

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2164102	(X3) Date Survey Completed 04/29/2021
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	A recertification survey was completed on 4/29/2021 at GABLES PEDIATRICS LLC. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were not met: 5200- General Laboratory Systems
D5200	<p>GENERAL LABORATORY SYSTEMS CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: The laboratory failed to perform an initial competency assessment for 1 out 7 clinical consultants (CC), assessments for 6 out of 8 CC and 2 assessments fo the 2 technical consultants (TC) in 2020. A six- month competency assessment was not performed for 1 out 9 testing personnel (TP) in 2021. (see 5209)</p>
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:</p>

Based on record review and interview, the laboratory failed to perform an initial competency assessment for 1 out of 7 clinical consultants (CC), annual competency assessments for 6 out of 8 CC and 2 assessments for the 2 technical consultants (TC) in 2020. A six- month competency assessment was not performed for 1 of 9 testing personnel (TP) in 2021. This is a repeated deficiency from 9/09/2019 . Finding Included: Review of Laboratory Personnel Report revealed the following: 1. TP-I as TP 2. CC-A, CC-B, CC-D, CC-E, CC-F, CC-G, CC-H, CC-I as CC 3. TC-A and TC-B as TC Review of Clinical Consultant Competency Assessment records revealed CC#I had no documentation of an initial competency assessment in 2020. CC-A,-B, D, -E, -F, -G, and H had no documentation of an annual competency assessment in 2020. Review of Technical Consultants Competency Assessment records revealed TC-A and TC-B had no documentation of an annual competency assessment in 2020. Review of Testing Personnel Competency Assessment records for TP-I had no documentation of a six-month competency assessment in 2021. During an interview on 4/28/2021 at 3:40pm, the laboratory manager confirmed no performance of an initial competency assessment for 1 out of 7 clinical consultants (CC), annual competency assessments for 6 out of 8 CC and 2 of 2 technical consultants (TC) in 2020, and a six- month competency assessment was not performed on 1 out of 9 testing personnel (TP) in 2021.