COVID-19 Diagnostic Testing

Technical Screening

Name of the ~~device~~ Licence	**BIOMEME SARS-COV-2 GO-STRIPS BIOMEME SARS-COV-2 GO-STRIPS**
Manufacturer	**Biomeme**
Application #:	**312839**

This comment applies to all categories with missing information:
The company had a teleconference with Health Canada on Monday March 23rd, and were instructed on what would be required in a submission under the Interim Order.
Specific deficiency questions are outlined below this table.

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences	Missing	Provide a clear detailed device description that includes: • The intended use, and the intended testing setting • The extraction method(s); • The targeted sequence, and the probes and primers sequences
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	Missing	Provide a Limit of Detection Study. The following components of a LoD study is required: **Initial study** Dilution series including 3 replicates for each concentration. **Confirmatory study** 20 replicates of the final concentration. Acceptance criteria: 19/20 positive Note: These studies require spiking RNA / inactivated virus into a clinical (preferred) or artificial matrix. The matrix chosen should represent the most challenging clinical matrix.
Inclusivity	• Provide results of in sillico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	Missing	Provide the complete test reports for your Inclusivity studies. Ensure that your results include the % identity to published COVID19 sequences.
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	Missing	Provide the complete test reports for your Cross-Reactivity studies. Ensure that your results include in silico analysis of primers and probes against common respiratory flora and other viral infections. Wet testing is recommended; concentrations of 10^6 CFU/ml or higher for bacteria and 10^5 pfu/ml or higher for viruses is recommended. Matrix-specific cross-reactivity should also be assessed and included in your submission. If in silico analysis reveals ≥ 80% homology between the cross-reactivity microorganisms and your test primers/ probe(s), we recommend that you perform a microbial interference study with SARS-CoV-2 and the microorganisms that your test primers/ probe(s) have homology to or provide justification as to why the performance of your test would not be impacted by the presence of a causative agent of a clinically significant co-infection, or explain why the in silico results are clinically irrelevant (e.g., low prevalence of MERS-CoV, etc.).
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.	Missing but not required	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	Missing	Provide a brief description of your stability test plan. Note that 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)	Missing	Provide your Clinical Evaluation test report. This assessment should include known positive samples or contrived clinical samples with a minimum of 30 reactive and 30 non-reactive specimens. Of these, include 20 samples at 1x-2x LoD (showing 95% agreement). Other concentrations and non-reactive samples are expected to show 100% agreement.

Point of Care	Near patient studies performed in clinical setting by intended users. Minimum of 9 operators and questionnaire to assess IFU clarity.	Missing	If your test system is intended for use at the Point of Care, you must provide evidence of appropriate use in this clinical setting, by the intended users. This evidence must include a minimum of 9 operators, and a questionnaire to assess IFU clarity.
Labeling	Instructions for use Reagent labels	Provided/deficient Labelling was provided for: • Franklin thermocycler and “Go” app • Sample prep cartridge kit • Go strips It does not appear to include Intended Use.	Provide a complete intended use in the package insert. Your labelling must also state the following: The patients being tested meet the CDC SARS-CoV-2 clinical criteria. Positive results are indicative of active infection. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information

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