Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D1035842	10/24/2024
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 unannounced, onsite, focused complaint survey was conducted at UPC Medpointe Family Medicine on October 24, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed and the complaint was found to be Substantiated. The laboratory was determined to be out of compliance with the following Conditions of the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493: 42 CFR 493.801 Proficiency Testing, Enrollment and Testing of Samples 42 CFR 493.1403 Laboratory Director, Moderate Complexity
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and staff interview, the laboratory failed to enroll in an approved proficiency testing (PT) program for Hematology in 2024. Findings: 1. Review of the CMS 155D report for the laboratory's PT revealed no enrollment for the specialty of Hematology in the 1st and 2nd testing events of 2024. 2. An interview with testing personnel (TP1), 10/24/24 at 12:15 PM, TP1 stated the laboratory had not enrolled in PT due to a "miscommunication" and contacted the PT provider by phone on 10/23/24. 3. An exit interview with TP1 and the office manager, 10/24/24 at 1:20 PM, confirmed the laboratory had not enrolled in PT for hematology testing in 2024.

D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of the CMS ASPEN system information for current laboratory personnel of record, lack of documentation, and interviews, the facility failed to ensure a current, qualified laboratory director (LD) was in place for the operation and oversight of the laboratory's moderate complexity hematology testing from June 2024 to the date of survey (10/24/24). Findings: 1. The State survey team arrived at UPC Medpointe Family Medicine on 10/24/2024 at 11:00 AM to conduct an onsite complaint survey. Surveyors provided identification, stated the purpose of the visit, and requested to speak with the laboratory director on record in the CMS ASPEN system. The receptionist stated the laboratory director had "left months ago". Surveyors then requested to speak to management. During an interview on 10/24/24 at 11:13 AM, the office manager stated that the LD had left months ago but was "still the lab director". 2. A phone interview was initiated with the hospital CEO, 10/24/24 at 11:22 AM. During interview, the CEO stated the LD had left but remained on the lab's CLIA certificate and that the LD "had not been here or employed by us for a while". The CEO stated no documentation could be provided to show the LD of record was fulfilling the required responsibilities from June 2024 through date of survey (10/24 /24). 3. A phone interview 10/24/24 at 1:00 PM, was conducted with the LD of record (CMS ASPEN system) for UPC Medpointe Family Medicine. The LD of record confirmed departure from the facility in May of 2024 and had not overseen or reviewed "anything since June 2024" for the laboratory. 4. An exit interview with the office manager and testing personnel (TP1), 10/24/24 at 1:20 PM, confirmed the position of laboratory director had not been filled since the LD of record left the facility in May of 2024.