COVID-19 Diagnostic Testing

NAT Technical Screening

Name of the device	**PERKINELMER NEW CORONAVIRUS NUCLEIC ACID DETECTION KIT**
Manufacturer	**PERKINELMER, INC.**
Application #	**313232**
DED Screener	**Patrice Sarrazin**

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences	Yes	received FDA's Emergency Use Authorization on March 24 oropharyngeal swab and nasopharyngeal swab Instruments PerkinElmer® PreNAT II Automated Workstation Applied Biosystems® 7500 Real-Time PCR system New Instrument Added see communication The sequences of the primers and probes were not found in the application: Requested via a clarification request.
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	Described in the Package Insert. Revised PI Provided on 2020-04-02 Level of description sufficient for review. Initial LoD + LoD confirmation provided Performed with inactivated SARS-CoV-2 virus (Isolate 2/231/human/2020/CHN)
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	Yes	100% identity to the available 2019-nCoV sequences. Very brief description but deemed acceptable for IO review
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	Described in the Package Insert. Level of description sufficient for review. Both in silico analysis and wet testing. List of pathogens tested is acceptable Endogenous and exogenous potential interference is provided
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	Not provided	Requested via a clarification request
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	Yes	Described in the Package Insert. Level of description sufficient for review. 141 healthy individuals collected with 2 swabs (OP + NP) 47 oropharyngeal + 47 nasopharyngeal swabs spiked with inactivated cultured virus (GenBank: MT135042.1) + 94 negative swabs
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	

Clarification Request

Response received on 2020-04-02

1. Provide the nucleic acid sequences of all primers and probes.

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).