

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0335934	(X3) Date Survey Completed 10/01/2025
Name of Provider or Supplier Preterm	Street Address, City, State 12000 Shaker Boulevard 4th Floor, Cleveland, OH	
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
D5209	<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 an interview with the Compliance Administrator, the laboratory failed to follow written policies and procedures to assess the competency of four out of four Testing Personnel (TP) based on the responsibilities of each position for the moderate complexity Rhesus Factor (Rh) testing procedures performed in the specialty of Immunohematology. This deficient practice had the potential to affect 700 out of 700 patient Rh testing procedures performed between 01/01/2024 through 03/01/2025. Findings Include: 1. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director (LD) on 09/26/2025 and provided on the date of the inspection, found four individuals listed as TP and qualified by the LD to perform moderate complexity Rh testing procedures. 2. Review of the "Laboratory Personnel Training and Competency Assessment Policy" approved by the LD signature on 07/22/2015, found the following statement: "The Director of Clinical Services completes an annual performance evaluation for all medical staff..." 3. The Inspector requested the laboratory's competency assessment documentation for TP #1, TP #2, TP #3 and TP #4 for the year 2024. The Compliance Administrator confirmed that the laboratory failed to conduct TP competency assessments for the year 2024 and could not produce the requested documentation. The interview occurred on 10/01/2025 at 1:52 PM.</p>