

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0675401	(X3) Date Survey Completed 10/27/2022
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 conducted on 10/27/2022 found the GABLES PEDIATRICS LLC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of form CMS 209, Laboratory Personnel form, personnel files, a review of College of American Pathologists (CAP) proficiency testing (PT) records and staff interview, the laboratory failed to have all testing personnel (TP) rotate through the testing of PT for the Hematology specialty during 2021 and 2022. Findings include: Review of CMS 209 form signed and dated by the Laboratory Director (LD) on 10/26/2022 revealed that the laboratory had nine Testing Personnel listed (TP# A, TP# B, TP# C, TP# D, TP# E, TP# F, TP# G, TP# H and TP# I). Personnel files review revealed that TP# A, TP# B, TP# C, TP# D and TP# F, had competency records in 2021 and 2022. Review of CAP PT records for 2021 and 2022, revealed that TP# A signed attestation for the three events of 2021 and the two events of 2022. During an interview on 10/27/2022 at 03:00 PM, TP# A confirmed that she was the TP that performed all the PT events for the period reviewed.</p>
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems</p>

identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on record review and interview, the Quality Assessment (QA) process failed to monitor, assess and correct deficiencies in the storage of complete blood controls (CBC); which were outside of the acceptable range for 19 out of 517 days reviewed.

Findings include: -Review of refrigerator temperature logs for 2021 and 2022 revealed that the temperatures were outside of the acceptable range of 35.6 to 46.4 Degrees Celsius on the following dates: 09/01/2021, 10/01/2021, 10/04/2021, 10/08/2021, 12/20/2021, 01/05/2022, 01/06/2022, 01/10/2022, 01/13/2022, 01/14/2022, 01/17/2022, 02/02/2022, 02/07/2022, 02/28/2022, 03/01/2022, 03/17/2022, 03/25/2022, 03/30/2022 and 04/28/2022. -No documentation of corrective actions for refrigerator temperatures outside of the required range was found. During an interview on 10/27/2022 at 02:07 PM, testing personnel # A confirmed that no corrective actions were documented for the temperatures that were outside of the acceptable range.