FIND Evaluation of SD BIOSENSOR STANDARD M10 SARS-CoV-2 Test External Report

Version 1.0 [22 December 2023]

Copyright and use of the report

Evaluation process – private sector engagement

FIND seeks to ensure equitable access to reliable diagnosis around the world. It works closely with the private and public sectors and receives funding from donors and some of its industry partners. It has internal fire walls, policies and processes to protect it against any undue influence in its work or the publication of its findings.

More information on our policy and guidelines for working with private sector partners can be found here: https://www.finddx.org/policies/

For the COVID-19 response, FIND has commissioned independent evaluations of in vitro diagnostics following an Expression of Interest (EOI) process available on FIND's website by which all test submissions were scored according to their regulatory status; ease-of-use of the test and instrument robustness; the manufacturing and distribution capacity of the supplier; and the supplier-reported clinical and analytical performance.

Document history

Document version	Date	Comment
1.0	22 December 2023	Initial release

1 Product Information:

Manufacturer name	SD Biosensor
Test name	STANDARD M10 SARS-CoV-2
Product code(s)	Reference No: M-NCOV-03 Catalogue No: 11COV10A
Pack size(s)	10 tests per kit
Contents of kit	Cartridge, quick reference instructions
Equipment and consumables required, but not provided	STANDARD M10 System: STANDARD™ M10 Console (11M1011) and STANDARD™ M10 Module (11M1012), COPAN Universal Transport Medium (recommended 3ml of UTM RT medium) STANDARD™ Fixed volume dropper (600μl – 90DR10), micropipette with filter tips, PPE
Product storage (temperature range)	2-28°C
Shelf-life (months)	12 months
Manufacturing site (country)	Republic of Korea

2 Study details:

Study design:	Diagnostic evaluation study in an independent site to determine the accuracy of COVID-19 point-of-care (POC) molecular assays. As SARS-CoV-2 prevalence and testing rates dropped, prospective sampling became more challenging and retrospective samples were used to supplement the sample size and reach study targets.
Index assays:	COVID-19 near point-of-care (POC) molecular assay that detect SARS-CoV-2 RNA
Reference method:	Results of the index test are compared to the routine, diagnostic RT-PCR result, which is used for clinical management
Limit of detection:	Analytical sensitivity, i.e. Limit of detection, was performed at the Liverpool School of Tropical Medicine in which standardized serial dilutions of cultured viral isolate were prepared. Proprietary swab provided in the kit was soaked in viral dilution series. Dilutions were tested in triplicate and the LOD was defined as the last dilution where all repeats were interpreted as positive.

Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by the STANDARD M10 SARS-CoV-2 test, among all positives by the reference method, and reported as a percentage. Specificity was calculated as the proportion of true negative specimens, identified as negative by the STANDARD M10 SARS-CoV-2 test, among all negatives by the reference method and reported as a percentage. The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size, using the Wilson's score method.

3 Evaluation details:

Country of collaborator	Switzerland
Location of clinical site(s) (city, town)	University Hospital of Geneva
Health care level of site(s)	National Referral Hospital
Enrolment and testing period	June 2023 to August 2023
Study cohort inclusion/exclusion	Inclusion criteria - Adult individuals (≥18 years of age) with symptoms suggesting plausible COVID-19 infection (as per WHO or national clinical case definitions) - Individuals who have voluntarily given written consent to participate in this study or who have given their written consent for their specimen to be used for future research studies - Individuals able to provide the specimens required for the study Exclusion criteria - Individuals on oxygen therapy - Individuals with recent history of excessive nose bleeds - Individuals with hemodynamic instability as determined by their treating physician - Patients/Individuals not in a condition that allows for enrolment (e.g. in pain, poor overall condition), as determined by the treating physician
Sample type, antigen test	Nasal swab
Reference PCR method	RT-PCR Cobas® SARS-CoV-2
Sample type, PCR test	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	**Switzerland***
Total N (valid PCR results)	214*
Age [mean (min-max), N]	47.6 (18-90), 214
Gender [%F, (n/N)]	53.7%, (115/214)
Symptoms present [%Yes, (n/N)]	89.3%, (191/214)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	3 (3-5); 186
Days < 0-3 (n, %)	96, 51.6%
Days 4-7 (n, %)	65, 34.9%
Days 8+ (n, %)	25, 13.4%
Positivity [%, (n/N)]	47.7%, (102/214)
PCR Ct [median (Q1-Q3); N]	18 (16-21.9); 102
Ct > 33 (n, %)	3, 2.9%
Ct > 30 (n, %)	7, 6.9%
Ct > 25 (n, %)	16, 15.7%

** To reach the sample size of 100 positive and 100 negative SARS-CoV-2 samples, we completed the sample collection from HUG with 30 negative samples from the Liverpool School of Tropical Medicine*

4.2 Estimation of Clinical Performance

Country	**Switzerland***
Clinical Sensitivity (95% CI), N	96% (90.3, 98.4), 101
Sensitivity days ≤7, N	96.8% (90.9, 98.9), 93
Sensitivity Ct ≤ 33, N	99% (94.4, 99.8), 98
Sensitivity Ct ≤ 25, N	100% (95.7, 100), 86
Clinical Specificity (95% CI), N	100% (96.5, 100), 106*
Invalid rate [% (n/N)]	2.3% (5/214)

** To reach the sample size of 100 positive and 100 negative SARS-CoV-2 samples, we completed the sample collection from HUG with 30 negative samples from the Liverpool School of Tropical Medicine*

4.2.1 Estimation of analytical performance

- Supplier-reported LOD

LOD (TCID50 /ml)	Gene target	
Virus isolate	**ORF1ab gene**	**E gene**
SARS-CoV-2 (2019 nCOV) NCCP 43326/2020/Korea)	$6.63x10^{-4}$ TCID50 /ml	$6.63x10^{-4}$ TCID50 /ml

- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
Omicron (BA.5)	**1.0 $x10^{-1}$ pfu/ml** ~ 1.41x 10^{-1} $TCID_{50}$/ml	**1.0 $x10^{-1}$ pfu/ml**	**3.0 $x10^{2}$ genome copies/ml** applied to test

Note: *viral dilution was applied directly to the test cassette, not to the provided swab*