Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471718	08/30/2023
Name of Provider or Supplier	**Street Address, City, State**	
Associates In Family Practice	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 08/30/2023. 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.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation, review of written policy, and interview with the testing person, the laboratory failed to follow it's policy to ensure positive identification for ten of 19 patients for CBC testing on the Medonic M analyzer. Findings include: (1) On 08/30 /2023 at 11:15 am, the testing person stated CBC testing was performed in the laboratory on the Medonic M analyzer; (2) On 08/30/2023 at 11:15 am, observation of the Hematology area of the laboratory identified ten of 19 tubes labeled with a first initial and last name; (3) A review of policy identified the following: (a) The policy titled, "Blood Specimen Collection using Venipuncture" stated " All blood tubes should be labeled with the patient's full name or other unique identifier"; (4) Interview with the testing person on 08/30/2023 at 11:15 am confirmed 10 of 19 EDTA tubes were not labeled according to the laboratory policy.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory failed to ensure control materials were not used beyond the expiration date for one of six lot numbers reviewed. Findings include: (1) On 08/30/2023 at 09:25 am, the 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. (2) A review of QC records for six lot numbers of QC materials used from 06/13/2023 through the day of the survey identified a control material had been used beyond the manufacturer's expiration date for one of nine lot numbers reviewed as follows: (a) High control lot #22302-33 - Used from 06/13/2023 through 07/17/2023; the manufacturer's expiration date was 07/14/2023. (3) The records showed a patient CBC had been reported on 07 /17/2023 when the laboratory had used expired level three QC material to assess the acceptable performance of the analyzer; (4) The findings were reviewed with the testing person who stated on 08/30/2023 at 12:20 pm, the control had been used beyond the expiration date. 48517 Based on observation and interview with testing person #1, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the storage room 08/30/2023 at 09:30 am, identified the following expired collection tubes that appeared to be available for use: (a) 12 Vacuette K2EDTA tubes - lot #454209 with an expiration date of 07/01/2023. (2) Interview with testing person #1 08/30/2023 at 09:30 am confirmed the Vacuette K2EDTA tubes were available for use.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory failed to ensure the reportable range had been utilized for one of four analytes reviewed. Findings include: (1) On 08/30/2023 at 10:45 am, the testing person stated, a new Medonic M-Series hematology analyzer was put into use to perform patient CBC (Complete Blood Count) testing in November of 2021; (2) A review of performance specification records identified the reportable range had been demonstrated as follows: (a) Platelet - 9-892(x10^9/L) (3) A review of the manufacturer's document titled, "QuestQuanum" under the section 11.3 titled, "Parameter Ranges" defined the reportable range as follows: (a) Platelet - 30-1800 (x10^9/L) (4) Interview with the testing person on 08/30/2023 at 10:45 am, confirmed the laboratory was using the manufacturer's reportable ranges instead of the reportable range that had been demonstrated by the laboratory.

D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. 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 manufacturer's instructions were followed for performing maintenance procedures during the review period of June 2022 through June 2023. Findings include: (1) On 08/30/2023 at 11:15 am, the testing person stated CBC (Complete Blood Count) testing was performed using the Medonic M analyzer; (2) A review of the manufacturer's maintenance log showed the following required monthly maintenance procedures: (a) "Monthly Cleaning (Hypochlorite)" (b) "Clot Prevention (enzymatic)" (3) A review of maintenance logs from June 2022 through June 2023 identified no documentation monthly maintenance had been performed between: (a) 06/27/2022 and 08/30/2022 (b) 09/30/2022 and 11/18/2022 (c) 12/28/2022 and 03/01/2023 (d) 04/28/2023 and 07/18/2023 (e) 03/17/2023 and 04 /03/2023 (4) The records were reviewed with the testing person who stated on 08/30 /2023 at 11:15 am, monthly maintenance had not been documented as performed as shown above.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory failed to have control procedures that monitored the accuracy and precision of the complete analytic process for nine of nine months reviewed for testing performed using the Medonic M-series Hematology analyzer. Findings include: (1) On 08/30 /2023 at 09:25 am, the 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. (2) A review of records from November 2022 through July 2023 identified no evidence, such as Levey-Jennings graphs and cumulative statistical data, to prove that QC results had been monitored for variances (i.e.,biases, shifts, trends); (3) Interview with the testing person on 08/30/2023 at 11:35 am confirmed that QC data to include Levey-Jennings graphs and cumulative statistical data had not been printed and reviewed during the review period.

D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (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. (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. (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. (g) The laboratory must document all control procedures performed. 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 six of six lot numbers. Findings include: (1) On 08/30/2023 at 09:25 am, the 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 six control lot numbers identified no evidence the provided ranges were verified before the lot numbers were put into use for six of six lot numbers as follows: (a) Low control lot #22302-31, Normal control lot #22302-32, and High control lot #22305-33 used from 06/13/2023 through 07/17/2023; (b) Low control lot #22304-31, Normal control lot #22304-32, and High control lot #22304-33 put into use on 07/18/2023 and currently in use. (3) The findings were reviewed with the testing person who stated on 08/30/2023 at 12:15 pm the manufacturer's ranges had not been verified before the above lot numbers had been put into use.
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 a review of records and interview with the testing person, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population for two of two patient reports reviewed. Findings include: (1) On 08/30/2023 at 10:50 am, the testing person stated the laboratory began using the Medonic M-Series hematology analyzer starting in November of 2021 to perform patient CBC (Complete Blood Count) testing; (2) On 08/30/2023 two patient CBC reports were reviewed - the first report was for an adult male patient with the testing performed on 04/28/2023; the second report was for an adult female patient with the testing performed on 04/03/2023. Both reports included the same reference intervals for the following CBC parameters: (a) RBC (red blood cell) count - 3.5-5.5(x10^12);

	(b) Hemoglobin - 11.5-16.5 g/dL; (c) Hematocrit - 35-55%. (3) The reports were reviewed with the testing person who stated on 08/30/2023 at 11:23 am, the patient reports did not include gender specific reference ranges for RBC, Hemoglobin, and Hematocrit.