

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0882643	<b>(X3) Date Survey Completed</b>  10/30/2023
<b>Name of Provider or Supplier</b>  Urology Group Of Florida Llc	<b>Street Address, City, State</b>  5350 W Atlantic Ave Ste 102, Delray Beach, FL	
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>	Recertification survey was conducted from 10/26/2023 to 10/30/2023. Urology Group of Florida LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories.
<b>D5219</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of 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 record review, and interview, the laboratory failed to perform 1 out of 2 verifications in 2021 and 2 out of 2 verifications in 2022 for twice annual verifications for urinary sediment. Findings Included: Review of Proficiency Test (PT) Policy read, "Analytes for which no PT exists are tested twice per year to verify accuracy using split-sample method missing was step by step process." Review of Urinary Sediment PT revealed no documentation of second PT in 2021 and twice annual PT in 2022 for urinary sediment. On 10/26/2023 at 4:00 PM, the Office Manager and Medical Assistant confirmed accuracy verification was not completed for urinary sediment in 2021 and 2022.</p>
<b>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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,</p>

accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review, and interview, the Technical Supervisor failed to perform annual competency assessments for 2 out of 2 Testing Personnel in 2021 and 2022, (Testing Personnel A and B). Findings Included: Review of Quality Assurance Plan revealed no policy documentation for Testing Personnel competency assessment performing fluorescence in situ hybridization (FISH) and urinary sediment. Review of Competency Assessment revealed no documentation of annual competency assessments completed in 2021 and 2022 for Testing Personnel A and B. On 10/26 /2023 at 3:40 PM, the Office Manager confirmed annual competency assessments were not completed for Testing Personnel A and B in 2021 and 2022. .