| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 52D0395481 | 12/09/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Aspirus Medford Hospital | 135 S Gibson St, Medford, WI | |

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** | Based on desk review of 2025 proficiency testing (PT) records and an initial on-site survey, the laboratory failed to meet the following conditions, resulting in initial unsuccessful PT participation: D2016 - 42 C.F.R. 493.803 Condition: Successful Participation [proficiency testing] D6076 - 42 C.F.R. 493.1441 Condition: Laboratories Performing High Complexity Testing; Laboratory Director |
| **D2016** | SUCCESSFUL PARTICIPATION<br>CFR(s): 493.803(a)(b)(c)<br><br>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of records from the Certification and Survey Provider Enhanced Reporting (CASPER) reports and American Proficiency Institute (API) proficiency testing (PT) records, and interview with the Laboratory Manager (Staff |

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| | A), the laboratory failed to successfully participate in a proficiency testing program approved by HHS, for each analyte or test in which the laboratory is certified under CLIA. The laboratory failed to successfully participate in compatibility testing in the specialty of immunohematology. Refer to D2181. |
| **D2181** | COMPATIBILITY TESTING<br>CFR(s): 493.863(e)<br><br>(e) Failure to achieve an overall testing event score of satisfactory for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor review of a Certification and Survey Provider Enhanced Reporting (CASPER) report and American Proficiency Institute (API) 2025 proficiency testing records and interview with the Laboratory Manager (Staff A), the laboratory failed to achieve satisfactory performance (100%) for compatibility testing (analyte #0895) in two of two consecutive testing events in the specialty of Immunohematology. Findings included: 1. Review of the CASPER 0155D report, "Individual Laboratory Profile", for this laboratory revealed the following results: Compatibility Testing 2025 first event: The laboratory received an unsatisfactory score of 80% for compatibility testing. Compatibility Testing 2025 second event: The laboratory received an unsatisfactory score of 0% for compatibility testing. 2. Review of the API "Performance Summary" reports for the 2025 Immunology / Immunohematology 1st and 2nd events confirmed the laboratory received the above results. 3. Interview with Staff A on December 9, 2025, at 11:15 AM confirmed the laboratory did not successfully participate in proficiency testing for compatibility testing. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor review of a Certification and Survey Provider Enhanced Reporting (CASPER) report and American Proficiency Institute (API) 2025 records, and interview with the Laboratory Manager (Staff A), the Laboratory Director failed to provide overall management and direction of the laboratory services. The Laboratory Director failed to ensure proficiency testing samples were tested and reported as required. Refer to D6089. |
| **D6089** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(4)(i)<br><br>(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on review of proficiency testing (PT) records from a Certification and Survey Provider Enhanced Reporting (CASPER) report and American Proficiency Institute records from 2025, the laboratory director failed to ensure successful participation for compatibility testing in an HHS approved proficiency testing program. Findings include: 1. Review of the CASPER 0155D report, "Individual Laboratory Profile", for this laboratory revealed the following results: Compatibility Testing 2025 first event: The laboratory received an unsatisfactory score of 80% for compatibility testing. Compatibility Testing 2025 second event: The laboratory received an unsatisfactory score of 0% for compatibility testing. 2. Review of the API "Performance Summary" reports for the 2025 Immunology / Immunohematology 1st and 2nd events confirmed the laboratory received the above results. 3. Interview with Staff A on December 9, 2025, at 11:15 AM confirmed the laboratory director did not ensure successful participation in PT for compatibility testing in 2025. |