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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 52D0394945 | (X3) Date Survey Completed 02/21/2018 |
| Name of Provider or Supplier N E W Community Clinic, Ltd | Street Address, City, State 610 N Broadway Street, Green Bay, 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 |
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| D3011 | <p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of testing personnel and review of laboratory procedures the laboratory has not established safety procedures to ensure protection from biohazardous materials. Findings include: 1. It was observed during the tour of the laboratory with the Laboratory Director that Testing Personnel A was eating toast in the laboratory. 2. During the survey of the laboratory with the Laboratory Director on February 21, 2018 at 2:30 PM and review of laboratory safety procedures on February 22, 2018 at 3:00 PM the surveyor confirmed the laboratory has not established safety procedures to ensure protection from biohazardous materials and unsafe safety practices.</p> |
| 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 competency assessment records, the CMS-209 form, and interview with the Laboratory Director the laboratory did not have a Technical Consultant who met the qualification requirements of 493.1411 of this subpart and</p> |

provides technical oversight in accordance with 493.1413 of this subpart. Findings include: 1. The personnel fulfilling the competency assessment responsibilities of Technical Consultant in 2016 and 2017 at Northeast Wisconsin Technical College (NWTC) and 2017 at N E W Community Clinic did not meet the qualification requirements of 493.1411. See D 6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(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 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 interview with the Laboratory Director, review of competency assessment records, staff credentials, and the CMS-209 Personnel Form, the individuals fulfilling the Technical Consultant responsibilities for competency assessment were not qualified to serve as technical consultants. Findings Include: 1. Review of competency assessment records for the Northeast Wisconsin Technical College (NWTC) site on the multi-site certificate show that Testing Personnel B (TP B) performed annual competency assessments for Testing Personnel C (TP C) at this site in 2016 and 2017. Credential review for TP B show they have a two year associate degree as a medical laboratory technician and do not qualify as a Technical Consultant to assess competency. 2. Review of competency assessment records for the

Northeast Wisconsin Technical College (NWTC) site on the multi-site certificate show that TP C performed annual competency assessments for TP B at this site in 2017. Credential review for TP C show they have a two year associate degree as a medical laboratory technician and do not qualify as a Technical Consultant to assess competency. 3. Review of competency assessment records for the N E W Community Clinic site for Testing Personnel A (TP A) in 2017 were performed by a registered nurse (RN 1) at the clinic that is not identified as a Technical Consultant or Testing Personnel on the CMS-209 Personnel Form. 4. Review of competency assessment records for the N E W Community Clinic site for Testing Personnel D (TP D) in January 2018 show the semi-annual assessment was performed by RN 1 who is not identified as a Technical Consultant or Testing Personnel on the CMS-209 Personnel Form. 5. Interview with TP D who is also the Laboratory Director on February 21, 2018 at 1:30 PM confirms TP A, TP B, and RN 1 have performed the Technical Consultant (TC) competency assessment responsibilities but TP A and TP B do not qualify as Technical Consultants and RN 1 was not identified as a TC on the CMS-209 Personnel Form.