

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D0321992	<b>(X3) Date Survey Completed</b>  03/13/2023
<b>Name of Provider or Supplier</b>  Springs Pediatrics	<b>Street Address, City, State</b>  6400 Dutchmans Pkwy Suite 15, Louisville, KY	
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>	A recertification survey was conducted on 03/13/2023 and the laboratory was found not to be in substantial compliance with the laboratory requirements at 42 CFR Part 493, with deficiencies cited.
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to perform twice annual accuracy verification of urine colony counts for two of two years (2021-2022). The findings include: Review of laboratory testing records revealed the required twice annual accuracy assessment for the urine colony counts by Uricult was not being performed. Review of the undated "Uricult CLIA Compliance Reference Guide", revealed "No standard proficiency survey required but must participate in a bi-annual assessment program". During an interview on 03/13/2023 at 3:05 PM, the Laboratory Director stated the required accuracy assessment was not performed because she was told by a former consultant that the Uricult device test was a waived device.</p>
<b>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview, it was determined the laboratory failed to run a negative and positive control for urine colony counts for two (2) of two (2) years reviewed (2021 and 2022). The findings include: Review of the laboratory procedure manual revealed there was not a procedure for performing quality control for the urine colony counts by the Uricult device test. A review of the "CLIA Application for Certification", signed by the Laboratory Director (LD) and dated 03/07/2023, revealed urine colony counts, a waived test, by the Uricult device test was performed. Review of the undated "Uricult CLIA Compliance Reference Guide", revealed "Quality Control 1. a - Prepare Individualized Quality Control Plan (IQCP) Risk Assessment or b - Perform a positive and negative control with each shipment or Lot Number every six (6) months and 2. Visually inspect Uricult vials for damage, contamination and excess moisture before use. 3. Remove Certificate of Analysis from package insert and save". During an interview on 03/13/2023 at 3:05 PM, the LD stated the required quality controls were not performed because she was told by a former consultant that the Uricult device test was a waived device.