

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  47D0670466	<b>(X3) Date Survey Completed</b>  09/23/2020
<b>Name of Provider or Supplier</b>  Lakeside Pediatrics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform bacteriology proficiency testing (PT) using the laboratory's routine methods in 6 of 6 events in 2018, 2019 and 2020. This is a repeat deficiency from the re-certification survey completed on 4/7/2016. Findings include: 1) Review on 9/23/2020 of patient records for the presumptive identification of group A Streptococcus (throat culture) from 2020 revealed that routine methods for each throat culture plate is read by one testing personnel. 2) Review on 9/23/2020 of Medical Laboratory Evaluation (MLE) PT records for throat cultures from 2018, 2019 and 2020 revealed five testing personnel read all 5 PT samples prior to the results due date in each of the following events: 2018 MLE-M3; 2019 MLE-M1, M2, and M3; 2020 MLE-M1 and M2. 3) Interview with Staff A (Medical Assistant) on 9/23/2020 at 10:30 a.m. confirmed the above findings.</p>
<b>D2009</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and staff interview, laboratory personnel performing bacteriology proficiency testing (PT) failed to sign the attestation form for 6 of 6 PT events in 2018, 2019, and 2020. Findings include: 1) Review on 9/23/2020 of Medical Laboratory Evaluation (MLE) PT records for presumptive identification of group A Streptococcus (throat cultures) and urine culture colony counts revealed 5 of 5 testing personnel failed to sign the attestation form for the following events: 2018 MLE-M3; 2019 MLE-M1, M2, and M3; 2020 MLE-M1 and M2. 2) Interview with Staff A (Medical Assistant) on 9/23/2020 at 10:30 a.m. confirmed the above finding.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

The laboratory director failed to ensure bacteriology proficiency testing (PT) samples were tested using routine methods in 2018, 2019, and 2020. Refer to tag D2007.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(iii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

The laboratory director failed to identify problems through evaluation of unacceptable results obtained for bacteriology proficiency testing (PT) for 2 of 6 events in 2018 and 2020. Findings include: 1) Review on 9/23/2020 of Medical Laboratory Evaluation (MLE) PT records for 6 events in 2018, 2019, and 2020 for the presumptive identification of group A Streptococcus (throat culture) revealed the laboratory obtained unacceptable results in events 2018 MLE-M2 for samples TC-6 and TC-9, and 2020 MLE-M2 for TC-8. Further review revealed repeat testing was performed for 2018 MLE-M2 and laboratory failed to obtain acceptable results for TC-9 and no further evaluation or follow up is documented for TC-9. Review of 2020 MLE-M2 PT records revealed no repeat testing and no documentation that an evaluation of PT results for TC-8 had been conducted. The PT evaluation reports for 2018 MLE-M2 sample TC-9 and 2020 MLE-M2 TC-8 revealed the expected microorganism was Streptococcus salivarius for both samples. 2) Interview with Staff A (Medical Assistant) on 9/23/2020 at 10:30 a.m. revealed the laboratory director and all testing personnel discussed the result for 2020 MLE-M2 TC-8 and that this discussion was not documented and confirmed the above finding. 3) Review on 9/23/2020 of a

picture taken by the laboratory of the cultured media plate for PT sample TC-8 (event 2020 MLE-M2) revealed alpha-hemolytic colonies, consistent with *Streptococcus salivarius*.