

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2043109	<b>(X3) Date Survey Completed</b>  10/17/2023
<b>Name of Provider or Supplier</b>  Spring Creek Urology Specialists Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced survey of the laboratory was conducted on 10/17/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories. STANDARD LEVEL DEFICIENCIES were cited.
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) instructions, laboratory's proficiency testing (PT) documents for 2022 and 2023, and staff interview, the laboratory failed to document attestation of PT being tested in the same manner as patients for one of four PT events reviewed. Findings included: 1. Review of API instructions for PT revealed:"SIGNATURES REQUIRED - For all PT results, an attestation statement must be signed by testing personnel and the laboratory director and retained for a minimum of 2 years. " 2. Review of laboratory's PT documents for 2022 and 2023 revealed the following one of four reviewed PT events did not have a signed attestation document: 2022 Microbiology - 2nd Event Submitted electronically to API on: 06/24/2022 3. In an interview on 10/17/2023 at 1000 hours in the office, the laboratory's Technical Supervisor (as indicated on submitted form CMS 209), after review of the data, confirmed the findings. Key: CMS - Centers for Medicare and Medicaid</p>