COVID-19 Diagnostic Testing

Minimum Requirements for SAP Authorization

Name of the device	**GeneFinder™ COVID-19 Plus RealAmp Kit**
Manufacturer	**OSANG Healthcare Co**
Application #:	**312757**

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences		No information on the primers and probes Extraction: QIAamp Viral RNA mini kit (Qiagen) Sample type : human respiratory specimens such as alveolar lavage fluid, nasopharyngeal swabs (NPS), sputum etc. Minimal device description Detection : RdRp gene, E gene ,N gene
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	Yes	Applied Biosystems® 7500 Real-time PCR Instrument System CFX96™ Real-time PCR Detection System
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	NO	Not included
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	Yes	WET TESTING: 14 DNA/RNA samples from reference strains of microorganisms
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/A	Not include but not
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	NO	They should provide ta plan for stability and commitment to start the stability immediately.
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	NO	Not provided
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	NO	Package insert provided. Intended use is deficient (not sample type). Reagent lables not provided.

AI Request for additional information

1. Provide a list of all primers and probe sets briefly describe what they detect. Include the nucleic acid sequences for all primers and probes used in the test. Indicate if biotin-streptavidin/avidin chemistry is used in any steps of the test.

2. Provide information about all controls (what they are, concentration of positive control relative to the LoD).

3. Provide results of in sillico analysis including the % identity to published COVID19 sequences support the assay inclusivity (100% of the published sequences should be detectable).

4. 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).

5. Provide results of a clinical evaluation study to confirm the performance of your assay with a series of natural clinical specimens (or contrived clinical specimens) by testing a minimum of 30 reactive specimens and 30 non-reactive specimens in a randomized blinded fashion. Twenty of the clinical specimens should be at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range.

6. Provide the labels for each component of the test.