FIND Evaluation of SD Biosensor, Inc.

STANDARD F COVID-19 Ag FIA

External Report

Version 2.2, 30 September 2022

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Evaluation process – private sector engagement

FIND, the global alliance for diagnostics, 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 and time to market; the manufacturing and distribution capacity of the supplier; and the supplier-reported clinical and analytical performance.

Document history

Document version	Date	Comment
1.0	16 October 2020	Interim version
2.0	20 October 2020	Data for Germany added
2.1	10 December 2020	LoD Methodology updated; EoU updated

2.2	30 September 2022	LOD data for new variants added

1 Product info:

Manufacturer name	SD Biosensor, Inc.
Test name	STANDARD F COVID-19 Ag FIA
Product code(s)	F-NCOV-01G, 10COV30D
Pack size(s)	25
Contents of kit	Test device (individually in a foil pouch with desiccant), Extraction buffer tube, Nozzle cap, Sterile Swab, Paper stand, IFU
Equipment and consumables required, but not provided	Equipment: STANDARD F Analyzer, Timer, refrigerator (optional, for storage of specimens prior to testing, if applicable) Consumables: PPE
Product storage (temperature range)	2-30°C
Shelf-life (months)	*To be confirmed*
Manufacturing site (country)	Republic of Korea

2 Study details:

Study design:	Prospective diagnostic evaluation studies across multiple, independent sites to determine the accuracy of COVID-19 antigen RDTs, using consecutive enrolment. Interim analyses are performed at 25% and 50% enrolment, and the evaluation is stopped if tests do not meet 95% specificity. Presence of symptoms, date of symptom onset and hospitalization status is collected for all enrolled participants.
Index assays:	Novel lateral flow format tests that detect recombinant SARS-CoV-2 antigens.
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 STANDARD F COVID-19 Ag FIA 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 STANDARD F COVID-19 Ag FIA 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.
Ease of use	A System usability survey and ease of use questionnaire assessing the quality of the test, test preparation, ease of test execution, procedure time, ease of result interpretation, storage conditions and perceived settings of use was completed by operators and a final score out of 100 was calculated.

3 Evaluation details

Country of Collaborator	Brazil	Germany
Location of clinical site(s) (city, town)	1. Macae, state of Rio de Janeiro 2. UFRJ	1. Heidelberg 2. Berlin
Health care level of site(s)	1. Community testing clinic 2. Tertiary level hospital	1. Heidelberg: Drive-in testing Center 2. Berlin: Ambulatory testing clinic of Charité – University Hospital
Study period (date to date)	1. Macae: 17 Aug – 9 Sept 2020 2. UFRJ: 11 Jul – 8 Aug 2020	1. Heidelberg: 15 June-18July 2020 2. Berlin: 6 July – 23 Sept 2020
Study cohort inclusion/exclusion	Adults in community meeting national suspect definition Provided informed consent	Adults able to ambulate and meeting suspect definition of the Department of public health Provided informed consent
Sample type, antigen test	Nasopharyngeal swab	1. HD: Nasopharyngeal swabs 2. Berlin: Combined naso-/oropharyngeal swab
Reference PCR method	• Lab-developed assay based on the US CDC protocol, which targets two regions	• Cobas SARS-CoV-2 (Roche Diagnostics Inc) ○ N = 342

	(N1 and N2) of the nucleocapsid (N) gene of SARS-CoV-2 (https://www.fda.gov/media/134922/download); • n = 407 • Lab-developed assay based on the Charité Universitätsmedizin Berlin protocol, which has 2 gene targets (E and RdRp) of SARS-CoV-2 (https://www.who.int/docs/default-source/coronaviruse/protocol-v2-1.pdf); • n = 46	• Abbott *RealTime* SARS-CoV-2 (Abbott Molecular, Inc) ○ N = 1 • Allplex 2019-nCov Assay (Seegene Inc) ○ N = 20 • LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol) ○ N = 233 • Cobas (Roche) or Thermofisher (Multiplex TaqPath COVID-19 CE-IVD RT-PCR Kit) ○ N = 80
Sample type, PCR test	Nasopharyngeal swab	Nasopharyngeal (n=305), Naso/oropharyngeal (n=342) and/or Oropharyngeal swabs (n=32)

4 Results

4.1 Study cohort

Country	**Brazil**	**Germany**
Total N (valid PCR results)	453	676
Age [mean (min-max), N]	39 (0-95), 451	37.8 (18-85), 676
Gender [%F, (n/N)]	59% (268/453)	54% (360/667)
Symptoms present [%Yes, (n/N)]	93.6% (421/450)	77.3% (517/669)
Hospitalized (n, % Yes)	Not available	Not available
Days from symptom onset [median (Q1-Q3); N]	4 (3-6); 421	3 (2-5); 505
Days < 0-3 (n, %)	131, 31%	257, 50.9%
Days 4-7 (n, %)	248, 59%	202, 40%
Days 8+ (n, %)	42, 10%	46, 9.1%
Positivity [%, (n/N)]	26%, (120/453)	5.77%, (39/676)
PCR Ct [median (Q1-Q3); N]	23.4 (19.9-27.7); 120	24.7 (21.73-27.81); 39
Ct > 33 (n, %)	10, 8.3%	3, 7.7%
Ct > 30 (n, %)	20, 16.7%	7, 18%

Ct > 25 (n, %)	54, 43.3%	19, 48.7%

4.2 Estimation of clinical performance

Country	Brazil	Germany
Clinical Sensitivity (95% CI), N	77.5% (69.2, 84.1), 120	69.2 (53.6, 81.4), 39[§]
Sensitivity days ≤7, N	80.2% (71.1, 86.7), 100	81.2 (64.7, 91.1), 32
Sensitivity Ct ≤ 33, N	80.9% (72.6, 87.2), 110	75 (58.9, 86.2), 36
Sensitivity Ct ≤ 25, N	87.9% (77.9, 93.7), 66	100 (83.9, 100), 20
Clinical Specificity (95% CI), N	97.9 (95.7, 99), 333	96.9 (95.2, 98), 637
Invalid rate (%, n/N)	0%, (0/453)	0%, (0/676)

[§] 37/39 positives were tested using Roche Cobas, 1/39 using Seegene Allplex and 1/39 using TibMolbiol.

4.3 Estimation of analytical performance

- Supplier-reported LOD = 3.28 x **10^2** TCID50/ml ~ inactivated SARS-CoV-2 (2019-nCoV) NCCP 43326/2020/Korea strain
- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	**1.0 x10^3 pfu/ml ~** 1.41 x 10^3 $TCID_{50}$/ml	**1.0 x10^3 pfu/ml**	**2.4 x10^6 genome copies/ml** applied to test
Alpha (B.1.1.7)	**1.0 x10^2 pfu/ml** ~ 1.41 x 10^2 $TCID_{50}$/ml	**1.0 x10^2 pfu/ml**	**6.3 x10^3 genome copies/ml** applied to test
Gamma (P1)	**5.0 x10^1 pfu/ml** ~ 7.05 x 10^1 $TCID_{50}$/ml	**5.0x10^1 pfu/ml**	**2.1 x10^4 genome copies/ml** applied to test
Delta (B.1617.2)	**5.0 x10^1 pfu/ml** ~ 7.05 x 10^1 $TCID_{50}$/ml	**5.0x10^1 pfu/ml**	**8.1 x10^4 genome copies/ml** applied to test
Omicron (BA.1)	**5.0 x10^2 pfu/ml** ~ 7.05 x 10^2 $TCID_{50}$/ml	**5.0 x10^2 pfu/ml**	**8.8 x10^4 genome copies/ml** applied to test

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

4.4 Ease of use

STANDARD F	82 out of 100	7 operators, Germany 5 operators, Brazil