Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1095483	07/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Riaza	#502 Calle Riaza, Urb Matienzo Cintron, Bo Oriente, 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 July 7, 2025 to Laboratorio Clinico Riaza, 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 2024-2025) and

	CASPER Report 0155D scores, it was determined that the laboratory obtained a unsuccessful participation in a Proficiency Testing Program for Hema Cell Id tests. Refer D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of Puerto Rico Proficiency Testing scores (years 2024-2025) and CASPER Report 0155D scores, it was determined that the laboratory obtained an initial unsuccessful performance in two consecutive testing events for Hema Cell Id tests. The finding includes: 1. The Puerto Rico Proficiency and Casper Report 0155D scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: Hema Cell Id a. Third testing event year 2024 - 0% b. First testing event year 2024 - 70%
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 2024-2025) and CASPER Report 0155D scores, its was determined that the laboratory director failed to ensure the laboratory's successful participation in a Proficiency Testing Program for hematology tests. Refer to D6089.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on Puerto Rico proficiency testing scores (years 2024-2025) and CASPER Report 0155D scores, it was determined that the laboratory director did not ensure that the laboratory had a satisfactory participation for Hema Cell Id tests during the third testing event of the year 2024 and first testing event of the year 2025. Refer to D2130.