Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1035842	04/05/2021
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
D0000	An announced, on site, recertification survey was conducted at UPC Medpointe Family Medicine on April 5, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on a review of the laboratory proficiency testing (PT) records and an interview with the laboratory manager, the laboratory failed to successfully participate in 1 of 3 PT events for Hematology in 2019. Findings: 1. Review of the laboratory American Proficiency Institute (API) PT records identified an unsatisfactory performance of 0% for the 1st API testing event of 2019 in Hematology. 2. During an interview with the laboratory manager, on 4-5-2021 at approximately 1:30 pm, the laboratory manager confirmed the findings.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of laboratory quality assessment (QA) records, written policies and procedures (P&P), and an interview with the laboratory director, the laboratory failed to perform and document the monthly quality assessment checklists for 12 of 12 months in 2020 and 4 of 4 months in 2021. Findings: 1. Review of the laboratory manual revealed a Quality Assessment P&P that states "once a month, complete the Monthly QA Checklist, including the chart review portion." 2. Review of QA records identified no Monthly QA Checklist forms documented for 2020 and 2021. 3. An exit interview with the laboratory director, on 4-5-2021 at approximately 1:30 PM, confirmed the findings.