

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0675401	(X3) Date Survey Completed 10/15/2024
Name of Provider or Supplier Gables Pediatrics Llc	Street Address, City, State 358 San Lorenzo Ave Ste 3230, Coral Gables, 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 October 15, 2024. GABLES PEDIATRICS LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have all attestations for Proficiency Testing (PT) signed as follow: Testing person (TP) failed to sign one (3rd event) out of 6 events of Hematology (1, 2, 3 events of 2023 and 1,2 and 3 events of 2024) reviewed and the laboratory director (LD) failed to sign two (3rd event 2023 and 1st event 2024) out of 6 events (1,2,3 for 2023 and 1,2,3 for 2024). Findings included: 1-Review of the PT records from College of American Pathologist (CAP) Hematology Automated Differential Survey FH1-C 2023 revealed that the TP and LD failed to sign attestation for the testing performed on 10/09/2023. 2-Review of PT records from CAP for 1st event of 2024 revealed that the LD failed to sign on 02/09/2024. 3-During the interview on 10/15/2024 at 11:26 AM, the LD confirmed that the signature for the events of reference were missing.</p>