

| | | |
|--|---|---|
| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D0268071 | (X3) Date Survey Completed 03/03/2026 |
| Name of Provider or Supplier Florida Urology Center Pa, The | Street Address, City, State 300 Clyde Morris Blvd Ste C, Ormond Beach, FL | |
| 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 CLIA recertification survey was conducted at The Florida Urology Center on 3/3/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies: |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with Testing Person (TP) #1, the laboratory failed to evaluate and document the competency for 7 of 7 testing personnel (TP #2 through #7) reviewed who perform urine sediment examinations. Findings include: A review of the laboratory's personnel records on 3/3/2026 revealed no documentation that competency assessments had been conducted for any of the 7 providers (TP #2 through TP #7) performing urine sediment examinations. In an interview on 3/3/2026 at 1:30 PM, Testing Person #1 confirmed that the laboratory has not performed or documented competency assessments for these seven providers.</p> |
| D5217 | <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:</p> |

Based on record review and interview with the Testing Person #1, the laboratory failed to verify the accuracy of patient testing at least twice yearly for urine microscopic examination and Adenovirus urine molecular testing. Findings include: 1. A review of the laboratory's 2025 quality records revealed the laboratory performed a peer review (accuracy verification) for the urine microscopic examinations once on 4/16/2025. The laboratory failed to provide documentation that a second verification of accuracy was performed for urine sediment during the 2025 calendar year. 2. A review of the laboratory's 2024 and 2025 Proficiency Testing (PT) records revealed that Adenovirus was not included in PT enrollment or split sample testing. In an interview on 3/3/2026 at 1:30 PM, Testing Person #1 (TP #1) confirmed the peer review dated 4/16/2025 was the only accuracy verification performed for urine microscopic examination in 2025. TP #1 further confirmed that the laboratory had not performed any accuracy verification for Adenovirus urine molecular testing during 2024 or 2025.