Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D2245814	(X3) Date Survey Completed 01/09/2024
Name of Provider or Supplier Northfield Hospital Clinics - Northfield Urgent	**Street Address, City, State** 2014 Jefferson Road, Suite C, Northfield, 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
D0000	The Northfield Hospital + Clinics - Northfield Urgent Care laboratory was found to be out of compliance with the regulations of the Clinical Laboratory Improvement Amendments of 1988 (42 C.F.R. part 493) upon completion of the recertification survey performed on January 9, 2024. The following standard-level deficiencies were cited: 493.1105 Retention Requirements 493.1253 Establishment and Verification of Performance Specifications 493.1256 Control Procedures .
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review, observation, and an interview with laboratory personnel, the laboratory failed to retain all analytic records of activities as specified in 493.1256 (e)(2), specifically records of lot numbers and expiration dates of the stains used by the laboratory each day of use from September 2022 through January 2024. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the Technical Consultant (TC) during a tour of the laboratory at 9:40 a.m. on January 9, 2024. 2. The VOLU-SOL Stat Stains and Nikon Eclipse SI microscope used to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. A patient who had a manual blood smear performed on November 17, 2023 (MRN XXX170) was reviewed on the day of survey. Records of the lot numbers and expiration dates of the staining material used could not be found. The laboratory was unable to provide the records at request. 4. In an interview at 11:38 a.m. on January 9, 2024, the TC confirmed the lot numbers and expiration dates of the staining material were not documented by the laboratory. .

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 performance verification (PV) activies completed in 2023 for eight Chemistry analytes. In addition, the laboratory failed to verify each analyte's reference interval (normal ranges) appropriate for the laboratory's patient population. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 9:35 a.m. on January 9, 2024. 2. An i-STAT Chemistry analyzer was observed as present and available for use during the tour of the laboratory. The laboratory began performing patient testing on the Chemistry analyzer, utilizing the Chem 8+ Cartridge, in January 2023 per interview with the TC during the tour of the laboratory at 9:35 a.m. on January 9, 2024. 3. PV activities on the i-STAT Chemistry analyzer were completed in January 2023, as indicated in laboratory records found within the i-STAT three ring binder. Laboratory records included raw data for the following: *Method comparison between the i-STAT and a reference laboratory *Quality control testing with positive and negative control material performed over 10 days. 4. An evaluation of the raw data to determine accuracy, precision, and reportable range for the eight Chemistry analytes were not found. The laboratory was unable to provide the evaluations upon request. 5. Evidence the laboratory had verified the reference intervals for the eight Chemistry analytes appropriate for the laboratory's patient population was not found. The laboratory was unable to provide the evaluation upon request. 6. In an interview at 12:15 p.m. on January 9, 2024, the TC confirmed the above findings. .
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to document Hematology quality control (QC) procedures performed to test VOLU-SOL stat stain for intended reactivity each day of use from September 2022 through January 2024. Findings are as follows: 1. The laboratory performed manual differential blood smear testing under the specialty of Hematology as confirmed the Technical Consultant (TC) during a tour of the laboratory at 9:40 a.

	m. on January 9, 2024. 2. The VOLU-SOL Stat Stains and Nikon Eclipse SI microscope used to perform manual blood smears were observed as present and available for use during the tour of the laboratory. 3. The Clinic Peripheral Blood Smear Preparation & Evaluation procedure, established under Quality Control section, All patient slides should be examined to ensure that the slide was properly prepared and stained. If it is determined that the slide is inadequate, a second slide will be made, stained and examined. Documentation of the acceptable staining was not established in the policy. 4. The hematology printout for patient MRN#: XXX170 who had a blood smear performed on November 17, 2023, was reviewed on the day of survey, January 9, 2024. Documentation of acceptable stain characteristics, quality control check, could not be found for the day of patient testing. 5. In an interview at 11:38 a.m. on January 9, 2024, the TC confirmed the above findings stating that the laboratory does not document the quality of the staining when performing a manual differential.