

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0998636	(X3) Date Survey Completed 02/15/2024
Name of Provider or Supplier University Of Miami Hospital And Clinics -	Street Address, City, State 8170 Royal Palm Blvd, Coral Springs, 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 02/15/2024 found the UNIVERSITY OF MIAMI HOSPITAL AND CLINICS - CORAL SPRINGS 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 current laboratory director (LD) failed to sign proficiency testing (PT) attestation for one out of four events reviewed for the specialty of Hematology. Findings Include: -Review of notification from the Laboratory & In-Home Services Unit Agency for Healthcare Administration revealed that the current LD was approved on 09/27/2022. -Review of the College of American Pathologists (CAP) records for the Hematology specialty for 2022 and 2023 revealed the following for the third event of 2022: the results were submitted on 10/05/2022 and the attestation for the event of reference was not signed by the LD instead was signed by a supervisor that at the time of the event was not signed as a designee by the current LD. During an interview on 02/15/2024 at 12:00 PM, the current supervisor confirmed that the LD failed to sign the attestation for the event of reference.</p>

D5407

PROCEDURE MANUAL

CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review and interview, the current laboratory director (LD) failed to approve, sign and date the procedure manual before use after her approval as LD. Findings included: -Review of notification from the Laboratory & In-Home Services Unit Agency for Healthcare Administration revealed that the current LD was approved on 09/27/2022. -Review of the procedure manual showed that the current LD approved, signed and dated the procedure manual on 11/2022. During an interview on 02/15/2023 at 11:45 AM, the supervisor acknowledged that the current LD failed to review, approve and sign procedure manual before use after her designation as LD.