

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0935548	<b>(X3) Date Survey Completed</b>  07/10/2025
<b>Name of Provider or Supplier</b>  New England Newborn Screening Program	<b>Street Address, City, State</b>  377 Plantation St, Worcester, MA	
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>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 confirmed through an interview with the Laboratory Director (LD) and General Supervisor #1 (GS1) the laboratory did not have a written policy to evaluate the Clinical Consultants (CC), Technical Supervisors (TS), and GS based on their CLIA responsibilities. Findings Include: 1. Record review on 7/10/2025 of the laboratory's CMS form 209, 'Laboratory Personnel Report', revealed the laboratory employs, two CC's, four TS's, and six GS's. 2. Record review on 7/10/2025 of the laboratory's 2023, 2024 and 2025 to date personnel competency records revealed the laboratory did not have documented competency evaluation for the two CC's, four TS's and six GS's based on their CLIA responsibilities. 3. Record review on 7/10/2025 of the laboratory's, electronic Policy and Procedures revealed the laboratory did not have a policy or procedure to assess the CC's, GS's, or TS's noted in #2 above based on their CLIA responsibilities. 4. During staff interview on 7/10/2025 at 2:30 PM with the LD and GS1, GS1 and the LD confirmed the laboratory does not have documented competency assessment for the CC's, GS's and TS's noted in #2 above based on their CLIA responsibilities and does not have a policy in place to assess them. GS1 also stated, a. "We have monthly Quality Assurance meetings, attended by supervisory personnel and we go over many of the responsibilities there. We just don't have it organized on a single document." b. "We were using the CMS Competency Workbook and misunderstood the part that addresses CC, GS and TS competency. We thought it meant they had to be assessed with the same criteria as testing personnel. I</p>

see what you mean now." 5. The laboratory performs 106,171 tests annually in the specialty of Diagnostic Immunology and 5,245,661 tests annually in the specialty of Chemistry.