

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0283533	(X3) Date Survey Completed 08/13/2026
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	An announced CLIA recertification survey was conducted at KINGS BAY PEDIATRICS LLC on August 13, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D6063 493.1421 Condition: Laboratory Testing Personnel
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) Proficiency Testing (PT) records, and staff interview, the Laboratory Director (LD) failed to sign attestations for six of six events (3rd event of 2024, 1st, 2nd and 3rd event of 2025, 1st event and 2nd event of 2026) and the Testing personnel (TP) in 2 (2026 1st and 2nd) out of six (3rd event of 2024, 1st, 2nd and 3rd event of 2025 and 2026 1st and 2nd) in the hematology specialty. Findings included: 1-Review of the API Attestation noted. "Signatures Required - for all PT results, and attestation statement must be signed by Testing personnel and Laboratory Director and retained for a minimum of 2 years." 2- Review of API PT attestations records for 3rd event of 2024, 1st, 2nd and 3rd event of 2025, revealed that in the line dedicated for the LD signature, they displayed a signature that was not of the LD or a qualify designee. In 2026 the LD and the TP did not sign the attestations for 1st and 2nd events. 3-During the interview on 08/13/2026 at 01:26 PM, TP #1 confirmed the following: the LD failed to sign attestation for the events for 3rd event of 2024,1st, 2nd and 3rd events of 2025 and confirmed that the laboratory failed to have signed attestations by LD and TP for 1st and 2nd events of 2026 in Hematology specialty.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document all required maintenance performed for three out of eight months reviewed for the Medonic M Series Complete Blood Count (CBC) Analyzer. Findings included: 1- Review of user manual for Medonic M Series analyzer requires the laboratory had to perform daily, weekly, monthly and semiannual maintenance actions. 2-Review of the Maintenance log for 2026 in January, February, March, April, May, June, July, and August revealed that the laboratory failed to document the maintenance task as follows: a. June: Missed to document daily maintenance from 06/15/2026 -06/19 /2026, 06/22/2026-06/26/2026 and 06/29/2026 -06/30/2026. b. July: Missed to document daily maintenance in 07/02/2026, 07/06/2026 - 07/10/2026, 07/13/2026 -07 /17/2026, 07/20/2026 - 07/27/2026, 07/24/2026 - 07/31/2026. No documentation of the monthly maintenance. c. August: No documentation of maintenance tasks. 3- During an interview on 08/13/2026 at 01:20 PM, Testing Personnel #1 confirmed that the laboratory missed documenting the maintenance tasks listed above.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to document the visits to the laboratory at least twice a year since 2025. Findings included: 1-Review of the laboratory's policies and procedures signed by the LD on 08 /01/2026, revealed that the LD job description included the activities of the Technical Consultant (TC). 2-During an interview on 08/13/2026 at 12.46 PM, Doctor #1, explained that the LD visits the laboratory and reviews documentation and confirmed that no documentation of the LD visits was available. The surveyor requested via email on 08/14/2026 confirmation from the LD about the documentation of the LD visits and no answer received.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure that a qualified Technical Consultant (TC) did competency assessments for 12 out of 12 Testing Personnel (TP) during 2024 to 2026. This failure resulted in the laboratory's inability to verify accuracy and proficiency of TP. Findings included: 1-Review of the Form CMS-209 Laboratory Personnel Report, signed and dated 08/13/2026 by the Laboratory Director (LD), listed the LD as Clinical Consultant and TC; and there were 12 TP (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12). 2-Review of competencies for all 12 TP during the period of 2024 to 2026, revealed that the signature was of a doctor, not listed in the CMS FORM-209 and who does not qualify as TC. 3-Review of the procedure manual signed by the LD on 08/01/2026, showed there was no procedure on competency evaluations. 3- During an interview on 08/13/2026 at 1:53 PM, TP#1, confirmed that the laboratory failed to have documentation to proof that the doctor who signed the competencies in this period qualified as TC.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure one (TP#5) of twelve (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9, TP#10, TP#11, TP#12) Testing Personnel (TP) met the educational requirements. (See D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure one (TP#5) of twelve (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9, TP#10, TP#11, TP#12) Testing Personnel (TP) met the educational requirements since 03/18/2025. Findings included: 1-Review of the form CMS-209 Laboratory Personnel Report, signed and dated by the Laboratory Director (LD) on 08/13/2026, revealed that there

were 12 moderate complexity TP listed (TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, TP#9, TP#10, TP#11, TP#12). 2-Review of personnel records for TP#5 revealed that failed to contain a college degree, high school diploma or GED. TP#5 had competency records since 03/18/2025 (Initial). 3- During an interview on 08/13 /2026 at 12:35 AM TP#1, confirmed that the laboratory failed to have documentation to proof that the TP#5 met the educational requirement.