

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0667985	(X3) Date Survey Completed 05/31/2018
Name of Provider or Supplier Northfield Hospital	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5403	<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 reference ranges in the procedure manual. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 05/30/18 at 8:05 a.m. 2. A Sysmex XT2000i Hematology Analyzer was observed as present and available for use during the tour of the laboratory. 3. The reference ranges in the Normal Values - Adult Table, located in the Lab / Hospital Lab / Hospital / Laboratory Forms on-line manual, did not reflect the reference range of values shown</p>

on a patient report (Female - 69 yrs, performed 1/4/18) reviewed on the day of the survey. See below. Analyte Patient Report Table % Neutrophils 50 - 70 42 - 70 % Lymphocytes 25 - 45 20 - 48 4. In an interview on 05/31/18 at 11:30 a.m., the GS confirmed the above finding. .

D5431

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory failed to establish function checks in procedure for all general laboratory equipment . Findings are as follows: 1. The laboratory performed Chemistry, Endocrinology, Hematology, Coagulation, Urinalysis, Immunology, Microbiology, and Immunochemistry as confirmed by the General Supervisor (GS) during a tour of the laboratory on 5/30/18 at 8:05 a.m. 2. Requirements for periodic function checks for the following laboratory equipment were not included in the Laboratory Quality Assessment - Equipment Verification procedure, located in the Lab / Hospital Lab / Hospital / Lab Procedures / Quality Control & Quality Assurance on-line manual: - Accuracy of mechanical pipettes - Air flow rate for biological safety hood - Accuracy of timers 3. In an interview on 5/30/18 at 3:50 p.m., the GS confirmed the above findings. .

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) at least once each day of patient specimen testing using Toxicology and Endocrinology test kit / systems. Findings are as follows: The laboratory performed Toxicology and Endocrinology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 05/30/18 at 8:05 a.m. A. Toxicology 1. A PROFILE-V MEDTOX Scan Drugs of Abuse Test System test system was observed as present and available for use during the tour of the laboratory. 2. GS stated external QC was performed with receipt of new lot numbers / kit shipments. 3. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC performance from each day of patient testing was not found in laboratory records. The laboratory was unable to provide an IQCP upon request. 4. In

an interview on 5/31/18 at 1:10 p.m., GS confirmed the above findings. B. Endocrinology 1. A Hologic TLIQ Fetal Fibronectin Test System test system was observed as present and available for use during the tour of the laboratory. 2. GS stated external QC was performed with receipt of new lot numbers / kit shipments. 3. An Individualized Quality Control Plan (IQCP) to reduce the frequency of QC performance from each day of patient testing was not found in laboratory records. The laboratory was unable to provide an IQCP upon request. 4. In an interview on 5/31/18 at 1:10 p.m., GS confirmed the above findings.