

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0930281	(X3) Date Survey Completed 03/29/2024
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview the laboratory failed to ensure proficiency testing (PT) was rotated amongst all testing personnel (TP) in the specialty of Hematology. Finding include: 1. Record review on 3/29/2024 of the laboratory's 2023 American Proficiency Institute (API) Hematology/Coagulation PT attestation sheets revealed, one of three TP (TP2) did not run PT samples in 2023. 2. Record review on 3/29/2024 of the laboratory's competency records for TP2, revealed, the section referring to PT performance was checked off and signed as as completed. 3. Staff interview on 3/29/2024 at 11:00 AM with the Technical Consultant (TC) who is also TP2 confirmed TP2 did not participate in PT in 2023, yet it was marked as completed on TP2's 2023 competency form. 4. The laboratory performs 12,457 tests annually in the specialty of Hematology.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and confirmed through an interview with the technical</p>

consultant (TC), the laboratory did not have an ongoing mechanism to evaluate the TC based on their CLIA responsibilities. Findings Include: 1. Record review on 3/29/2024 of the laboratory's 2022, 2023 and 2024 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the TC based on their CLIA responsibilities. 2. Staff Interview on 3/29/2024 at 11:00 AM with the TC confirmed the TC did not have competency evaluation based on their CLIA responsibilities.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on American Proficiency Institute (API) proficiency testing (PT) record review and staff interview with the technical consultant (TC), the laboratory failed to verify the accuracy of non regulated analytes and did not document corrective action when scores of less than 100 were received. Findings include: 1. Record review on 3/29/2024 of the laboratory's 2022, 2023 and 2024 to date API Core Chemistry PT records revealed: a. The laboratory received a score of 50% for the nonregulated analyte Vitamin D for 2023 event 1. b. The laboratory received a score of 50% for the nonregulated analyte Ferritin for 2023, event 2. c. The laboratory received a score of 60% for the nonregulated analyte Total Iron Binding Capacity for 2024 event 1. d. The API review sheet for 2023 event 1 had the words, "manual dilution," written on it. e. The laboratory did not investigate or document corrective action or retraining for the regulated analytes noted above. 2. Record review of the laboratory's 2023 API Core Chemistry event 1 PT attestation sheet revealed, the attestation sheet was signed by testing personnel #2 (TP2). 3. Staff interview with TC (who is also TP2) and the laboratory supervisor (who is also TP1) on 3/29/2024 at 11:30 AM confirmed the above PT scores were not investigated or documented with corrective action or retaining. TP1 stated, "The Vitamin D was a manual dilution, but it was never investigated and the lab did not document retraining with TP2." TP2 stated, "TP2 was not sure who actually did the Vitamin D testing because the results were not in TP2's handwriting." 4. The laboratory performs 32,887 tests annually in the subspecialty of Routine Chemistry.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on American Proficiency Institute (API) proficiency testing (PT) record review and staff interview with the technical consultant (TC), the laboratory failed to investigate and perform corrective action when a (PT) score of less than 100% was received for regulated analytes. Findings include: 1. Record review on 3/29/2023 of the CASPER 0096D, 'CLIA Application and Survey Summary' report revealed: a. The laboratory received a score of 60% for the regulated analyte Total Bilirubin for 2022 event 3. b. The laboratory received a score of 80% for the regulated analyte Chloride for 2023 event 1. c. The laboratory received a score of 80% for the regulated analyte

Sodium for 2024 event 1. d. The laboratory received a score of 80% for the regulated analyte Potassium for 2024 event 1. 2. Record review on 3/29/2024 for the laboratory's 2022, 2023 and 2024 to date API Core Chemistry PT records revealed: a. The laboratory received a score of 60% for the regulated analyte Total Bilirubin for 2022, Event 3. b. The laboratory received a score of 80% for the regulated analyte Chloride for 2023 event 1. c. The laboratory received a score of 80% for the regulated analyte Sodium for 2024 event 1. d. The laboratory received a score of 80% for the regulated analyte Potassium for 2024 event 1. e. The laboratory did not investigate or document corrective action or retraining for the regulated analytes noted in 1 and 2 above. 3. Staff interview with the TC on 3/29/2024 at 11:30 AM confirmed the above findings. 4. The laboratory performs 32,887 tests annually in the subspecialty of Routine Chemistry.

D5807

TEST REPORT
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on record review and staff interview the laboratory failed to ensure the reference ranges on the Male (M) and Female (F) final patient test report (FPTR) matched the reference ranges in the procedure manual (PM) in the speciality of Hematology. Findings include: 1. Record review on 3/29/2024 of a male and female FPTR compared to the PM revealed the following differences, white blood cell count (WBC), Hemoglobin (Hgb), Hematocrit (Hct), Mean Corpuscular Hemoglobin (MCH), Red Cell Distribution Width SD (RDWSD) Neutrophils Relative (NeR) female only, and Monocytes Absolute (MA) female only. Note: a. Range on FPTR is the same for both male and female unless otherwise indicated. b. NR = No Range. c. M = Male. d. F= Female. e. The FPTR lists RDWSD and the PM lists RDW-CV. Test FPTR PM WBC K/UL 4.0-15 4.0-11 K/uL Hgb M g/dL 12-17.5 13-17.5 g/dL Hgb F g/dL 12-17.5 12-16 g/dL Hct M % 35-50 35-50% Hct F % 35-50 35-45% MCH pg /RBC 26-32 32-36 pg RDWSD M Fl 35.1-43.9 NR RDWSD F Fl 36.4-46.3 NR NeR F % 34.0-71.1 11.7-14.4% MA F 1000 uL 0.3-0.82 0.32-0.8 K/uL MPV fL 9.4-12.3 NR 2. Staff interview with the technical consultant (TC) on 3/29/2024 at 12:30 PM confirmed the above findings. 3. The laboratory performs 12,457 tests annually in the speciality of Hematology.

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), the TC failed to evaluate and document the performance of testing personnel (TP) responsible for moderate complexity testing at least semiannually during the first year the individual tested patient specimens. Findings Include: 1.

Record review on 3/29/2024 of the laboratory's CMS 209 form signed by the laboratory director on 3/8/2024 revealed 2 new TP. 2. Record review on 3/29/2024 of the laboratory's 2022, 2023, and 2024 to date personnel competency records revealed, a. One of two new TP did not have documented competency using the required 6 elements twice during the first year of patient testing. b. TP2 only had one documented competency assessment in the first year of patient testing using all 6 required elements. TP2's competency records also contained a written quiz and a blank competency sheet. 3. Staff interview with the TC on 3/29/2024 at 12:30 PM confirmed the above findings. *This is a repeat deficiency*