

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D0661966	<b>(X3) Date Survey Completed</b>  04/26/2024
<b>Name of Provider or Supplier</b>  Memorial Hospital Of Lafayette County	<b>Street Address, City, State</b>  800 Clay St, Darlington, WI	
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>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(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.</p> <p>This CONDITION is not met as evidenced by: Based on off-site desktop review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) and Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records, and interview with laboratory staff, the laboratory failed to successfully obtain an overall 100% satisfactory testing event score in PT for the Rh(D) analyte in the subspecialty of ABO Group/Rh Type within the specialty of Immunohematology for two out of two consecutive events for 2023-3 and 2024-1 (refer to D2162); and failed to successfully obtain an overall 100% satisfactory testing event score for the subspecialty of ABO Group/Rh Type within the specialty of Immunohematology for two out of two</p>

	<p>consecutive events for 2023-3 and 2024-1(refer to D2163) resulting in unsuccessful PT performance.</p>
<b>D2162</b>	<p><b>ABO GROUP AND D(RHO) TYPING</b> CFR(s): 493.859(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on off-site desktop proficiency testing review of the federal Certification and Survey Provider Enhanced Reports (CASPER) proficiency testing reports and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, and interview with laboratory staff, the laboratory failed to obtain an overall 100% satisfactory PT scores for two out of two consecutive events for the Rh(D) analyte in the ABO Group/Rh Type subspecialty within the Immunohematology specialty in events 2023-3 and 2024-1 which resulted in unsuccessful PT performance. Findings include: 1. Review of PT records in the federal CASPER reporting system on April 26, 2024 showed the laboratory had unsatisfactory performance for Rh(D) testing for PT events 2023-3 and 2024-1. Event 2023-3, score 80% Event 2024-1, score 80% 2. Desktop review of WSLH PT evaluation reports and phone interview with the laboratory director (Staff A) and laboratory manager (Staff B) on April 26, 2024 at 1: 30 PM, confirmed the unsatisfactory scores for Rh(D) testing for two consecutive PT events which results in unsuccessful performance in PT for Rh(D) testing.</p>
<b>D2163</b>	<p><b>ABO GROUP AND D(RHO) TYPING</b> CFR(s): 493.859(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on off-site desktop proficiency testing review of the federal Certification and Survey Provider Enhanced Reports (CASPER) proficiency testing reports and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records, and interview with laboratory staff, the laboratory failed to successfully obtain 100% satisfactory PT scores for two out of two consecutive events for the ABO Group/Rh Type subspecialty within the Immunohematology specialty in events 2023-3 and 2024-1 which resulted in unsuccessful PT performance. Findings include: 1. Review of PT records in the federal CASPER reporting system on April 26, 2024 showed the laboratory had unsatisfactory performance for ABO Group/Rh Type testing for PT events 2023-3 and 2024-1. Event 2023-3, score 90% Event 2024-1, score 90% 2. Desktop review of the WSLH PT evaluation reports, and phone interview with the laboratory director (Staff A) and laboratory manager (Staff B), on April 26, 2024 at 1: 30 PM, confirmed the unsatisfactory scores for two consecutive PT events which results in unsuccessful PT performance in the subspecialty of ABO Group/Rh Type within the Immunohematology specialty.</p>
<b>D6076</b>	<b>LABORATORY DIRECTOR</b>

CFR(s): 493.1441

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.

This CONDITION is not met as evidenced by:

Based on off-site desktop review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) and Wisconsin State Laboratory of Hygiene (WSLH) Proficiency Testing (PT) records, the laboratory failed to obtain satisfactory PT scores for the Rh(D) analyte in the subspecialty of ABO Group/Rh Type within the specialty of Immunohematology for two out of two consecutive events for 2023-3 and 2024-1; and failed to successfully obtain satisfactory testing event scores for the subspecialty of ABO Group/Rh Type within the specialty of Immunohematology for two out of two consecutive events for 2023-3 and 2024-1 which resulted in unsuccessful PT performance. The laboratory director did not ensure the laboratory did not fail two consecutive PT events. (Refer to D6092).

**D6092**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on off-site desktop review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) reports and Wisconsin State Laboratory of Hygiene (WSLH) PT records, the laboratory had two out of two consecutive unsatisfactory PT scores for events 2023-3 and 2024-1, for Rh(D) analyte and ABO Type/Rh Group in the Specialty of Immunohematology which resulted in overall unsuccessful PT performance for two consecutive PT events. Findings include: 1. Off-site desktop proficiency testing review on April 26, 2024, of the federal Certification and Survey Provider Enhanced Reports (CASPER) proficiency testing reports and Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing (PT) records showed the laboratory failed to successfully perform in PT for two out of two consecutive events (2023-3 and 2024-1) for the Rh(D) analyte in the ABO Group/Rh Type subspecialty within the Immunohematology specialty (Refer to D2162); and failed to successfully perform in PT for the same two consecutive events for the ABO Group/Rh Type subspecialty of Immunohematology (Refer to D2163). 2. The laboratory director did not ensure that acceptable corrective action was effective in preventing consecutive unsatisfactory PT performance in the Immunohematology subspecialty of ABO Group/Rh Type and the Rh(D) analyte (Refer to D2162 and D2163).