Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0915517	01/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Neighborhood Health Source Sheridan Clinic	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) 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. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to document required Hematology analyzer maintenance. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 01/18/18 at 10:10 a.m. 2. A Beckman Coulter AcT Diff 2 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. Requirements for daily maintenance of the analyzer were established in the Coulter AcT diff 2 Analyzer Operators Guide provided by the manufacturer. 4. Documentation of daily maintenance was not found during review of laboratory records from January 2016 through January 2018. The laboratory was unable to provide daily maintenance documentation upon request. A Coulter Act*T Diff 2 Preventative Maintenance form was present in laboratory records but was not in use. 5. In an interview on 01/18/18 at 1:00 p.m., the TC confirmed the daily maintenance had not been documented in 2016 and 2017.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to follow an established policy to verify the accuracy of test results manually entered into the electronic patient record. Findings are as follows: 1. The laboratory performed Microscopic Examinations and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 01/18/18 at 10:10 a.m. The TC indicated the test results were entered manually into the electronic patient record. 2. A requirement for scheduled and non-scheduled quality assurance reviews was established in Section 10 - Quality Assurance of the Laboratory Manual. A blank Laboratory Quality Assurance Form found in laboratory records indicated a 5 chart audit was required annually. 3. Documentation of chart audits from 2016 and 2017 was not found. The laboratory was unable to provide documentation of chart audits for this time period upon request. 4. In an interview on 01/18/18 at 1:40 p.m., the TC confirmed the above finding and stated the laboratory most recently verified the accuracy of manually entered test results in 2015.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the technical consultant failed to ensure testing personnel were assessed through testing previously analyzed specimens, blind samples, or proficiency testing samples at least annually. Findings are as follows: 1. The laboratory performed Microscopic Examinations and Hematology testing as confirmed by the Technical Consultant (TC) during a tour of the laboratory on 01/18/18 at 10:10 a.m. 2. Requirements to assess testing personnel competency via blind testing using a split sample or proficiency testing sample were established in the Test Personnel, Moderately Complex Laboratory procedure located in the Laboratory Manual. 3. Documentation of blind testing was not included on the Competency Assessment: Analytic for Non-Waived Testing form for Testing Personnel 2 (TP2) as indicated below. Year Test 2016 Microscopic Examinations 2017 Hematology, Microscopic Examinations 4. In an interview on 01/18/18 at 10:50 a.m., Testing Personnel 1 verified TP2 performed Microscopic Examinations and Hematology testing. The TC indicated the blind testing assessment should have been completed for TP2 in 2016 and 2017 and confirmed the assessment was not performed. *This is a repeat finding from the 01/06/16 survey*