

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0401786	(X3) Date Survey Completed 02/19/2026
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	<p>. 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 February 19, 2026. The following standard-level deficiencies were cited: 493.1291 Test report 493.1407 Laboratory director responsibilities .</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure one of two reviewed Hematology patient test results was accurately entered into the laboratory's electronic health record in 2025. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on at 10:00 a.m. on 02/19/26. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour. The laboratory performed Complete Blood Count (CBC) with automated differential testing using this analyzer. The CBC included a Mean Platelet Volume (MPV). 3. The laboratory manually entered CBC test results from the Sysmex XP-300 analyzer into the Centricity electronic health record. 4. The MPV value from one of two patient CBC test results reviewed on date of survey was not</p>

consistent with the MPV value indicated on the Centricity patient test report. See below. Patient xxx666, adult male Tested on 08/15/25 Analyte Sysmex result Centricity report MPV 9.3 271 Note: 271 was the Platelet result for this patient 5. A procedure requiring verification of accurate manual result entry into the electronic health record prior to release of the result was not found during review of the laboratory's written policies and procedures. 6. In an interview at 12:25 p.m. on 02/19/26, the TC confirmed the above finding. .

D6005

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:
. Based on document review and interview with laboratory personnel, the laboratory director (LD) failed to document at least two site visits in 2025. Findings are as follows: 1. The laboratory performed Microbiology and Hematology testing as indicated by the Technical Consultant (TC) during a tour of the laboratory at 10:00 a.m. on 02/19/26. 2. Documentation of LD site visits was not found during review of 2025 laboratory records and documents. 3. A policy establishing the frequency, content, and documentation of required LD site visits was not found during review of the laboratory's written policies and procedures. 4. In an interview at 11:10 a.m. on 02/19/26, the TC confirmed the above finding. The TC indicated, per an email communication with the LD on 02/19/26, LD site visits occurred in January, May, and October 2025 but no formal documentation had been completed.