

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0683000	<b>(X3) Date Survey Completed</b>  01/17/2023
<b>Name of Provider or Supplier</b>  Urology Group Of Florida Llc	<b>Street Address, City, State</b>  4889 S Congress Ave, Lake Worth, 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>	An announced CLIA recertification survey was conducted at Urology Group of Florida LLC on 01/17/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5213</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(b)(1)</p> <p>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on review of API (American Proficiency Institute) proficiency testing and interview with General Supervisor, the laboratory failed to evaluate ungraded results in microbiology proficiency testing for one (1st testing event in 2021) out of seven ( 3rd testing event 2020 , 1st, 2nd, and 3rd testing event in 2021, and 1st, 2nd, and 3rd testing event 2022) testing events for urine culture susceptibility interpretation for sulfisoxazole and trimethoprim. Findings Included: Review of API proficiency testing results for the 1st testing event for 2021 found two ( sulfisoxazole and trimethoprim) out of 10 ( ampicillin, cefazolin, ciprofloxacin, levofloxacin, nitrofurantoin, oxacillin, sulfisoxazole, tetracycline, and trimethoprim) urine susceptibility testing scores were ungraded (not graded due to no appropriate peer group) by API and the laboratory had not performed a self evaluation. On 01/17/2023 at 02:30 PM, General Supervisor stated she did not know that the laboratory was to perform a self evaluation of ungraded results and did not know how to perform self evaluation for ungraded scores.</p>
<b>D5221</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(d)</p>

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on record review of American Proficiency Institute (API) proficiency testing, laboratory's policies and procedure, and interview with the General Supervisor, the laboratory failed to ensure corrective action was taken and documented for unacceptable samples for (API) proficiency testing for three proficiency testing events (1st testing event in 2021 for Microbiology, the 2nd testing event in 2021 for Hematology/Coagulation and the 1st testing event in 2022 in Microbiology) out of seven events (2020 Microbiology 3rd Event, 2021 Microbiology 1st, 2nd, and 3rd Events, 2021 Hematology/Coagulation 1st, 2nd, and 3rd Event, 2022 Microbiology 1st, 2nd Event, and 3rd, and 2022 Hematology/Coagulation 1st, 2nd, and 3rd Events). Findings included: A review of the API proficiency testing documentation, revealed that for the 1st Microbiology testing event in 2021, samples UR - 02 and UR - 04 had unacceptable results for Urine Colony Count, which gave a score of 60%. The results were reviewed by the General Supervisor on 06/07/2022 with no corrective action documented. A review of API proficiency testing documentation, revealed that for the 2nd Hematology/Coagulation testing event in 2021, sample US - 03 had an unacceptable result for Urine Sediment, which gave a score of 50% . The results were reviewed by the General Supervisor on 06/07/2022 with no corrective actions documented for a clerical error. A review of API proficiency testing documentation , revealed that for the 1st Microbiology testing event in 2022, samples UR - 02 and UR - 05 had unacceptable results for Urine Colony Count which gave a score of 60%. The results were reviewed by the General Supervisor on 06/07/2022 with no corrective action documented. Record review of the laboratory's procedure ""Proficiency Testing" revealed "...Corrections will be documented on a remedial action form". On 01/17/23 at 02:20 PM, the General Supervisor confirmed she did not perform corrective action for Urine Sediment and stated she performed Microbiology proficiency testing review but did not document corrective action for unacceptable Urine Colony Counts because the overall bacteriology score was acceptable.