Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1061073	11/25/2024
Name of Provider or Supplier	**Street Address, City, State**	
Northfield Hospital & Clinics - Farmington Clinic	4645 Knutsen Drive, Farmington, 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 Farmington Clinic 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 November 14, 2024. The following condition level deficiency was cited: 493.1441 Laboratories performing high complexity testing, laboratory director The following standard-level deficiencies were cited: 493.1235 Personnel Competency Assessment Policies 493.1252 Test system, equipment, instruments, reagents, materials, and supplies 493.1443 Laboratory director qualifications .
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure the Technical Consultant (TC) received a competency assessment in 2023 which included the specific TC position responsibilities listed in Subpart M. Findings are as follows: 1. The laboratory performed Microbiology, Chemistry, and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 11/14/24. 2. The following non-waived test systems, analyzers, and tests were in use in 2023 as indicated in the test menu provided by the laboratory: Abbott i-STAT blood analysis system Sysmex XS 1000i hematology analyzer Alcor miniiSED ESR analyzer Nikon Eclipse E200 microscope, stains, and reagents for the following microscopic examinations: Manual differential Urine sediment KOH fungal exam Vaginal wet preparation Post vasectomy 3. The TC was listed as the sole Technical Consultant on the Form CMS-209 Laboratory Personnel Report (CLIA) obtained on date of survey. The TC indicated she entered this role in

	April 2023. 4. A TC competency assessment was not found during review of 2023 laboratory personnel records. The laboratory was unable to provide the missing competency assessment upon request. 5. Annual TC competency assessments were required as indicated in the electronic Personnel Competency procedure located in the laboratory's Shared Drive. 6. In an interview at 2:08 p.m. on 11/14/24, the Laboratory Director confirmed the above finding. .
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure blood collection tubes were not used after the expiration date had been exceeded in November 2024. Findings are as follows: 1. The laboratory performed Routine Chemistry testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 11/14/24. 2. Approximately 20 BD PST Lithium Heparin blood collection tubes with lot number 3290678 and expiration date 10/31/24 were observed as present and available for use in one of two draw stations evaluated during the tour of the laboratory. 3. The laboratory performed Basic Metabolic Panel chemistry testing using the Lithium Heparin collection tubes as indicated by the TC. 4. Monthly checks for supply expiration dates were required as established on the General Clinic Laboratory Maintenance/QA Log in use by the laboratory. 5. In an interview at 10:05 a.m. on 11 /14/24, the TC confirmed the above finding. .
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: . Based on observation, review of current and previous survey documents, and on-site and video interviews with laboratory personnel, the laboratory failed to ensure personnel performing high complexity laboratory director (LD) responsibilities met the qualification requirements of 493.1441. Findings are as follows: The laboratory failed to ensure one of one individuals named as laboratory director met the qualification criteria required to perform high complexity LD responsibilities. See D6078. .
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory

director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:
. Based on observation, review of current and previous survey documents, and on-site and video interviews with laboratory personnel, the laboratory failed to ensure the Laboratory Director (LD) met the qualification criteria required to perform high complexity LD responsibilities in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory at 10:05 a.m. on 11/14/24. 2. High complexity white blood cell manual differentials were performed by laboratory testing personnel as confirmed by the TC during the tour. 3. A Nikon Eclipse E200 microscope and differential stains were observed as present and available for use during the tour. 3. The LD listed on the Form CMS-209 Laboratory Personnel Report (CLIA) obtained on date of survey was previously qualified as a moderate complexity laboratory director possessing a Bachelor's degree in Clinical Laboratory Science and having greater than two years of laboratory experience and laboratory supervisory experience. 4. In a video call at 3:32 p.m. on 11/25/24, the LD indicated high complexity manual differentials have been performed in the laboratory since prior to the previous survey in November 2022 and also confirmed she was not qualified to hold the high complexity laboratory position.