

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D2067362	(X3) Date Survey Completed 03/16/2022
Name of Provider or Supplier Corelab Diagnostics	Street Address, City, State 10854 Midwest Industrial Blvd, Saint Louis, 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 the performance verification procedures for the Sysmex XN-350 hematology analyzers, Alcor Scientific mini-iSED analyzer and interview with the laboratory director (LD), the laboratory failed to verify performance specifications prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Sysmex XN-350 hematology analyzers showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, white blood cell (WBC) and differential prior to the beginning of patient testing in January 2022. 2. Review of patient results from January 2022 to date March 16, 2022 showed 511 complete blood count (CBC) patient results were reported. 3. Review of the performance specifications for the Alcor Scientific mini-iSED analyzer showed the laboratory failed to verify that the manufacturer's reference intervals (normal ranges) were appropriate for the laboratory's patient population for the analyte: erythrocyte sedimentation rate (ESR) prior to the beginning of patient testing in January 2022. 4. Review of patient results from January 2022 to date March 16, 2022 showed 7 ESR patient results were</p>

reported. 5. Interview with the LD on March 16, 2022 at 10:00 AM confirmed the laboratory failed to verify performance specifications prior to reporting patient test results.