

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0235365	<b>(X3) Date Survey Completed</b> 01/31/2024
<b>Name of Provider or Supplier</b> Access Health Rural Acres Clinic	<b>Street Address, City, State</b> 228 Mellon Street, Beckley, WV	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A routine recertification survey was conducted at Access Health Rural Acres Clinic on January 31, 2024, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of written policies and procedures, lack of documentation, and interview the laboratory failed to establish the (5) calibration verification procedure</p>

on the Abbott Alinity chemistry analyzer for 26 of 26 analytes used in patient testing. Findings: 1. Review of P&P revealed no established policy for the performance and evaluation of calibration verification for 26 of 26 chemistry analytes. 2. An interview with the technical consultant (TC), 1/31/24 at 10:45 AM, confirmed no documentation of the process to perform and evaluate the calibration verification of the chemistry analytes could be located. 3. An exit interview with the TC, 1/31/24 at 12:50 PM, confirmed the findings.