

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1036403	(X3) Date Survey Completed 10/16/2025
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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA Recertification survey at the CDT Hospital de La Concepcion on October 16, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. During a recertification survey on October 16, 2025, the laboratory was found out of compliance with the following conditions: 42 CFR 493.1208 Condition: General Immunology 42 CFR 493.1441 Condition: Laboratory performing high complexity testing; general supervisor. In addition, the laboratory was found out of compliance with the following standard level deficiencies found during the recertification CLIA survey on October 16, 2025.
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 October 16, 2025 at 11:40 A.M., and laboratory director 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>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the Mycoplasma pneumoniae IgM test quality control records reviewed, patient test worksheet and laboratory director interview on October 16, 2025 at 11:36 A.M., it was determined that the laboratory did not include an external positive and negative control material each day of patient testing. The laboratory processed and reported 59 out of 582 patients sample from August 2025 to October 2025. The findings include: 1. The manufacturer's instructions were reviewed on October 17, 2025 at 11:19 A.M. The manufacturer established that the external positive and negative control must be performed every day of patient testing. 2. Review of the Mycoplasma pneumoniae IgM test quality control records on October 17, 2025 at 11:22 A.M., showed that the laboratory did not perform the external negative and positive control material each day of patient testing. The laboratory processed and reported 59 out of 582 patients sample from August 2025 to October 2025. 3. The laboratory director confirmed on October 16, 2025 at 11:36 A.M., that the laboratory failed to perform the negative and positive external control material each day of patient testing. The laboratory processed and reported 59 out of 582 patients sample from August 2025 to October 2025.

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, manufacturer's instructions, and interview with the laboratory director on October 16, 2025 at 11:40 A.M., it was determined that the laboratory director failed to fulfill her 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)

(e)(5) Ensure that the quality control and quality assessment 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 director on October 16, 2025 at 11:40 A.M., it was determined that the laboratory director did not ensure that the laboratory were perform the positive and negative control material each day of patient testing for Mycoplasma pneumoniae IgM test. Refer to D5449.