

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0933354	(X3) Date Survey Completed 09/08/2022
Name of Provider or Supplier Lab CI Migrant Health Center Ensenada	Street Address, City, State Carr Pr-324, Km 2, Hm 1, Barrio Ensenada El Batey, Ensenada, 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 by Immunocard) quality control records review (years 2021-2022) and laboratory general supervisor interview, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing. The findings include: 1. General Immunology (Mycoplasma pneumoniae test) quality control records were review on September 8, 2022 at 11:26 A.M., from January 1, 2021 to September 7, 2022. 2. Review of Mycoplasma pneumoniae quality control and patient results record showed that the laboratory did not include any control material each day of patient testing in the following days 5/12/2022; 5/18/2022; 5/19 /2022; 5/20/2022; 7/29/2022 and 8/31/2022. In this days 9 patients were processed and reported. 3. The laboratory general supervisor confirmed on September 8, 2022 at 11:32 A.M, that the laboratory failed to include a negative and positive control material each day of testing when performed Mycoplasma pneumonia test.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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</p>

failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Mycoplasma pneumonia IgM quality control records and interview with the laboratory supervisor on September 8, 2022 at 11:40 AM, it was determined that the laboratory director failed to ensure that external positive and a negative control material were run each day of patient testing for Mycoplasma pneumonia tests. Refer to D5449.