

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 51D0694471	<b>(X3) Date Survey Completed</b> 09/09/2020
<b>Name of Provider or Supplier</b> Cabin Creek Health Center	<b>Street Address, City, State</b> 5722 Cabin Creek Road, Dawes, 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>	An announced, on site, recertification survey was conducted at Cabin Creek Health Center on September 9, 2020, 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.
<b>D5203</b>	<p><b>SPECIMEN IDENTIFICATION AND INTEGRITY</b> CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory written policies and procedures (P&amp;P) and an interview with the testing personnel (TP) and laboratory director (LD), the laboratory failed to establish a written P&amp;P for the positive identification of patients and patient's specimens through specimen collection, labeling, accessioning, processing, testing, and reporting of results. Findings: 1. A review of written P&amp;P could not locate a process for the positive identification of patients from specimen collection through reporting of patient results. 2. During interviews with TP1 and TP2, on 9/9/2020 at approximately 10:00 AM, they both explained the laboratory process for the positive identification of patient samples from specimen collection through reporting results. 3. During an interview with the LD, on 9/9/2020 at approximately 10:10 AM, the LD stated that no written P&amp;P could be located.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</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.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory written policies and procedures (P&P) and an interview with the testing personnel (TP) and the laboratory director (LD), the laboratory failed to include (1) criteria for specimen acceptability and rejection in the written processes of the laboratory. Findings: 1. A review of the laboratory P&P could not locate a specified criteria for the acceptability or rejection of a patient specimen. 2. During an interview with TP1 and TP2, on 9/9/2020 at approximately 10:00 AM, TP1 and TP2 explained cases where the patient specimen would not meet acceptability criteria and the corrective action that would be taken. 3. During an interview with the LD, on 9/9/2020 at approximately 10:10 AM, the LD stated that the criteria for specimen and acceptability could not be located.