FIND Evaluation of Guangzhou Wondfo Biotech Co., Ltd Wondfo 2019-nCoV Antigen Test (Lateral Flow Method) Public Report

Version 2.1, 02 June 2022

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 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	25 February 2021	Initial version
2.0	23 September 2021	Data for Brazil added
2.1	03 June 2022	LOD results on new variants added

1 Product info:

Manufacturer name	Guangzhou Wondfo Biotech Co., Ltd
Test name	Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)
Product code(s)	W196P0003
Pack size(s)	20 tests/kit
Contents of kit	Test cassette, desiccant pouch, extraction tubes, drippers, sterile swabs, extraction buffer, IFU
Equipment and consumables required, but not provided	PPE, Timer, Biohazard container
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
Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by Wondfo 2019-nCoV Antigen 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 Wondfo 2019-nCoV Antigen 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	Brazil
Location of clinical site(s) (city, town)	University Hospital of Geneva	1. Rio de Janeiro 2. Guapimirim State of Rio de Janeiro
Health care level of site(s)	Community Testing Clinic	1. Tertiary hospital 2. Community testing clinics
Study period (date to date)	3-11 December 2020	17 August – 3 September 2021
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	Children over 2 years old and adults in community meeting national suspect definition Provided informed consent or assent
Sample type, antigen test	Nasopharyngeal swab	Nasopharyngeal swab
Reference PCR method	Cobas SARS-CoV-2 (Roche Diagnostics Inc) (n=137) Xpert Xpress SARS-CoV-2 (Cepheid) (n=1) TaqPath™ COVID-19 CE IVD RT PCR Kit (Thermo Fisher Scientific) (with Nimbus Presto Extraction instrument) (n=192)	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)
Sample type, PCR test	Nasopharyngeal swab	Nasopharyngeal swab

4 Results

4.1 Study cohort

Country	Switzerland	Brazil
Total N (valid PCR results)	328	237
Age [mean (min-max), N]	37.9 (16-76), 328	37.0 (3-107), 237
Gender [%F, (n/N)]	60.6% (198/327)	60.8% (144/237)
Positivity [%, (n/N)]	17% (56/328)	32% (76/237)
Symptoms present [%Yes, (n/N)]	100% (56/56) [1]	99.6% (236/237)
Hospitalized (n, % Yes)	Not available	Not available
Days from symptom onset[1] [median (Q1-Q3); N]	2 (1-4); 44	4 (3-5); 236
Days < 0-3 (n, %)	31, 70%	98, 42%
Days 4-7 (n, %)	11, 25%	132, 56%
Days 8+ (n, %)	2, 5%	6, 3%
PCR Ct [median (Q1-Q3); N]	20.4 (19-24.8); 56	18.5 (14.4-23.8); 76
Ct > 33 (n, %)	5, 9%	1, 1%
Ct > 30 (n, %)	7, 12%	6, 8%
Ct > 25 (n, %)	13, 23%	15, 20%

[1]*Note: data on symptom onset only available for individuals who tested PCR positive.*

4.2 Estimation of clinical performance

Country	Switzerland	Brazil
Clinical Sensitivity (95% CI), N	85.7% (74.3, 92.6), 56	89.5% (80.6, 94.6), 76
Sensitivity days ≤7, N	85.7% (72.2, 93.3), 42	90.4% (81.5, 95.3), 73
Sensitivity Ct ≤ 33, N	92.2% (81.5, 96.9), 51	89.3% (80.3, 94.5), 75
Sensitivity Ct ≤ 25, N	100% (91.8, 100), 43	96.7% (88.8, 99.1), 61
Clinical Specificity (95% CI), N	100% (98.6, 100), 272	98.8% (95.6, 99.7), 161
Invalid rate (%, n/N)	0% (0/328)	0% (0/237)

4.3 Estimation of analytical performance

- Supplier-reported LOD = $8.5x10^2$ $TCID_{50}$/ml~5.95×10^2pfu/ml (wild type isolate)

- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	**$1.0 x10^3$** pfu/ml ~ 1.41×10^3 $TCID_{50}$/ml	$1.0 x10^3$ pfu/ml	$2.4 x10^6$ copies/ml applied to test
Alpha (B.1.1.7)	**$1.0 x10^3$ pfu/ml** ~ 1.41×10^3 $TCID_{50}$/ml	$1.0 x10^3$ pfu/ml	$2.1 x10^4$ copies/ml applied to test
Gamma (P1)	**$1.0 x10^3$ pfu/ml** ~ 1.41×10^3 $TCID_{50}$/ml	$1.0 x10^3$ pfu/ml	$5.6 x10^5$ copies/ml applied to te
Delta (B.1617.2)	**$2.5 x10^2$ pfu/ml** ~ 3.525×10^2 $TCID_{50}$/ml	$2.5 x10^2$ pfu/ml	$9.9 x10^5$ copies/ml applied to test
Omicron (BA.1)	**$2.5 x10^2$ pfu/ml** ~ 3.525×10^2 $TCID_{50}$/ml	$2.5 x10^2$ pfu/ml	$4.4 x10^4$ copies/ml applied to test

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