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| <b>Statement of Deficiencies</b>                                                                                           | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>18D0031474        | <b>(X3) Date Survey Completed</b><br><br>07/24/2026 |
| <b>Name of Provider or Supplier</b><br><br>Caldwell Medical Center                                                         | <b>Street Address, City, State</b><br><br>100 Medical Center Drive, Princeton, KY |                                                     |
| 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 recertification survey was initiated on 07/23/2026 and concluded on 07/24/2026. The facility was found to not be in compliance with the laboratory requirements of 42 CFR Part 493 with standard deficiencies cited.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| D2014              | <p>TESTING OF PROFICIENCY TESTING SAMPLES</p> <p>(b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by:<br/>Citation 2014 Based on review of American Proficiency Institute (API) events for years 2024 and 2025, review of Laboratory Policy/API directions, and confirmed in staff interview, the laboratory failed to have director/designee signed attestation forms for 12 of 20 events. Findings include: Review of the laboratory API proficiency testing events revealed the following: a. 2024 Hematology/Coagulation 3rd Event - No Laboratory director/designee signature b. 2024 Immunology/Immunohematology 3rd Event - No Laboratory director/designee signature c. 2024 Microbiology 3rd Event- No Laboratory director/designee signature d. 2025 Chemistry Core 2nd Event- No Laboratory director/designee signature e. 2025 Chemistry Core 3rd Event - No Laboratory director/designee signature f. 2025 Immunology/Immunohematology 1st Event - No Laboratory director/designee signature g. 2025 Immunology /Immunohematology 2nd Event - No Laboratory director/designee signature h.2025 Immunology/Immunohematology 3rd Event - No Laboratory director/designee signature i. 2025 Microbiology 3rd Event - No Laboratory director/designee signature</p> |

j. 2025 Hematology/Coagulation 1st Event - No Laboratory director/designee signature  
k. 2025 Hematology/Coagulation 2nd Event-No Laboratory director/designee signature  
l. Chemistry Miscellaneous 2nd Event - No Laboratory director/designee signature  
Review of Caldwell Medical Center Clinical Laboratory General Manual (director signature review 12/13/2023) titled "Proficiency Testing Protocol" stated: "Directions received from the testing agency with the PT samples will be strictly followed." "Each person performing testing will sign and date the attestation statement." Review of American Proficiency Institute (API) directions stated: "SIGNATURES REQUIRED: For all PT results, an attestation statement must be signed by testing personnel and the laboratory director (or designee) and retained for a minimum of 2 years. An attestation statement can be found either online or in your worksheet packet." In an interview on 07/24/2026 at 12:30 PM in the conference room near the laboratory, the Technical Supervisor (TS) was asked if the attestation forms were signed for the PT events. The TS confirmed the attestation results were not signed for the PT events. This confirmed the findings.