

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0894133	(X3) Date Survey Completed 08/04/2023
Name of Provider or Supplier Centro De Salud Familiar De Lajas	Street Address, City, State Ave Los Veteranos 237, Lajas, 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
D5449	<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 General Immunology (Mycoplasma pneumoniae test) quality control records review (year 2023), patient's reports review and laboratory general supervisor interview on August 4, 2023 at 10:30 AM, it was determined that the laboratory did not include an external positive and negative control material each testing day when performed and reported 651 of 889 Mycoplasma pneumoniae patient testing from January 2, 2023 to August 3, 2023. The findings include: 1. The laboratory performed Mycoplasma pneumoniae patient's test by Immunocard method. (Reviewed on August 4, 2023 at 10:30 AM) 2. The general immunology (Mycoplasma pneumoniae test) quality control records and patient's report were review from January 2, 2023 to August 3, 2023. (Reviewed on August 4, 2023 at 10:40 AM) 3. The general immunology (Mycoplasma pneumoniae test) quality control showed that the laboratory did not include an external negative and positive control material each day of patient testing on 143 of 173 days. (Reviewed on August 4, 2023 at 10:45 AM) 3. The laboratory general supervisor confirmed on August 4, 2023 at 10:48 AM that the laboratory failed to include a negative and positive external control material each day of testing when performed Mycoplasma pneumonia test. The laboratory nclude the internal procedure control with each patient. (Reviewed on August 4, 2023 at 10:50 AM) 4. The laboratory performed and reported eight hundred eighty nine (889) patient's specimen were tested for Mycoplasma pneumoniae from January 2, 2023 to August 3, 2023.</p>

D6093

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 general immunology quality control records review (year 2023), patient's reports worksheets review and laboratory general supervisor interview on August 4, 2023 at 10:30 AM, it was determined that the laboratory director did not make sure that the technical supervisor maintained the quality control requirements for Mycoplasma pneumonia patient test. The finding include: 1. The laboratory did not include an external negative and positive control material for Mycoplasma pneumoniae each day of testing. Refer to D5449.

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 general immunology quality control records review (year 2023), and laboratory general supervisor interview on August 4, 2023 at 10:30 AM, it was determined that the general supervisor did not ensure that the testing personnel follow the written instructions control procedures for Mycoplasma pneumoniae patient's test. Refer to D5449.