Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D1041742	**(X3) Date Survey Completed** 01/04/2019
Name of Provider or Supplier Jacksonville Beach Pediatric Care Center	**Street Address, City, State** 274 3rd Ave S, Jacksonville Beach, 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 January 4, 2019. Jacksonville Beach Pediatric Care Center was found to be in non-compliance with the CLIA requirements of 42 CFR Part 493.
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 interview, it was determined that the laboratory failed to perform competency evaluations on testing personnel for 2 out of 2 years (2017-2018) reviewed. Findings Included: Review of the CMS 209 revealed 6 Testing Personnel. Review of the 6 Testing Personnel files revealed no competency evaluations in January 2017 through December 2018. During the interview on 1/4/19 at 10:30 AM , testing person # 2 confirmed that no documentation of competency evaluation were performed.
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, it was determined that the laboratory did not monitor the humidity to assure optimal operation of the hematology analyzer, Sysmex XP-300 for 2 out of 2 years (2017-2018) of the documents reviewed. Findings included: Review of the documents from January 2017 through December 2018, showed that there was no humidity recorded on the logbook. Interview on 1/4/19 at 10: 15 AM, testing person # 2 confirmed that the laboratory was not aware of the requirements of the XP-300 hematology analyzer to check and record the humidity daily.