

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0690924	(X3) Date Survey Completed 06/10/2024
Name of Provider or Supplier Laboratorio Clinico De Inmunologia Mayaguez	Street Address, City, State 2do Piso Edificio Clinica De Inmunologia, Mayaguez, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director (LD) and technical consultant (TC), the laboratory failed to ensure patient test reports included the name, as stated on the CLIA certificate, for two of two patient reports. Findings include: 1. Interview on 06/10/2024 at 09:30 am with the TC confirmed the following: a. The laboratory performed RPR (Rapid Plasma Reagin) testing using the "ASI RPR CARD TEST FOR SYPHILIS". 2. Record review on 06/10/2024 of two patient reports revealed that the laboratory name was listed as "PUERTO RICO PUBLIC HEALTH LABORATORY" for two of two patient reports: a. Patient (529378) RPR testing on 12/06/23 b. Patient (178274) RPR testing on 12/06/23 2. Review of the laboratory's CLIA certificate on 06/10/2024 listed the laboratory's name as "LAB IMMUNOLOGIA ETS REGIONAL". 3. Interview with the LD and TC on 06/10/24 at 11:45 am confirmed the the laboratory failed to ensure patient reports included the name, as stated on the CLIA certificate, as indicated above.</p>