

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D0697034	<b>(X3) Date Survey Completed</b> 05/22/2018
<b>Name of Provider or Supplier</b> New England Pediatrics Llp	<b>Street Address, City, State</b> 31 Strawberry Hill Ave, Stamford, CT	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory did not verify accuracy bi-annually for Uricult testing. Findings include: 1. Record review of the laboratory's proficiency testing records on 5/22/18 revealed the laboratory did not verify the accuracy of the Uricult test at least twice annually for 2016 and 2017. 2. Staff interview with laboratory director on 5/22/18 at 11:45 AM confirmed the laboratory did not have a system in place to verify the accuracy of Uricult testing bi-annually in 2016 and 2017. 3. The laboratory performs 130 Uricult tests annually.</p>
<b>D6045</b>	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7)</p> <p>(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical consultant failed to assure new testing personnel (TP) received training in order to perform moderate complexity testing in the specialty of microbiology. Findings include: 1. Record review of 2016 and 2017 TP files on 5/22/18 revealed the laboratory failed to provide training documentation for 3 of 3 new TP for throat culture testing. 2. Staff interview with the</p>

laboratory director on 5/22/18 at 11:00 AM confirmed 3 of 3 new TP did not have training documentation available for throat culture testing in 2016 and 2017. 3. Laboratory performs approximately 707 throat culture tests annually.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to evaluate testing personnel to ensure competency to perform and report accurate test results in the specialty of microbiology. Findings include: 1. Record review of the 2016 & 2017 competency records on 5/22/18 revealed documentation for 6 of 6 TP was not available. 2. Staff interview with laboratory director (LD) on 5/22/18 at 11:30 AM confirmed the above findings. LD stated he/she wasn't aware the physicians had to be assessed for competency. 3. Laboratory performs 707 moderate complexity tests annually.

**D6051**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)(v)

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, testing personnel had not tested unknown samples to assess their knowledge and skills to maintain their competency in the specialty of microbiology. Findings include: 1. Record review of the College of American Pathologists (CAP) throat culture attestation sheets on 5/22/17 revealed 6 of 15 testing personnel (TP) did not examine proficiency testing material to accurately assess their knowledge and skills in 2016 and 7 of 15 TP in 2017. 2. Record review of competency records on 5/22/18 revealed assessment documentation of previously analyzed specimens or internal blind testing was not available. 3. Staff interview with the laboratory director on 5/22/17 at 11:30 AM confirmed not all testing personnel had examined unknown samples including proficiency testing material to accurately assess their skills for the above in 2016 and 2017. 4. Laboratory performs approximately 707 throat culture and 130 uricult tests annually.