

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0669427	(X3) Date Survey Completed 03/29/2022
Name of Provider or Supplier Muhammed I Khokar Md	Street Address, City, State 608 New Hope Road Suite 3, 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, routine recertification survey was conducted at Muhammed I Khokar MD on March 29, 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.
D5431	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document a passing background check on the Act Diff 2 Hematology analyzer for 25 of 33 days reviewed (January 2022 thru the date of survey). Findings: 1. Review of background checks from January 2022 thru date of survey identified 25 of 33 days with a failing parameter documented and patient testing conducted. 2. An interview with the laboratory director, on 3/29/22 at approximately 10:45 AM, confirmed the findings.</p>
D5481	<p>CONTROL PROCEDURES CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:

Based on policies and procedures (P&P), record review, and interview the laboratory failed to ensure the Hematology quality control (QC) met the established criteria of acceptability for 22 of 33 days reviewed on the Act Diff 2. Findings: 1. Review of P&P identified a "Quality Control Procedure" allowing patient specimens to be ran if two of the three QC levels are within the acceptable ranges. 2. Review of QC records from January 2022 thru date of survey identified 22 of 33 days that unacceptable QC values were accepted for two or more levels and patient testing conducted. 2. An interview with the laboratory director, 3/29/22 at approximately 11:30 AM, confirmed the findings.