FIND Evaluation of SD Biosensor, Inc.

STANDARD Q COVID-19 Ag Test

External Report

Version 2.0, 3 November 2020

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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.

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 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.
2.0	1 November 2020	Data for Switzerland added

Product Info:

Manufacturer Name	SD Biosensor, Inc.
Test name	STANDARD Q COVID-19 Ag Test
Product Code(s)	09COV30D in BR/DE; 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

1 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.

2 Evaluation Details

Country of Collaborator	**Germany**	**Brazil**	**Switzerland**
Location of clinical site(s) (city, town)	1. Heidelberg (HD) 2. Berlin	Macae, state of Rio de Janeiro	University Hospital of Geneva
Health care level of site(s)	1. Heidelberg: Drive-in testing Center 2. Berlin: Ambulatory testing clinic of Charité – University Hospital	Community Testing Clinic	Hospital
Study period (date to date)	1. HD: 20-31 July 2. Berlin: 03 June -31 July	13-30 July	19-23 October 2020
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	Adults in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care. Provided informed consent
Sample type, antigen test	1. HD: Nasopharyngeal swabs 2. Berlin: Combined naso-/oropharyngeal swab	Nasopharyngeal swabs	Nasopharyngeal swab
Reference PCR Method	• Cobas SARS-CoV-2 (Roche Diagnostics Inc)	Lab-developed assay based on the US CDC protocol,	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 • LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol) ○ N = 131	which targets two regions (N1 and N2) of the nucleocapsid (N) gene of SARS-CoV-2 (https://www.fda.gov/media/134922/download)	
Sample type, PCR test	Naso/oropharyngeal swabs	Nasopharyngeal swabs	Nasopharyngeal swabs

3 Results

3.1 Study Cohort(s)

Country	**Brazil**	**Germany**	**Switzerland**
Total N (valid PCR results)	400	1259	529
Age [mean (min-max), N]	37 (2-94); 397	35 (18-80.4); 1242	35 (16-78); 529
Gender [%F, (n/N)]	57.3%, (229/398)	48.9%, (616/1222)	53.9%, (285/529)
Symptoms present [%Yes, (n/N)]	98.7%, (392/397)	84.7%, (1039/1227)	99.8%, (528/529)
Hospitalized (n, % Yes)	Not available	Not available	Not available
Days from symptom onset [median (Q1-Q3); N]	5 (4-6); 397	3 (2-4); 1002	3 (2-4); 183*
Days < 0-3 (n, %)	85 (21.4%)	628 (62.7%)	122 (66.7%)
Days 4-7 (n, %)	273 (68.8%)	310 (30.9%)	54 (29.5%)
Days 8+ (n, %)	39 (9.8%)	64 (6.4%)	7 (3.8%)
Positivity [%, (n/N)]	26.5%, (106/400)	3.7%, (47/1259)	36.1%, (191/529)

PCR Ct [median (Q1-Q3); N]	25.5 (22.8-29.2); 106	25.3 (21.8-29.1); 47*	21.8 (18.9-25.7); 191
Ct > 33 (n, %)	7 (6.6%)	6 (12.8%)	8 (4.19%)
Ct > 30 (n, %)	19 (17.9%)	11 (23.4%)	17 (8.9%)
Ct > 25 (n, %)	57 (53.8%)	26 (55.3%)	50 (26.2%)

** days post symptom onset only available for individuals who tested PCR positive.*

3.2 Estimation of Clinical and Analytical Performance

Country	**Brazil**	**Germany**	**Switzerland**
Clinical Sensitivity (95% CI); N	88.7% (81.3, 93.4); 106	76.6% (62.8, 86.4); 47*	89% (83.8, 92.7); 191
Sensitivity days ≤7, N	90.7% (83.3, 95.0); 97	80% (64.1, 90.1); 35	89.8% (84.4, 93.4); 176
Sensitivity Ct ≤33, N	91.9% (84.9, 95.9); 99	87.8% (74.5, 94.7); 41	91.8% (86.9, 95); 183
Sensitivity Ct ≤ 25, N	95.9% (86.3, 98.9); 49	100% (84.5, 100); 21	97.2% (92.9, 98.9); 141
Clinical Specificity (95% CI), N	97.6% (95.2, 98.8); 294	99.3% (98.6, 99.6); 1212	99.7% (98.3, 99.9); 338
Invalid rate (%, n/N)	0%, 0/400	0%, 0/1259	0%, 0/529
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.

3.3 Ease of Use

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