COVID-19 Diagnostic Testing

Technical Screening

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

Patrice Sarrazin

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences	No	The regulatory conctact don't have access to sequence information. Other information can be found in the IFU.
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	
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	No	**AI Request** No evidence supporting the incluisivity of the assay was provided. Provide in sillico analysis including the % identity to published COVID19 sequences (100% of the published sequences should be detectable).
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	
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	
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	Yes	
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	**AI Request** The IFMR Analytical Performance Test Report is not deemed adequate to support the clinical performance of the assay. In the absence of known positive samples available for testing, contrived clinical specimens can be tested (minimum of 30 contrived reactive specimens and 30 non-reactive specimens) in a randomized blinded fashion. Contrived reactive specimens can be created by spiking RNA (SARS-CoV-2) or inactivated virus (SARS-CoV-2) into leftover individual clinical specimens. Twenty of the contrived clinical specimens should be spiked at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range. Minimum acceptance criteria for the performance would be 95% agreement at 1x-2x LoD, and 100% agreement at all other concentrations and for negative specimens.
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	Yes	Intended use to be revised No Clinical Performance included

AI Requests

1. No evidence supporting the inclusivity of the assay was provided. Provide in sillico analysis including the % identity to published COVID19 sequences (100% of the published sequences should be detectable).

2. The IFMR Analytical Performance Test Report is not deemed adequate to support the clinical performance of the assay. In the absence of known positive samples available for testing, contrived clinical specimens can be tested (minimum of 30 contrived reactive specimens and 30 non-reactive specimens) in a randomized blinded fashion. Contrived reactive specimens can be created by spiking RNA (SARS-CoV-2) or inactivated virus (SARS-CoV-2) into leftover individual clinical specimens. Twenty of the contrived clinical specimens should be spiked at a concentration of 1x-2x LoD, with the remainder of specimens spanning the assay testing range. Minimum acceptance criteria for the performance would be 95% agreement at 1x-2x LoD, and 100% agreement at all other concentrations and for negative specimens.