FIND Evaluation of Wondfo U-Card Dx 2019-nCoV/Flu Test External Report

Version 1.0 [22 December 2023]

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Evaluation process – private sector engagement

FIND 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; ease-of-use of the test and instrument robustness; the manufacturing and distribution capacity of the supplier; and the supplier-reported clinical and analytical performance.

Document history

Document version	Date	Comment
1.0	22 December 2023	Initial release

1 Product Information:

Manufacturer name	Guangzhou Wondfo Biotech Co., Ltd.
Test name	U-Card Dx – 2019-nCoV/Flu Test
Product code(s)	WG01P0002
Pack size(s)	24 tests per kit
Contents of kit	Test cartridges, Nasopharyngeal swabs, Sample collection tubes, Specimen transfer pipettes, Instruction for use, Quick reference instruction
Equipment and consumables required, but not provided	U-Card Dx Instrument (MDX-301), Personal protective equipment
Product storage (temperature range)	2-30°C
Shelf-life (months)	18 months
Manufacturing site (country)	Republic of China

2 Study details:

Study design:	Diagnostic evaluation study in an independent site to determine the accuracy of COVID-19 point-of-care (POC) molecular assays. As SARS-CoV-2 prevalence and testing rates dropped, prospective sampling became more challenging and retrospective samples were used to supplement the sample size and reach study targets.
Index assays:	COVID-19 near point-of-care (POC) molecular assays that detect SARS-CoV-2 RNA
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 the U-Card Dx – 2019-nCoV/Flu 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 the U-Card Dx – 2019-nCoV/Flu 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	United Kingdom
Location of clinical site(s) (city, town)	Liverpool School of Tropical Medicine
Health care level of site(s)	National Referral Hospital
Enrolment and testing period	April 2023 to September 2023
Study cohort inclusion/exclusion	Inclusion criteria - Adult individuals (≥18 years of age) with symptoms suggesting plausible COVID-19 infection (as per WHO or national clinical case definitions) - Individuals who have voluntarily given written consent to participate in this study or who have given their written consent for their specimen to be used for future research studies - Individuals able to provide the specimens required for the study Exclusion criteria - Individuals unable to cooperate with respiratory sample collection - Individuals on oxygen therapy - Individuals with recent history of excessive nose bleeds - Individuals with hemodynamic instability as determined by their treating physician - Individuals enrolled in similar studies using similar respiratory samples being collected on the same day
Sample type, antigen test	Nasopharyngeal swab
Reference PCR method	TaqPath COVID-19 CE-IVD RT-PCR Kit (Thermo Fisher Scientific)
Sample type, PCR test	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	**United Kingdom**
Total N (valid PCR results)	222
Age [mean (min-max), N]	55 (18-90), 222
Gender [%F, (n/N)]	47.3%, (105/222)
Symptoms present [%Yes, (n/N)]	99.1%, (220/222)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-6.5); 219
Days < 0-3 (n, %)	86, 39.3%
Days 4-7 (n, %)	89, 40.6%
Days 8+ (n, %)	44, 20.1%
Positivity [%, (n/N)]	46.8%, (104/222)
PCR Ct [median (Q1-Q3); N]	20.5 (16.6-24.2); 104
Ct > 33 (n, %)	4, 3.8%
Ct > 30 (n, %)	6, 5.8%
Ct > 25 (n, %)	22, 21.2%

4.2 Estimation of Clinical Performance

Country	**United Kingdom**
Clinical Sensitivity (95% CI), N	97.1% (91.9, 99), 104
Sensitivity days ≤7, N	96.8% (91, 98.9), 94
Sensitivity Ct ≤ 33, N	100% (96.3, 100), 100
Sensitivity Ct ≤ 25, N	100% (95.5, 100), 82
Clinical Specificity (95% CI), N	99.2% (95.3, 99.9), 117
Invalid rate [% (n/N)]	0.5% (1/222)

4.2.1 Estimation of analytical performance

- Supplier-reported LOD

Viral strain	Target	Reported LOD
SARS-CoV-2 (USA-WA1/2020)	2019-nCoV N Gene	**5.0 x10^2 genome copies/ml** applied to test

- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
Omicron (BA.5)	**1.0 x10^0 pfu/ml** ~ 1.41x 10^0 $TCID_{50}$/ml	**1.0 x10^0 pfu/ml**	**3.0 x10^3 genome copies/ml** applied to test

Note 1: *Viral dilution was applied directly to the test cassette, not to the provided swab.*

Note 2: *Gene target was detected but the instrument reported an invalid result as the internal control result was negative due to the absence of human DNA in the spiked viral dilutions used for the LOD determination.*