

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  51D2007163	<b>(X3) Date Survey Completed</b>  07/30/2024
<b>Name of Provider or Supplier</b>  Greenbrier Day Report Center	<b>Street Address, City, State</b>  147 Main Street, Ronceverte, 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 performed at Greenbrier Day Report Center on July 30, 2024, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with the Federal Clinical Laboratory Improvement Amendments (CLIA) regulations under 42 CFR 493. Specific deficiencies cited are explained below.
<b>D3033</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)(i)</p> <p>In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to retain the signed review and approval for the verification of the performance specifications for two of 13 analytes validated on the Thermo Scientific Indiko Plus analyzer in December 2022. Findings: 1. Review of the December 2022 toxicology verification records revealed no documentation for the review and approval of the performance specifications for heroin metabolite (6AM) and Oxycodone testing on the Indiko Plus. 2. Review of patient toxicology test results (July 2024) from the Thermo Scientific Indiko Plus identified 6AM and Oxycodone qualitative results released. 3. An interview with the testing personnel (TP1) and the laboratory director (LD), 7/30/24 at 9:10 AM, confirmed the lack of documentation retention for the review and approval of the performance specifications for the two analytes. 4. An exit interview with the LD and TP1, 7/30/24 at 11:30 AM, confirmed the findings.</p>