

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  52D2182699	<b>(X3) Date Survey Completed</b>  06/18/2021
<b>Name of Provider or Supplier</b>  Accelerated Clinical Laboratories, Llc	<b>Street Address, City, State</b>  10101 W Innovation Dr Suite 600, Wauwatosa, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6076</b>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on surveyor review of the CMS Form 209 (Centers for Medicare and Medicaid Services Laboratory Personnel Report) and laboratory records, and interview with the Administrative Director, the laboratory did not have a director who met the qualification requirements of 493.1443 of this subpart. Findings include: 1. The Laboratory Director did not hold a Wisconsin license to practice medicine or osteopathy, and did not meet the qualification requirements for a laboratory director of high complexity testing. See D6078.</p>
<b>D6078</b>	<p>LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443</p> <p>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to</p>

practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification.

This STANDARD is not met as evidenced by:

Based on surveyor review of the CMS Form 209 (Centers for Medicare and Medicaid Services Laboratory Personnel Report) and laboratory records, and interview with the Administrative Director, the Laboratory Director did not hold a license to practice medicine or osteopathy in Wisconsin, and did not meet the qualification requirements to manage and direct high complexity testing. Findings include: 1. Review of the CMS Form 209 submitted by the laboratory for the survey on June 18, 2021 showed staff A identified as the Laboratory Director. The form also showed the laboratory performed high complexity testing. 2. Review of laboratory records showed no evidence Staff A was licensed in Wisconsin to practice medicine or osteopathy. 3. Interview with the Administrative Director (staff B) on June 18, 2021 at 9:44 AM confirmed the laboratory did not have documentation showing licensure of staff A to practice medicine or osteopathy in Wisconsin to meet the qualification requirements for laboratory director of a high complexity laboratory.

**D6134**

**CLINICAL CONSULTANT**

CFR(s): 493.1453

The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.

This CONDITION is not met as evidenced by:

Based on surveyor review of the CMS Form 209 (Centers for Medicare and Medicaid Services Laboratory Personnel Report) and laboratory records, and interview with the Administrative Director, the laboratory did not have a clinical consultant who met the qualification requirements of 493.1455 of this subpart. Findings include: 1. The Clinical Consultant did not hold a Wisconsin license to practice medicine or osteopathy, and did not meet the qualification requirements for a clinical consultant for high complexity testing. See D6135.

**D6135**

**CLINICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1455

The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493.1443(b)(1), (2), or (3)(i) or, for the subspecialty of oral pathology, 493.1443(b)(6); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located.

This STANDARD is not met as evidenced by:

Based on surveyor review of the CMS Form 209 (Centers for Medicare and Medicaid Services Laboratory Personnel Report) and laboratory records, and interview with the Administrative Director, the Clinical Consultant did not hold a license to practice medicine or osteopathy in Wisconsin, and did not meet the qualification requirements for a clinical consultant for a laboratory performing high complexity testing. Findings include: 1. Review of the CMS Form 209 submitted by the laboratory for the survey on June 18, 2021 showed staff A identified as the Clinical Consultant. The form also showed the laboratory performed high complexity testing. 2. Review of laboratory records showed no evidence Staff A was licensed in Wisconsin to practice medicine or osteopathy. 3. Interview with the Administrative Director (staff B) on June 18, 2021 at 9:44 AM confirmed the laboratory did not have documentation showing licensure of staff A to practice medicine or osteopathy in Wisconsin to meet the qualification requirements for clinical consultant of a high complexity laboratory.