Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0403966	03/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Lake Superior Community Health Center	4325 Grand Avenue Suite 1, Duluth, 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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on document review and interview with laboratory personnel, the laboratory failed to test Hematology proficiency testing samples in the same manner it tests patient specimens. Findings are as follows: 1. The laboratory performed proficiency testing (PT) through the American College of Physicians Medical Laboratory Evaluation (MLE) program. 2. The laboratory tested hematology proficiency testing samples from the 2017 MLE-M1 event on multiple days as indicated on the test reports obtained from the Abbott Cell-Dyn Emerald hematology analyzer. See below Sample Test date 1 Test date 2 HD-2 02/13/17 02/16/17 HD-5 02/13/17 02/16/17 3. In an interview on 03/05/19 at 2:30 p.m., the Laboratory Director confirmed the above finding and indicated patient specimens would not be tested in this manner.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years.

	This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for at least 2 years. Findings are as follows: 1. The laboratory performed proficiency testing (PT) through the American College of Physicians Medical Laboratory Evaluation (MLE) program. 2. The MLE PT attestation statement for the 2018 MLE-M2 event was not present in laboratory records on date of survey. The laboratory was unable to provide this document upon request. 3. In an interview on 03/05/19 at 2:30 p.m., the Laboratory Director confirmed the 2018 MLE-M2 event attestation statement was not retained.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to investigate an unacceptable Microbiology proficiency testing (PT) result for 1 analyte in 2017. Findings are as follows: 1. The laboratory performed proficiency testing (PT) through the American College of Physicians Medical Laboratory Evaluation (MLE) program. 2. The laboratory received an unacceptable PT result in the 2017 MLE-M3 event for the analyte listed below. Sample Test Lab MLE result K-5 KOH* absent present 3. An investigation of the unacceptable PT result was not found during review of laboratory records. The laboratory was unable to provide investigation documentation upon request. 4. In an interview on 03/05/19 at 11:30 a. m., the Laboratory Director confirmed a documented investigation of the unacceptable result was not performed. * Note KOH - Potassium Hydroxide
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by:

	. Based on observation, document review and interview with laboratory personnel, the laboratory failed to ensure the reportable range obtained during performance verification of a new Hematology analyzer was accurate in the procedure manual (6). Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 (TP1) during a tour of the laboratory on 03/05/19 at 12:30 p.m. 2. A Sysmex XP-300 hematology analyzer was observed as present and available for use during the tour of the laboratory. The laboratory completed performance verification (PV) activities in January 2019 and began testing patient specimens using this analyzer on 02/01/19 as indicated by TP1 during the tour and confirmed via laboratory records. 3. The Hemoglobin (HGB) and Hematocrit (HCT) reportable ranges found in the Sysmex XP-300 Operating procedure, located in the Lab Manual Policy and Procedure Book 1, did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Analyte PV Procedure HGB 0-22.9 0.1-25 HCT 0.0-58.8 10.0-60.0 4. In an interview on 03/05/19 at 3:20 p. m., the Laboratory Director confirmed the above finding and indicated the laboratory had included the manufacturer's analytical measurement range for HGB and HCT as the reportable range in procedure.
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 document review and interview with laboratory personnel, the laboratory failed to perform and document required Hematology analyzer maintenance. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by Testing Personnel 1 during a tour of the laboratory on 03/05/19 at 12:30 p.m. 2. An Abbott Cell-Dyn Emerald hematology analyzer was in use in the laboratory until 02/01 /19 as indicated in laboratory records. 3. Semi-annual piston lubrication was required by the manufacturer and established on the manufacturer's Maintence Log. 4. Documentation of the semi-annual piston lubrication was not found in the Maintenance Log from January 2018 - January 2019 . The most recent piston lubrication was performed on 12/05/17. The laboratory was unable to provide documentation of piston lubrication which occurred between January 2018 - January 2019 upon request. 5. In an interview on 03/05/19 at 3:50 p.m., the Laboratory Director confirmed the semi-annual piston lubrication had not been documented between January 2018 - January 2019.