

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2164102	(X3) Date Survey Completed 09/09/2019
Name of Provider or Supplier Gables Pediatrics Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An initial certification survey conducted at Gables Pediatrics LLC Doral on 9/09/2019 found that the laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 personnel competency record review and interview with staff, the laboratory failed to have initial competencies for 1 out of 2 technical consultant (TC) and 6 out of 6 (CC#A, CC#B, CC#C, CC#D, CC#E, and CC#F) Clinical Consultants (CC) for year 2019. The findings include: -A review of CMS -209 laboratory personnel report revealed that: a) Laboratory Director (LD) is TC #A and CC#A b) CC# B is TC # B c) CC#C, CC#D, CC#E, and CC#F were clinical consultants. -Personnel competency review revealed that there was no initial competency assessments for the TC # B and CC B, C, D, E and F. During an interview with LD, on 09/09/2019 at 2:30 PM, he confirmed that the there was no initial competency assessment for the personnel listed above.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if</p>

applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on observation, user manual review and interview with the office manager (OM), the laboratory failed to document room humidity requirement to assure optimal operation of the Beckman coulter AcT Diff in 2019. The findings include: AcT coulter manual review revealed a room temperature requirement range of 16-35 C and humidity not greater than 85 %. Observation of laboratory indicated no thermometer /humidity meter to measure room temperature and humidity. Temperature log record review revealed no records of room temperature and humidity in 2019. During an interview on 09/9/2019 at 12:30 p.m., the OM confirmed that there was no record of room temperature and humidity control check.