PRoDTEC
Puerto Rico Diagnostic Test Evaluation Commission

Validation Report

1. **Purpose of submission**
   Provide a full description of the purpose of your application, including the test name, laboratory(ies) submitting the application, and claimed specimens types (e.g., nasopharyngeal/ oropharyngeal swabs, sputa, BAL, stool, and serum, etc. Also, submit additional testing and confirmation procedures performed upon consultation with the PRoDETC. Positive results should also be reported in accordance with local, state, and federal regulations.

2. **Measure**
   Please specify the specific nucleic acid sequences from the genome of SARS-CoV-2 targeted in the assay.

3. **Laboratory/Sponsor**
   Document the official name of the laboratory, contact information, and all locations where testing will be performed.

4. **Regulatory Status of the Assay**
   Establish the regulatory status of the assay (i.e., not cleared, CLIA waived, or subject to an approved investigational device exemption.

5. **Intended Use**
   Document the intended use of the assay in terms of the test technology (e.g., RT-PCR, Sanger Sequencing, NGS, etc.)

6. **Instruments Used with Test**
   Describe all instruments required in where the assay was validated, and it is known to work. Instruments may include different RT-PCR machines, equipment for RNA extraction, software, among others.

7. **Test Principle**
   Describe the main test principle and product overview of the assay in detail.
   i. **Description of Test Steps**
      Describe in sufficient detail the procedure for performing the assay in sequential order as a list, including the extraction methodology. Please also include all the names of the equipment used in the assay. If a well-documented laboratory procedure is available, please append it to the report.
   ii. **Controls and Materials Required**
      Describe the assay controls to be performed in the laboratory, including the positive and negative control; ideally, the positive control will be used to confirm performance near the test LoD. If a template control is used, please describe in general terms the sequence used, the extraction control, and the internal control, if applicable. Please also describe the frequency that controls will be tested.
   iii. **Assay results and interpretation**
      Explain in detail the results of the test procedure, e.g., reactive (positive/detected), non-reactive (negative/non-detected), or invalid (no result reported).
   iv. **Performance Results**
      Describe in detail the results of the validation studies, in terms of the LoD - Analytical Sensitivity, Inclusivity (analytical sensitivity), Cross-reactivity (Analytical Specificity), and Clinical Evaluation results.

8. **Fact Sheet for Healthcare Providers and Patients (no patients)**

9. **Instructions for Use/ Proposed Labeling/Package Insert**

10. **Record Keeping and Reporting Information Requirements**