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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 26D0447998 | (X3) Date Survey Completed 06/09/2021 |
| Name of Provider or Supplier Ferrell-Duncan Clinic | Street Address, City, State 1001 E Primrose, Springfield, 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 Sysmex XN2000 hematology analyzers performance specifications and interview with the technical supervisor #1, the laboratory failed to ensure verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population. Findings: 1. Review of the Sysmex XN2000 hematology analyzers performance specifications showed no verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population for the analytes: white blood cell, red blood cell, hemoglobin, hematocrit and platelets since the start of patient testing in July 2020. 2. Interview with the TS #1 on June 9, 2021 at 11:00 AM confirmed the laboratory failed to ensure verification of the manufacturer's reference intervals (normal values) are appropriate for the laboratory's population.</p> |