an interview on 8/26/26 at 11:00 a.m. in the laboratory, after review of the records, the laboratory director confirmed the above findings. II. Based on a review of the laboratory's AutoUA Relocation, Reference Interval Range, and Comparison Verification Studies from May 2026, raw data from the urinalysis analyzer, the laboratory's records, and staff interview, the laboratory failed to ensure the values for two of twenty samples used for the accuracy study matched the raw data from the analyzer. Findings include: 1. A review of the laboratory's AutoUA Relocation, Reference Interval Range, and Comparison Verification Studies revealed an accuracy study was completed on the following analyzer in May 2026: - Scitek AUA-450 urinalysis analyzer (Serial number: AUA-450-7257-0024) 2. Further review of the laboratory's AutoUA Relocation, Reference Interval Range, and Comparison Verification Studies revealed the following test values for samples #16 and #19: a) Sample #16 Albumin N/A Bilirubin NEG Creatinine N/A Glucose NEG Hemoglobin NEG Ketone NEG Leukocyte NEG Nitrite NEG pH 7.0 Protein NEG Specific Gravity 1.005 Urobilinogen 2.0 b) Sample #19 Albumin N/A Bilirubin NEG Creatinine N/A Glucose NEG Hemoglobin NEG Ketone NEG Leukocyte NEG Nitrite NEG pH 8.5 Protein NEG Specific Gravity 1.010 Urobilinogen 1.0 3. A review of the raw data from the urinalysis analyzer revealed the following test values did not match the values in the accuracy study: a) Sample #16 pH 6.0 Hemoglobin Small Specific Gravity 1.020 b) Sample #19 pH 6.0 Urobilinogen 2.0 Specific Gravity 1.030 4. A review of the laboratory's records revealed the laboratory estimated performing 6,000 urinalysis tests annually. 5. In an interview on 8/26/26 at 11:00 a.m. in the laboratory, after review of the records, the laboratory director confirmed the above findings. III. Based on a review of the laboratory's AutoUA Relocation, Reference Interval Range, and Comparison Verification Studies from May 2026, the laboratory's records, and staff interview, the laboratory failed to ensure the linearity study was acceptable for one of twelve analytes included in the AutoUA 12-Panel Urine test verification. Findings include: 1. A review of the laboratory's AutoUA Relocation, Reference Interval Range, and Comparison Verification Studies revealed a linearity study was completed on the following analyzer in May 2026: - Scitek AUA-450 urinalysis analyzer (Serial number: AUA-450-7257-0024) 2. Further review of the laboratory's AutoUA Relocation, Reference Interval Range, and Comparison Verification Studies revealed the following: "Recovery/Linearity/AMR is acceptable if SD is less than 2.0 with R2 of >0.90." 3. A review of the Hemoglobin linearity study revealed a SD for Sample #3 of 74.9. 4. A review of the laboratory's records revealed the laboratory estimated performing 6,000 urinalysis tests annually. 5. In an interview on 8/26/26 at 11:00 a.m. in the laboratory, after review of the records, the laboratory director confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a random review of patient's 12-Panel Urine Test reports from August 2026 and staff interview, the laboratory failed to include the correct specimen source on five of five patient's final test reports reviewed. Findings include: 1. A random review of patient's final reports from August 2026 revealed the laboratory ran a 12-Panel Urine Test on the following 5 patients: Patient ID: B2608211852 Resulted: 8/24/26 Patient ID: B2608211842 Resulted: 8/24/26 Patient ID: B2608211843 Resulted: 8/24/26 Patient ID: B2608211845 Resulted: 8/24/26 Patient ID: B2608211847 Resulted: 8/24/26 2. Further review of those patient's final reports revealed the laboratory listed the specimen source as SST/Serum. 3. In an interview on 8/26/26 at 11:40 a.m. in the laboratory, after review of the records, the laboratory director confirmed the above findings.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on a random review of patient's 12-Panel Urine Test reports from August 2026 and staff interview, the laboratory failed to include the reference intervals for Albumin and Nitrate on five of five patient's final reports reviewed. Findings include: 1. A random review of patient's final reports from August 2026 revealed the following 5 patient's 12-Panel Urine Test reports failed to include the reference intervals for Albumin and Nitrate: Patient ID: B2608211852 Resulted: 8/24/26 Patient ID: B2608211842 Resulted: 8/24/26 Patient ID: B2608211843 Resulted: 8/24/26 Patient ID: B2608211845 Resulted: 8/24/26 Patient ID: B2608211847 Resulted: 8/24/26 2. In an interview on 8/26/26 at 11:40 a.m. in the laboratory, after review of the records, the laboratory director confirmed the above findings.