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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 51D2007155 | (X3) Date Survey Completed 06/26/2024 |
| Name of Provider or Supplier Wv Drug Testing Laboratories | Street Address, City, State 1531 Garfield Avenue, Parkersburg, 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 |
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| D0000 | A routine recertification survey was conducted at WV Drug Testing Laboratories on June 26, 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 are explained below. |
| D3033 | <p>RETENTION REQUIREMENTS 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 establishment of the performance specifications for 3 of 3 analytes validated on the Thermo Transcend II LX-2 TSQ Quantis LC-MS analyzer in January 2024. Findings: 1. Review of the January 2024 toxicology validation records revealed no documentation for the review and approval of the performance specifications established in January 2024 for Carfentanil, Acetylfentanyl, and Xylazine testing on the Thermo Transcend II LX-2 TSQ Quantis. 2. Review of patient toxicology test results from the Thermo Transcend II LX-2 TSQ Quantis (May 2024) identified Carfentanil, Acetylfentanyl, and Xylazine quantitative results released. 3. An interview with the general supervisor and technical supervisor, 6/26/24 at 3:00 PM, confirmed the lack of documentation retention for the review and approval of the established performance specifications for the 3 analytes.</p> |