

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2269799	(X3) Date Survey Completed 04/24/2023
Name of Provider or Supplier University Of Miami Hospital & Clinics	Street Address, City, State 1120 Nw 14 Street 14th Floor Suite 1432, 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	An initial certification survey conducted at UNIVERSITY OF MIAMI HOSPITAL & CLINICS on 04/24/2023 found the clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D6127	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Technical Supervisor (TS) failed to evaluate the Initial for seven Testing Personnel (TP) and semiannual competency for one TP. Findings included: -Review of policy "EMPLOYEE COMPETENCY EVALUATION POLICY # GEN-03" revealed that on page 2 on topic 7 it stated: "Competency evaluation will be done by the Direct Supervisor/Manager/Director who is licensed as a State of Florida." -Review of the FORM CMS-209 signed by the Laboratory Director (LD) on 04/24/2023 revealed that the LD was also the Clinical Consultant (CC), TS and General Supervisor (GS). Listed also that the laboratory had eight TP (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7 and TP#8). -Review of personnel records revealed that TP# 2 had an initial evaluation on 10/26/2022 and a semiannual competency on 04/06/2023. Competency records for TP#3, TP#3, TP#5, TP#6, TP# 7 and TP#8 revealed that they had the initial competency done on 04/06 /2023. Review of all competencies revealed that they were performed by a pathologist that was not listed in the FORM CMS209. During an interview on 04/24/2023 at 11: 30 AM with the quality manager, she confirmed that the TS failed to perform the competencies listed above.</p>