FIND Evaluation

Beijing Wantai Biological Pharmacy Enterprise Co. Ltd.

Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold)

External Report

Version 1.0, [3 November 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	3 November 2022	First release

1 Product Info:

Manufacturer name	Beijing Wantai Biological Pharmacy Enterprise Co. Ltd.
Test name	Wantai SARS-CoV-2 Ag Rapid Test (Colloidal Gold)
Product code(s)	WJ-2901
Pack size(s)	10 tests per kit
Contents of kit	Test Cassette, extraction vial, disposable sterile swab, plastic sealable bag, instructions for use, operation guide
Equipment and consumables required, but not provided	PPE, timer
Product storage (temperature range)	2-30°C
Shelf-life (months)	18 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 Wantai SARS-CoV-2 Ag 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 Wantai SARS-CoV-2 Ag 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	Peru
Location of clinical site(s) (city, town)	Lima
Health care level of site(s)	Community Testing Clinic
Study period (date to date)	17 May - 5 September 2022
Study cohort inclusion/exclusion	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, saliva
Reference PCR method	2019-nCoV TaqMan RT-PCR Kit (Norgen Biotek Corp)
Sample type, PCR test	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	Peru
Total N (valid PCR results)	248
Age [mean (min-max), N]	37.7 (18-88), 248
Gender [%F, (n/N)]	68.1%, (169/248)
Symptoms present [%Yes, (n/N)]	100%, (248/248)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	3.5 (3-5), 248
Days < 0-3 (n, %)	124, 50%
Days 4-7 (n, %)	116, 47%
Days 8+ (n, %)	8, 3%
Positivity [%, (n/N)]	30% (75/248)
PCR Ct [median (Q1-Q3); N]	18 (13.8-23.6), 75
Ct > 33 (n, %)	4, 5%
Ct > 30 (n, %)	14, 19%
Ct > 25 (n, %)	17, 23%

4.2 Estimation of Clinical Performance

Country	Peru
	Nasal
Clinical Sensitivity (95% CI), N	74.7% (63.8, 83.1), 75
Sensitivity days ≤7, N	75% (63.9, 83.6), 72
Sensitivity Ct ≤ 33, N	78.9% (68, 86.8), 71
Sensitivity Ct ≤ 25, N	91.4% (81.4, 96.3), 58
Clinical Specificity (95% CI), N	87.9% (82.2, 91.9), 173
Invalid rate (%, n/N)	0% (0/248)

4.3 Estimation of analytical performance

- Supplier-reported LOD = 137 TCID50/ml (isolate wild type)

- 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)	**1.0 x10^2 pfu/ml** ~ 1.41 x 10^2 $TCID_{50}$/ml	**1.0 x10^2 pfu/ml**	**3.8 x10^3 genome copies/ml** applied to test
Gamma (P1)	**1.0 x10^2 pfu/ml** ~ 1.41 x 10^2 $TCID_{50}$/ml	**1.0 x10^2 pfu/ml**	**4.3 x10^4 genome copies/ml** applied to test
Delta (B.1617.2)	**1.0 x10^2 pfu/ml** ~ 1.41 x 10^2 $TCID_{50}$/ml	**1.0 x10^2 pfu/ml**	**1.6 x10^5 genome copies/ml** applied to test
Omicron (BA.1)	**5.0 x10^2 pfu/ml** ~ 7.05 x 10^2 $TCID_{50}$/ml	**5.0 x10^2 pfu/ml**	**8.8 x10^4 genome copies/ml** applied to test

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