

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2164102	<b>(X3) Date Survey Completed</b>  03/13/2025
<b>Name of Provider or Supplier</b>  Gables Pediatrics Llc	<b>Street Address, City, State</b>  2000 Nw 87 Ave Suite 212, Doral, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at GABLES PEDIATRICS LLC from 03/12/2025 to 03/13/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions was cited: - D6063 Laboratory Personnel Qualifications. 493.1421
<b>D2009</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>(b)(1) 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 attestations for Proficiency Testing (PT) three out of seven events reviewed from 2023 to 2025. Findings included: 1-Review of the PT records from College of American Pathologist (CAP) Hematology Automated Differential Survey FH16, revealed the following: a) FH16-C 2023 no attestation signed. b) FH16-A 2024 no attestation signed. c) FH16-B 2024 no attestation signed. 2-During the interview on 03/11/2025 at 12:20 PM, the LD confirmed that the attestations for the reference events were missing.</p>
<b>D6063</b>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on record review and Laboratory Director (LD) interview, the Laboratory failed to verify the education of 1 out of 14 Testing Personnel. See D6065

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on record review and Laboratory Director (LD) interview, the Laboratory failed to verify the education of 1 out of 14 testing personnel (TP). Findings included: 1- Review of FORM CMS-209 Laboratory Personnel Report dated and signed by the Laboratory Director on 03/11/2025 listed 14 TP (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9, TP#10, TP#11, TP#12, TP#13 and TP#14). 2-Review of employee files revealed that TP#9 who was hired since 06/07/2024, had a Foreign High School Diploma, the laboratory failed to have the equivalence for her Diploma. 3-During an interview on 03/12/2024 at 12:30 PM with LD, she confirmed that the Laboratory failed to have the equivalence for the Foreign High School Diploma for TP#9.