FIND Evaluation of SD Bionsensor, Inc.

STANDARD Q COVID-19 Ag Test

External Report (Continue from V2.1)

Version 1, 22 April 2021

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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	22 April 2021	Initial release

1 Product Info:

Manufacturer name	SD Biosensor, Inc.
Test name	STANDARD Q COVID-19 Ag Test
Product code(s)	09COV30D-EN-P1 in India, 99COV30D-EN01 in CH
Pack size(s)	25 tests per kit
Contents of kit	Test device (individually in a foil pouch with desiccant), Extraction buffer tube, Nozzle cap, Sterile swab, Film and Instructions for Use
Equipment and consumables required, but not provided	Equipment: Timer, refrigerator - optional (for storage of specimens prior to testing, if applicable). Consumables: PPE
Product storage (temperature range)	2-30 °C.
Shelf-life (months)	24 months
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:	*See Standard Q COVID-19 Ag Test report (V2.1)*
Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by STANDARD Q COVID-19 Ag 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 Q COVID-19 Ag 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 Q COVID-19 Ag Test report (V2.1)*

3 Evaluation details:

Country of collaborator	**India**	**Peru**
Location of clinical site(s) (city, town)	ESIC Medical College and Hospital, Faridabad	Universidad Peruana Cayetano Heredia
Health care level of site(s)	Tertiary care Hospital	Community Testing Clinic
Study period (date to date)	16 October 2020 - 9 November 2020	19 October 2020 - 6 January 2021
Study cohort inclusion/exclusion	Inclusion: • Any person > 6 years of age presenting to ESIC volunteering for study (parents or guardians provided consent for <18). 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.	Adults with acute respiratory illness who meets WHO case definition of a COVID-19 suspected case presenting to temporary testing locations around clinical sites. Provided informed consent
Sample type, antigen test	Nasopharyngeal swab	Nasopharyngeal swab
Reference PCR method	RealStar SARS-CoV-2 RT-PCR Kit (Altona)	2019-nCoV TaqMan RT-PCR Kit (Norgen Biotek Corp)

Sample type, PCR test	Nasopharyngeal and oropharyngeal swab (combined)	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	**India**	**Peru**
Total N (valid PCR results)	334	335
Age [mean (min-max), N]	37.7 (7-82), 334	38.7 (18-82), 335
Gender [%F, (n/N)]	40.4%, (135/334), 334	56.1% (188/335)
Symptoms present [%Yes, (n/N)]	93.4% (311/333)	100% (335/335)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset [median (Q1-Q3); N]	3 (2-6), 311	6 (4-8), 335
Days < 0-3 (n, %)	163, 52%	72, 21%
Days 4-7 (n, %)	113, 36%	170, 51%
Days 8+ (n, %)	35, 11%	93, 28%
Positivity [%, (n/N)]	33%, (110/334)	30%, (100/335)
PCR Ct [median (Q1-Q3); N]	26.5 (21.5-31.8), 334	24.6 (19.1-31.1);100
Ct > 33 (n, %)	22, 20%	16, 16%
Ct > 30 (n, %)	40, 36%	28, 28%
Ct > 25 (n, %)	62, 56%	48, 48%

4.2 Estimation of Clinical Performance

Country	**India**	**Peru**
Clinical Sensitivity (95% CI), N	54.1% (44.8, 63.2), 109	71% (61.5, 79); 100
Sensitivity days ≤7, N	58.3% (48.3, 67.7), 96	81.4% (70.8, 88.8); 70
Sensitivity Ct ≤ 33, N	65.5% (55.1, 74.7), 87	83.3% (73.9, 89.8); 84

Sensitivity Ct ≤ 25, N	89.4% (77.4, 95.4), 47	96.2 (87, 98.9); 52
Clinical Specificity (95% CI), N	97.3% (94.3, 98.8), 224	99.6% (97.6, 99.9); 235
Invalid rate (%, n/N)	0%, (0/333)	0%, 0/335