

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

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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 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	5 (3-7), 134	5 (3-7), 71	6 (3-8), 63	
(Q1-Q3); N]				
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	

¹Missing 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)		

¹Two samples with invalid antigen results excluded from analysis

4.3 Estimation of analytical performance

- Supplier-reported LOD = 1.0 x 10³TCID50/ml ~ 7.0 x 10² pfu/ml (isolate USA-WA1/2020)
- Verified LOD

Variant	Lowest dilution	Verified LOD	Viral Copy equivalent	
(lineage)	detected	concentration		
UK wild type	1.0 x10 ³ pfu/ml ~	1.0 x10 ³ pfu/ml	2.4 x10 ⁶ genome copies/ml	
(B1)	1.41 x 10 ³		applied to test	
	TCID₅₀/ml			
Alpha	1.0 x10 ² pfu/ml ~	1.0 x10 ² pfu/ml	6.3 x10 ³ genome copies/ml	
(B.1.1.7)	1.41 x 10 ²		applied to test	
	TCID₅₀/ml			
Gamma (P1)	5.0 x10 ¹ pfu/ml ~	5.0x10 ¹ pfu/ml	2.1 x10 ⁴ genome copies/ml	
	7.05 x 10 ¹		applied to test	
	TCID₅₀/mI			
Delta	5.0 x10 ¹ pfu/ml ~	5.0x10 ¹ pfu/ml	8.1 x10 ⁴ genome copies/ml	
(B.1617.2)	7.05 x 10 ¹		applied to test	
	TCID ₅₀ /ml			
Omicron	5.0 x10² pfu/ml ~	5.0 x10 ² pfu/ml	8.8 x10 ⁴ genome copies/ml applied to test	
(BA.1)	7.05 x 10 ²			
	TCID₅₀/mI			

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