Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0869394	05/01/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cdc Natl Ctr Infect Disease Dengue Lab	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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of Document No. DBMOL.DR.009 entitled " Respiratory Viruses Real Time rRT-PCR, observation, and interview with the Virology technical supervisor and general supervisor on May 1, 2019 at around 10:30 am, the laboratory failed to include in the document the requirements for patient preparations, specimen collection, and transportation of specimens. The findings included: a. The "Purpose" section of the document states that "...nasopharyngeal swabs from patients with acute febrile illness..." was the specimen for testing. b. A universal viral transport collection kit was shown during the survey. The technical supervisor stated the kit was used as

	the mode of collection. c. The document did not include the use of the specimen collection kit. d. The document did not include instructions for specimen handling and transportation.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the general supervisor and technical supervisor, the laboratory failed to evaluate, at least semi annually, the competency of one testing personnel that was hired on 9/15/2017. The findings included: a. The training was approved by the laboratory director on January 19, 2018 b. Personnel records showed only one competency assessment in 2018 that was completed on July 16, 2018.