

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 47D0670466	(X3) Date Survey Completed 04/05/2018
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
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to check for positive and negative reactivity in 2016 and 2017, each lot number and shipment of bacitracin disks used for bacteriology testing. Findings include: 1) Review on 4/5/18 of quality control records from 2016 and 2017 revealed no documentation that the laboratory checked each lot number and shipment of "BD BBL Taxo A discs" (bacitracin disks) for positive and negative reactivity. The bacitracin disks were used in throat cultures for the presumptive identification of beta-hemolytic group A Streptococcus. 2) Review on 4/5/18 of the laboratory's "Throat Culture" procedure dated 6/2/2016 revealed no instruction to check each lot number and shipment of bacitracin disks for positive and negative reactivity. 3) Interview on 4/5/18 at 11:45 a.m. with a licensed practical nurse (LPN) who has administrative responsibilities for the laboratory confirmed the laboratory did not check each lot number and shipment of bacitracin disks for positive and negative reactivity. The LPN revealed the laboratory typically receives two shipments of bacitracin disks each year. 4) The laboratory performs approximately 850 throat cultures annually.</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p>

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the technical consultant failed to include assessment of bacteriology test performance in procedures for evaluation of competency in 2017. Findings include: 1) Review on 4/5/18 of proficiency testing (PT) records from 2017 revealed 3 of 6 testing personnel did not participate in PT for throat cultures and urine colony counts. 2) Interview on 4/5/18 with a licensed practical nurse (LPN) who has administrative responsibilities for the lab confirmed the above finding and revealed that no other methods were used in 2017 to assess the throat culture and urine colony count test performance for the 3 of 6 testing personnel who did not participate in PT.