

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0667985	<b>(X3) Date Survey Completed</b>  04/04/2024
<b>Name of Provider or Supplier</b>  Northfield Hospital	<b>Street Address, City, State</b>  2000 North Avenue, Northfield, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to include accurate Hematology reference ranges in the procedure manual for five of six analytes reviewed for Complete Blood Count (CBC) testing since December 2022. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:45 a.m. on April 3, 2024. 2. A Sysmex XN-550 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Reference ranges for five of six reviewed CBC analytes were inaccurate in the</p>

Complete Blood Count of Whole Blood and Body Fluids on the Sysmex XN-550 procedure, when compared to a patient CBC test report from 02/02/2023. The procedure was signed by the Laboratory Director on 12/22/2022 and was located in the Sysmex three ring binder. The inaccurate analytes were White Blood Cells (WBC), Red Blood Cells (RBC), Hematocrit (HCT), Mean Corpuscular Volume (MCV) and Platelets (PLT). See below. Patient report from 02/02/2023 Analyte Procedure Report WBC 5.0-10.0 4.5-11.0 K/uL RBC 4.32-5.72 4.3-5.9 m/uL HCT 38.8-50 37.0-53.0% MCV 81-95 80-100 fL PLT Blank 140-440 K uL 4. In an interview at 9:55 a.m. on April 4, 2024, the General Supervisor confirmed the above finding. The GS stated the ranges on the final report were the correct ranges and those found in procedure were incorrect. .

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to perform, and document required maintenance at the frequency required for one of one Hematology analyzer since July of 2022. Findings are as follows: 1. The laboratory performed Erythrocyte Sedimentation Rate (ESR) testing which falls under the specialty of Hematology as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:45 a.m. on April 3, 2024. 2. An Excyte Mini Automated ESR analyzer was observed as present and available for use during the tour of the laboratory. 3. Maintenance requirements for the Excyte Mini Automated ESR analyzer were established in the Excyte Mini ESR Analyzer procedure, located in the ESR three ring binder. The maintenance requirements, found on page three of the procedure, were to turn the Excyte Mini off and on once each day so it can go through a self check. During the self check the instrument checks electronic parts and configurations. Maintenance requirements were also to wipe the outer surface of the Excyte Mini with a cloth moistened with disinfectant solution monthly to disinfect. 4. Documentation of the required maintenance performed on the Excyte Mini was not in laboratory documents provided when reviewing records from the third quarter of 2022. The records could not be produced when requested on April 3, 2024. 5. In an interview at 3:47 p.m. on April 3, 2024, the GS confirmed the instrument maintenance required by procedure has not and is not being documented, stating it can be added to the current quality control log that is kept. In an interview at 11:50 am on April 4, 2024, the GS stated that the analyzer produces a daily print-off that may record the daily shut down, start up, and self-check. She confirmed further this would not capture the monthly disinfection required. .

**D5445**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--  
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number

and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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 perform quality control (QC) activities as established in the i-STAT Troponin Individualized Quality Control Plan (IQCP) in 11 of 24 months reviewed in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed Troponin testing which falls under the specialty of Chemistry as confirmed by the General Supervisor (GS) during a tour of the laboratory at 9:45 a.m. on April 3, 2024. 2. An Abbott i-STAT chemistry analyzer, which the laboratory utilizes for Troponin testing, was observed as present and available for use during the tour. 3. i-STAT Troponin QC performance was required monthly in addition to with each new lot and shipment of cartridges as established in the laboratory's Quality Control Plan - i-STAT Troponin procedure, located in the i-STAT three ring binder. 4. The laboratory exceeded the monthly time interval for QC performance in 11 of 24 months reviewed, potentially affecting multiple patient test results. See below for dates of QC performance, please note the "\*" symbol indicates overdue QC performance. QC date Days elapsed 04-22-2022 N/A 05-19-2022 27 days 07-29-2022 71 days\* 09-01-2022 34 days\* 10-22-2022 51 days\* 11-18-2022 27 days 01-07-2023 50 days\* 01-25-2023 18 days 02-23-2023 29 days 03-11-2023 16 days 03-22-2023 11 days 04-19-2023 28 days 05-16-2023 27 days 07-12-2023 57 days\* 08-21-2023 40 days\* 09-22-2023 32 days\* 10-31-2023 39 days\* 12-08-2023 38 days\* 01-09-2024 32 days\* 01-17-2024 08 days 02-15-2024 29 days 03-27-2024 41 days\* 5. In an interview at 3:30 p.m. on April 3, 2024, the GS confirmed QC was only being performed when a new shipment /lot was received and not being done monthly as required in the established Quality Control Plan. .