Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1035842	03/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Upc Medpointe Family Medicine	469 Emily Drive, Clarksburg, WV	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with the technical consultant, the laboratory failed to rotate proficiency testing samples among all testing personnel. Findings: 1. Review of the 2018 proficiency testing records in the binder labeled "American Proficiency Institute" demonstrated that the three testing events for 2018 were completed by only two of the eight employed testing personnel. Events 1 and 3 were completed by Testing Personnel 1 (TP1), while event 2 was completed by Testing Personnel 2 (TP2). 2. Interview with technical consultant on 3/25/2019 at approximately 1:10PM confirmed the findings.
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 review of the laboratory's records and interview with the technical consultant, a procedure for storage of specimens analyzed for complete blood counts (CBCs) could not be found. Findings: 1. Review of the binder titled "Laboratory Safety Manual and Policy and Procedure Manual" found that no procedure was included for storage of CBC patient samples after analysis. There was also no instruction for sample storage in the instrument procedure, titled "Beckman Coulter AcT Diff", located in the same manual. 2. Interview with the technical consultant on 3/25.2019 at approximately 2:10PM confirmed that a procedure could not be found.
D5789	TEST RECORDS CFR(s): 493.1283(b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on interview with the technical consultant, instrument printouts from the Beckman Coulter AcT Diff instrument are not retained as required. Findings: 1. Interview with the technical consultant on 3/25/2019 at approximately 1:35PM found that instrument printouts are not retained. The printouts are scanned into the patients' charts and then shredded.
D6053	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 semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, the technical consultant failed to evaluate and document semiannual personnel competency for three of eight employees during their first year of testing. Findings: 1. Review of personnel binders for TP5 and TP6 found that no initial competency assessment had been completed. Both employees had previously been employed, terminated employment, and had been rehired. Initial competency assessments could not be found for either after their rehire. 2. Review of the personnel binder for TP8 found that a 6-month competency assessment had not been completed.