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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>10D0675401               | <b>(X3) Date Survey Completed</b><br><br>09/10/2026 |
| <b>Name of Provider or Supplier</b><br><br>Gables Pediatrics Llc                                                           | <b>Street Address, City, State</b><br><br>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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
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| D0000              | An announced CLIA recertification survey was conducted at GABLES PEDIATRICS LLC on September 10, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited were as follows:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| D6047              | <p>TECHNICAL CONSULTANT RESPONSIBILITIES<br/>CFR(s): 493.1413(b)(8)(i)</p> <p>(b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;</p> <p>This STANDARD is not met as evidenced by:<br/>Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of patient testing during competency evaluation for testing personnel (TP) on one (TP-A in 2025) and one (TP-G in 2026) out seven (TP-A, TP-C, TP-E, TP-G, TP-J, TP-M and TP-N) randomly selected personnel from 10/16/2024 through 9/10/2026. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 09/09/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC). The laboratory had a Technical Consultant (TC) and 20 testing personnel (TP-A, TP-B, TP-C, TP-D, TP-E, TP-F, TP-G, TP-H, TP-I, TP-J, TP-K, TP-L, TP-M, TP-N, TP-O, TP-P, TP-Q, TP-R, TP-S and TP-T) for the Hematology specialty. 2- Review of the LABORATORY PERSONNEL COMPETENCY ASSESSMENT records for TP-A (12/11/2025) and TP-G (06/09/2026) revealed that direct observations (DO) of patient testing were not indicated in the forms, but observed by assessor TP1, who had no delegation letter to do competency. 3- During interview on 09/10/2026 at 2:00 PM, the LD admitted to not have performed direct observation of patient testing during personnel competency evaluations in 2025 and 2026.</p> |
| D6050              | <p>TECHNICAL CONSULTANT RESPONSIBILITIES<br/>CFR(s): 493.1413(b)(8)(iv)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

(b)(8)(iv) Direct observation of performance of instrument maintenance and function checks;

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Technical Consultant (TC) or a designee failed to do direct observation of performance of instrument and function check of the SYSMEX XP-300 Hematology analyzer during competency evaluation testing personnel (TP) on one (TP-A in 2025) and one (TP-G in 2026) out seven (TP-A, TP-C, TP-E, TP-G, TP-J, TP-M and TP-N) randomly selected personnel from 10/16/2024 through 9/10/2026. Findings included: 1- Review of FORM CMS 209 signed by the Laboratory Director on 09/09/2026, revealed the following: Laboratory Director (LD) was also Clinical Consultant (CC). The laboratory had a Technical Consultant (TC) and 20 testing personnel (TP-A, TP-B, TP-C, TP-D, TP-E, TP-F, TP-G, TP-H, TP-I, TP-J, TP-K, TP-L, TP-M, TP-N, TP-O, TP-P, TP-Q, TP-R, TP-S and TP-T) for the Hematology specialty. 2- Review of the LABORATORY PERSONNEL COMPETENCY ASSESSMENT records for TP-A (12/11/2025) and TP-G (06/09/2026) revealed that direct observations (DO) for the performance of instrument and function check of the SYSMEX XP-300 Hematology analyzer were not indicated in the forms, but observed by assessor TP1, who had no delegation letter to do competency. 3- During interview on 09/10/2026 at 2:00 PM, the LD admitted to not have performed direct observation in 2025 for the performance of instrument and function check during personnel competency evaluations in 2025 and 2026