COVID-19 Diagnostic Testing

NAT Technical Screening

Name of the device	**Real-time fluorescent RT-PCR kit for detecting 2019-nCoV**
Manufacturer	**BGI Americas Corp**
Application #	**312912**
DED Screener	**Elana Cherry**

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences	Yes	• Qualitative detection of SARS-CoV-2 nucleic acids in throat swabs and bronchoalveolar lavage fluid (BALF) from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories. • Detects the ORF1a/b of SARS-CoV-2; target sequence provided • Sequences of primers and probes are provided • For use by trained clinical lab personnel
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	• Appropriate Spiking RNA used • Appropriate initial LOD and confirmatory LOD studies using all sample types • LOD validated for each clinical matrix for 3 lots of kits in 20 replicates
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	Yes	• In silico inclusivity analysis provided in Annexes 2-1-1 to 2-10 and 2-2-2 • % homology identified
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	• In silico testing to all HC required pathognes, • Wet testing performed • not all FDA/HC required pathognes wet tested (review issue) • Interference with human RNA tested • Endogenous interference studies not provided; application indicates it is not applicable.
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.	No	Not provided
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	• Sample storage and sample transportation info provided; reagent stability info provided • Specimen stability and fresh-frozen testing results provided • Stability testing protocol provided in Annex 9
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) *Serological assay* Positive samples should include infection times of 4-10 days and 11-24 days	Yes	384 clinical specimens tested. Positivity validated by RT-PCR and sequencing
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	Box labelling provided Vial labelling provided PI provided

No AI needed