

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2182699	(X3) Date Survey Completed 01/19/2023
Name of Provider or Supplier Accelerated Clinical Laboratories, Llc	Street Address, City, State 10101 W Innovation Dr Suite 600, Wauwatosa, 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 a technical supervisor, staff A, the laboratory did not evaluate the performance specifications for the Clinitek Advantus urinalysis analyzer. Findings include: 1. Review of laboratory records showed no evaluation of the performance for the Clinitek Advantus urinalysis analyzer. 2. Interview with staff A on January 19, 2023, at 11:40 AM confirmed the laboratory did not evaluate the performance specifications for the Clinitek Advantus urinalysis analyzer.</p>