

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2336972	(X3) Date Survey Completed 09/15/2026
Name of Provider or Supplier Gables Pediatrics Llc	Street Address, City, State 13780 Sw 88th Street, 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 initial survey was conducted at GABLES PEDIATRICS LLC on September 15, 2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited were as follows:
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to have documentation that the Laboratory Director reviewed and approve the DxH500 Series Complete Blood Counter (CBC) analyzer verification of performance study conducted prior to going live on 01/26/2026. Findings included: 1. Review of the Method Validation for the DxH500 Series CBC analyzer study performed on January 15, 2026, revealed that the study failed to have the acceptance signature of the Laboratory Director. The laboratory tested 606 patients from 01/26/2026 to 09/14/2026. 2. Review of the DxH500 Series Performance Verification Checklist PN C42118AA Appendix D displayed a table header stated "Hematology - To be completed during implementation by laboratory staff. Table D.1 Performance Verification Checklist" ... last item listed "Pathology/Lab Director sign-off and Date Completed" was not signed by the Laboratory Director. 3. During an interview on 09/15/2025 at 11:41 AM, the Laboratory Director confirmed that the laboratory failed to have documentation that the Laboratory Director reviewed and approved the verification of performance study.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b)(3) The criteria for proper storage of reagents and specimens, as specified under

493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on records review and staff interview, the laboratory failed to document corrective action when the monitored refrigerator temperature was out of range for one out of 22 days during March of 2026. Findings included: 1. During review of Daily Temperature Log for randomly selected months January, March, May and July of 2026, revealed a refrigerator temperature of 47.4 on 03/24/2026, was outside the range (35.6-46.4 F or 2-8 C). The Laboratory Director confirmed that two patients were tested on this day. 2. During an interview on 09/15/2025 at 12:16 PM, Testing Personnel A confirmed that the laboratory failed to document corrective action for the refrigerator temperature outside manufacturer specifications for the DxH 500 Series Hematology controls on 03/24/2026. 3. Email on 09/15/2025 at 4:16 PM, Testing Personnel A confirmed with image of DxH 500 Series control box displayed temperature range 2-8 C.