

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0682383	(X3) Date Survey Completed 03/27/2024
Name of Provider or Supplier University Of Miami Department Of Urology	Street Address, City, State 1150 Nw 14th St Ste 309, Miami, 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 conducted on 03/27/2024 found the UNIVERSITY OF MIAMI DEPARTMENT OF UROLOGY clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure the analysts signed proficiency testing (PT) attestation for two out of four events reviewed for the specialty of Hematology. Findings included: Review of the American Association of Bioanalysts (AAB) Proficiency Testing records for years 2022 and 2023 in the specialty of Hematology for Semen Analysis study, revealed that the two events in 2023 were missing analyst attestation signatures. During an interview on 3/27/2024 at 12:10 PM, the Laboratory Director stated that the attestations were signed electronically at the AAB site, and he was unable to add the analyst signatures on the AAB site.</p>