

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473055	(X3) Date Survey Completed 01/19/2022
Name of Provider or Supplier Family Medicine Associates	Street Address, City, State 3100 S Elm Place, Suite A, Broken Arrow, OK	
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	The recertification survey was performed on 01/19/2022 and 01/20/2022. The findings were reviewed with the laboratory supervisor at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory supervisor, the laboratory director or designee and testing person failed to sign proficiency testing attestation statements for two of 21 events. Findings include: (1) The surveyor reviewed 2020 and 2021 proficiency testing records and identified the following for two of 13 events: (a) Third Microbiology Event - The attestation statement had not been signed by the laboratory director or designee and by the person performing the test; (b) Third Hematology Event - The attestation statement had not been signed by the laboratory director or designee. (2) The surveyor reviewed the findings with the laboratory supervisor. The laboratory supervisor stated to the surveyor on 01/19/2022 at 11:30 am, the attestation statements had not been signed by the laboratory director or designee and the person performing the test as shown above.</p>

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory supervisor, the laboratory failed to review and evaluate proficiency testing results for four of 21 events. Findings include: FAILURE (1) On 01/19/2022, the surveyor reviewed 2020 and 2021 proficiency testing records and identified the following failure: (a) Third 2020 Chemistry Event (i) Sodium - The laboratory failed the results for 1 of 5 samples (CH-15) (2) The surveyor could not locate evidence in the records proving the failure had been addressed; (3) The surveyor reviewed the records with the laboratory supervisor, and asked if corrective action had been taken and documented for the failure. The laboratory supervisor stated on 01/19/2022 at 11:22 am corrective action had not been taken. BIASES (1) On 01/19/2022, the surveyor reviewed 2020 and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) 2020 Second Chemistry Core Event (i) Cholesterol, HDL (High-Density Lipoprotein) - five of five results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.2 (bb) Sample CH-07 - SDI of 2.6 (cc) Sample CH-08 - SDI of 2.7 (dd) Sample CH-09 - SDI of 2.8 (ee) Sample CH-10 - SDI of 2.2 (ii) CO₂ - five of five results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.0 (bb) Sample CH-07 - SDI of 2.6 (cc) Sample CH-08 - SDI of 3.0 (dd) Sample CH-09 - SDI of 3.3 (ee) Sample CH-10 - SDI of 2.5 (b) 2020 Third Chemistry Event (i) Cholesterol, HDL - three of five results exhibited a positive bias (aa) Sample CH-11 - SDI of 2.5 (bb) Sample CH-13 - SDI of 2.5 (cc) Sample CH-14 - SDI of 2.2 (c) 2021 Second Chemistry Event (i) CO₂ - three of five results exhibited a positive bias (aa) Sample CH-06 - SDI of 2.3 (bb) Sample CH-07 - SDI of 2.3 (cc) Sample CH-10 - SDI of 2.0 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory supervisor. The laboratory supervisor stated on 01/19/2022 at 11:20 am the biases had not been addressed.