Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1061073	11/15/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northfield Hospital & Clinics - Farmington Clinic	4645 Knutsen Drive, Farmington, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to properly enroll in five challenges per proficiency testing event as required under 493.801 for regulated analyte testing performed under the subspecialty of Routine Chemistry. Findings are as follows: 1. The laboratory performed chemistry testing using a Chem8+ cartridge on the Abbott iSTAT as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:10 a.m. on 11/15/22. 2. An Abbott iSTAT analyzer was observed as present and available for use during the tour of the laboratory. 3. The American Proficiency Institute 2021 Chemistry-Core 1st, 2nd and 3rd events and 2022 Chemistry-Core 1st and 2nd events were reviewed the day of survey. The records indicated the laboratory was enrolled in 3 testing events annually with 2 challenges per event for the regulated Routine Chemistry analytes tested using the iSTAT Chem8+ cartridge. 4. In an interview at 1:00 p.m. on 11/15/22, the TC and Laboratory Director confirmed the above findings. .
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 review and evaluate data obtained during the single performance verification (PV) activity completed in 2021 for a Hematology analyte. In addition, the laboratory failed to adopt the analyte's reportable range obtained during the PV and failed to verify the analyte's reference interval (normal range) appropriate for the laboratory's patient population. Findings are as follows: 1. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing under the specialty of Hematology as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:10 a.m. on 11/15/22. 2. An ALCOR Scientific miniiSED ESR analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began performing ESR testing on this analyzer in August 2021. 3. PV activities on the ALCOR Scientific miniiSED analyzer were completed in August 2021 as indicated in laboratory records found with the miniiSED manual. Laboratory records included raw data for the following: *Method comparison between the miniiSED and a reference laboratory *Method comparison between the miniiSED and the old method, the Excyte analyzer. *Quality control testing with positive and negative control material performed over 30 days. An evaluation of the raw data to determine accuracy, precision, and reportable range was not found. The laboratory was unable to provide the evaluation upon request. 4. The ESR reportable range adopted by the laboratory did not reflect the actual reportable range values obtained by the laboratory during the PV as indicated in the PV documents and the Erythrocyte Sedimentation Rate (ESR) using the ALCOR Scientific miniiSED procedure located in the MiniiSED manual. The reportable range value found in the procedure was the analytical measuring range provided by the manufacturer. See below. Analyte PV Procedure ESR 1-67 mm/hr 1-130 mm/hr 5. ESR normal range verification documentation was not found in laboratory records. The laboratory was unable to provide this information upon request 6. In an interview at 12:55 p.m. on 11/15/22, the TC confirmed the above findings. .