

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1099014	(X3) Date Survey Completed 09/14/2021
Name of Provider or Supplier Lab Clinico Del Atlantico	Street Address, City, State Carr Pr-2 Km 78 Hm 02 Ave Miramar 860, Arecibo, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on personnel records review and laboratory general supervisor interview on September 14, 2021, it was determined that the laboratory did not follow the established schedule for testing personnel competence evaluation. The findings include: a. The laboratory general supervisor stated that personnel competence evaluation must be performed every year. b. Review of the laboratory testing personnel and supervisor (MT #6223) competence evaluation , on September 14, 2021 at 9:45 a.m.. showed that the last documented competence was performed on July 9, 2019. c. The supervisor stated during the interview that, effectively, the last competence was on July 9, 2019.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on testing personnel records review and supervisor interview on September 14, 2021, it was found that the laboratory director did not make sure that the testing personnel # 3435 received the necessary training before beginning to perform patient tests. The findings include: a. The testing personnel # 3435 was hired and performed patient testing since April 1, 2021. b. The laboratory did not have any documents related to testing personnel training. c. The laboratory supervisor stated on September 14, 2021 at 9:55 a.m. that the laboratory did not document the testing personnel training prior to perform patient tests.