FIND Evaluation of SD Biosensor, Inc.

STANDARD Q COVID-19 Ag Test

External Report

Version 1.1, [30 September 2022]

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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	10 February 2022	First release
1.1	30 September	LOD data for new variants added

1 Product Info:

Manufacturer name	SD Biosensor, Inc.
Test name	STANDARD Q COVID-19 Ag Test (NP and Nasal)
Product code(s)	09COV30D (Nasopharyngeal) and 09COV31D (Nasal)
Pack size(s)	25 tests per kit
Contents of kit	09COV30D Test device (individually in a foil pouch with desiccant), Extraction buffer tube, Nozzle cap, Sterile swab (Nasopharyngeal swab), Film and Instructions for Use 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
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

Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by STANDARD Q 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 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.

3 Evaluation details:

Country of collaborator	South Africa
Location of clinical site(s) (city, town)	Hilcrest and Durban central
Health care level of site(s)	Drive-through testing centers
Study period (date to date)	9 December to 20 December 2021
Study cohort inclusion/exclusion	Prospective, cohort with consecutive enrolment Inclusion criteria Residents of the selected communities falling under any of the following criteria: tested COVID-19 positive <7 days; presence of COVID-19 symptoms <7 days; Exposed to COVID-19 5-10 days ago; Heath care worker; Doctor referral for testing; Exclusion criteria: Anyone in the selected communities not willing to participate or unable to provide consent to participate.
Sample type, antigen test	Nasopharyngeal and nasal swab
Reference PCR method	Abbott RealTime SARS-CoV-2 (Abbott Molecular, Inc) Ct values adjusted to account for unread cycles (n=10) by the Abbott platform.
Sample type, PCR test	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	South Africa
Total N (valid PCR results)	299
Age [mean (min-max), N]	37.4 (4-84), 299
Gender [%F, (n/N)]	56.5%, (169/299)
Symptoms present [%Yes, (n/N)]	72.6%, (217/299)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	2 (0-4), 217
Days < 0-3 (n, %)	150, 69%
Days 4-7 (n, %)	53, 24%
Days 8+ (n, %)	14, 6%
Positivity [%, (n/N)]	42%, (126/299)
Percentage of Omicron sequences [%, (n/N)]	100%, (124/124)
PCR Ct [median (Q1-Q3); N]	23.9 (20.4-28), 126
Ct > 33 (n, %)	16, 5%
Ct > 30 (n, %)	25, 18%
Ct > 25 (n, %)	54, 18%

4.2 Estimation of Clinical Performance

Country	South Africa	South Africa
	Nasopharyngeal	Nasal
Clinical Sensitivity (95% CI), N	78.6% (70.6, 84.8), 126	79.4% (71.5, 85.5), 126
Sensitivity days ≤7, N	81.2% (72.5, 87.6), 101	82.2% (73.6, 88.4), 120
Sensitivity Ct ≤ 33, N	87.3% (79.8, 92.3), 110	88.2% (80.8, 93), 110
Sensitivity Ct ≤ 25, N	97.2% (90.4, 99.2), 72	98.6% (92.5, 99.8), 72
Clinical Specificity (95% CI), N	99.4% (96.8, 99.9), 173	100% (97.8, 100), 173
Invalid rate (%, n/N)	0% (0/299)	0% (0/299)

4.3 Estimation of analytical performance

- Supplier-reported LOD = 2.48 x **10^2** TCID50/ml ~ inactivated SARS-CoV-2 (2019-nCoV) NCCP 43326/2020/Korea strain
- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	**2.5 x10^2 pfu/ml** ~ 3.525 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**5.9x10^5 genome copies/ml** applied to test
Alpha (B.1.1.7)	**2.5 x10^2 pfu/ml** ~ 3.525 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**5.1 x10^3 genome copies/ml** applied to test
Gamma (P1)	**5.0 x10^1 pfu/ml** ~ 7.05 x 10^1 $TCID_{50}$/ml	**5.0 x10^1 pfu/ml**	**2.1x10^4 genome copies/ml** applied to test
Delta (B.1617.2)	**5.0 x10^1 pfu/ml** ~ 7.05 x 10^1 $TCID_{50}$/ml	**5.0 x10^1 pfu/ml**	**8.1 x10^4 genome copies/ml** applied to test
Omicron (BA.1)	**2.5 x10^2 pfu/ml** ~ 3.525 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**4.4x10^4 genome copies/ml** applied to test