COVID-19 Diagnostic Testing

NAT Technical Screening

Name of the device	**SPARTAN COVID-19 SYSTEM**
Manufacturer	**SPARTAN BIOSCIENCE INC.**
Application #	**313012**
DED Screener	**Patrice Sarrazin**

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences		Assay Intended use does not include POC indication. CUBE Instrument Comparison with predicate Spartan RX Instrument using a similar assay CYP2C19 (MDL 94118; application# 222368) Look at CUBE CYP2C19 FDA package for description of the instrument, instrument equivalence (CUBE vs RX), CUBE electrical safety, collection system. The manufacturer provided IFU of a similar assay (CYP2C19) performed on the Cube instrument using the same specimen collection procedure. This not clear if the swab used can collected nasopharyngeal specimen. Based on discussion with the manufacturer, the COVID-19 assay will use the same components as the CYP2C19 except for the primers.
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	To come	This study should be submitted on April 2, 2020
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	Yes	
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	NO	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
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	To come	To come
Point of Care	Near patient studies performed in clinical setting by intended users. Minimum of 9 operators and questionnaire to assess IFU clarity.		Near Patient Study provide for the CYP2C19 performed on the Spartan RX. The workflow is different than for the CUBE. Transferability of the study should be assessed. There is the possibility that NML validates the POC

			performance, to consider for a condition.
Labeling	Instructions for use Reagent labels	To come	To be submitted on or before: 02-Apr-2020