Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2012469	02/27/2020
Name of Provider or Supplier	**Street Address, City, State**	
Jacksonville Beach Pediatric Care Center	8990 Rg Skinner Pkwy, Jacksonville, 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 February 27, 2020 . Jacksonville Beach Pediatric Care Center was found NOT in compliance with 42 CFR 493, Requirements for Clinical Laboratories. .
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to rotate proficiency testing to include all testing personnel who perform patient testing for all testing events in 2019. The findings include: Review of the Testing Personnel sheet revealed that 9 people performed patient testing (Testing Person #A, B, C, D, E, F, G, H, and I). Review of American Proficiency Institute (API) proficiency testing attestation statements showed that only Testing Person #E performed proficiency testing for the 1st, 2nd, and 3rd events of 2019. During an interview on 2/27/20 with the Technical Consultant #1/Testing Person #E, it was confirmed that no other Testing Persons had performed proficiency testing and that it was only being performed by "management".
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed

	by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the laboratory did not have documentation of signed attestations for two of two years reviewed (2018-2019). The findings include: Review of all proficiency records for 2018-2019 showed that the Laboratory Director or Designee had not signed the attestations. During an interview with Technical Consultant #1, it was confirmed the Laboratory Director had not signed the attestations for the last two years.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to complete verification for Complete Blood Count testing on the Sysmex XP-300 hematology analyzer. The findings include: Review of the laboratory's records for performance verification for Complete Blood Counts (CBCs) on the new Sysmex XP-300 analyzer showed that the laboratory had not completed the correlation studies and reference range verification for CBCs. During an interview on 2/27/20 at 10:41 AM, Technical Consultant #1 confirmed that the laboratory had not performed correlation studies or reference range verification because they thought the manufacturer had performed all necessary validation procedures.