

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  37D0471718	<b>(X3) Date Survey Completed</b>  08/26/2021
<b>Name of Provider or Supplier</b>  Associates In Family Practice	<b>Street Address, City, State</b>  210 Sw 89th, Oklahoma City, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The recertification survey was performed on 08/26/2021. The findings were reviewed with testing person #1 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with testing person #1, the laboratory failed to retain records for at least 2 years for 1 of 18 months. Findings include: (1) On 08/26/2021 at 10:20 am, testing person #1 stated the following to the surveyor: (a) Routine CBC (Complete Blood Count) testing was performed on the Beckman Coulter AcT Diff 2 analyzer; (b) Three levels of Coulter 4C-ES QC (quality control) materials were stored in the laboratory refrigerator; (2) The surveyor reviewed laboratory refrigerator temperatures from January 2020 through June 2021 with the following identified: (a) Records between 10/31/2020 and 12/02/2020 were not available (3) The surveyor asked testing person #1 if the records between 10/31/2020 and 12/02/2020 could be located; (4) Testing person #1 stated on 08/26/2021 at 02:10 pm the records between 10/31/2020 and 12/02/2020 for the laboratory refrigerator could not be located. The surveyor could not determine if the temperatures had been monitored for 1 of 18 months.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing</p>

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 testing person #1, the laboratory failed to review and evaluate proficiency testing results for 2 of 10 events. Findings include: FAILURES (1) On 08/26/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records and identified the following failures: (a) Third 2020 Hematology Event (FH2-C) (i) Blood Cell Identification - The laboratory failed the results for 1 of 5 samples (BCP-23); (2) The surveyor could not locate evidence in the records proving the failure had been addressed; (3) The surveyor reviewed the records with testing person #1, and asked if corrective action had been taken and documented for the failure. Testing person #1 stated on 08/26/2021 at 01:03 pm corrective action had not been taken. BIASES (1) On 08/26/2021, the surveyor reviewed 2019, 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) Third 2019 Hematology Event (FH2-C) (i) MCV (Mean Corpuscular Volume) - 3 of 5 results exhibited a negative bias (aa) Sample FH2-13- SDI of -2.2 (bb) Sample FH2-14 - SDI of -2.6 (cc) Sample FH2-15- SDI of -3.0 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with testing person #1. The laboratory manager stated on 08/26/2021 at 12:50 pm the biases had not been addressed.

**D5215**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on a review of records and interview with testing person #1, the laboratory failed to verify the accuracy of testing when the proficiency testing program did not evaluate submitted results for 1 of 10 events. Findings include: (1) On 08/26/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records and identified the following had not been evaluated by the proficiency testing program: (a) Hematology (i) 2021 Second Event (FH2-B) - Red Blood Cell Identification sample BCP-13 (2) The surveyor further reviewed the records and could not locate documentation verifying the laboratory had performed a self-evaluation of the non-graded result; (3) The surveyor asked testing person #1 if the result had been documented as evaluated. Testing Person #1 reviewed the records and stated on 08/26/2021 at 01:06 pm the non-graded result had not been documented as reviewed.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions, and interview with testing person #1, the laboratory failed to ensure materials were stored as required by the manufacturer for 5 of 6 months. Findings include: (1) On 08/26/2021 at 10:20 am, testing person #1 stated the following to the surveyor: (a) Blood collection tubes were stored in the laboratory and used for the following: (i) Routine CBC (Complete Blood Count) testing performed on the Beckman Coulter AcT Diff 2 analyzer. (2) The surveyor reviewed the manufacturer's environmental requirements for the blood collection tubes, which required a room temperature 4-25 degrees C (Celsius) or 39.2-77 degrees F (Fahrenheit). The following were examples of blood collection tubes stored in the rooms: (i) Vacutte Tubes K2 EDTA (50 tubes of lot# 5072). (3) The surveyor reviewed laboratory temperature records from January 2020 through June 2020 and identified the following for 5 months of 6 months: (a) Temperatures documented warmer than 4-25 degrees C or 39.2-77 degrees F (i) January 2020 - 10 of 22 days temperature was documented at 78 degrees F (days 13,14,16,17,21,22,23,27,28,29); (ii) March 2020 - 7 of 21 days temperature was documented at 78 degrees F (days 2,3,6,17,18,19,30); (iii) April 2020 - 5 of 22 days temperature was documented at 78 degrees F (days 10,24, 27,29,30); (iv) May 2020 - 6 of 20 days temperature was documented at 78 degrees F (days 4,5,6,7,8,11); (v) June 2020 - 4 of 19 days temperature was documented at 78 degrees F (days 10,12,15,18) (4) The surveyor reviewed the records with the testing person #1. Testing person #1 stated on 08/26/2021 at 02:12 pm the laboratory failed to ensure materials were stored as required by the manufacturer as indicated above.