FIND Evaluation of SD Biosensor, Inc.

STANDARD Q COVID-19 Ag Test, nasal swab

External Report

Version 2.0, 12 April 2021

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	19 January 2021	Initial release
2.0	12 April 2021	Data for Brazil added

1 Product info:

Manufacturer name	SD Biosensor, Inc.
Test name	STANDARD Q COVID-19 Ag Test
Product code(s)	**09COV31D**, 09COV30D
Pack size(s)	25 tests per kit
Contents of kit	**09COV31D** Test device (individually in a foil pouch with desiccant), Extraction buffer tube, Nozzle cap, Sterile swab (**Nasal swab**), Film and Instructions for Use Optional: positive control and negative control 09COV30D Test device (individually in a foil pouch with desiccant), Extraction buffer tube, Nozzle cap, Sterile swab (Nasopharyngeal swab), Film and Instructions for Use Optional: positive control and negative control
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 accuracy study to demonstrate the equivalency of nasal swab to nasopharyngeal swab for COVID-19 antigen RDTs, using consecutive enrolment.
Index assays:	Novel lateral flow format tests that detect recombinant SARS-CoV-2 antigens used with nasal swab as sample type.
Reference method:	Results of the index test are compared to the routine, diagnostic RT-PCR result, which is used for clinical management. Comparability between nasal swab Ag RDT results and nasopharyngeal swab Ag RDT results was also analysed.

Limit of detection:	*Not conducted. See STANDARD Q COVID-19, nasopharyngeal swab report.*
Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by STANDARD Q COVID-19 Ag 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 STANDARD Q COVID-19 Ag test among all negatives by the reference method and reported as a percentage. Positive and negative percent agreement between the two sample types was also calculated as the proportion of nasal swab positive/negative among all positive/negative by nasopharyngeal swab by STANDARD Q COVID-19 Ag, 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	*Not conducted. See STANDARD Q COVID-19, nasopharyngeal swab report.*

3 Evaluation details

Country of Collaborator	**Germany**	**Brazil**
Location of clinical site(s) (city, town)	Berlin	Marica and Guapimirim, state of Rio de Janeiro
Health care level of site(s)	Ambulatory testing clinic of Charité – University Hospital	Community testing clinic
Study period (date to date)	11-18 November 2020	14-20 January 2021; 2-4 March 2021
Study cohort inclusion/exclusion	Adults able to ambulate, at high risk for SARS-CoV-2 according to clinical suspicion, and meeting suspect definition of the Department of Public Health Provided informed consent	Adults in community meeting national suspect definition Provided informed consent
Sample type, antigen test	Anterior nasal (Nasal) and Nasopharyngeal (NP)	Nasal mid-turbinate (Nasal) and Nasopharyngeal (NP)
Reference PCR method	• Cobas SARS-CoV-2 (Roche Diagnostics Inc) ○ N = 158 • LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol)	Lab-developed assay based on the US CDC protocol, which targets two regions (N1 and N2) of the nucleocapsid (N) gene of SARS-

	○ N = 21	CoV-2 (https://www.fda.gov/media/134922/download)
Sample type, PCR test	Nasopharyngeal (NP)	Nasopharyngeal (NP)

4 Results

4.1 Study cohort

Country	**Germany**	**Brazil**
Total N (valid PCR results)	179	214
Age [mean (min-max), N]	36.2 (18-72), 179	41.31 (18-77), 214
Gender [%F, (n/N)]	48%, (86/179)	39.7%, (129/214)
Symptoms present [%Yes, (n/N)]	96.6% (173/179)	100%, (214/214)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-5); 173	5 (3-6.75); 214
Days < 0-3 (n, %)	79, 46%	68, 32%
Days 4-7 (n, %)	76, 44%	116, 54%
Days 8+ (n, %)	18, 10%	30, 14%
Positivity [%, (n/N)]	22.9%, (41/179)	36%, (78/214)
PCR Ct [median (Q1-Q3); N]	24.7 (22.6-29.9); 39	23.6 (18.8-28.8); 78
Ct > 33 (n, %)	7, 18%	6, 8%
Ct > 30 (n, %)	9, 23%	17, 22%
Ct > 25 (n, %)	18, 46%	32, 41%

4.2 Estimation of clinical performance

Country	**Germany**	
	Nasal swab	**Nasopharyngeal swab**
Clinical Sensitivity (95% CI), N	80.5% (66, 89.8); 41	73.2 (58.1, 84.3); 41
Sensitivity days ≤7, N	81.2% (64.7, 91.1); 32	81.2 (64.7, 91.1); 32
Sensitivity Ct ≤ 33, N	87.5% (71.9, 95); 32	84.4 (68.2, 93.1); 32

Sensitivity Ct ≤ 25, N	100% (84.5, 100); 21	95.5 (77.3, 99.2); 21
Clinical Specificity (95% CI), N	99.3% (96, 99.9);138	99.3 (96, 99.9); 138
Invalid rate (%, n/N)	0%, 0/179	0%, 0/179
Positive percent agreement – nasal/NP (95% CI), N	93.5% (79.3, 98.2); 31	NA
Negative percent agreement – nasal/NP (95% CI), N	96.6% (92.3, 98.5); 148	NA

[*]Note:20/41 positives were tested using Roche, 21/41 were tested using TibMolbiol.

Country	**Brazil**	
	Nasal swab	**Nasopharyngeal swab**
Clinical Sensitivity (95% CI), N	84.6% (75,91), 78	84.6% (75,91), 78
Sensitivity days ≤7, N	81.2% (64.7, 91.1), 66	81.2% (64.7, 91.1), 66
Sensitivity Ct ≤ 33, N	91.7% (83, 96.1), 72	91.7% (83, 96.1), 72
Sensitivity Ct ≤ 25, N	100% (92.3, 100), 46	100% (92.3, 100), 46
Clinical Specificity (95% CI), N	99.3% (96, 99.9), 136	99.3% (96, 99.9), 136
Invalid rate (%, n/N)	0%, (0/214)	0%, (0/214)
Positive percent agreement – nasal/NP (95% CI), N	100% (94.6, 100), 67	NA
Negative percent agreement – nasal/NP (95% CI), N	100% (97.5, 100), 147	NA