

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2275917	(X3) Date Survey Completed 07/13/2023
Name of Provider or Supplier Laboratorio Clinico Familiar Zarza	Street Address, City, State Carr 2, Km 90 Interior Sector Zarza Bo Puente, Camuy, 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
D5014	<p>GENERAL IMMUNOLOGY CFR(s): 493.1208</p> <p>If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Mycoplasma pneumoniae quality control records on July 13, 2023 at 12:00P.M., and laboratory director interview, it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae test. Refer to D5449.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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 syphilis serology quality control and patient test worksheet records, manufacturer's instructions review, and laboratory director interview, on July 13, 2023 at 11:43 A.M., it was determined that the laboratory failed to follow the manufacturer's instructions for the syphilis serology tests, when 8 out of 8 patient specimens were tested from April 26, 2023 to June 26, 2023. The findings include: 1. The laboratory uses the ASI's reagent kit to perform patient syphilis serology test.</p>

	<p>Review of the ASI's manufacturer's instructions on July 13, 2023 at 11:43 A.M., showed that the laboratory must remove and wash the needle at the end of the day. 2. On July 13, 2023 at 11:48 A.M., the syphilis serology quality control and patient test worksheet records were reviewed. The records showed that the laboratory did not perform the needle wash as required by the manufacturer, when they processed and reported 8 out of 8 patient specimens from April 26, 2023 to June 26, 2023. 3. The laboratory director confirmed on July 13, 2023 at 11: 53 A.M., that the laboratory did not follow the manufacturer's instructions related to the needle wash, from April 26, 2023 to June 26, 2023.</p>
<p>D5449</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae test quality control and patient test worksheet records review on July 13, 2023 at 12:00 P.M., and laboratory director interview, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing, neither documented the patient's internal procedural control. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae test. 2. Review of Mycoplasma pneumoniae quality control and patient test worksheet records on July 13, 2023 at 12:00 P.M., showed that the laboratory did not include any control material each day of patient testing from June 2, 2023 to June 29, 2023, when 13 out of 13 patients were processed and reported. The laboratory neither documented the patient's internal procedural control. 3. The laboratory director confirmed on July 13, 2023 at 12:10 P.M., that the laboratory failed to include a negative and positive control material, nor documented the procedural control.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of quality control records it was determined that the laboratory director failed to fulfill her responsibilities with the syphilis serology and Mycoplasma pneumoniae analytic requirements. Refer to D6020.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform</p>

test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on syphilis serology and Mycoplasma pneumoniae quality control records review from April 26, 2023 to June 29, 2023, and interview with the laboratory director on July 13, 2023 at 12:00 P.M., it was determined that the laboratory director (sole personnel) did not establish quality control procedures for the syphilis serology, nor the Mycoplasma pneumoniae tests. Refer to D5411. Refer to D5449.