Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0668011	08/08/2024
Name of Provider or Supplier	**Street Address, City, State**	
Cdt-Cmt Group, Corp	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	A Proficiency Test Desk Review off site survey was performed on August 8, 2024 to Laboratorio Clnico CDT CMT Group, Corp. , the laboratory was found out of compliance with the following conditions: 42 CFR 493.803 Proficiency Testing, Successful Participation 42 CFR 493.1441 Laboratory Director, high complexity
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of Puerto Rico proficiency testing scores (years 2023-2024) and

	CASPER Report 0155D scores, it was determined that the laboratory obtained a unsuccessful participation in a Proficiency Testing Program for Anti-HBs tests. Refer to D2085.
D2085	GENERAL IMMUNOLOGY CFR(s): 493.837(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing scores (years 2023-2024) and CASPER Report 0155D scores, it was determined that the laboratory obtained a unsuccessful performance in two out two consecutive testing events for Anti-Hbs tests. The findings include: 1. The Puerto Rico Proficiency and CASPER Report 0155D scores, showed that the laboratory obtained following unsuccessful scores: Analyte: Anti-Hbs a. Third testng event year 2023 -40%. b. First testing event year 2024 -20%.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on review of Puerto Rico proficiency testing scores (years 2023-2024) and CASPER Report 0155D scores, it was determined that the laboratory director failed to ensure the laboratory's successful participation in a Proficiency Testing Program for Anti-HBs tests. Refer to D6079.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Puerto Rico proficiency scores (years 2023-2024) and CASPER Report

	0155D scores, it was determined that the laboratory director did not ensure that the laboratory had a satisfactory participation in the Anti-HBs tests during the third testiing event of year 2023 and first testing event of year 2024. Refer to D2028.