

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0721195	(X3) Date Survey Completed 05/04/2020
Name of Provider or Supplier Lakeview Specialty Hospital & Rehab	Street Address, City, State 1701 Sharp Rd, Waterford, 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 interview with the hospital Chief Executive Officer (CEO), the laboratory does not have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. Findings include: 1. The laboratory does not have a technical consultant who meets the qualification requirements of 493.1411 of this subpart. See D6034 and D6035.</p>
D6034	<p>TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411</p> <p>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of records and interview with the Chief Executive Officer (CEO), the laboratory does not have a qualified technical consultant employed. Findings include: 1. Surveyor review of complaint intake records from April 22, 2020 identified the technical consultant had resigned. 2. Interview with CEO on May 4,</p>

2020 at 10:30 AM confirmed the laboratory does not have a technical consultant employed.

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 review of records and interview with the Chief Executive Officer (CEO), the laboratory does not have a qualified technical consultant. Findings include: 1. Surveyor review of complaint intake records from April 22, 2020 identified the technical consultant had resigned. 2. Interview with CEO on May 4, 2020 at 10:30 AM confirmed the laboratory does not have a qualified technical consultant, and also confirmed the laboratory director is not qualified to function as a technical consultant.