

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0675401	(X3) Date Survey Completed 11/19/2018
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
D2122	<p>HEMATOLOGY CFR(s): 493.851(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on College of American Pathologists (CAP) proficiency testing (PT) record review and interview with laboratory director, the laboratory failed to achieve an 80% testing score for Red Blood Cell (RBC), Hematocrit (HCT), Hemoglobin (HGB) and Hematology for 1 out of 6 events reviewed for the specialty of Hematology. Findings include: Review of CAP PT records for 2017 and 2018, revealed that the laboratory failed first event of 2017 with 60 % score for RBC, HCT, HGB and 77 % score for Hematology specialty. During an interview on 11/19/2018 at 12:00 PM, the laboratory director confirmed that the laboratory had unsatisfactory score on that PT event.</p>
D5293	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c)</p> <p>(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assurance policy and laboratory records from 2016 to 2018 and interview with Testing Personnel (TP) #A revealed that the laboratory failed to document the quality assurance (QA) activity during the years 2016, 2017 and 2018.</p>

Findings include: Review of quality control records revealed that there was no documentation of the QA activity during the years 2016 to 2018. During an interview on 11/19/2018 at 12:00 PM, with the TP#A, she confirmed that there were no records of QA activity for the years of reference.