

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0693572	(X3) Date Survey Completed 02/03/2021
Name of Provider or Supplier Lakeshore Medical Clinic, Llc D/B/A Aurora Health	Street Address, City, State 2000 E Layton Ave Ste 120, Saint Francis, 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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 surveyor review of laboratory records and interview with the technical consultant, the laboratory director did not review the performance specification verification records on the replacement Sysmex Pochi hematology analyzer prior to reporting patient results. Findings include: 1. Review of the "Replacement Pochi Validation Review" form showed the laboratory installed a replacement Sysmex Pochi analyzer on November 5, 2020 and started reporting patients on November 6, 2020. Further review showed the laboratory director reviewed and accepted the validation on November 16, 2020. 2. Interview with the technical consultant, staff A, on February 3, 2021 at 11:10 AM confirmed the laboratory director did not review and accept the validation for the replacement Sysmex Pochi hematology analyzer prior to reporting patient results.</p>