FIND Evaluation of SD Biosensor, Inc.

STANDARD Q COVID-19 Ag Test

External Report

Version 1.1, 16 October 2020

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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 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	18 September 2020	Initial release
1.1	16 October 2020	Corrected PCR sample type; added N per PCR comparator assay in Germany.

1 Product Info:

Manufacturer Name	SD Biosensor, Inc.
Test name	STANDARD Q COVID-19 Ag Test
Product Code(s)	09COV30D
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 97% 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:	Analytical sensitivity, i.e. Limit of detection, was performed at the Liverpool School of Tropical Medicine and/or the Institute of Virology, Charité-Universitätsmedizin Berlin in which standardized serial dilutions of cultured viral isolate were prepared. Dilutions were done in triplicate and the LOD was defined as the last dilution where all repeats were interpreted as positive.
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 in order to assess the level of uncertainty introduced by sample size, using the Wilson's score method.
Ease of Use	A System usability survey and ease of use questionnaire assessing the quality of the test, test preparation, ease of test execution, procedure time, ease of result interpretation, storage conditions and perceived settings of use was completed by operators and a final score out of 100 was calculated.

3 Evaluation Details

Country of Collaborator	**Germany**	**Brazil**
Location of clinical site(s) (city, town)	1. Heidelberg (HD) 2. Berlin	Macae, state of Rio de Janeiro
Health care level of site(s)	1. Heidelberg: Drive-in testing Center 2. Berlin: Ambulatory testing clinic of Charité – University Hospital	Community Testing Clinic
Study period (date to date)	1. HD: 20-31 July 2. Berlin: 03 June -31 July	13-30 July
Study cohort inclusion/exclusion	Adults able to ambulate 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	1. HD: Nasopharyngeal swabs 2. Berlin: Combined naso-/oropharyngeal swab Proprietary swab/media provided by SD Biosensor	Nasopharyngeal swabs Proprietary swab/media provided by SD Biosensor
Reference PCR Method	• Cobas SARS-CoV-2 (Roche Diagnostics Inc) ○ N = 908 • Abbott *RealTime* SARS-CoV-2 (Abbott Molecular, Inc) ○ N = 78 • Genesig COVID-19 Real-Time PCR assay (Primerdesign, Inc) ○ N = 19 • Allplex 2019-nCov Assay (Seegene Inc) ○ N = 125	• Lab-developed assay based on the US CDC protocol, which targets two regions (N1 and N2) of the nucleocapsid (N) gene of SARS-CoV-2 (https://www.fda.gov/media/134922/download)

	• LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol) ○ N = 131	
Sample type, PCR test	Naso/oropharyngeal swabs	Nasopharyngeal swabs

4 Results

4.1 Study Cohort(s)

Country	Germany	Brazil
Total N (valid PCR results)	1259	400
Age [mean (min-max), N]	35 (18-80.4); 1242	37 (2-94); 397
Gender [%F, (n/N)]	48.9%, (616/1222)	57.3%, (229/398)
Symptoms present [%Yes, (n/N)]	84.7%, (1039/1227)	98.7%, (392/397)
Hospitalized (n, % Yes)	Not available	Not available
Days from symptom onset [median (Q1-Q3); N]	3 (2-4); 1002	5 (4-6); 397
Days < 0-3 (n, %)	628 (62.7%)	85 (21.4%)
Days 4-7 (n, %)	310 (30.9%)	273 (68.8%)
Days 8+ (n, %)	64 (6.4%)	39 (9.8%)
Positivity [%, (n/N)]	3.7%, (47/1259)	26.5%, (106/400)
PCR Ct [median (Q1-Q3); N]	25.3 (21.8-29.1); 47*	25.5 (22.8-29.2); 106
Ct > 33 (n, %)	6 (12.8%)	7 (6.6%)
Ct > 30 (n, %)	11 (23.4%)	19 (17.9%)
Ct > 25 (n, %)	26 (55.3%)	57 (53.8%)

4.2 Estimation of Clinical and Analytical Performance

Country	Germany	Brazil
Clinical Sensitivity (95% CI); N	76.6% (62.8, 86.4); 47*	88.7% (81.3, 93.4); 106
Sensitivity days ≤7, N	80% (64.1, 90.1); 35	90.7% (83.3, 95.0); 97
Sensitivity Ct ≤33, N	87.8% (74.5, 94.7); 41	91.9% (84.9, 95.9); 99

Sensitivity Ct ≤ 25, N	100% (84.5, 100); 21	95.9% (86.3, 98.9); 49
Clinical Specificity (95% CI), N	99.3% (98.6, 99.6); 1212	97.6% (95.2, 98.8); 294
Invalid rate (%, n/N)	0%, 0/1259	0%, 0/400
Analytical Sensitivity (pfu/ml)[1]	5.0 x 10^3 pfu/ml ~ 7.14 x 10^3 $TCID_{50}$/ml	

[*]Note:40/47 positives were tested using Roche, 5/47 positives were tested using Seegene and 2/47 were tested using TibMolbiol.

[1] The claimed LOD by the supplier is 3.06 x $10^{2.2}$ TCID50/ml, which is the equivalent of approximately 3.9 x 10^2 pfu/ml. Therefore, we verify the LOD to be 10-fold higher than that found by the supplier, using a different viral strain.

4.3 Ease of Use

STANDARD Q COVID-19 Ag Test (SD Bionsensor, Inc.)	86 out of 100	6 operators, Germany 1 operator, UK