

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397081	(X3) Date Survey Completed 11/07/2018
Name of Provider or Supplier Northlakes Community Clinic	Street Address, City, State 600 Shell Creek Rd, Minong, 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 laboratory procedures and interview with the technical consultant, the laboratory's procedure for microscopic urinalysis does not include a date of initial use in this laboratory. Findings include: 1. Review of the laboratory's procedure manual revealed the "Clinitek Procedure" includes instructions for the microscopic portion of the urinalysis exam. The procedure did not include a date of initial use. 2. Interview with the technical consultant on November 7, 2018 at 1:30 PM confirmed the procedure did not include a date of initial use.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of test reports and interview with the technical consultant,</p>

	<p>the test report does not indicate the address of the laboratory location where the test was performed. Findings include: 1. Review of patient test reports 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 on November 7, 2018 at 1:30 PM confirmed the address of the testing laboratory is not indicated on the Centricity test report.</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 qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 titled "Laboratory Personnel Report (CLIA)" and personnel records, and interview with the technical consultant, one of four testing personnel does not have credentials available showing they meet the qualification requirements for moderate complexity testing personnel. Findings include: 1. One of four testing personnel does not have credentials showing they meet the qualification requirements for moderate complexity testing. See D 6065.</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(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</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form CMS-209 title "Laboratory Personnel Report (CLIA)" and personnel records, and interview with the technical consultant, one of four testing personnel does not have documented evidence showing they meet the qualification requirements to perform moderate complexity testing. Findings include: 1. Review of Form CMS-209 titled "Laboratory Personnel Report (CLIA)" shows staff A is one of four testing personnel in this lab. 2. Review of personnel records showed no evidence of credentials for staff A. 3. Interview with the technical consultant on November 7, 2018 at 1:00 PM confirmed documented credentials were not available showing staff A meets the minimum requirements for moderate complexity testing personnel.</p>