

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0288708	(X3) Date Survey Completed 07/01/2024
Name of Provider or Supplier Urology Center Of South Florida Pa	Street Address, City, State 10151 Enterprise Center Blvd Ste 201, Boynton 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	A recertification survey was conducted on July 1, 2024. Urology Center of South Florida PA clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview, the laboratory failed to include instruction on labeling for urine and semen specimens, complete instructions on the processing of urine sediment specimens, and instructions on how the laboratory</p>

identified which slide chamber patient specimens were added to for urine sediment and semen specimens from 05/25/2022 to 07/01/2024. Findings: Review of the procedures titled Recording Automated Urinalysis Results, and Qualitative Semen Analysis revealed the procedures did not include instructions on the labeling of patient urine specimens and semen specimens. Review of the procedure Staining of Urine Specimens for Microscopic Analysis revealed the procedure did not have instruction for the labeling of the centrifuge tubes used for urine sediment testing. Review of the procedure titled Staining of Urine Specimens for Microscopic Analysis revealed the procedure failed to include the length of time the urine needed to be spun. Review of the procedures titled Staining of Urine Specimens for Microscopic Analysis and Qualitative Semen Analysis revealed the procedures did not include how the laboratory identified which chamber on the slides the patient specimen was added to. On 07/01/2024 at 12:30 PM, Testing Personnel B stated the were no instructions on the specimen labeling, the amount of time the urine sediment specimens needed to spin, and how the laboratory identified which chamber on the slides the patient specimen was added to in the above mentioned procedures.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on review of personnel records and interview, the Laboratory Directory (Technical Consultant) failed to evaluate and document the initial training, semiannually (six month), and annual performance evaluation (competency) for 1 (B) of 2 (A, B) Testing Personnel. Findings: Review of personnel records showed there was no documentation of the initial training, the six month competency evaluation, and the annual competency evaluation for Testing Personnel B. On 07/01/2024 at 12: 20 PM, an interview with Testing Personnel B found she stated she started working in the laboratory at the end of 2022 and does not have any training or competency evaluation documentation.