

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2012469	(X3) Date Survey Completed 04/21/2022
Name of Provider or Supplier Jacksonville Beach Pediatric Care Center	Street Address, City, State 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 April 21, 2022 . Jacksonville Beach Pediatric Care Center was found NOT in compliance with 42 CFR 493, Requirements for Clinical Laboratories. .
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to perform the calibration verification at least once every 6 months for the Sysmex XP-300</p>

hematology analyzer. Findings include: The record review on 4/21/22 of the calibration documentation for the Sysmex XP-300 hematology analyzer showed calibration was performed 10/21/20 and 10/15/21. The interview with Testing Person A on 4/21/22 at 8:45am confirmed calibration had not been performed every 6 months.