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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>51D0898048 | <b>(X3) Date Survey Completed</b><br><br>09/16/2026 |
| <b>Name of Provider or Supplier</b><br><br>Central Labs Inc                                                                | <b>Street Address, City, State</b><br><br>97 Main Avenue, Pineville, 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 Central Labs Inc. on September 16, 2026, by the West Virginia Office of Laboratory Services. The laboratory was assessed for compliance with 42 CFR 493, Requirements for Laboratories with the following deficiencies cited.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| D5779              | <p>CORRECTIVE ACTIONS<br/>CFR(s): 493.1282(a)</p> <p>(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on review of complete blood count with differential (CBC/Diff) patient reports, the Medonic M-Series analyzer Instructions for use (IFU), interview with testing personnel (TP1), and interview with the laboratory director (LD), the laboratory failed to document the corrective actions (CA) taken for 33 of 75 CBC/Diffs released for patients on 9/11/26 and 9/15/26. Findings: 1. Review of 75 CBC/Diff reports from the Medonic analyzer (9/11/26 and 9/15/26) revealed 33 reports released had a "HL" error flag indicator for the hemoglobin parameter and no corrective action documented. 9/11/26: 00177788, 00177792, 00177806, 00177811, 00177798, 00177794, 00177780 9/15/26: 00177896, 00177878, 00177867, 00177866, 00177873, 00177851, 00177875, 00177882, 00177883, 00177892, 00177886, 00177880, 00177889, 00177854, 00177861, 00177863, 00177856, 00177884, 00177868, 00177858, 00177860, 00177893, 00177885, 00177898, 00177894, 00177856 2. Review of the procedure for CBC/Diff testing (Medonic M-Series IFU) identified section 9.2 System Information Messages stating the "HL" error flag indicates a hemoglobin measuring problem and to run the prime cycle on the analyzer before rerunning the sample. 3. During an interview, on 9/16/26 at 11:00 AM, TP1 verified the 33 hemoglobin results released with a "HL" error indicator flag had no corrective action documented. 4. An exit</p> |

interview with the LD, 9/16/26 at 12:00 PM, verified the lack of CA for the 33 hemoglobin results released with "HL" error indicator flags.