

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0669618	(X3) Date Survey Completed 05/20/2025
Name of Provider or Supplier Lab Clinico Clets Inst Of Health Labs	Street Address, City, State Edificio Casa De Salud, 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	A recertification survey was conducted May 20, 2025. Standard level deficiencies were cited.
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory procedure, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for the Medical Chemical Corporation Gram Stain procedure for two of two years. Findings included: 1. During a tour of the laboratory area on May 20, 2025, at 10:00 am, a Medical Chemical Corporation (MCC) Gram's Stain Kit, Lot number A4820, Expiration date 05/31/2028, was observed opened and in use. 2. The manufacturer's instructions (Document number PR038, Revision date 03-21-2022) stated, " ...Procedure 1. Place the fixed smear on a staining rack and cover with crystal violet for 30 to 60 seconds ...3. Cover the slide with the iodine solution for 30 seconds ...5. Decolorize with decolorizer until the rinse solution runs clear (about 10 to 15 seconds for reagent alcohol, much shorter for acetone alcohol) ... 7. Stain with safranin O counter stain for 30 to 60 seconds ..." 3. The laboratory's procedure titled "Gram Stain" stated, " ...1. Primary dye crystal violet 15 seconds ...2. Gram's Iodine 15 seconds ...3. Decolorizer acetone alcohol ...10-15 seconds ...4. Secondary dye Safranin...15 seconds..." The staining times stated in the laboratory procedure differed from the staining times per manufacturer's instructions. 4. In an interview on 05/20/2025 at 10:35 am, the Laboratory Director confirmed that the laboratory procedure did not follow manufacturer's instructions.</p>

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on direct observation, review of manufacturer's instructions, and confirmed in interview, the laboratory failed to ensure one of one bottles containing rapid plasma regain (RPR) carbon antigen was labeled to indicate identification and revised expiration dates. Findings included: 1. During a tour of the laboratory area on May 20, 2025, at 10:00 am, one Arlington Scientific (ASI) RPR kit (Lot number 4D22R6) was observed in the laboratory refrigerator. The dropping bottle containing carbon antigen was not labeled with identifying and revised expiration date information. 2. The manufacturer's instructions for the ASI RPR test kits stated, "...Handling and Procedural Notes 1. In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed ...Carbon antigen may be stored for up to one month in the dropping bottle ..." 3. In an interview on 05/20/2025 at 10:35 am, the Laboratory Director confirmed that the laboratory did not label the dropping bottle with reagent identity and revised expiration date.