Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2118976	12/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Urgent Care Of Oconee - Watkinsville	2061 Experiment Station Road, Suite 505, Watkinsville, GA	

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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on December 18, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
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 Hematology calibrations document review and interviews with the Technical Consultant (TC), the laboratory failed to perform instrument calibrations every six months as required in 2018 and 2019 for the Cell dyn Emerald Hematology Analyzer. Findings include: 1. The Cell Dyn Emerald hematology analyzer calibrations document review revealed the laboratory performed instrument calibrations: 8/1/2017 to 4/2/2018 (8 months), 4/2/2018 to 8/6/2018 (4 months), 01/22 /2019 to 08/24/2019 (8 months). 2. An interview with the the (TC) on December 18, 2019 in the conference room at approximately 12:20 p.m. confirmed hematology analyzer calibrations were not performed during the aforementioned intervals in 2018 and 2019.