

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658102	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier Laboratorio Clinico Campo Alegre	Street Address, City, State Carr 130 Mk 11 4 Bo Campo Alegre, Hatillo, 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 Mycoplasma pneumoniae quality control records patient records review and interview with the laboratory director on September 29 2021 at 9:46 AM, it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The finding includes: a. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to: 5449- (The laboratory did not include positive and negative control material for Mycoplasma Pneumoniae).</p>
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 review of Mycoplasma pneumoniae IgM quality control results, patient test results records and phone interview with the laboratory director on September 29, 2021 at 9:46 AM, it was found that the laboratory did not include a positive and a</p>

negative control material each day of patient testing. The findings include: a. Review of the quality control and patient test results records, on September 29, 2021 at 9:46 AM, showed that positive and negative controls were included when a new reagent lot number. b. Review of Mycoplasma pneumoniae quality control and patient results records showed that the laboratory perform patient testing on; 9/30/2020, 10/19/2020, 12/02/2020, 12/03/2020, 12/17/2020, 1/11/2021, 4/28/2021, 6/15/2021, 6/29/2021, 7/22/2021, 8/2/2021, 8/5/2021, 8/6/2021, 8/13/2021, 8/17/2021, 8/25/2021, 8/30/2021, 9/01/2021, 9/10/2021, 9/15/2021, 9/16/2021. No external control material were included each day of patient testing. c. The records showed that from 9/30/2020 to 9/16/2021 the laboratory processed and reported 30 patient samples. d. The laboratory director confirmed on September 29,2021 at 9:46 AM, that the laboratory failed to include a negative and positive control material in these days of testing when performed Mycoplasma pneumonia test.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform 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 quality control records review and laboratory director interview on September 29, 2021 at 9:46 AM, it was determined that laboratory director failed to establish quality control procedures for Mycoplasma pneumoniae test. Refer to D5449.

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
Based on quality control records review and laboratory director interview at 9:46 A. M. on September 29, 2021 it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory general immunology quality control requirements . Refer to D 6020.