COVID-19 Diagnostic Testing

NAT Technical Screening

Name of the device	**Simplexa COVID-19 Direct Assay**
Manufacturer	**Diasorin Molecullar LLC**
Application #	**313264**
DED Screener	M. Carballo
QMS Certiicate	Not Provided

	Guidance	Acceptable	Comment
Device Description	Intended use Testing setting Extraction methods Targeted sequence Probes and primers Sequences	Yes	Provided in the IFU and in the Supplemental document. The method does not required RNA extraction Primers and probes sequences provided Sample validation studies are referred to previous licencsed applications using NS swab, however those are class 2. The clinical study can be used to leverage the sample validity
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	Deficient	Reference is made to the LOD protocol of assays licensed by HC, however these are class 2 which have not been reviewed. AI: You make reference to HC licensed assays for the LOD study design. Hwever the licensed assays you refered to are class II devices which have not undergone pre-market review. Please provide the protocol and results of the LOD study.
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.	Yes	
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		Mfr. refers to a 3 month initial stability based on previous licensed class II medical devices, w.hich are not subject to premarket review AI: Describe the stability test plan for reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time the IO is authorized. The stability studies should start immediately following authorization, if not before.
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)	Yes	Done on clinical samples
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	
Labelling	Instructions for use Reagent labels	Yes	IFU, labels for the assay, Reaction Mix and Positive Control Pack

AI request (screening):

1. You make reference to HC licensed assays for the LOD study design. However the licensed assays you refered to are class II devices which have not undergone pre-market review. Please provide the protocol and results of the LOD study.

2. Describe the stability test plan for reagents and include any accelerated stability information if available. Please note that reagent stability studies do not need to be completed at the time the IO is authorized. The stability studies should start immediately following authorization, if not before.
3. Provide a copy of your Quality Manufacturing System Certificate.
4. Provide the LIAISON® MDX software version and/or associated Assay Specific File version