

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0283533	(X3) Date Survey Completed 10/07/2020
Name of Provider or Supplier Kings Bay Pediatrics Llc	Street Address, City, State 13101 S Dixie Hwy Ste 320, Miami, 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 10/07/2020 found that Kings Bay Pediatrics LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 record review, lack of documentation and staff interview, the laboratory failed to document their Quality Assurance (QA) activity for 2 out of 2 years reviewed (2019-2020). Findings include: Review of the QA policy revealed that the laboratory will perform a semiannual review and complete documentation of the pre-analytic, analytic and post analytic components review of the QA and at the end of every year a random review of 10 charts will be done. No documentation of this review was found at the time of the survey. During an interview on 10/07/2020 at 11:30 AM, with the Laboratory Director, she confirmed that there was no documentation of the QA activity.</p>