Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658075	08/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Menonita Ponce	Road 506 Km 1 Bo Coto Laurel, Coto Laurel, 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 18, 2025 to Laboratorio Clinico Hospital Menonita de Ponce, 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: A. Based on review of the Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2025), it was determined that the laboratory obtained a unsuccessful participation in a Proficiency Testing Program for pO2 (arterial blood gases) tests.

	Refer D2096. B. Based on review of the Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), it was determined that the laboratory obtained a unsuccessful participation in a Proficiency Testing Program for T3 Uptake tests. Refer D2107.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in 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 the Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2025), it was determined that the laboratory obtained an initial unsuccessful performance in two out of two consecutive testing events for pO2 (arterial blood gases) tests. The finding includes: 1. The Casper Report 0155D and PRPTSP scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: pO2 a. First Testing event year 2025 - 60% b. Second testing event year 2025 - 40%
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) (f) Failure to achieve satisfactory performance for the same analyte or test in 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 the Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), it was determined that the laboratory obtained an initial unsuccessful performance in two out of three consecutive testing events for Triiodothyronine (T3) Uptake tests. The finding includes: 1. The Casper Report 0155D and PRPTSP scores, showed that the laboratory obtained the following unsuccessful scores: Analyte: T3 Uptake a. Third testing event year 2024 - 0% b. Second testing event year 2025 - 0%
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 the Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP)

	scores (year 2025), its was determined that the laboratory director failed to ensure the laboratory's successful participation in a Proficiency Testing Program for Sodium tests and pO2 (arterial blood gases) tests.. 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: A. Based on review of the Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (year 2025), it was determined that the laboratory director did not ensure that the laboratory had a satisfactory participation for pO2 (areterial blood gases) tests during the first testing event of the year 2025 and second testing event of the year 2025. Refer to D2096. B. Based on review of the Certification And Survey Provider Enhanced Reports (CASPER) 0155D and Puerto Rico Proficiency Testing Service Program (PRPTSP) scores (years 2024-2025), it was determined that the laboratory director did not ensure that the laboratory had a satisfactory participation for T3 Uptake tests during the third testing event of the year 2024 and second testing event of the year 2025. Refer to D2107.