

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2041383	(X3) Date Survey Completed 09/23/2026
Name of Provider or Supplier Laboratorio De Emergencias Biologicas Y Quimicas	Street Address, City, State Calle Canada # 1334 Bosque San Patricio, San Juan, PR	
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
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on technical supervisor interview and DENV Detect IgM Capture ELISA quality control record review on September 23, 2026 at 11:30 am, the laboratory failed to include a negative quality control material at least once each day patient dengue IgM specimens were assayed. Findings included: a. It was the practice of the laboratory to test patient dengue IgM specimens using the InBios International DENV Detect IgM Capture ELISA test system. b. For 38 of 38 patient dengue IgM specimens tested on September 17, 2026, the laboratory maintained no documentation to indicate that a negative quality control material was included and tested when performing the laboratory's dengue IgM assay. c. This finding was confirmed by the technical supervisor on September 23, 2026 at 11:30 am. Routinely, a negative quality control material was not included in the test run each day patient dengue IgM specimens were assayed. d. According to the technical supervisor, the laboratory performed and reported approximately 600 patient dengue IgM assays annually.