Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 24D1046873	**(X3) Date Survey Completed** 08/14/2019
Name of Provider or Supplier Northfield Hospital Clinics - Lonsdale Clinic	**Street Address, City, State** 103 15th Avenue Se, Lonsdale, MN	
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 observation, document review and interview with laboratory personnel, the laboratory failed to demonstrate one of two new analyzers could obtain all performance characteristics comparable to those established by the manufacturer prior to testing patient specimens. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant during a tour of the laboratory on 08/14/19, at 10:10 a.m. 2. An Abbott Cell-Dyn Emerald hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began testing patient specimens using this analyzer in April 2019 per laboratory personnel. 3. Documents found in the Cell-Dyn Emerald Correlation Study manual indicated accuracy and precision performance verification activities were completed in March 2019. The Laboratory Director approved the results on 03/26/19. 4. Reportable range verification documents were not found in the Cell-Dyn Emerald Correlation Study manual. The laboratory was unable to provide reportable range verification documents upon request. 5. In an interview on 08/14/19 at 10:50 a.m., the Laboratory Director confirmed the above finding.