

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 26D0438768	(X3) Date Survey Completed 12/08/2020
Name of Provider or Supplier Carestl Health	Street Address, City, State 5471 Dr Martin Luther Dr, 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 lack of verification of performance specifications for the Sysmex Hematology Analyzer, Clinitek Advantis Urine Analyzer, review of patient testing records for 2020 and interview with the technical supervisor (TS), the laboratory failed to verify manufacturer performance specifications for accuracy, precision, reportable range of test results and reference intervals (normal values) for the laboratory's patient population before reporting patient results. Findings: 1. The lack of verification of performance specifications for the Sysmex hematology analyzer for white blood cells, red blood cells, hemoglobin, hematocrit, platelets and WBC auto differential showed the laboratory failed to obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable range, and verifying the reportable range of test results. 2. The lack of verification of performance specifications for the Advantis urine analyzer for glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, and leucocytes, showed the laboratory failed to obtain performance specifications comparable to those established by the manufacturer for accuracy, precision, reportable range, and verifying the reportable range of test results. 3. Review of patient testing records for 2020 showed, 3,591 Sysmex Hematology patient results were reported since May of 2020 and 516 Clinitek Advantis Urine patient results were</p>

reported since October 2020. 4. Interview with the TS on December 08, 2020 at 10:30 AM confirmed the laboratory failed to ensure the verification of performance specifications were completed for the Sysmex Hematology Analyzer and the Advantis Clinitek Urinalysis Analyzer before reporting patient results.

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on the lack of verification performance procedures, 148 total patient results reported in 2020 and interview with technical supervisor (TS), the laboratory failed to establish test system performance characteristics for a non-FDA cleared /approved Confirm Biosciences Covid -19 IgG IgM Rapid Test Cassette before reporting patient results in 2020. Findings: 1. No documentation was available to show the laboratory established performance specifications for accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range for test results of the test system and reference intervals (normal patient values) for the Confirm Biosciences Covid-19 IgG IgM Rapid Test Cassette test system. 2. Review of patient records showed the laboratory performed 148 Confirm Biosciences Covid-19 IgG IgM Rapid tests since beginning Covid testing in 2020. 3. Interview on December 08, 2020 at 10:30 AM, with the TS confirmed the laboratory failed to establish performance specifications for The Confirm Biosciences Covid-19 IgG IgM Rapid Test before reporting patient results.