

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0930888	(X3) Date Survey Completed 08/27/2026
Name of Provider or Supplier Laboratorio Clinico Montehiedra	Street Address, City, State Montehiedra Tower Center Mall #206, 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	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Montehiedra on August 27, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on August 27, 2026.
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 technical supervisor interview on August 27, 2026 at 12:05 PM, the laboratory failed to include an external negative and positive control material, each day of patient testing. The laboratory processed and reported 8 hCG patient samples from April 25, 2026, to August 27, 2026. 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 August 27, 2026 at 12:01 PM, 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 8 patient samples on the following dates: April 25, 2026, May 8, 2026, June 19, 2026, June 20, 2026, July 20, 2026, August 21, 2026, August 24, 2026 and August 27, 2026. 3. The laboratory technical supervisor confirmed on August 27, 2026 at 12:05 PM, that the laboratory failed to perform the external negative and positive control material each day of patient testing. The laboratory processed and reported 8 patient samples from April 25, 2026, to August 27, 2026.
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 the Human Chorionic Gonadotropin (hCG) quality control records review (years 2025-2026), and laboratory technical supervisor interview on August 27, 2026 at 12:05 PM, the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D5449.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on the Human Chorionic Gonadotropin (hCG) quality control records review (years 2025-2026), and laboratory technical supervisor interview on August 27, 2026 at 12:05 PM, the laboratory technical supervisor failed to fulfill his responsibilities to ensure compliance with the quality control requirements. Refer to D5449.
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 the Human Chorionic Gonadotropin (hCG) quality control records review (years 2025-2026), and laboratory technical supervisor interview on August 27, 2026 at 12:05 PM, the laboratory testing personnel failed to perform and document all quality control activities to ensure compliance with the endocrinology quality control requirements. Refer to D5449.