

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0688950	(X3) Date Survey Completed 03/21/2023
Name of Provider or Supplier National B Virus	Street Address, City, State 100 Piedmont Avenue, Atlanta, GA	
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 Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on March 21, 2023. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on document review for Proficiency Testing (PT) and staff interview, the laboratory failed to perform corrective action on all unsatisfactory scores for nonchemistry analytes. The Findings include: 1. A review of Proficiency Test (PT) data with AAB (American Association of Bioanalysts Medical Laboratory Evaluation) revealed unsatisfactory scores for the Nonchemistry Q1 2021 and Q3 2021 for Herpes Type I, IgG or Ig non-specific, and failed to perform corrective action. 2. During an interview with the Laboratory Director #2 (CMS-209) on March 21, 2023 in an office suite, confirmed that the laboratory failed to perform corrective action on all unsatisfactory scores for Proficiency Testing for Q1 2021 and Q3 2021 for Nonchemistry Herpes Type I, IgG.</p>
D6024	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that all necessary remedial actions are taken and</p>

documented whenever significant deviations from the laboratory's established performance specifications are identified,

This STANDARD is not met as evidenced by:

Based on document review of the Proficiency Testing(PT) AAB(American Association of Bioanalysts Medical Laboratory Evaluation) and staff interview, the Laboratory Director(LD) failed to ensure a corrective action for unsatisfactory scores for Nonchemistry analytes in 2021. The Findings include: 1. Proficiency Test(PT) with AAB(American Association of Bioanalysts Medical Laboratory Evaluation) revealed that the Laboratory Director failed to ensure corrective action for the unsatisfactory scores. 2. During an interview with the Laboratory Director #2(CMS-209) on March 29, 2023 in an office suite, confirmed the Laboratory Director did not document corrective action for the unsatisfactory scores for Proficiency Testing.