Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0868250	10/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Northlakes Community Clinic	15397 St Hwy 32, Lakewood, WI	

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
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 surveyor review of the hematology procedures and interview with the technical consultant, the hematology procedures did not include reference intervals for testing performed on the Coulter AcT Diff 2 hematology analyzer. Findings include: 1. Review of the "COULTER ACT DIFF 2" procedure revealed that reference intervals were not included within the procedure. Further review of hematology procedures showed no evidence the laboratory included reference intervals for testing

	performed on the Coulter AcT Diff 2 hematology analyzer in their procedures. 2. Interview with the technical consultant on October 29, 2019 at 10:00 AM, confirmed that reference intervals were not included in the hematology procedures.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with the technical consultant, the laboratory director had not signed and dated the procedures prior to use at the laboratory. Findings include: 1. Review of the procedures revealed the laboratory director had not signed and dated the procedures prior to use in the laboratory. 2. Interview with the technical consultant on October 29, 2019 at 10:00 AM, confirmed the laboratory director had not signed and dated the procedures prior to use in the laboratory.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency test records, enrollment documentation and interview with the technical consultant, the laboratory director did not ensure that the laboratory was enrolled in a HHS approved proficiency testing program between March and July 2019, for the regulated analytes in hematology. Findings include: 1. Review of proficiency testing records for 2019 showed the laboratory had no records until the third event in 2019. 2. Review of the proficiency testing enrollment documentation showed the laboratory enrolled with the Wisconsin State Laboratory of Hygiene proficiency testing program in July 2019. 3. Interview with the technical consultant on October 29, 2019 at 9:45 AM, confirmed that the clinic performed patient testing beginning in March 2019 but did not enroll with a proficiency testing provider until July 2019.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on surveyor review of competency assessments, quality control records and

	interview with the technical consultant, the technical consultant did not evaluate testing personnel competency prior to August 6, 2019 and did not review quality control to maintain oversight of the laboratory. Findings include: 1. Review of competency assessments revealed the technical consultant did not perform competency assessments until August 6, 2019 on four of four testing personnel. Further review revealed the technical consultant had not evaluated competency assessments for testing personnel who were assessed by Staff A. 2. Review of quality control records on the Coulter AcT Diff 2, revealed the technical consultant did not document review of quality control records. 3. Interview with the technical consultant on October 29, 2019 at 9:40 AM, confirmed the technical consultant had not performed competency assessments between March and August 6, 2019, and did not evaluate competency assessments for personnel assessed by Staff A who is not qualified as a technical consultant. Further interview with the technical consultant on October 29, 2019 at 10:55 AM, confirmed that the technical consultant had not reviewed quality control to maintain oversight within the laboratory.