Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2046627	05/18/2021
Name of Provider or Supplier	**Street Address, City, State**	
Advanced Urgent Care Center	1980 N Roosevelt Blvd, Key West, 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 conducted on 05/18/2021 found that the ADVANCED URGENT CARE CENTER clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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 interview with technical consultant (TC) B, the laboratory failed to perform calibration verification procedures of the Medonic M Series

	Analyzer at least every 6 months from 4/3/2019 to 10/23/2020. Findings include: - Review of the Medonic M Series Analyzer calibration records revealed that the laboratory performed calibrations on 4/3/2019, 1/24/20 and 10/23/20. During an interview on 05/18/2021 at 2:00 p.m., TC B confirmed that the laboratory failed to perform instrument calibration every 6 months in the period of 4/3/2019 to 10/23 /2020.