Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2068574	10/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pinecrest Pediatrics Group Llc	11635 S Dixie Hwy, 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 was conducted on October 24, 2019. Pinecrest Pediatrics Group LLC clinical laboratory was found not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(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 record review and interview, the Laboratory Director and Testing Personnel failed to sign the attestation forms for proficiency testing (PT) for 2017 (3rd event), 2018 (1st, 2nd, and 3rd events), and 2019 (1st, 2nd, and 3rd events) for the specialty of hematology. Review of the American Proficiency Institute (API) PT showed that the laboratory failed to verify that PT samples were run in the same manner as patients by signing the attestation statement. Attestation statements were not signed by the Laboratory Director and Testing Personnel for 3rd event in 2017, the 1st, 2nd, and 3rd events in 2018, and the 1st and 2nd event in 2019. During an interview on 10/24 /19 at 12:18 PM, the Laboratory Director acknowledged the attestation forms were not signed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document competency assessment on 1 (A) of 6 (A, B, C, D, E, F) testing personnel from 10/24 /17 to 10/24/19. Findings: Review of the annual competency records showed that the laboratory failed to have documentation of competency assessment on the Laboratory Director (Testing Personnel A) from 10/24/17 to 10/24/19. During an interview on 10 /24/19 at 12:13 PM, the Laboratory Director stated she did not have competency evaluations performed on herself..
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document the review and evaluation of proficiency testing (PT) for the 2017 (3rd event), 2018 (1st, 2nd, and 3rd events), and 2019 (1st, 2nd, and 3rd events) for the specialty of hematology Findings: Review of the American Proficiency Institute (API) PT showed that the laboratory director failed to sign "Proficiency Testing Performance Evaluation" forms for 3rd event in 2017, the 1st, 2nd, and 3rd events in 2018, and the 1st and 2nd event in 2019. During an interview on 10/24/19 at 12:18 PM, the Laboratory Director acknowledged she did not sign the evaluation forms.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to record the humidity of the room where testing was performed from 10/24/17 to 10/24/19. Findings: The manual for the Medonic M Series hematology analyzer used in the laboratory noted that the humidity of the laboratory should be between 10% - 90%. A review of the laboratory's logs showed that the laboratory failed to record the humidity of the room where testing was performed. On 10/24/19 at 12:15 AM, the Laboratory Director acknowledge that they did not record the humidity of the laboratory.