

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  24D0915517	<b>(X3) Date Survey Completed</b>  01/30/2020
<b>Name of Provider or Supplier</b>  Neighborhood Health Source Sheridan Clinic	<b>Street Address, City, State</b>  342 13th Ave Ne, Minneapolis, MN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate unacceptable Hematology proficiency testing (PT) results for 1 analyte in 2019. 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 01/30/20. 2. The laboratory performed PT using the College of American Pathologists (CAP) program. 3. The laboratory received unacceptable PT results in the CAP FH2-A 2019 Hematology Auto Diff event. See below. Sample Test FH2-02 Granulocyte, Absolute FH2-05 Granulocyte, Absolute 4. Investigation of unacceptable PT results was required as established in the Proficiency Testing Procedure located in the Laboratory Manual. 5. An investigation of the unacceptable PT results was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 6. In an interview at 11: 20 a.m., on 01/30/20, the TC confirmed the above finding.</p>
<b>D5807</b>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure a reference interval was consistent between a Hematology procedure and a patient test report. 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 01/30/20. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour. 3. The Hematocrit reference interval for adult females listed in the Complete Blood Count (CBC) on the Sysmex XP-300 Automated Hematology Analyzer procedure was not consistent with those included on patient test reports reviewed on date of survey as indicated below. Adult female, date of birth = 12/31/91, tested on 7/24/19 Adult female, date of birth = 3/6/97, tested on 11/26/19 Analyte Procedure Report Hematocrit 35.5 - 40.0 % 35.0 - 45.0% 4. In an interview at 12:10 p.m., on 01/30/20, the TC confirmed the above finding. .