Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2142555	**(X3) Date Survey Completed** 01/08/2020
Name of Provider or Supplier Alto Family Medical Clinic	**Street Address, City, State** 123 Busy Bee Street, Alto, TX	

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 laboratory performance verification documentation for the Medonics M series hematology analyzer, confirmed by staff interview, the laboratory failed to verify that the manufacturer's reference intervals were appropriate for the laboratory's patient population before reporting patient test results. Findings: 1. Method validation materials for hematology were reviewed. The instructions for the kit used included the following statement: "The laboratory medical director must examine all reference ranges provided by the manufacturer and determine if they are appropriate for the lab's patient population." (Medonic M Series Method Validation Evaluation) Also included were specific instructions and worksheets for performing the validation. The forms were unsigned and worksheets were blank. 2. In an interview at the site on 01-08-2020, the clinic executive administrator (Entrance-Exit Conference Attendance Record) confirmed that no initial reference interval verification had been performed for the instrument, which had been in service since January 2018.