FIND Evaluation of Hangzhou AllTest Biotech Co.,Ltd AllTest SARS-Cov-2 Antigen Rapid Test External Report

Version 2.0 [11 Aug 2022]

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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 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	21 March 2022	Initial release
1.1	03 June 2022	Omicron results added (analytical assessment)
2.0	11 August 2022	Data added for South Africa

1 Product Info:

Manufacturer name	Hangzhou AllTest Biotech Co.,Ltd
Test name	SARS-CoV-2 Antigen Rapid Test
Product code(s)	REF INCP-502-N
Pack size(s)	20 tests per kit
Contents of kit	Test cassettes, sterile swabs, package insert, extraction buffer, extraction tubes and tips, workstation, procedure card
Equipment and consumables required, but not provided	PPE and timer
Product storage (temperature range)	2-30°C
Shelf-life (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 ALLTEST SARS-CoV-2 Rapid 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 ALLTEST SARS-CoV-2 Rapid 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	**Brazil**	**South Africa**
Location of clinical site(s) (city, town)	Marica, state of Rio de Janeiro	Hilcrest and Durban central
Health care level of site(s)	Community testing clinic	Drive-through testing centers
Study period (date to date)	1-7 February 2022	11 May -20 June 2022
Study cohort inclusion/exclusion	Adults in community meeting national suspect definition Provided informed consent	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	Nasal swab	Nasal swab
Reference PCR method	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	Abbott RealTime SARS-CoV-2 (Abbott Molecular, Inc) (n=540) Xpert SARS-CoV-2 (Cepheid) (n=4)

	(https://www.fda.gov/media/134922/download)	
Sample type, PCR test	Nasopharyngeal swab	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	**Brazil**	**South Africa**
Total N (valid PCR results)	363	544
Age [mean (min-max), N]	44.6 (18-89), 363	43.7 (0-92), 544
Gender [%F, (n/N)]	56.5%, (205/363)	56.8%, (309/544)
Symptoms present [%Yes, (n/N)]	100%, (363/363)	88.8%, (480/544)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset [median (Q1-Q3); N]	3 (2-5), 363	4 (2-5), 480
Days < 0-3 (n, %)	206, 57%	228, 48%
Days 4-7 (n, %)	130, 36%	214, 45%
Days 8+ (n, %)	27, 7%	38, 8%
Positivity [%, (n/N)]	52%, (190/363)	29%, (158/544)
PCR Ct [median (Q1-Q3); N]	26.2 (21.9-31.4), 190	12.3 (9.4-19.1), 154*
Ct > 33 (n, %)	34, 9%	0, 0%
Ct > 30 (n, %)	58, 16%	2, 1%
Ct > 25 (n, %)	109, 30%	18, 12%

* Ct values for four samples tested with Xpert not included

4.2 Estimation of Clinical Performance

Country	Brazil	South Africa
Clinical Sensitivity (95% CI), N	77.9% (71.5, 83.2), 190	73.4% (66, 79.7), 158
Sensitivity days ≤7, N	79.7% (73.1, 84.9), 177	77.4% (69.7, 83.6), 137
Sensitivity Ct ≤ 33, N	89.1% (83.2, 93.1), 156	73.4% (65.9, 79.7), 154
Sensitivity Ct ≤ 25, N	95.1% (88, 98.1), 81	81.6% (74.3, 87.2), 136
Clinical Specificity (95% CI), N	94.8% (90.4, 97.2), 173	97.4% (95.3, 98.6), 386
Invalid rate (%, n/N)	0% (0/363)	0% (0/544)

4.3 Estimation of analytical performance

- Supplier-reported LOD = 250 TCID50/ml (isolate USA-WA1/2020,UV Inactivated)

- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	**1.0 x10^3 pfu/ml ~** 1.41 x 10^3 $TCID_{50}$/ml	**1.0 x10^3 pfu/ml**	**2.1 x10^5 genome copies/ml** applied to test
Alpha (B.1.1.7)	**2.5 x10^1 pfu/ml** ~ 3.525 x 10^1 $TCID_{50}$/ml	**2.5 x10^1 pfu/ml**	**9.5 x10^3 genome copies/ml** applied to test
Gamma (P1)	**2.5 x10^1 pfu/ml** ~ 3.525 x 10^1 $TCID_{50}$/ml	**2.5 x10^1 pfu/ml**	**1.7 x10^4 genome copies/ml** applied to test
Delta (B.1617.2)	**1.0 x10^1 pfu/ml** ~ 1.41 x 10^1 $TCID_{50}$/ml	**1.0 x10^1 pfu/ml**	**4.1 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**	**4.4 x10^4 genome copies/ml** applied to test

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