

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 22D0991667	(X3) Date Survey Completed 08/22/2024
Name of Provider or Supplier Bedford Research Foundation, Inc	Street Address, City, State 124 South Road, Bedford, MA	
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
D0000	A CLIA recertification survey was conducted for the Bedford Research Foundation laboratory on 08/22/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
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 interview the laboratory did not have an ongoing mechanism to evaluate the competency of the General Supervisor (GS). Findings Include: 1. Record review on 8/22/2024 of the laboratory's personnel competency records revealed the laboratory did not have a policy for documenting the competency of the GS in the specialties of Virology and Diagnostic Immunology. 2. Staff Interview on 8/22/204 at 10:00 AM: the Laboratory Director stated "We do not have a performance evaluation for the General Supervisor."</p>