COVID-19 Diagnostic Testing

Technical Screening

Name of the device	**SARS-COV-2 VIRUS DETECTION DIAGNOSTIC KIT (RT-QPCR METHOD)**
Manufacturer	**NINGBO HEALTH GENE TECHNOLOGIES CO., LTD**
Application #:	**312918**

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences	Y	The intended use does not include all the required statements, but additional changes to labelling will be required; at this time the file can be reviewed.
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	N	It is not clear what matrix was used for testing the LoD; the assay is indicated for NP, OP and sputum. AI: Provide information on sample preparation for the LoD study, including the matrix that was used. NOTE: 20 replicates were done for the initial concentrations, and the confirmatory study appears to have done only 5 replicates
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	N	AI: Regarding evidence of inclusivity, 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).
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	Wet testing and in silico cross reactivity study performed
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.	Y	Repeatability data provided Reproducibility unfinished (some raw data provided). However, this is 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	Y	Real time stability and in-use stability interim studies provided
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	A clinical evaluation was provided comparing against other known PCR kits.
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	Not applicable
Labeling	Instructions for use Reagent labels		

AI Requests:

1. Provide information on sample preparation for the LoD study, including the matrix that was used.
2. Regarding evidence of inclusivity, 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).

2020-03-31
Received acceptable responses to AI requests.

Recommendation: Application Ready for Review