Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2107872	07/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
Shands Jacksonville Medical Ctr Dba	2141 Loch Rane Blvd Ste 116, Orange Park, 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	At the time of the announced, onsite recertification survey, UF Health Oncology Orange Park was found to not be in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) 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. 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 XS-1000

	hematology analyzer. Findings include: The record review on 7/30/19 of the calibration documentation for the Sysmex XS-1000 hematology analyzer showed calibration was performed 1/12/17, 9/13/17, 6/25/18, 12/19/18, and 2/21/19. The interview with the Technical Consultant on 7/30/19 at 9:26am confirmed calibration had not been performed every 6 months as manufacturer instructions require due to the service contract expiring.