Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1097944	03/05/2026
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Beatriz Inc	Car Pr-787 Km 4 Hm 7 Barrio Bayamon, Cidra, 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 Beatriz, Inc. on March 5, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on March 5, 2026, the laboratory was found out of compliance with the following conditions: 493.1212 Condition: Endocrinology. 493.1441 Condition: Laboratory performing high complexity testing; laboratory director.
D5020	ENDOCRINOLOGY CFR(s): 493.1212 If the laboratory provides services in the subspecialty of Endocrinology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Human Chorionic Gonadotropin (hCG) quality control records review (years 2025 - 2026) and interview with the laboratory supervisor on March 4, 2026, at 10:45 AM, the laboratory failed to meet the quality control requirements for Endocrinology specialty. Refer to D5449.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on the Human Chorionic Gonadotropin (hCG) quality control records review (years 2025-2026), and laboratory supervisor interview on March 5, 2026 at 10:45 AM, the laboratory failed to include an external negative and positive control

	material, each day of patient testing. The laboratory processed and reported 41 hCG patient samples from January 2025 to December 2025. The findings include: 1. The laboratory uses the AimStep Combo Pregnancy kit to perform the hCG tests. 2. Review of the hCG test quality control records (years 2025-2026), on March 5, 2026 at 10:23 AM, showed that the laboratory failed to include an external negative and positive control material, each day of patient testing, when the laboratory processed and reported 41 hCG patient samples from January 2025 to December 2025. 3. The laboratory supervisor confirmed on March 5, 2026 at 10:45 AM, that the laboratory failed to perform the external negative and positive control material each day of patient testing in the 2025 year. The laboratory processed and reported 41 hCG patient samples from January 2025 to December 2025.
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 Human Chorionic Gonadotropin (hCG) quality control records and interview with the laboratory supervisor on March 5, 2026 at 10:45 AM, the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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 Human Chorionic Gonadotropin (hCG) quality control records and interview with the laboratory supervisor on March 5, 2026 at 10:45 AM, the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D5020.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) (b)(3) Adhere to the laboratorys quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed; This STANDARD is not met as evidenced by: Based on review of Human Chorionic Gonadotropin (hCG) quality control records (years 2025-2026), and interview with the laboratory supervisor (also testing personnel) on March 5, 2026 at 10:45 AM; the laboratory testing personnel failed to perform and document all quality control activities to ensure compliance with the hCG quality control requirements. Refer to D5449.