Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0471718	06/11/2019
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 06/11/19. 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.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the laboratory director and/or testing person failed to sign proficiency testing attestation statements. Findings include: (1) During the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following for 2 of 7 events: (a) FH2-B 2018 Hematology Event - The attestation statement had not been signed by the laboratory director and testing person; (b) CM-A 2019 Clinical Microscopy Event - The attestation statement had not been signed by the laboratory director. (2) The surveyor reviewed the findings with the testing person who stated the attestations had not been signed as indicated above.
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. Findings include: (1) During the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following failures and biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2018 Clinical Microscopy Event (CM-B) (i) Urine Sediment ID - The laboratory failed the result for 1 of 3 samples (USP-06). (b) Second 2018 Hematology Event (FH2-B) (i) MCV (Mean Corpuscular Volume) - The laboratory failed the results for 3 of 5 samples. In addition, 5 of 5 results exhibited a positive bias: (aa) FH2-11 - SDI of 3.1 (bb) FH2-12 - SDI of 2.3 (cc) FH2-13 - SDI of 3.7 (this resulted in a failure) (dd) FH2-14 - SDI of 3.2 (this resulted in a failure) (ee) FH2-15 - SDI of 3.8 (this resulted in a failure) (2) The records were then reviewed further by the surveyor. There was no evidence corrective action had been taken for the failures and that the biases had been identified and addressed; (3) The surveyor reviewed the records with the testing person, and asked if corrective action had been taken and documented for the failures and if the biases had been identified and addressed. The testing person stated corrective action had not been taken and the biases had not been addressed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the testing person, the laboratory failed to have complete written policies and procedures. Findings include: (1) At the beginning of the survey, the testing person stated to the surveyor CBC (Complete Blood Count) testing was performed using the Beckman Coulter AcT Diff2 analyzer; (2) The surveyor reviewed CBC policies and procedures

	contained in the "Laboratory Procedure Manual". The following could not be located: (a) Calibration Procedures (including the frequency for performing calibrations on the analyzer); (b) Reportable Range for test results as established or verified in 493.1253; (c) Control Procedures (e.g., number and frequency of testing, how to verify new lot numbers of quality control materials, criteria to determine acceptable control results); (d) Corrective Action to take when calibration or control results fail to meet the laboratory's criteria for acceptability; (e) Reference Intervals (normal values); (f) Imminently life-threatening test results, or panic or alert values; (g) The laboratory's system for entering the results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values; (h) Description of the course of action to take if the test system becomes inoperable. (3) The surveyor reviewed the findings with the testing person, and asked if the above procedures were available. The testing person stated the procedures had not been written.
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, observation, and interview with the testing person, the laboratory failed to use materials that had not expired. Findings include: (1) At the beginning of the survey, the testing person verified to the surveyor manual differential testing was performed in the laboratory; (2) The surveyor observed the bottle of Wright's stain stored in the cabinet under the laboratory sink, and identified Healthlink QuickLink Wright's Stain, lot #8095, with an expiration date of 03/12/19; (3) The surveyor showed the bottle of Wright's stain to the testing person and asked if it was currently being used for patient testing. The testing person stated the stain was currently in use and was not aware it had expired; (4) The surveyor reviewed patient testing records and identified patient manual differential testing had been performed using the expired stain on 03/28,29/19; 04/01,04,23,30/19; 05/01,13,16,22, 30/19.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the testing person, the laboratory failed to follow their written protocol for ensuring the urine centrifuge was functioning properly. Findings include: (1) At the beginning of the

	survey, the testing person stated to the surveyor urine sediment examinations were performed in the laboratory. The specimens were processed in the Henry Schein Power Spin LX centrifuge at a speed of 2000 rpm for 5 minutes; (2) The surveyor reviewed the policy titled "Instrument Calibration and Maintenance". It stated, "The urine centrifuge speed and accuracy of the timer will be checked twice yearly by the testing personnel"; (3) The surveyor reviewed the centrifuge maintenance records. The records verified the laboratory purchased the centrifuge and checked the speed and timer on 09/18/17, prior to putting into use for patient testing on 09/25/17. There was no documentation the speed and timer checks had been performed twice annually since 09/18/17; (4) The surveyor reviewed the findings with the testing person who stated the centrifuge speed and timer had not been checked since 09/18/17.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that 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; 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 were reviewed. Findings include: (1) During the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. The Oringinal Evaluations included a space for the laboratory director signature and date (indicating review of the graded evaluation). 7 of 7 events reviewed had not been signed and dated as reviewed by the laboratory director: (a) First 2018 Clinical Microscopy Event (CM-A) (b) First 2018 Hematology Event (FH2-A) (c) Second 2018 Clinical Microscopy Event (CM-B) (d) Second 2018 Hematology Event (FH2-B) (e) Third 2018 Hematology Event (FH2-C) (f) First 2019 Clinical Microscopy Event (CM-A) (g) First 2019 Hematology Event (FH2-A) (2) The surveyor reviewed the records with the testing person who stated, the graded evaluations as indicated above, had not been signed and dated as reviewed by the laboratory director.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the testing person, the technical consultant failed to evaluate the testing person performing moderate complexity testing at least annually. Findings include: (1) During the survey, the surveyor reviewed personnel records for the testing person, who had been performing moderate complexity testing during 2017, 2018, and to date in 2019. There was no evidence the

	testing person had annual evaluations between 08/19/16 and 06/10/19; (2) The surveyor reviewed the findings with the testing person who stated evaluations had not been performed between 08/19/16 and 06/10/19.