

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2238490	(X3) Date Survey Completed 08/31/2022
Name of Provider or Supplier Solutions Lab & Healthcare Services, Llc	Street Address, City, State 1714 Gilsinn Dr, Fenton, MO	
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 review of Arkray urinalysis analyzer, Iris IQ200 Elite analyzer, Siemens Atellica CH analyzer, Siemens Atellica IM analyzer, Sysmex XN2000 analyzer, Miniised, Sysmex CA600 analyzer verification of performance specifications and interview with the technical supervisor (TS) #4, the laboratory failed to verify performance specifications before reporting patient test results. Findings: 1. Review of Arkray urinalysis, Iris IQ200 Elite, Siemens Atellica CH, Siemens Atellica IM, Sysmex XN2000, Miniised, Sysmex CA600 analyzer verification of performance specifications showed the laboratory failed to verify the manufacturer's reference intervals (normal values). 2. Review of Sysmex CA600 showed the laboratory failed to verify reportable range of test results for the test system. 3. Interview with TS #4 on August 31, 2022 at 9:30 AM confirmed the laboratory failed to verify performance specifications before reporting patient test results.</p>