

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0667985	(X3) Date Survey Completed 07/28/2026
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
D0000	The Northfield Hospital 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 completed on July 23, 2026. The following standard-level deficiencies were cited: 493.1281 Comparison of test results .
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. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to evaluate and document the relationship between four of five duplicate testing methods at least twice annually in 2024 and 2025. Findings are as follows: 1. The laboratory performed Chemistry, Hematology, and Immunohematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory at 10:45 a.m. on 7/22/26. 2. The following test systems were observed as present and available for use during the tour: Chemistry: QuidelOrtho Vitros 7600 XT (primary implemented in December 2025) Abbott iStat (high sensitivity troponin and creatinine) Radiometer ABL90-Flex Plus (lactate) Hematology: Sysmex XN-550 (autodifferential) Nikon Exlipse E400 (manual differential) Immunohematology: QuidelOrtho VisionSwift (primary) Manual Ortho Workstation Manual Tube Method A QuidelOrtho Vitros 5600 was used for the primary Chemsitry testing prior to the implementation of the QuidelOrtho Vitros 7600 XT. 3. Twice annual comparison of test results obtained from multiple non-waived test methods was required as established in the Comparison of Test Results from

Different Platforms policy found in the laboratory's Quality Control and Quality Assurance manual reviewed on the date of survey. 4. Laboratory records included twice annual comparison for hemoglobin between the Radiometer ABL90-Flex Plus and the Sysmex XN-550. Comparison documentation of the following non-waived test systems were not found in laboratory records. See below. Chemistry: High sensitivity troponin: Abott iStat vs. Vitros 7600 XT Creatinine: Abott iStat vs. Vitros 7600 XT Lactate: Vitros 7600 XT vs. Radiometer ABL90-Flex Plus Hematology: Differential: manual (Nikon Eclipse E400) vs. automated Sysmex XN-550 Immunohematology: Type and Screen: QuidelOrtho VisionSwift vs Manual Ortho Workstation vs. tube method Crossmatch: QuidelOrtho VisionSwift vs Manual Ortho Workstation vs. tube method The laboratory was unable to provide missing documentation upon request. 5. In an interview at 3:25 p.m. on 7/23/26, the GS confirmed the above findings. .