

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658316	(X3) Date Survey Completed 06/21/2024
Name of Provider or Supplier Lab Clinico Brumbaugh	Street Address, City, State Calle Pinero #80 Esquina Camelia Soto, Rio Piedras, 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 Mycoplasma pneumoniae IgM test quality control and patient test worksheet records review on June 21, 2024 at 10:00 AM, and laboratory supervisor interview, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae IgM patient testing, when 53 out of 53 patients were processed and reported from January 31, 2024 to June 21, 2024. The findings include: 1. The laboratory uses the Immunocard reagent kit to perform patient Mycoplasma pneumoniae IgM test. 2. Review of Mycoplasma pneumoniae IgM quality control and patient test worksheet records on June 21, 2024 at 10:00 AM, showed that the laboratory did not include any control material each day of patient testing from January 31, 2024 to June 21, 2024, when 53 out of 53 patients were processed and reported. 3. The laboratory supervisor confirmed on June 21, 2024 at 10:05 AM, that the laboratory failed to include a negative and positive control material each day of patient testing.</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 pneumoniae* IgM quality control and patient test worksheet records review, and laboratory supervisor interview on June 21, 2024 at 10:00 AM, it was determined that the laboratory director did not ensure to include a positive and a negative control material each day of patient testing for *Mycoplasma pneumoniae* tests. Refer to D5449.