Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2329974	10/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Bienestar	Carr 2 Km 68 Hm 9 Bo Santana, Arecibo, 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 October 5, 2026 to Laboratorio Clnico Bienestar, the laboratory was found out of compliance with the following conditions: 42 CFR 493.803 Proficiency Testing, Successful Participation 42 CFR 493.1403 Laboratory Director, Moderate 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 Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year

	2026), the laboratory failed to achieve satisfactory performance (80% or better) for two (2) out of two (2) consecutive testing events for the specialty of hematology in the analyte for Hematocrit (HCT) tests. Refer to 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 Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2026), the laboratory failed to achieve satisfactory performance (80% or better) for two (2) out of two (2) consecutive testing events for the specialty of hematology in the analyte for Hematocrit (HCT) tests. The findings include: 1. Review of the Casper Report 0155D and PRPTSP scores on September 27, 2026, confirmed that the laboratory had a PT (Proficiency Test) failure for the analyte Hematocrit (HCT) tests in the specialty of hematology. The laboratory obtained the following testing scores: Analyte: Hematocrit (HCT) a. First testing event year 2026 - 60% b. Second testing event year 2026 - 60% 2. A review of the PRPTSP records confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2026), the laboratory director failed to provide overall management and direction of the laboratory services. The laboratory director failed to ensure proficiency testing samples were tested as required. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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 review of Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2026), the laboratory director failed to ensure successful participation in an HHS-approved proficiency testing program. Refer to D2130.