Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D0930281	11/08/2019
Name of Provider or Supplier	**Street Address, City, State**	
Medical Affiliates Of Cape Cod, Inc	5 Industrial Drive, Mashpee, MA	

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 CLIA recertification survey was conducted for the Medical Affiliates of Cape Cod, Inc. dba Cape Cod Healthcare Physicians laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 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 interview, the laboratory failed to perform calibration

	verifications every six months or, as appropriate, as evidenced by the following: a) The surveyor reviewed quality control records for calendar years 2018 and 2019 on 11 /8/19. b) The review revealed that calibration verifications of at least 3 points were not performed once every six months for one (1) out of one (1) general immunology and four (4) out of four (4) chemistry analytes requiring calibration verification on the Ortho Clinical Diagnostics Vitros 5600 analyzer. Six month calibration verifications for hemoglobin A1C, high-sensitivity C-reactive protein, total iron binding capacity, Vitamin B12, and Vitamin D were performed on 12/28/18 and were not performed every six months. c) The laboratory manager and testing person confirmed through interview on 11/8/19 at 11 AM that calibration verifications had not been performed every six months for five (5) out of 5 (5) analytes requiring calibration verification. d) The laboratory performs 1173 general immunology and 699,890 chemistry tests annually. .