

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2153215	(X3) Date Survey Completed 12/14/2022
Name of Provider or Supplier Wvu Medicine - Weston	Street Address, City, State 107 Staunton Dr, Weston, 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 WVU Medicine Weston on December 14, 2022, 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.
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to retain a signed attestation statement by the person performing the testing and the laboratory director (LD) for 6 of 6 2021 proficiency testing (PT) events and 4 of 4 2022 PT events. Findings: 1. Review of American Proficiency Institute (API) PT records identified attestation statements not signed by the person performing the test and the laboratory director for 2021 Chemistry Core 1st, 2nd, and 3rd Events; 2021 Hematology 1st, 2nd, and 3rd Events; 2022 Chemistry Core 1st and 2nd Events; 2022 Hematology 1st</p>

and 2nd Events. 2. An interview with the laboratory manager, 12/14/22 at approximately 9:00 AM, confirmed the attestation statements did not have the required signatures.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on record review, lack of documentation, and interview the laboratory failed to establish and follow an effective procedure or policy for the continuous review and documentation of the assessment and evaluation of the quality control (QC) process to detect any outliers, shifts or trends in control values due to instrument malfunctions or changes in the analytical system. Findings: 1. Review of 2022 QC records identified a daily review of hematology QC values. No documentation demonstrating the cumulative review of QC data could be located. 2. An exit interview with the laboratory manager, 12/14/22 at approximately 11:15 AM, confirmed the findings.