

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2095191	(X3) Date Survey Completed 06/25/2025
Name of Provider or Supplier Laboratorio Clinico Quest Diagnostics Gurabo	Street Address, City, State Shopping Praderas De Navarro, Pr-931, Km 5, Hm 4, Gurabo, 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) conducted a CLIA recertification survey at Laboratorio Clinico Quest Diagnostics Gurabo on June 25, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on June 25, 2025.
D6101	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11)</p> <p>(e)(11) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart;</p> <p>This STANDARD is not met as evidenced by: Based on personnel records review (years 2024-2025) and laboratory technical supervisor interview, on June 25, 2025 at 8:35 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure that the clinical consultant meets the qualification requirements of 493.1455. Refer to D6135.</p>
D6134	<p>CLINICAL CONSULTANT CFR(s): 493.1453</p> <p>The laboratory must have a clinical consultant who meets the requirements of 493.1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on laboratory personnel records review and laboratory supervisor interview, on June 25, 2025 at 8:35 AM; it was determined that the laboratory clinical consultant position does not meet the requirements from June 1, 2025 until present. Refer to D6135.

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:

Based on personnel records review (years 2024-2025) and laboratory technical supervisor interview on June 25, 2025 at 8:35 AM, it was determined that the clinical consultant did not meet the qualification requirements. The findings include: 1. The laboratory personnel records were reviewed (years 2024-2025), on June 25, 2025 at 8:30 AM, and showed that the laboratory had a new clinical consultant since June 1, 2025. 2. Review of the laboratory personnel records, on June 25, 2025 at 8:32 AM, showed that the new clinical consultant did not meet the qualification requirements to have a license to practice medicine in the state of Puerto Rico, in which the laboratory is located. 3. The laboratory technical supervisor confirmed on June 25, 2025 at 8:35 AM, that the clinical consultant did not meet the qualification requirements of having a license to practice medicine in the state in which the laboratory is located.