

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 07D0098683	<b>(X3) Date Survey Completed</b> 01/06/2026
<b>Name of Provider or Supplier</b> East Haven Pediatrics Pc	<b>Street Address, City, State</b> 300 Main St, East Haven, 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>D2003</b>	<p>ENROLLMENT CFR(s): 493.801(a)(2)(ii)</p> <p>(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1).</p> <p>This STANDARD is not met as evidenced by: A. Based on record review and staff interview, the laboratory failed to verify the accuracy of the Uricult test system twice annually in the subspecialty of bacteriology. Findings include: 1. Surveyor observation on 01/07/2026 at 11:00 AM revealed the laboratory utilizes a Uricult CLED/EMB test system for bacterial colony count in the subspecialty of Bacteriology. 2. Record review on 01/07/2026 of the laboratory procedures revealed no documentation for the verification of the accuracy of the Uricult CLED/EMB test system twice annually. 3. Staff interview on 01/07/2026 at 11:30 AM with the office manager confirmed the findings listed above.</p>
<b>D5209</b>	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish competency assessment policy and procedures to assess competency for the regulatory responsibilities for the Clinical Consultant (CC) and Technical Consultant (TC) in the subspecialty of bacteriology. Findings include: 1. Record review on 1/6/2026 of the</p>

laboratory's competency assessment records revealed lack of documentation of competency assessment for the regulatory positions of CC and TC. 2. Record review on 1/6/2026 of the laboratory's policy and procedure section 'Testing Personnel' revealed lack of an established competency assessment policy and procedure to assess competency for the regulatory positions CC and TC and defining frequency of such assessments. 3. Staff interview on 1/6/2026 at 11:38 AM with the laboratory director confirmed the above findings. 4. The laboratory performs 446 moderate complexity tests annually in the subspecialty of bacteriology.

**D6046**

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

(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. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:  
Based on record review and staff interview, the laboratory failed to follow their established policies and procedures as well as to document the annual competency assessment for the testing personnel (TP) in the subspecialty of bacteriology. Findings include: 1. Record review on 1/6/2026 of the laboratory's personnel report 'CMS 209' form revealed 8 of 8 TP performing moderate complexity testing in the laboratory. 2. Record review on 1/6/2026 of the laboratory's policy and procedure section 'Testing Personnel' revealed, "All personnel are evaluated annually". 3. Record review on 1/6/2026 of the laboratory's competency assessment records revealed lack of documentation of competency assessment for 8 of 8 TP performing moderate complexity testing for the year 2024. 4. Staff interview on 1/6/2026 at 11:37 AM with the laboratory director confirmed the above findings. 5. The laboratory performs 446 moderate complexity tests annually in the subspecialty of bacteriology.