FIND Evaluation of Core Technology Co., Ltd

Core tests COVID-19 Ag Test

External Report

Version 2.0, [19 July2022]

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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	14 December 2021	First release
2.0	19 July 2022	Analytical data from several variants added Clinical data from Uganda added

1 Product Info:

Manufacturer name	Core Technology Co., Ltd.
Test name	Coretests COVID-19 Ag Test
Product code(s)	B291-20A
Pack size(s)	25 tests per kit
Contents of kit	COVID-19 Ag Test Cassette, Instructions for use, Sample collection tube containing processing solution, nasal swab
Equipment and consumables required, but not provided	PPE, timer
Product storage (temperature range)	2-30°C
Shelf-life (months)	24 months
Manufacturing site (country)	China

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
Limit of detection:	Analytical sensitivity, i.e. Limit of detection, was performed at the Liverpool School of Tropical Medicine in which standardized serial dilutions of cultured viral isolate were prepared. Proprietary swab provided in the kit was soaked in viral dilution series. Dilutions were tested 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 Core tests COVID-19 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 Core tests COVID-19 Test 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	**Switzerland**	**Uganda**
Location of clinical site(s) (city, town)	University Hospital of Geneva	• Mulago National Referral Hospital • Kiruddu National Referral Hospital • Mbarara Regional Referral Hospital • Masaka Regional Referral Hospital
Health care level of site(s)	Community Testing Clinic	National or regional referral hospitals
Study period (date to date)	19 November – 3 December 2021	2- 22 June 2022
Study cohort inclusion/exclusion	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	Adults with acute respiratory illness who meets WHO case definition of a COVID-19 suspected case presenting to temporary testing locations around clinical sites. Provided informed consent
Sample type, antigen test	Nasal swab	Nasopharyngeal swab
Reference PCR method	Cobas SARS-CoV-2 (Roche Diagnostics) n=227; Xpert Xpress SARS-CoV-2 (Cepheid) n=5	cobas® SARS-CoV-2 Test (Roche Diagnostics)
Sample type, PCR test	Nasopharyngeal	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	Switzerland	Uganda
Total N (valid PCR results)	230	437
Age [mean (min-max), N]	38.7 (16-77), 230	35.2 (18-86), 437
Gender [%F, (n/N)]	62.7%, (142/230)	44.9%, (196/437)
Symptoms present [%Yes, (n/N)]	100%, (58/58)[1]	100%, (437/437)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset [median (Q1-Q3); N]	2 (1-3), 55[2]	4 (2-5), 437
Days < 0-3 (n, %)	44, 80%	214, 49%
Days 4-7 (n, %)	10, 18%	183, 42%
Days 8+ (n, %)	1, 2%	40, 9%
Positivity [%, (n/N)]	23%, (54/230)	26%, (115/437)
PCR Ct [median (Q1-Q3); N]	21.7 (19.3-25), 54	26.4 (22.6-29), 115
Ct > 33 (n, %)	4, 7%	6, 5%
Ct > 30 (n, %)	5, 9%	23. 20%
Ct > 25 (n, %)	13, 24%	60, 52%

[1]Symptom data only available for PCR and/or RDT positive samples

[2]Symptom onset data missing for n=3

4.2 Estimation of Clinical Performance

Country	Switzerland	Uganda
Clinical Sensitivity (95% CI), N	87% (75.6, 93.6), 54	83.5% (75.6, 89.2), 115
Sensitivity days ≤7, N	88% (76.2, 94.4), 50	80.4% (71.2, 87.3), 92
Sensitivity Ct ≤ 33, N	92% (81.2, 96.8), 50	88.1% (80.7, 92.9), 109
Sensitivity Ct ≤ 25, N	97.6 (87.4, 99.6), 41	96.4% (87.7, 99), 55
Clinical Specificity (95% CI), N	98.3% (95.1, 99.4), 176	98.8% (95.5, 96), 322

Invalid rate (%, n/N)	0% (0/230)	0% (0/437)

4.3 Estimation of analytical performance

- Supplier-reported LOD = 2.25 x 10^1 TCID50/ml ~ 3.17 x 10pfu/ml (isolate Gamma (P1))

- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	**5.0 x10^3 pfu/ml ~** 7.05 x 10^3 $TCID_{50}$/ml	**5.0 x10^3 pfu/ml**	**9.8 x10^6 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**	**9.3 x10^3 genome copies/ml** applied to test
Gamma (P1)	**1.0 x10^1 pfu/ml** ~ 1.41 x 10^1 $TCID_{50}$/ml	**1.0 x10^1 pfu/ml**	**3.1 x10^3 genome copies/ml** applied to test
Delta (B.1617.2)	**2.5 x10^2 pfu/ml** ~ 3.525 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**9.9 x10^5 genome copies/ml** applied to test
Omicron (BA.1)	**1.0 x10^3 pfu/ml** ~ 1.41 x 10^3 $TCID_{50}$/ml	**1.0 x10^3 pfu/ml**	**1.8 x10^5 genome copies/ml** applied to test

Note: viral dilution was applied directly to the test cassette, not to the provided swab