

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2031737	(X3) Date Survey Completed 01/29/2026
Name of Provider or Supplier Biochemical And Molecular Genetics	Street Address, City, State 1501 Nw 10th Ave Brb Rm 531, 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 announced CLIA recertification survey was conducted at BIOCHEMICAL AND MOLECULAR GENETICS DIAGNOSTICS LABORATORY from January 28, 2026 to January 29, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
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 staff interview, the laboratory procedure manual failed to include how to do competency evaluations for the Technical Supervisor and General Supervisor positions in the specialty of Chemistry and Clinical Cytogenetics in 2025 and 2026. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 01/05/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant. The laboratory had one Technical Supervisor (TS#1), who was also the General Supervisor (GS) for Chemistry specialty and Testing Person (TP#1). The laboratory had TS#2 for the specialty of Clinical Cytogenetics, who was also TP#2, and seven additional testing persons (TP#3, TP#4, TP#5, TP#6, TP#7, TP#8 and TP#9). 2-Review of personnel record's competency evaluations for GS/TS#1 on 01/09/2025 and 01/14/2026 revealed that it was titled for Supervisor, but it was assessed as a testing person; competency evaluations for TS#2 on 01/14/2026 revealed that he was assessed as a Medical Technologist (TP#2). Both the GS/TS#1 and the TS#2 each had an LD designation/authorizations checklist signed by the LD on 01/06/2025 and 01/05/2026. 3- Review of the laboratory procedure manual, signed by the Laboratory Director on 01/05/2026, revealed that Employee Competency Evaluation procedure with effective date 05/30/2017 did not include how to do</p>

evaluations for the supervisory roles. 4- During interview on 01/27/2025 at approximately 4:39 PM, the Laboratory Director admitted that the procedure did not include how to do evaluations for a supervisor.