Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D1061073	(X3) Date Survey Completed 12/15/2020
Name of Provider or Supplier Northfield Hospital & Clinics - Farmington Clinic	**Street Address, City, State** 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
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 ensure the reportable range obtained during performance verification for two of eight new Chemistry analytes was adopted by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 12/15/20, at 10:05 a.m. 2. An Abbott i-STAT chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. Performance verification (PV) activities for the i-STAT were completed and approved by the Laboratory Director (LD) on 04/17/20. The laboratory began testing patient specimens using this analyzer on 04/20/20 as indicated by the TC. 3. The lower limit of the reportable ranges for Blood Urea Nitrogen (BUN) and Creatinine (Crea) found in the I-STAT Daily Operation procedure located in the Clinical Laboratory Policy and Procedure Manual did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Analyte PV Procedure BUN 5-118 3-60 Crea 0.3-17.9 0.2-5.0 4. Laboratory records provided by the LD on date of survey indicated 8 BUN patient results and 3 Crea patient results that were below the obtained reportable ranges for the analytes were reported between 04/20/20 and date of survey, 12/15/20. 5. In an interview at 1:50 p.m. on 12/15/20, the TC confirmed the above finding and indicated

	the laboratory had not updated the procedure or the electronic health record software Meditech with the reportable ranges obtained during the PV.