Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	51D0941532	11/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Beckley Area Medical Clinic	1842 Harper Road, Beckley, 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, routine recertification survey was conducted at Beckley Area Medical Clinic on November 29, 2022, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to ensure that laboratory testing personnel signed the attestation statements for two of two proficiency testing (PT) events in 2021. Findings: 1. Review of College of American Pathologists (CAP) PT records revealed the two 2021 testing events had no attestation statements signed by the laboratory director and testing personnel. 2. An exit interview with the laboratory director, 11/29/22 at approximately 12:35 PM, confirmed the 2021 PT events had no signed attestation statements.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: Based on written policies and procedures (P&P), record review, lack of documentation, and interview the laboratory failed to ensure the post-analytical quality assurance (QA) was documented for 9 of 12 months in 2021 and 10 of 11 months in 2022. Findings: 1. Review of P&P identified a daily Post Analytical Procedure for Checking Data Entry and a Monthly QA Review that reviews 5 random patient samples from specimen collection to release of patient test results. 2. Review of QA records revealed a lack of documentation for the daily and monthly post analytical QA for 9 of 12 months in 2021: 4/21, 5/21, 6/21, 7/21, 8/21, 9/21, 10/21, 11 /21, and 12/21. 3. Review of QA records revealed a lack of documentation for the daily and monthly post analytical QA for 10 of 11 months in 2022: 1/22, 2/22, 3/22, 4 /22, 5/22, 6/22, 7/22, 8/22, 9/22, and 10/22. 4. An exit interview with the laboratory director, 11/29/22 at approximately 12:35 PM, confirmed the findings.