

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D2119195	(X3) Date Survey Completed 01/05/2021
Name of Provider or Supplier Dr Brandon Lingenfelter	Street Address, City, State 411 12th Street Ext, Princeton, 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 Dr Brandon Lingenfelter on January 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.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based upon a review of the laboratory current test menu, proficiency testing (PT) records, and an interview with the technical consultant (TC), the laboratory failed to enroll the qualitative serum Human Chorionic gonadotropin (HCG) testing, listed in Subpart I, in an HHS approved proficiency testing program. Findings: 1. A comparative review of the laboratory test menu and the enrolled analytes in American Association of Bioanalysts (AAB), the laboratory chosen PT program for proficiency testing, identified no enrollment for qualitative serum HCG testing in 2019 and 2020. A review of the test menu identified the laboratory performs qualitative HCG testing on serum with the McKesson Consult testing kits. 2. A review of 2019 and 2020 American Association of Bioanalysts (AAB) PT records identified no record of PT results for the analyte HCG qualitative serum testing. 3. During an interview with the</p>

TC, on 1/5/2021 at approximately 11:45 AM, the TC stated that the serum qualitative HCG testing was not enrolled in PT and would be fixed immediately.