

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D0471718	<b>(X3) Date Survey Completed</b> 05/15/2025
<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 05/15/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the testing person at the conclusion of the survey.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, observation, and interview with the testing person, the laboratory failed to follow the manufacturer's instructions for expiration dates for four of four waived testing materials. Findings include: I. LIQUID URINE CONTROLS (1) On 05/15/2025 at 09:45 am, observation of the laboratory refrigerator contents identified the following expired materials which appeared to be available for use: (a) One bottle of Consult Diagnostics Liquid urine control Level 1, lot #230321022, manufacturer's expiration date 03/20/2025; (b) One bottle of Consult Diagnostics Liquid urine control Level 2, lot #230316019, manufacturer's expiration date 03/15/2025. (2) The findings were reviewed with the testing person, who stated on 05/15/2025 at 10:00 am the test materials had expired and were available for use. II. HEMOGLOBIN A1C CONTROLS (1) On 05/15/2025 at 09:45 am, an observation of the laboratory refrigerator contents on 05/15/2025 at 09:30 am, identified the following: (a) One bottle of Affinion HbA1c level 1 Control, lot #92964408, with an opened date of 02/13/2025; (b) One bottle of Affinion HbA1c level 2 Control, lot #72964410, with an opened date of 02/13/2025. (2) A review of the manufacturer's package inserts for the QC materials under the heading "Open control vials" stated, "Opened controls vials are stable for 60 days when stored refrigerated 2-8 degree Centigrade (36-46 degrees Fahrenheit." (3) The findings were discussed with the</p>

testing person who stated on 05/15/2025 at 09:50 am, the expired HbA1c controls were available for use beyond the modified expiration date.

**D5211**

**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 testing person, the laboratory failed to review and evaluate proficiency testing results for one of four Hematology Proficiency testing events reviewed in 2024 and 2025. Findings include: (1) A review of Hematology Proficiency testing records for four events (First 2024, Second 2024, Third 2024, and First 2025) identified the following failure with no evidence that a corrective action had been documented as performed: (a) First 2025 Event - The laboratory attained a score of 80% for Hematocrit (Sample FH2-02). (2) Interview with the testing person on 05/15/2025 at 12:32 am confirmed a corrective action had not been taken and documented for the failure.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(b)

(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 the testing person, the laboratory failed to ensure the room temperature, relative humidity, and refrigerator temperatures had been documented as observed during the review period of August 2024 through April 2025. Findings include: I. RT (ROOM TEMPERATURE) AND RH (RELATIVE HUMIDITY): (1) On 05/15/2025 at 08:55 am the testing person stated the laboratory performed CBC (Complete Blood Count) using the Medonic M-Series analyzer; (2) A review of the operator manual titled, "Medonic M-series User's Manual" under Section 2: Installation/Operating Environment required an operating temperature range of 64 to 90 degrees F (Fahrenheit) and a maximum of 80% RH; (3) A review of the "Daily Log" from August 2024 through April 2025 identified RT and RH readings had not been recorded as follows: (a) Room Temperature: (i) August 2024 - three of 31 days (days 9, 23, 30) (ii) September 2024 - three of 30 days (days 2, 6, 17) (iii) October 2024 - four of 31 days (days 3, 4, 18, 25) (iv) November 2024 - four of 30 days (days 1, 8, 15, 28) (v) December 2024 - one of 31 days (day 6) (vi) January 2025 - five of 31 days (days 2, 3, 10, 27, 31) (vii) February 2025 - three of 28 days (days 7, 21, 28) (viii) March 2025 - three of 31 days (days 7, 21, 28) (ix) April 2025 - two of 30 days (days 4, 18) (b) Relative Humidity: (i) August 2024 - three of 31 days (days 9, 23, 30) (ii)

September 2024 - three of 30 days (days 2, 6, 17) (iii) October 2024 - four of 31 days (days 3, 4, 18, 25) (iv) November 2024 - four of 30 days (days 1, 8, 15, 28) (v) December 2024 - one of 31 days (day 6) (vi) January 2025 - five of 31 days (days 2, 3, 10, 27, 31) (vii) February 2025 - three of 28 days (days 7, 21, 28) (viii) March 2025 - three of 31 days (days 7, 21, 28) (ix) April 2025 - two of 30 days (days 4, 18) (4) The records were reviewed with the testing person who stated on 05/15/2025 at 04:26 pm, the RT and RH readings had not been documented as stated above. II. REFRIGERATOR TEMPERATURE: (1) Observation of the laboratory on 05/15/2025 at 08:55 am, identified three bottles of Boule Con-Diff quality control materials (lot #22503-01, lot #22503-02, and lot #22503-01) stored in the refrigerator with a manufacturer's storage requirement of 2-8 degrees Centigrade (C); (2) A review of temperature logs for four months showed the temperature had not been documented as follows: (a) August 2024 - three of 31 days (days 9, 23, 30) (b) September 2024 - three of 30 days (days 2, 6, 17) (c) October 2024 - four of 31 days (days 3, 4, 18, 25) (d) November 2024 - four of 30 days (days 1, 8, 15, 28) (e) December 2024 - one of 31 days (day 6, 2024) (f) January 2025 - five of 31 days (days 2, 3, 10, 27, 31) (g) February 2025 - three of 28 days (days 7, 21, 28) (i) March 2025 - three of 31 days (days 7, 21, 28) (h) April 2025 - two of 30 days (days 4, 18) (3) Interview with the testing person 05/15/2025 at 04:20 pm confirmed the temperatures had not been documented as performed as stated above.

**D5469**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10) (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the testing person, the laboratory failed to verify the stated value of control materials before they were put into use for eight of 12 lot numbers. Findings include: (1) On 05/15/2025 at 08:55 am testing person stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Medonic M-Series analyzer; (b) Three levels of QC (quality control) materials were tested each day of patient testing. (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records for 12 control lot numbers identified no evidence the provided ranges were verified before the lot numbers were put into use for eight of 12 lot numbers as follows: (a) Low control lot #2240831 and Normal control lot #2240832 put into use on 10/15/2024; (b) Low control lot #2241131, Normal control lot #2241132, and High control lot #2241133 put into use on 03/11/2025; (c) Low control lot #2250301, Normal control lot #2250302, and High control lot #2250303 put into use on 04/15/2025 and currently in use. (3) The findings were reviewed with the testing person who stated on 05/15/2025 at 12:15 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use.

**D6018****LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the testing person, the laboratory director failed to ensure proficiency testing reports received were reviewed for two of seven events reviewed in 2024 and 2025. Findings include: (1) A review of 2024 and 2025 proficiency testing events identified the "Original Evaluation" form included a space for the laboratory director or designee's signature and date (indicating a review of the laboratory's performance). The following were identified for two of seven events: (a) First 2025 Hematology Auto Differential Event (FH2-A-2025) - There was no evidence the evaluation form had been signed and dated as reviewed by the laboratory director or designee; (b) First 2025 Clinical Microscopy (CMA-A-2025) - There was no evidence the evaluation form had been signed and dated as reviewed by the laboratory director or designee. (2) The records were reviewed with the testing person who stated on 05/15/2025 at 12:32 pm, the evaluation forms had not been signed and dated as reviewed.