

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0930281	(X3) Date Survey Completed 07/22/2022
Name of Provider or Supplier Medical Affiliates Of Cape Cod, Inc	Street Address, City, State 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. .
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on the deficiencies cited herein, the laboratory failed to meet the the applicable analytic systems requirements in 493.1251 through 493.1283 as evidenced by the following: The laboratory failed to perform calibration verifications of at least three points once every six months in 2020 and 2021 for high-sensitivity C-reactive protein, ferritin, total iron binding capacity, Vitamin B12, and Vitamin D. This is a repeat deficiency. Refer to D5439. .</p>
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)</p>

-- (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 the Technical Consultant (TC) and Testing Person 1 (TP1) on 7/22/2022, the laboratory failed to perform calibration verifications every six months or, as appropriate, as evidenced by the following: The surveyor reviewed the quality control records for calendar years 2020, 2021, and 2022. The review revealed that calibration verifications of at least three 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 high-sensitivity C-reactive protein, ferritin, total iron binding capacity, Vitamin B12, and Vitamin D were performed on 7/1/2022, 2/25/2021, and 5/26/2020. The calibration verifications were not performed every six months. The TC and TP1 confirmed in an interview on 7/22/2022 at 1:32 P.M. that calibration verifications had not been performed every six months for five (5) out of five (5) analytes requiring calibration verification. The laboratory performs 484 general immunology tests and 220,376 chemistry tests annually. This deficiency was cited at the last CLIA inspection performed on 11/08/19. .

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

. Based on personnel competency record review and interview with the Technical Consultant (TC) on 7/22/2022, the TC failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens as evidenced by the following: The surveyor asked for the personnel competency records for review. The review revealed that semiannual competency evaluations were not performed and documented for two (2) out of the two (2) newly hired testing persons (TP) in their first year of performing moderate complexity testing. The TC confirmed in an interview on 7/22/2022 at 11:20 AM that the TC failed to perform and document

semiannual competency evaluations for two (2) newly hired TP's in their first year of performing moderate complexity testing. The laboratory performs 484 general immunology tests, 220,376 chemistry tests, and 86,077 hematology tests annually. . .

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

. Based on personnel competency record review and interview with the Technical Consultant (TC) on 7/22/2022, the TC failed to evaluate and document the performance of individuals responsible for moderate complexity testing at least annually, after the first year the individual tested patient specimens as evidenced by the following: The surveyor asked for the personnel competency records for review. The review revealed that annual competency evaluations were not performed and documented at least annually for one (1) out of the one (1) newly hired testing person (TP) after the first year of performing moderate complexity testing. The TC confirmed in an interview on 7/22/2022 at 11:20 AM that the TC failed to perform and document an annual competency evaluation for one (1) of the newly hired TP's after the first year of performing moderate complexity testing. The laboratory performs 484 general immunology tests, 220,376 chemistry tests, and 86,077 hematology tests annually.