

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0448356	(X3) Date Survey Completed 12/18/2019
Name of Provider or Supplier Free State Family Medicine	Street Address, City, State 1220 Biltmore Drive, Lawrence, KS	
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 performance verification documentation for the ABX Micros 60 analyzer and interview, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population. Findings: 1. Review of the verification documentation of the ABX Micros 60 analyzer, S/N 810CS98340, installed April 8, 2019, for the analytes: White Bloodcell Differential, Red Bloodcell Count, Hemoglobin, Hematocrit, White Bloodcell Count, and Platelet testing showed no verification of normal values. 2. Interview with test personnel (TP) #1 on December 18, 2019 at 10:30 a.m. confirmed, the laboratory failed to verify the reference intervals (normal values) were appropriate for the laboratory's patient population.</p>
D5433	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system</p>

performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on the lack of documentation, and interview, the laboratory failed to establish a maintenance protocol and perform maintenance on their microscope. Findings: 1. Request was made to review the microscope maintenance protocol and records. No documentation was available at the time of survey. 2. Interview with the TP #1 on December 18, 2019 at 11:15 a.m. confirmed, the laboratory failed to establish a maintenance protocol and perform maintenance on their microscope.