

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0670466	(X3) Date Survey Completed 02/08/2024
Name of Provider or Supplier Lakeside Pediatrics	Street Address, City, State 128 Lakeside Ave, Burlington, VT	
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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory (lab) failed to follow manufacturer's instructions for performing rapid antigen testing for Streptococcus Group A (Group A Step) in January and February 2024. Findings include: 1. Review on 2/8/2024 of the package insert for the lab's Group A Strep antigen tests revealed under intended use it was for the qualitative detection of Group A Strep using throat swab specimens. 2. Interview on 2/8/2024 at 11:30 p.m. with lab personnel revealed the lab ran out of bacitracin discs after 1/8/2024 and began using the rapid Group A Strep antigen test sourcing the specimen from growth obtained on culture plates. 3. Review of patient test logs from 1/9/2024 to 2/8/2024 revealed 5 patient throat cultures for presumptive identification of Group A Strep had been reported in the absence of bacitracin discs and using the rapid Group A Strep test. Further review of the 5 patient reports revealed 4 of the 5 had been reported as negative 1 of the 5 had been reported as positive for Group A Strep.</p>
D6076	<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>

This CONDITION is not met as evidenced by:
Based on record review and staff interview, the Laboratory Director (LD) failed to meet qualification requirements for high complexity testing in bacteriology in 2024. Refer to D6078.

D6078

LABORATORY DIRECTOR QUALIFICATIONS
CFR(s): 493.1443

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 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 record review and staff interview, the Laboratory Director (LD) failed to meet qualification requirements to director high complexity bacteriology testing in 2024. Findings include: 1. The laboratory failed to follow manufacturer's instructions for performing waived rapid antigen testing for Group A Streptococcus (Strep) resulting in the performance of high complexity testing in January and February 2024. 2. Review 2/8/2024 of the FDA test complexity database revealed the presumptive identification with a selective media, hemolysis, and bacitracin disk using a specimen director from throat swab specimen are categorized as moderate complexity. Use without bacitracin disks defaults to high complexity testing. 3. Interview with laboratory personnel on 2/8/2024 at 11:30 a.m. confirmed the off-label use of the waived rapid antigen testing for Group Strep and reporting of throat cultures for the

presumptive identification of Group A Strep without the use of bacitracin disks. 4.
The LD did not have documentation at the time of survey of qualifications to director
high complexity bacteriology testing.