

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2041383	(X3) Date Survey Completed 08/26/2022
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
D0000	The Centers for Medicare & Medicaid Services (CMS) New York CLIA Branch Location federal surveyors conducted an announced CLIA recertification survey at LABORATORIO DE EMERGENCIAS BIOLOGICAS Y QUIMICAS on August 25, 2022 and August 26, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following deficiency was found during the announced routine CLIA recertification survey performed on August 25, 2022.
D5775	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Biological and Chemical Emergencies Laboratory (BCEL) equipment comparison binders, interview with the laboratory director (LD) and technical supervisor (TS), the laboratory failed to evaluate the relationship between six of six Applied Biosystems (ABI) 7500 Dx Real-Time PCR analyzers that analyzed the Centers for Disease Control and Prevention (CDC) Triplex, the CDC Dengue 1-4 serotyping and the CDC Influenza SARS-CoV2 assays twice a year to each other from 2021 to 2022. Findings Include: 1. Six ABI 7500 Dx Real-Time PCR analyzers (serial numbers: 275030353, 275030932, 275030391, 275031108, 275032403, and 275032386), were used to analyze the following assays: - CDC Triplex assay. - CDC Dengue 1-4 serotyping assay - CDC Influenza SARS-CoV2 assay. 2. On the days of the survey (August 25, 2022, and August 26, 2022) review of the ABI 7500 Dx Real-Time PCR analyzers comparison records in the 2021 and 2022 BCEL equipment</p>

comparison binders revealed, the laboratory evaluated the relationship between two of six ABI 7500 Dx Real-Time PCR analyzers for the above assays twice a year from 2021 to 2022. 3. On 08/26/2022 at 10:30 am, the LD and TS confirmed the comparison studies performed did not evaluate the six of six ABI 7500 Dx Real-Time PCR analyzers to each other for the above three assays from 2021 to 2022.