Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 26D2267404	**(X3) Date Survey Completed** 06/13/2023
Name of Provider or Supplier Empowerme Diagnostics - Kansas City	**Street Address, City, State** 9001 State Line Rd, Suite 110, Kansas City, 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	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) 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. This STANDARD is not met as evidenced by: Based on review of the performance verification procedures for the Sysmex XN2000 hematology analyzer, Sysmex CA-6000 coagulation analyzer, and Siemens Atellica chemistry analyzer and interview with the technical supervisor (TS), the laboratory failed to verify the manufacturer's reference intervals (normal ranges) prior to reporting patient test results. Findings: 1. Review of the performance specifications for the Sysmex XN2000 hematology 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 analytes: red blood cell (RBC), hemoglobin, hematocrit, platelet, and white blood cell (WBC) prior to the beginning of patient testing. 2. Review of the performance specifications for the Sysmex CA-6000 coagulation 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 analytes, Protime, fibrinogen, and d-dimer. 3. Review of the performance specifications for the Siemens Atellica chemistry 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 following analytes: sodium, potassium, chloride, carbon dioxide, calcium, BUN, creatinine, glucose, total protein, albumin, total bilirubin, alkaline phosphatase, AST, ALT, cholesterol,

	triglyceride, HDL, valproic acid, magnesium, phosphorous, BNP, vitamin D 25, TSH, vitamin B12, free T4, free T3, hsCRP, folate, iron, transferrin, vancomycin, ferritin, and hemoglobin A1C. 4. Interview with the TS on June 13, 2023 at 12:00 PM confirmed the laboratory failed to verify the manufacturer's reference intervals prior to reporting patient test results.