



FIND Evaluation of SD Biosensor, Inc.
STANDARD Q COVID-19 Ag Test, nasal swab
External Report
Version 1.0, 19 January 2021

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Evaluation Process – private sector engagement

FIND is a non-for-profit foundation, whose mission is to find diagnostic solutions to overcome diseases of poverty in lower- and middle-income countries. 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.

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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 webpage 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

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	<p>09COV31D</p> <p>Test device (individually in a foil pouch with desiccant), Extraction buffer tube, Nozzle cap, Sterile swab (Nasal swab), Film and Instructions for Use</p> <p>Optional: positive control and negative control</p> <p>09COV30D</p> <p>Test device (individually in a foil pouch with desiccant), Extraction buffer tube, Nozzle cap, Sterile swab (Nasopharyngeal swab), Film and Instructions for Use</p> <p>Optional: positive control and negative control</p>
Equipment and consumables required, but not provided	<p>Equipment: Timer, refrigerator - optional (for storage of specimens prior to testing, if applicable).</p> <p>Consumables: PPE</p>
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:	<p>Results of the index test are compared to the routine, diagnostic RT-PCR result, which is used for clinical management.</p> <p>Comparability between nasal swab Ag RDT results and nasopharyngeal swab Ag RDT results was also analysed.</p>

Limit of detection:	<i>Not conducted. See STANDARD Q COVID-19, nasopharyngeal swab report.</i>
Clinical Performance:	<p>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.</p> <p>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.</p> <p>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.</p> <p>The 95% confidence intervals were calculated in order to assess the level of uncertainty introduced by sample size, using the Wilson's score method.</p>
Ease of Use	<i>Not conducted. See STANDARD Q COVID-19, nasopharyngeal swab report.</i>

3 Evaluation Details

Country of Collaborator	Germany
Location of clinical site(s) (city, town)	Berlin
Health care level of site(s)	Ambulatory testing clinic of Charité – University Hospital
Study period (date to date)	11-18 November 2020
Study cohort inclusion/exclusion	<p>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</p> <p>Provided informed consent</p>
Sample type, antigen test	Anterior nasal (Nasal) and Nasopharyngeal (NP)
Reference PCR Method	<ul style="list-style-type: none"> • Cobas SARS-CoV-2 (Roche Diagnostics Inc) <ul style="list-style-type: none"> ○ N = 158 • LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol) <ul style="list-style-type: none"> ○ N = 21
Sample type, PCR test	Nasopharyngeal (NP)

4 Results

4.1 Study Cohort

Country	Germany
Total N (valid PCR results)	179
Age [mean (min-max), N]	36.2 (18-72), 179
Gender [%F, (n/N)]	48%, (86/179)
Symptoms present [%Yes, (n/N)]	96.6% (173/179)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-5); 173
Days < 0-3 (n, %)	79, 46%
Days 4-7 (n, %)	76, 44%
Days 8+ (n, %)	18, 10%
Positivity [%, (n/N)]	22.9%, (41/179)
PCR Ct [median (Q1-Q3); N]	24.7 (22.6-29.9); 39
Ct > 33 (n, %)	7, 18%
Ct > 30 (n, %)	9, 23%
Ct > 25 (n, %)	18, 46%

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.*