FIND Evaluation of SD Biosensor, Inc.

STANDARD™ F COVID-19 Ag FIA

External Report Site Specific Report

Version 1.1 3 June 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	27 April 2021	First release
1.1	3 June 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 study to determine the accuracy of COVID-19 antigen RDTs using a **case-control design** with enrolment of confirmed COVID-19 PCR positive individuals (cases) and a matched number of randomly selected COVID-19 PCR negative patients (controls). Dedicated PCR and Antigen samples were collected at the time of enrolment. The operators of both PCR and Ag RDTs are blinded to the results of the other test. 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:	*See STANDARD F COVID-19 FIA v2.1 Report*

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	*See STANDARD F COVID-19 FIA v2.1 Report*

3 Evaluation details:

Country of collaborator	India
Location of clinical site(s) (city, town)	King George's Medical University, Lucknow, Uttar Pradesh
Health care level of site(s)	Tertiary Care hospital
Study period (date to date)	14 October 2020 to 25 November 2020
Study cohort inclusion/exclusion	Cases: Symptomatic and asymptomatic patients admitted for care at KGMU and tested positive for COVID-19 by PCR Controls: Outpatient COVID-19 suspects (symptomatic cases as well as contacts of confirmed cases) who tested negative for COVID-19 by PCR Inclusion: • Adult age (≥ 18 years) • Voluntarily given written consent and the willing to participate in this study Exclusion: • Hemodynamic instability as determined by the treating physician. • Patient unable to cooperate with respiratory sample collection. • Patient unable to give informed consent. Recent history of excessive nose bleeds.

Sample type, antigen test	Nasopharyngeal swab collected at the same time as the study-specific PCR sample
Reference PCR method	RealStar® SARS-CoV-2 RT-PCR Kit (Altona Diagnostic)
Sample type, PCR test	A second study-specific PCR swab was collected: Combined oropharyngeal and nasopharyngeal swab (n=406), Nasopharyngeal swab (n=5), or nasal swab (n=6)

4 Results:

4.1 Study cohort

Country	**India**		
	Overall	**Cases**	**Controls**
Total N (valid PCR results)	417	208	209
Age [mean (min-max), N]	45.6 (19-83), 417	48 (19-83), 208	43.2 (19-80), 209
Gender [%F, (n/N)]	34.9%, (143/410)	30.7%, (63/205)	39%, (80/205)
Symptoms present [%Yes, (n/N)]	32.1%, (134/417)	34.1% (71/208)	30.1% (63/209)
Hospitalized (n, % Yes)	Not applicable		
Days from symptom onset [median (Q1-Q3); N]	5 (3-7), 134	5 (3-7), 71	6 (3-8), 63
Days < 0-3 (n, %)	38, 28%	21, 30%	17, 27%
Days 4-7 (n, %)	65, 49%	36, 51%	29, 46%
Days 8+ (n, %)	31, 23%	14, 20%	17, 27%
Positivity [%, (n/N)]	49.8%, (208/417)	100% (208/208)	0% (0/209)
PCR Ct [median (Q1-Q3); N]	Not applicable	24 (22-28), 205[1]	Not applicable
Ct > 33 (n, %)	Not applicable	10, 5%	Not applicable
Ct > 30 (n, %)	Not applicable	25, 12%	Not applicable
Ct > 25 (n, %)	Not applicable	94, 46%	Not applicable

[1]Missing Ct values for n=3 PCR positive samples

4.2 Estimation of Clinical Performance

Country	India
Clinical Sensitivity (95% CI), N	51.5% (44.7-58.2), 206[1]
Sensitivity days ≤7, N	61.8 (59.3, 76.4), 55
Sensitivity Ct ≤ 33, N	53.6% (46.6, 60.5), 194
Sensitivity Ct ≤ 25, N	68.5% (59.3, 76.4), 111
Clinical Specificity (95% CI), N	99.5% (97.3, 99.9), 209
Invalid rate (%, n/N)	0.5% (2/417)

[1]Two samples with invalid antigen results excluded from analysis

4.3 Estimation of analytical performance

- Supplier-reported LOD = 1.0 x 10^3TCID50/ml ~ 7.0 x 10^2 pfu/ml (isolate USA-WA1/2020)
- 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*