

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0869394	(X3) Date Survey Completed 07/11/2023
Name of Provider or Supplier Cdc Natl Ctr Infect Disease Dengue Lab	Street Address, City, State 1324 Calle Canada, San Juan, 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
D5433	<p> MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) </p> <p> For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. </p> <p> This STANDARD is not met as evidenced by: Based on the tour of the laboratory, review of laboratory procedures, and lack of function check documents, and interview with the general supervisor (GS) #1 the laboratory failed to perform and document function checks for three of three thermometers used for Serology and Molecular testing from July 11, 2021, to July 11, 2023. Findings Include: 1. Doc. No. DBMOL.DR.009 - 10.1.2.1 states, "Incubate at room temperature for 10 minutes". 2. Doc. No. DBMOL.DR.022 - 10.2.4 states, "solution, samples in cartridge and let it set for 15 minutes". 3. On the day of the survey, while on tour of the laboratory the following thermometers used for Serology and Molecular testing were due for a function check: - Serology Lab - Room L013 - VWR Timer - Serial Number 18769984 - Exp. 11/10/2020. - Serology Lab - Room L019 - Fisher Timer - Serial Number 150063388 - Exp. 01/29/2017. - Molecular Lab - Room L003 -VWR Timer - Serial Number 170881798 - Exp. 12/15/2019. 4. GS #1 confirmed the finding above on July 11, 2023 around 900 am. </p>