

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2308470	(X3) Date Survey Completed 06/04/2025
Name of Provider or Supplier University Of Michigan Health - West	Street Address, City, State 4285 Parkway Place Sw, Grandville, MI	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs Technician (MT), the laboratory failed to perform establishment and verification of performance specifications for histopathology testing for 5 (January 2025 to June 2025) of 5 months. Findings include: 1. A record review of the laboratory quality control and maintenance records revealed a lack of documentation for establishment and verification of performance specifications for histopathology tissue examination. 2. An interview with the MT on 06/04/2025 at 11:30 am confirmed that the establishment of verification of performance specifications had not been conducted.</p>