

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2126577	(X3) Date Survey Completed 10/17/2025
Name of Provider or Supplier Metro Pavia Clinic - Aguadilla	Street Address, City, State Carretera 107 Barrio Camaseyes, Aguadilla, 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 Metro Pavia Clinic - Aguadilla on October 17, 2025. 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 October 17, 2025.
D5471	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.</p> <p>This STANDARD is not met as evidenced by: A. Based on a review of rapid plasma reagin (RPR) quality control records (year 2025) and an interview with the laboratory general supervisor on October 16, 2025, at 12:00 PM, it was determined that the laboratory failed to evaluate the new lot of RPR test kits for positive and negative reactivity prior to placing the lot in routine use on September 30, 2025. The findings include: 1. The laboratory performed RPR tests for syphilis using the ASI RPR Card Test. 2. The RPR quality control records were reviewed from January 1, 2025, to October 16, 2025, and showed that the laboratory did not evaluate the new lot of RPR test kits for positive and negative reactivity prior to use in patient testing. Lot Number: 5C07R6 Expiration date: December 31,2026 Date opened: September 30,2025 3. The laboratory performed and reported 26 out of 26 RPR patient tests from September 30, 2025, to October16, 2025. 4. The laboratory general supervisor confirmed on October 17, 2025, at 12:05 PM, that the laboratory did not evaluate the new lot of RPR tests for positive and negative reactivity prior to</p>

placing it into routine use. B. Based on the review of human chorionic gonadotropin (hCG) test quality control records (year 2025) and an interview with the laboratory general supervisor on October 17, 2025, at 12:10 PM, it was determined that the laboratory failed to evaluate the new lot of hCG test kits for positive and negative reactivity prior to placing the lot in routine use on September 24, 2025. The findings include: 1. The laboratory performed hCG testing using the Alere hCG Combo Cassette method. 2. The hCG quality control test records were reviewed from January 1, 2025, to October 16, 2025, and showed that the laboratory did not evaluate the new lot of hCG test kits for positive and negative reactivity prior to use in patient testing. Lot Number: 953985 Expiration date: January 1, 2027 Date opened: September 24, 2025 3. The laboratory performed and reported 18 out of 18 hCG patient tests from September 24, 2025, to October 16, 2025. 4. The laboratory general supervisor confirmed on October 17, 2025, at 12:20 PM, that the laboratory did not evaluate the new lot of hCG test for positive and negative reactivity prior to placing it in routine use.

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 review of RPR and hCG quality control records (year 2025) and an interview with the laboratory general supervisor on October 17, 2025, at 12:30 PM, it was determined that the laboratory director failed to ensure that the general supervisor monitored compliance with analytic system requirements for new lots of RPR and hCG test kits for positive and negative reactivity prior to placing them in routine use. Refer to D6144.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:
Based on the review of RPR and hCG quality control records review and an interview with the laboratory general supervisor on October 17, 2025, at 12:30 PM, it was determined that the laboratory general supervisor failed to verify the new lots of RPR and hCG test kits for positive and negative reactivity prior to placing them in routine use. Refer to D5471 (A) and (B).