

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

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)	12 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:	<p>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.</p> <p>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.</p> <p>The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size, using the Wilson's score method.</p>

3 Evaluation details

Country of collaborator	Switzerland
Location of clinical site(s) (city, town)	University Hospital of Geneva
Health care level of site(s)	Community Testing Clinic
Study period (date to date)	3-11 December 2020
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
Sample type, antigen test	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)
Sample type, PCR test	Nasopharyngeal swab

4 Results

4.1 Study cohort

Country	Switzerland
Total N (valid PCR results)	328
Age [mean (min-max), N]	37.86 (16-76), 328
Gender [%F, (n/N)]	60.6% (198/327)
Positivity [%, (n/N)]	17% (56/328)
Symptoms present ¹ [%Yes, (n/N)]	100% (56/56)
Hospitalized (n, % Yes)	Not available
Days from symptom onset ¹ [median (Q1-Q3); N]	2 (1-4); 44
Days < 0-3 (n, %)	31, 70%

Days 4-7 (n, %)	11, 25%
Days 8+ (n, %)	2, 5%
PCR Ct [median (Q1-Q3); N]	20.4 (19-24.8); 56
Ct > 33 (n, %)	5, 9%
Ct > 30 (n, %)	7, 12%
Ct > 25 (n, %)	13, 23%

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

4.2 Estimation of clinical performance

Country	Switzerland
Clinical Sensitivity (95% CI), N	85.7% (74.3, 92.6), 56
Sensitivity days ≤7, N	85.7% (72.2, 93.3), 42
Sensitivity Ct ≤ 33, N	92.2% (81.5, 96.9), 51
Sensitivity Ct ≤ 25, N	100% (91.8, 100), 43
Clinical Specificity (95% CI), N	100% (98.6, 100), 272
Invalid rate (%; n/N)	0% (0/328)

4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	1 x 10 ³ pfu/ml ~ 1.42 x 10 ³ TCID ₅₀ /ml	1 x 10³ pfu/ml	2.4 x 10⁶ copies/ml	8.5x10 ² TCID ₅₀ /ml ~5.95 x 10² pfu/ml

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