

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0397042	(X3) Date Survey Completed 12/03/2020
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
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form 209 "Laboratory Personnel Report" and academic credentials, and interview with the regional laboratory manager, the laboratory did not have a technical consultant who met the qualification requirements of 493.1411 of this subpart for the last four months. Findings include: 1. The assigned technical consultant does not hold the minimum academic credentials to meet the qualification requirements for technical consultant. See D6035.</p>
D6035	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or</p>

subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Centers for Medicare and Medicaid Services (CMS) Form 209 "Laboratory Personnel Report" and academic credentials, and interview with the regional laboratory manager, the technical consultant who has been in the role for the last four months did not hold academic credentials that met the qualification requirements for a technical consultant. Findings include: 1. Review of the CMS Form 209 showed the laboratory identified staff A as the technical consultant for the laboratory. 2. Review of academic credentials showed the highest academic credential held by staff A was an Associate's Degree in medical laboratory science. 3. Interview with the regional laboratory manager, staff A, on December 3, 2020 at 8:30 AM confirmed their academic credentials did not meet the requirements for the technical consultant position. Further interview confirmed staff A has been in the technical consultant role for four months.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Center for Medicare and Medicaid Services (CMS) Form 209 "Laboratory Personnel Report" and personnel records, and interview with the regional laboratory manager, the technical consultant did not document testing personnel competency for three of three testing personnel in 2019. Findings include: 1. Review of the CMS Form 209 shows four testing personnel employed in the laboratory. 2. Review of personnel records showed three of the four identified testing personnel were performing testing during 2019. Review of competency records in 2019 showed no evidence of competency evaluation of staff A, B, or C in 2019. 3.

Interview with the regional laboratory manager on December 3, 2020 at 9:00 AM confirmed staff A, B, and C were performing testing in 2019 and confirmed the technical consultant did not document competency of testing personnel in 2019.