

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0401786	(X3) Date Survey Completed 03/13/2024
Name of Provider or Supplier Neighborhood Health Source - Fremont Clinic	Street Address, City, State 3300 Fremont Ave N, Minneapolis, 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 Neighborhood Health Source Fremont 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 March 13, 2024. The following standard-level deficiencies were cited: 493.1254 Maintenance and function checks .
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>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.</p> <p>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 manufacturer required quarterly maintenance for the single Hematology analyzer in use in 2022, 2023, and 2024. Findings are as follows: 1. The laboratory performed moderate complexity Hematology testing as confirmed by Technical Consultant (TC) during a tour of the laboratory at 1:00 p.m. on 03/13/24. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Quarterly maintenance of the sample rotor valve (SRV) on the Sysmex XP-300 analyzer was required as established in the Analytic: Sysmex XP-300 Operation and Maintenance procedure found in the Fremont Clinic Laboratory Manual and on the manufacturer's XP-300 Maintenance Log in use by the laboratory. 4. Documentation of the above required maintenance was not found on the laboratory's XP-300 Maintenance Log for the time period reviewed, March 2022 - March 2024. SRV maintenance documentation completed approximately every six months by a Sysmex service representative was found in service records - see below. Date performed Time elapsed 05/16/22 N/A 10/20/22 5 months, 7 days 04/10/23 5 months, 21 days 10/03</p>

/23 5 months, 24 days Date of survey Time elapsed 03/13/24 5 months, 11 days The laboratory was unable to provide the missing quarterly maintenance documentation upon request. 5. The laboratory performed approximately 2994 hematology tests annually as indicated on documentation provided by the laboratory on date of survey. 6. In an interview at 3:35 p.m. on 03/13/24, the TC confirmed the above findings. .