

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 30D2149259	(X3) Date Survey Completed 03/31/2022
Name of Provider or Supplier Elliot Urgent Care Lab At Bedford	Street Address, City, State 25 Leavy Dr, Bedford, NH	
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 record review and staff interview, the laboratory failed to verify performance specifications for the hematology analyzer after receiving the instrument from the manufacturer for service repairs in November 2021. Findings include: 1. Review on 3/31/2022 of service records for the POCH-100i hematology analyzer revealed the instrument was serviced at the manufacturer and shipped back to the laboratory on 11/3/2021. 2. Review on 3/31/2022 of calibration records for the POCH-100i hematology analyzer revealed the laboratory performed a 1 point calibration upon receiving the instrument back from the manufacturer. There were no records that the laboratory verified accuracy, precision and reportable range after receiving the instrument back from the manufacturer. 3. Interview with the Technical Consultants on 3/31/2022 at 10:00 a.m. confirmed the laboratory did not verify performance specifications for accuracy, precision and reportable range after receiving the instrument back from the manufacturer. The Technical Consultants revealed that instrument was down from 10/18/2021 to 11/5/2021. The laboratory performs 1,100 complete blood counts on the POCH-100i analyzer annually.</p>