Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0667985	05/19/2022
Name of Provider or Supplier	**Street Address, City, State**	
Northfield Hospital	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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to verify the accuracy of one 2021 non-graded proficiency testing (PT) results for a non-regulated analyte when the PT program did not obtain the agreement required for scoring. Findings are as follows: 1. The laboratory performed Bacteriology, Mycology, and Bacteriology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 05/19/22. 2. The laboratory performed PT using the American Proficiency Institute (API) PT provider. 3. One Vaginal Wet Preparation (VWP) result from the third 2021 Hematology /Coagulation PT event was not graded by API due to lack of consensus. See below. Sample ID Analyte VKP-03 VWP 4. The API report referred the laboratory to the expected result data summary for evaluation of the non-graded test result. The data summary for the above sample was not present in laboratory records. An evaluation of the non-graded result was not found in laboratory records. The laboratory was unable to provide an evaluation of the non-graded result upon request. 5. The laboratory's Proficiency Testing Policy found in the Laboratory Standard Operating Procedures manual did not include direction to evaluate non-graded PT results. 6. In an interview at 12:20 p.m. on 05/19/22, the GS confirmed the above finding. .
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 minimum quality control activities required for a Microbiology test system. Findings are as follows: 1. The laboratory performed Microbiology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 05/19/22. 2. A Cepheid GeneXpert System was observed as present and available for use during the tour. The GS stated the SARS-CoV-2/Flu/RSV test was performed on this system. 3. Quality control (QC) testing with positive and negative control materials was required with each new lot and shipment as indicated in the SARS-CoV-2/Flu/RSV on the Cepheid GeneXpert System procedure located in the Procedure Manual/GeneXpert manual. 4. The laboratory's QC log indicated QC was performed upon receipt of new lots and shipments in the timeframe reviewed, July - September 2021. 5. The laboratory did not establish an Individual Quality Control Plan to reduce the frequency of QC performance from 2 levels of control material each day of patient testing. 6. In an interview at 4:00 p.m. on 05/19/22, the GS confirmed the above finding. .
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to evaluate the relationship between test results obtained from two Immunohematology testing methods at least twice annually 2021. Findings are as follows: 1. The laboratory performed Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 8:05 a.m. on 05/19/22. 2. The following Immunohematology methods were observed as present and available for use during the tour: Ortho Vision automated analyzer - primary method Bio-Rad IH-Centrifuge L and IH-Incubator L manual system - back up method 3. A twice annual process for comparison of test results obtained from multiple methods was not found in the laboratory's procedure manuals. 4. Comparison of test results obtained from the two Immunohematology methods was not found in laboratory records from 2021. The laboratory was unable to provide documentation of test comparisons upon request. 5. In an interview at 4:25 p.m. on 05/19/22, the GS confirmed the above finding.