

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2043109	(X3) Date Survey Completed 10/21/2025
Name of Provider or Supplier Spring Creek Urology Specialists Llc	Street Address, City, State 1020 Riverwood Ct Ste 330, Conroe, 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 survey of the laboratory was conducted on 10/21/2025. 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.
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's analytes' list, proficiency testing (PT) records, policies /procedures, test accuracy verification records and staff interview, the laboratory failed to document twice-yearly evaluation of accuracy for two of two molecular microbiology targets for which PT agency did not offer samples, Prevothella bivia and Citrobacter braakii. Findings included: 1. Review of laboratory's molecular microbiology target/analyte list revealed Prevothella bivia and Citrobacter braakii as reportable targets. 2. Review of laboratory's PT records revealed the laboratory used American Proficiency Institute (API) as their PT provider. Further review of the API molecular microbiology target list revealed API did not offer samples for testing of Prevothella bivia and Citrobacter braakii. 3. Review of laboratory's "Split sample Analysis Protocol" (document SOP# QUAL 21.0.0, effective 03/01/2022) revealed: "Split sample analysis may be defined as the analysis of a sample by the laboratories primary method and a comparison method (a similar method used by another CLIA-certified laboratory)." And, "Split sample analysis may be used to determine the following: ... As a means of verifying the accuracy of testing non-regulated analytes for which the laboratory does not participate in proficiency testing." 4. The laboratory was asked to provide documentation of twice-yearly evaluation of accuracy for</p>

detection of *Prevotella bivia* and *Citrobacter braakii* and no such documentation was available for review. 5. In an interview on 10/21/2025 at 1030 hours in the breakroom, the laboratory's Technical Supervisor (as indicated on submitted Form CMS 209) stated that the laboratory sent samples for the above targets for split sample analysis with another laboratory, but was unable to obtain that laboratory's final reports, and thus unable to perform split sample accuracy evaluation. This confirmed the 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 review of laboratory's random patient reports and staff interview, the laboratory failed to document name and address of the testing laboratory for five of five random patient reports reviewed from August 2025. Findings included: 1. Review of five random patient reports from August 28, 2025, revealed no name and address of the testing facility documented on the final reports. The reports reviewed were for the following patients' samples: Sample: 4793C894879 4793C890407 4793C895901 4793C896188 4793C889302 2. In an interview on 10/21/2025 at 1130 hours in the breakroom, the laboratory's Technical Supervisor (as indicated on submitted Form CMS 209) confirmed the findings.