

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0862901	(X3) Date Survey Completed 03/05/2026
Name of Provider or Supplier Laboratorio Clinico Paseos II	Street Address, City, State Calle Bolivia 76 Suite 102, Hato Rey, 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 Clinico Paseos II on March 5, 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 March 5, 2026.
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters.</p> <p>This STANDARD is not met as evidenced by: Based on a review of Sperm Count Quality Control (QC) records (years 2024-2026), the manufacturer's instructions for QwikCheck Beads Control and the interview with the laboratory director on March 5, 2026, at 11:30 a.m., the laboratory failed to verify the manufacturer's stated values of the QwikCheck Beads Control prior to placing new controls lots into routine use. The laboratory processed and reported 210 out of 210 semen analysis patient samples from January 4, 2024, through March 4, 2026. The findings include: 1. The review of Sperm Count Quality Control (QC) records showed that the laboratory used QwikCheck beads control (Levels 1 and 2) to monitor the precision of semen analysis testing on the SQA V Sperm Quality Analyzer. (Reviewed on March 5, 2026, at 11:30 a.m.) 2. The manufacturer's instructions for</p>

QwikCheck Beads Control establish that the laboratory must verify the manufacturer's stated values when a new control lot is introduced before placing the control materials into routine use. (Reviewed on March 5, 2026, at 11:40 a.m.) 3. The review of QC records showed that the laboratory placed the following lots of Sperm Count control materials into routine use without verifying the manufacturer's stated values: a. Control Lot: Level 1 (Lot 040423001) / Level 2 (Lot 040423002) Exp. Dates: 4/30 /2024 Use dates: January 4, 2024, through April 23, 2024. Patient samples processed and reported: 28 b. Control Lot: Level 1 (Lot 060823001) / Level 2 (Lot 060823002) Exp. Dates: 8/31/2024 Use dates: May 7, 2024, through August 27, 2024. Patient samples processed and reported: 18 c. Control Lot: Level 1 (Lot 031223001) / Level 2 (Lot 031223002) Exp. Dates: 12/31/2024 Use dates: September 3, 2024, through December 17, 2025. Patient samples processed and reported: 28 d. Control Lot: Level 1 (Lot 110724001) / Level 2 (Lot 110724002) Exp. Dates: 7/31/2025 Use dates: January 14, 2025, through July 24, 2025. Patient samples processed and reported: 59 e. Control Lot: Level 1 (Lot 060325001) / Level 2 (Lot 060325002) Exp. Dates: 3/31 /2026 Use dates: March 4, 2026, through December 30, 2025. Patient samples processed and reported: 39 4. During the interview on March 5, 2026, at 11:55 a.m., the laboratory director confirmed that the laboratory placed the Sperm Count control materials into routine use without first verifying the manufacturer's stated values. 5. The laboratory processed and reported 210 out of 210 semen analysis patient samples from January 4, 2024, through March 4, 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 quality control records review (years 2024-2026) and interview with the laboratory director on March 5, 2026, at 1:00 p.m., the laboratory director failed to ensure compliance with the Hematology quality control requirements. Refer to D5469.