

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 40D0869394	<b>(X3) Date Survey Completed</b> 07/08/2021
<b>Name of Provider or Supplier</b> Cdc Natl Ctr Infect Disease Dengue Lab	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at CDC NATL CTR INFECT DISEASE DENGUE LAB on 07/07 - 07/08/2021 by a Centers for Medicare & Medicaid Services (CMS) federal surveyor. The laboratory was survey under 42 CFR part 493 CLIA requirements. The specific deficiencies are as follows:
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) records review and staff interview the laboratory failed to document and maintain the documentation of the handling, preparation, processing, examination of each step of testing for all (PT) samples in the virology section of the laboratory. Findings include: On 07/07,2021, at approximately 2:45 pm, during a review of the PT records the laboratory notified the CMS surveyor that the laboratory conducts a Molecular alternative assessment (AA) Panel for proficiency test in the form of blind testing of materials with known values. The review revealed no records of sample handling, preparation and processing documents for the testing personnel to ensure the accuracy and verification of each step of the proficiency testing evaluation for the virology section of the laboratory for the following test: 1-</p>

Dengue Serotyping Test 2- Trioplex Test 3- Respiratory Test 4-COVID-19 During the exit interview on July 08, 2021 at approximately 1:30 pm, technical supervisor #1 (TS #1) confirmed , the laboratory did not have the documentation for the (AA) with each of the laboratory results.