

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397042	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Northlakes Community Clinic	Street Address, City, State 15954 Rivers Edge Dr, Hayward, 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
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of procedures and interview with the technical consultant, four out of five laboratory procedures reviewed do not include dates of initial use. Findings include: 1. Review of five laboratory procedures revealed four procedures that did not include the effective date or any indication of the date of initial use: *Cell Dyn Emerald *Clinitek Procedure *Streck ESR Procedure, Automated Method (ESR, Erythrocyte Sedimentation Rate) *Vaginal Wet Prep 2. Interview with the technical consultant, staff C, on November 7, 2018 at 11:00 AM confirmed the procedures did not include a date of initial use. This is a repeat deficiency previously cited on September 19, 2014.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of blood collection tubes and interview with the technical consultant, the red top Vacuette tubes available for use in the phlebotomy area were past their May 17, 2018 expiration date. Findings include: 1. Observation of blood collection tubes in the phlebotomy area on November 7, 2018 at 11:15 AM</p>

revealed all red top Vacuette tubes observed showed an expiration date of 2018-05-17 (May 17, 2018). 2. Interview with the technical consultant, staff C, on November 7, 2018 at 11:15 AM confirmed the red top Vacuette tubes had exceeded the expiration date after May 17, 2018 and were still in use.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory records and interview with the technical consultant the laboratory did not verify that the manufacturer's reference intervals for the Emerald hematology analyzer, including age and sex specific ranges, were appropriate for the laboratory's patient population before using the analyzer for patient testing. Findings include: 1. Review of the laboratory's studies of performance specifications for the Emerald hematology analyzer showed no evaluation of the manufacturer's or other published reference ranges. 2. Interview with the technical consultant, staff C, on November 7, 2018 at 10:30 AM confirmed the laboratory did not verify the reference ranges for the Emerald hematology analyzer were appropriate for their patient population. Further interview revealed the Emerald hematology analyzer has been used for patient testing since September 7, 2018.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on surveyor review of test reports and interview with the technical consultant, the test report does not indicate the address of the laboratory where the test was performed for testing performed at this laboratory. Findings include: 1. Review of patient test reports for tests performed in this laboratory in the Centricity electronic medical record showed no indication of the address of the laboratory where testing was performed. 2. Interview with the technical consultant, staff C, on November 7, 2018 at 11:30 AM confirmed the address of the testing laboratory is not indicated on the Centricity test report for testing performed at this laboratory.

<p>D6026</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8)</p> <p>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)(8) Ensure that reports of test results include pertinent information required for interpretation.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of laboratory procedures and interview with the technical consultant, the laboratory director has not ensured that reference ranges for hematology reports are appropriate for interpretation based on the patient age and sex. Findings include: 1. Review of laboratory procedures shows hematology reference ranges are not age and sex specific. 2. Interview with the technical consultant, staff C, on November 7, 2018 at 11:00 AM, confirmed the laboratory does not provide age and sex specific reference ranges for the appropriate interpretation of hematology test results.</p>
<p>D6031</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory procedure manual and interview with testing personnel, the director has approved two procedures for microscopic urinalysis testing with different sample preparation instructions. Findings include: 1. The procedure manual includes a cover sheet signed by the laboratory director in 2017 and 2018 showing approval of the entire procedure manual. 2. Review of the procedure manual reveals two procedures that include instructions for microscopic urine evaluation. Neither procedure shows a discontinuation date. The "Clinitek Procedure" shows 9 mL (milliliters) of supernatant is removed from a centrifuged 10 mL sample; the sediment is mixed in the resulting 1 mL of supernatant. The "Routine Urinalysis Visual Method" procedure shows 9.5 mL of supernatant is removed from a centrifuged 10 mL sample; the sediment is mixed with the resulting 0.5 mL of supernatant. 3. Interview with the technical consultant, staff C, on November 7, 2018 at 11:00 AM confirms use of the two urinalysis procedures would produce different results and that the director did not ensure the instructions in the procedure manual are consistent for microscopic urine evaluation.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the</p>

qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on surveyor review of personnel records and interview with the technical consultant, two testing personnel do not have credentials available showing they meet the qualification requirements for moderate complexity testing personnel. Findings include: 1. Two of four testing personnel do not have credentials showing they meet the qualification requirements for moderate complexity testing. See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on surveyor review of personnel records and interview with the technical consultant, two out of four testing personnel do not have documented evidence showing they meet the qualification requirements to perform moderate complexity testing. Findings include: 1. Review of personnel records showed no evidence of credentials for staff A or staff B. 2. Interview with the technical consultant, staff C, on November 7, 2018 at 9:15 AM revealed the laboratory has four testing personnel. Further interview confirmed Staff A and B perform moderate complexity testing and confirmed documented credentials were not available showing staff A or B meet the minimum requirements for moderate complexity testing personnel.