

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0721195	(X3) Date Survey Completed 09/04/2024
Name of Provider or Supplier Lakeview Specialty Hospital & Rehab	Street Address, City, State 1701 Sharp Rd, Waterford, 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
D2016	<p>SUCCESSFUL PARTICIPATION 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 proficiency testing desk review of the federal Certification and Survey Provider Enhanced Reports (CASPER) 0153D and 0155D Proficiency Testing (PT) and graded copies of American Proficiency Institute (API) 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 Activated Partial Thromboplastin Time (aPTT) analyte (0835) in the specialty of Hematology for two out of three events for 2023-3 and 2024-2 (refer to D2130) resulting in unsuccessful PT performance. This deficiency (D2016) was previously cited on January 10, 2022.</p>

<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing desk review of the federal Certification and Survey Provider Enhanced Reports (CASPER) 0153D and 0155D proficiency testing reports and graded copies of American Proficiency Institute (API) proficiency testing (PT) records, and interview with laboratory staff, the laboratory failed to obtain an overall 100% satisfactory PT scores for two out of three events for the Activated Partial Thromboplastin Time (aPTT) analyte (0835) in the Hematology Specialty in events 2023-3 and 2024-2 which resulted in unsuccessful PT performance. Findings include: 1. Review of PT records in the federal CASPER reporting system and the 0153D and 0155D reports on September 3, 2024 showed the laboratory had unsatisfactory performance for aPTT testing for PT events 2023-3 and 2024-2. Event 2023-3, score 0% Event 2024-2, score 60% 2. Desktop review of graded copies of API PT evaluation reports and phone interview with laboratory personnel (Staff A) September 4, 2024 at 2:00 PM, confirmed the unsatisfactory scores for aPTT testing for two out of three PT events which results in unsuccessful performance in PT for aPTT testing.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on proficiency testing desk review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) and graded copies of American Proficiency Institute(API) Proficiency Testing (PT) records, the laboratory failed to obtain satisfactory PT scores for the Activated Partial Thromboplastin Time (aPTT) analyte (0835) in the specialty of Hematology for two out of three events for 2023-3 and 2024-2 which resulted in unsuccessful PT performance. The laboratory director did not ensure the laboratory did not fail two out of three PT events. (Refer to D6019).</p>
<p>D6019</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on proficiency testing desk review of the federal Certification and Survey Provider Enhanced Reports (CASPER) Proficiency Testing (PT) 0153D and 0155D reports and graded copies of American Proficiency Testing (API) PT records, the laboratory had two out of three unsatisfactory PT scores for events 2023-3 and 2024-2, for the Activated Partial Thromboplastin Time (aPTT) analyte (0835) in the specialty of Hematology which resulted in overall unsuccessful PT performance for two out of three PT events. Findings include: 1. Desk review of proficiency testing records on September 3, 2024, of the federal Certification and Survey Provider Enhanced Reports (CASPER) 0153D and 0155D proficiency testing reports and API proficiency testing (PT) records showed the laboratory failed to successfully perform in PT for two out of three events (2023-3 and 2024-2) for the aPTT analyte in the Hematology specialty (Refer to D2130). 2. Phone interview with laboratory personnel (Staff A) September 4, 2024 at 2:00 PM, confirmed the unsatisfactory scores for aPTT testing for two out of three PT events which results in unsuccessful performance in PT for aPTT testing. The laboratory director did not ensure that acceptable corrective action was effective in preventing unsatisfactory PT performance for aPTT testing in the specialty of Hematology.