

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1036403	(X3) Date Survey Completed 11/17/2023
Name of Provider or Supplier Cdt Hospital De La Concepcion	Street Address, City, State Carr Pr-102 Km 39 Hm 1, Sabana Grande, 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 IgM quality control records on November 17, 2023 at 12:00 PM, and laboratory supervisor and laboratory testing personnel interview, it was determined that the laboratory failed to meet the quality control requirements for Mycoplasma pneumoniae IgM test. Refer to D5449.</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 Mycoplasma pneumoniae IgM test quality control record and patient test worksheet records review and laboratory testing personnel and laboratory supervisor interview on November 17, 2023 at 12:00 PM, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae IgM patient testing from August 1, 2023 to October 31, 2023, when 1,658 out of 1,658 patients were processed and reported. The findings</p>

include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. 2. Review of Mycoplasma pneumoniae IgM quality control records and patient test worksheet records on November 17, 2023 at 11:23 AM, showed that the laboratory did not include any control material each day of patient testing from August 1, 2023 to October 31, 2023, when 1,658 out of 1,658 patients were processed and reported. 3. The laboratory testing personnel and laboratory supervisor confirmed on November 17, 2023 at 12:00 PM, that the laboratory failed to include a negative and positive control material, for Mycoplasma pneumoniae IgM test, each day of patient testing.

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 Mycoplasma pneumoniae IgM quality control records review, and laboratory supervisor and testing personnel interview on November 17, 2023 at 12:00 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093.

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 Mycoplasma pneumoniae IgM quality control records and interview with the laboratory supervisor and laboratory testing personnel on November 17, 2023 at 12:00 PM, it was determined that the laboratory director did not ensure that the laboratory will perform the positive and a negative control material each day of patient testing for Mycoplasma pneumoniae IgM test. Refer to D5014 and D5449.