Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0717802	04/23/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Sepulveda	Mendez Vigo 63 Este Cond Centro Plaza, Mayaguez, 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	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the Laboratorio Clnico Sepulveda on April 23, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following standard level deficiencies were found during the unannounced routine CLIA recertification survey ending on April 23, 2026.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) (c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on serology quality control record review (years 2025 - 2026), manufacturer's test system insert review, and laboratory director interview on April 23, 2026, at 11:20 a.m., the laboratory failed to include the weakly reactive control each day of patient testing. The laboratory processed and reported 45 out of 45 syphilis serology patient tests by the ASI Rapid Plasma Reagin (RPR) Card Test from June 4, 2025, through April 22, 2026. The findings included: 1. On April 23, 2026, at 11:20 a.m., review of serology quality control records showed that the laboratory used the ASI Rapid Plasma Reagin (RPR) Card Test for syphilis serology patient testing. 2. On April 23, 2026, at 11:32 a.m., review of the manufacturer's test system insert showed that controls with graded reactivity were required to be included each day of patient testing. 3. On April 23, 2026, at 11:40 a.m., review of the RPR quality control records showed that the laboratory did not include the weakly reactive control material each day of patient testing. 4. The laboratory processed and reported 45 out of 45 RPR patient specimens from June 4, 2025, through April 22, 2026. 5.On April 23, 2026, at

	12:15 p.m., the laboratory director confirmed during interview that the laboratory processed only the reactive and non-reactive control materials each day of testing and did not process the weakly reactive control.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of syphilis serology quality control records, patient testing worksheet records (years 2025 - 2026), the manufacturer's instructions, and laboratory director interview on April 23, 2026, at 11:20 a.m., the laboratory failed to follow the manufacturer's instructions regarding cleaning of the needle assembly for the ASI Rapid Plasma Reagin (RPR) reagent kit. The laboratory processed and reported 45 out of 45 RPR patient specimens from June 4, 2025, through April 22, 2026. The findings included: 1. On April 23, 2026, at 11:32 a.m., review of the ASI manufacturer's instructions showed that the needle assembly had to be thoroughly washed in distilled or deionized water and air-dried after each shift. 2. On April 23, 2026, at 11:40 a.m., review of the syphilis serology quality control and patient testing worksheet records showed that the laboratory did not perform or document the needle assembly wash after each shift. 3. The laboratory processed and reported 45 out of 45 RPR patient specimens from June 4, 2025, through April 22, 2026. 4. On April 23, 2026, at 12:15 p.m., the laboratory director confirmed during interview that the laboratory did not follow the manufacturer's instructions regarding the needle assembly wash.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on serology quality control record review (years 2025 - 2026), ASI Rapid Plasma Reagin (RPR) Card Test verification of performance specifications records, and interviews with the laboratory director on April 23, 2026, at 11:20 a.m., the laboratory failed to verify the performance specifications of the ASI Rapid Plasma Reagin (RPR) Card Test before the laboratory used the test system to process and report patient results. The laboratory processed and reported 45 out of 45 RPR patient specimens from June 4, 2025, through April 22, 2026. The findings included: 1. On April 23, 2026, at 11:20 a.m., review of serology quality control records showed that the laboratory used the ASI Rapid Plasma Reagin (RPR) Card Test for syphilis serology patient testing. The laboratory director stated that the laboratory previously

	used an RPR test kit manufactured by TECO Diagnostics. 2. On April 23, 2026, at 11: 20 a.m., the verification of performance specifications records for the ASI Rapid Plasma Reagin (RPR) Card Test were requested. The laboratory director stated on April 23, 2026, at 12:15 p.m., that the laboratory did not perform the required performance verification before using the ASI RPR test system for patient testing. 3. The laboratory processed and reported 45 out of 45 RPR patient specimens from June 4, 2025, through April 22, 2026.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of syphilis serology quality control records, RPR patient testing records (years 2025 - 2026), ASI Rapid Plasma Reagin (RPR) Card Test manufacturer's instructions, and interviews with the laboratory director on April 23, 2026, at 1:00 p.m., the laboratory director failed to ensure compliance with analytical requirements for the subespecialty of Syphilis Serology. Refer to D5405, D5411 and D5421.