

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0668011	(X3) Date Survey Completed 03/26/2025
Name of Provider or Supplier Cdt-Cmt Group, Corp	Street Address, City, State Clemson 300 University Gardens Rio Piedras, 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	<p>The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the CDT-CMT Group, Corp. on March 26, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on March 26, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.801 Enrollment and testing of samples 42 CFR 493.1441 Laboratory director; high complexity testing</p>
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing (PRPT) scores (years 2023 - 2025), CASPER Report 0155D scores, toxicology patient's testing record and laboratory director interview on March 26, 2025 at 9:30 AM, it was determined that the laboratory failed to enroll in a HHS approved Proficiency Testing Program for valproic acid test, when processed and reported 480 to 523 valproic acid patient's test from January 1, 2023 to March 25, 2025. The findings include: 1. On March 26, 2025, at 9:30 AM, review the PRPT and CASPER Report 0155D scores, showed no results for valproic acid test from January 1, 2023, to December 31, 2024. 2. On March 26, 2025, at 10:00 AM, the toxicology patient's testing records showed that the laboratory</p>

	<p>processed and reported 480 to 523 valproic acid patients tests from January 1, 2023 to March 25, 2025. 3. The laboratory director confirmed on March 26, 2025, at 10:15 AM that the laboratory failed to enroll in a HHS approved Proficiency Testing Program for valproic acid test. 4. This deficiency was cited on February 7, 2023.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review PRPT, CASPER Report 0155D scores, toxicology patients testing record and laboratory director interview on March 26, 2025, at 10:15 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory Proficiency Testing Program. Refer to D6088. The findings include: 1. This deficiency was cited on February 7, 2023.</p>
<p>D6088</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)</p> <p>(e)(4) Ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed and that--</p> <p>This STANDARD is not met as evidenced by: Based on review PRPT, CASPER Report 0155D scores, toxicology patients testing record and laboratory director interview on March 26, 2025, at 10:15 AM, it was determined that the laboratory director failed to ensure the laboratory enrollment in an HHS approved Proficiency Testing Program for valproic acid test.</p>