COVID-19 Diagnostic Testing

Technical Screening

Name of the device	**ALLPLEX 2019-NCOV ASSAY**
Manufacturer	**SEEGENE INC.**
Application #:	**313001**

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences	N	**AI:** **Provide a clear detailed device description that includes:** **-The intended use and intended testing setting** **-The extraction method** **-The seqiemces of the primers and probes used, as well as the target for the internal process control** **-The identity of the positive and negative controls used with the test and the internal control**
Limit of Detection	Spiking RNA / inactivated virus into clinical (preferred) or artificial matrix. The matrix should represent the most challenging clinical matrix. **Initial study** Dilution series including 3 replicates for each concentration. **Confirmatory study** 20 replicates of the final concentration. Acceptance criteria: 19/20 positive	Y	
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	Y	
Cross-Reactivity	• Provide results of in silico analysis of primers and probes against: common respiratory flora, other viral infections • Wet testing is recommended • Cross-reactivity is defined as greater than 80% homology • Matrix-specific cross-reactivity should be assessed	Y	
Precision (This is not an essential requirement)	Conduct internal precision testing (i.e., at the manufacturer's site) in accordance with CLSI, EP5-A2. In the context of SAP, the 3x5x5 (3 instruments x 5 days x 5 replicates) design is acceptable to provide preliminary estimates of the repeatability (within run) and reproducibility of the assay. Full assessment of repeatability using the 20x2x2 (20 days × 2 run per day × 2 replicates) is expected at time of licensing.	N	Not provded, but not an essential requirement
Stability	• Briefly describe stability test plan • reagent stability studies do not need to be completed at the time of IO issuance, however the study design should be agreed upon during review and the stability studies started immediately following authorization	N	AI: Provide all evidence currently available supporting the stability of test kit. Alternatively, submit a plan for stability studies (Health Canada expects that stability studies will be initiated upon authorization).
Clinical Evaluation	Known positive samples or contrived clinical samples Minimum of 30 reactive and 30 non-reactive specimens • 20 samples at 1x-2x LoD (95% agreement) • Other concentrations and non-reactive (100% agreement) *Seroloical assay* Positive samples should include infection times of 4-10 days and 11-24 days	Y	
Point of Care	Near patient studies performed in clinical setting by intended users. Minimum of 9 operators and questionnaire to assess IFU clarity.	N/A	
Labeling	Instructions for use Reagent labels	N	Instructions for Use not provided

1. Provide a clear detailed device description that includes:
   - The intended use and intended testing setting
   -The extraction method
   -The seqiemces of the primers and probes used, as well as the target for the internal process control
   -The identity of the positive and negative controls used with the test and the internal control
2. Provide all evidence currently available supporting the stability of test kit. Alternatively, submit a plan for stability studies (Health Canada expects that stability studies will be initiated upon authorization).
3. Provide a copy of the package insert

NOTE ADDED on 2020-04-01
On 2020-04-01 the manufacturer provided an acceptable response to the questions asked.

RECOMMENDATION: Application Ready for Review