Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0688950	02/20/2025
Name of Provider or Supplier	**Street Address, City, State**	
National B Virus	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 February 20, 2025. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2062	VIROLOGY CFR(s): 493.831(d) (d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unsatisfactory testing events, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: A review of the 2023 - 2024 AAB Medical Laboratory Proficiency Records, confirmed that the lab failed to conduct the required corrective action investigations and resolutions for all proficiency scores that were less than 100%. THE FINDINGS INCLUDE: 1. A review of the AAB records confirmed that the required investigation and corrective action for failed score of 67% (TORCH Herpes II in 2023 Nonchemistry M3 Event) was not documented. 2. This review was conducted off-site on Proficiency Records delivered electronically on February 21, 2025 for review, as the records were not available for review during site visit.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers

	established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: A review of instrumentation during a tour of the lab, the manufacturers' user manuals, and the verbal confirmation by the Laboratory Director (LD) and Lab Staff, confirmed that Testing Personnel (TP) failed to perform preventive maintenance as required by the manufacturer. THE FINDINGS INCLUDE: 1. In Room 910, review of the pipettes confirmed that two (2) of eight (8) pipettes, in use, was last calibrated in March 2023. 2. While touring Room 911, it was confirmed that the manufacturer's preventive maintenance schedule, for the ThermoFisher KingFisher Flex Analyzer, was not performed. 3. A tour of Room 911 confirmed that two (2) of the ten (10) pipettors, in use, was last calibrated in March 2023. 4. While touring the large laboratory testing area, it was confirmed that the preventive maintenance for the Fisher Scientific (FS) IsoTemp Refrigerator, the FS IsoTemp -20C Freezer, and the FS IsoTemp -80C Freezer was not performed per manufacturer's reccomendations. 5. A review of the manufacturer's reccomendations confirmed the lack of routine preventive maintenance for the Applied BioSystems QuantStudio 3 Analyzer. This service was last performed on February 28, 2023. 7. While touring the large laboratory testing area, it was confirmed that the manufacturer's required preventive maintenance for the Eppendorf Centrifuge 5810R was not performed. 8. While touring the large laboratory testing area, the LD verbally stated that the manufacturer's required cleaning, calibrations, and preventive maintenance for the ThermoFisher Series II Water Incubators HP-5 and HP-6 were performed however documentation of performance was not available on the day of inspection. 9. An exit interview, conducted with the LD and Lab Team, on February 20, 2025, at 2:45pm confirmed that laboratory did not perform preventive maintenance as required by the manufacturer.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: A review of 2023 - 2025 quality control records, 2023 - 2025 maintenance records, and 2023 - 2025 temperature logs, confirmed that the Laboratory Director (LD) failed to perform Quality Assurance (QA) reviews. THE FINDINGS INCLUDE: 1. A review of existing Quality Control Records, Maintenance Records, and Temperature/ Humidity Records for the 2023 - 2024 certificate period confirmed that there was no documentation to support that the LD reviewed these records. 2. An exit interview, conducted with the LD and Lab Team, on February 20, 2025, at 2:45pm, confirmed that the LD failed to provide documented Quality Assurance oversight.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15)

	(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: A review of 2023 - 2025 Personnel Records, confirmed that the LD failed to assure the competency for all CLIA personnel roles in the laboratory. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2024 Personnel Competencies Records confirmed that the LD failed to perform competencies on Technical Supervisors (TS): TS #1, TS #2, TS #3, TS #4 and on General Supervisors (GS): GS #1, and GS #2. 2. A request for Job Descriptions for all lab personnel positions, confirmed that Job Description documents did not exist for all CLIA defined positions currently filled in the laboratory. 4. An exit interview, conducted with the LD and Lab Team, on February 20, 2025, at 2:45pm, confirmed that the LD failed to assure that lab personnel were competent in each role assigned in the laboratory.
D6135	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1455 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1443(b)(1), (2), or (3) for the subspecialty of oral pathology, 493.1443(b)(5); or (b) Be a doctor of medicine, doctor of osteopathy, doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: A review of 2023 - 2025 Personnel Records, confirmed that Clinical Consultant Credentials were not validated. THE FINDINGS INCLUDE: 1. A review of the 2023 - 2025 Personnel Records confirmed that credentials for the Clinical Consultant were not available for verification on the date of inspection. 2. An exit interview, conducted with the LD and Lab Team, on February 20, 2025, at 2:45pm, confirmed that the credentials for the Clinical Consultant were not available to assess qualifications the day of survey or provided after the allotted 24 hours post inspection.