FIND Evaluation

Tigsun COVID-19 Antigen Rapid Test

External Report

Version 1.1, [3 June 2022]

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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 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	29 November 2021	Initial release
1.1	03 June 2022	LOD results for new variants added

1 Product Info:

Manufacturer name	Tigsun
Test name	Tigsun COVID-19 Antigen Rapid Test
Product code(s)	TG-1416
Pack size(s)	25 tests per kit
Contents of kit	Individually sealed pouches, each containing one test cassette; Treatment reagent; Reagent tubes; Swabs, Instructions for use
Equipment and consumables required, but not provided	Timer, PPE
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 Tigsun COVID-19 Antigen 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 Tigsun COVID-19 Antigen 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	Uganda	Peru
Location of clinical site(s) (city, town)	• Mulago National Referral Hospital • Kiruddu National Referral Hospital • Mbarara Regional Referral Hospital Masaka Regional Referral Hospital	Universidad Peruana Cayetano Heredia, Lima
Health care level of site(s)	National or regional referral hospitals	Community Testing Clinic
Study period (date to date)	16 September – 21 October 2021	9 June – 17 August 2021
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	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	Nasopharyngeal swab	Nasopharyngeal swab
Reference PCR method	cobas® SARS-CoV-2 Test (Roche Diagnostics)	2019-nCoV TaqMan RT-PCR Kit (Norgen Biotek Corp)
Sample type, PCR test	Nasopharyngeal swab	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	Uganda	Peru
Total N (valid PCR results)	479	200

Age [mean (min-max), N]	37.7 (18-91), 464	39.6 (18-86), 200
Gender [%F, (n/N)]	41.4, (195/471)	60%, (120/200)
Symptoms present [%Yes, (n/N)]	97.3%, (466/479)	100%, (200/200)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (2-5), 268	4 (3-6), 200
Days < 0-3 (n, %)	133, 50%	91, 46%
Days 4-7 (n, %)	104, 39%	89, 44%
Days 8+ (n, %)	31, 11%	20, 10%
Positivity [%, (n/N)]	12%, (59/481)	25%, (50/200)
PCR Ct [median (Q1-Q3); N]	32.2 (24.8-34.2), 58	25 (19.2-34.1), 50
Ct > 33 (n, %)	20, 34%	15, 30%
Ct > 30 (n, %)	35, 60%	18, 36%
Ct > 25 (n, %)	43, 74%	25, 50%

4.2 Estimation of Clinical Performance

Country	**Uganda**	**Peru**
Clinical Sensitivity (95% CI), N	*45.8% (33.7, 58.3), 59	*50% (36.6, 63.4), 50
Sensitivity days ≤7, N	*56.7% (39.2, 72.6), 30	*48.7% (33.9, 63.8), 39
Sensitivity Ct ≤ 33, N	*68.4% (52.5, 80.9), 38	*68.6% (52, 81.4), 35
Sensitivity Ct ≤ 30, N	*91.3% (73.2,97.58), 23	*75% (57.9,86.8), 32
Sensitivity Ct ≤ 25, N	100% (79.6, 100), 15	84% (65.3, 93.6), 25
Clinical Specificity (95% CI), N	99.8% (98.7, 100), 417	99.3% (96.3, 99.9), 150
Invalid rate (%, n/N)	0.6% (3/479)	0% (0/200)

*__Important note__: The clinical sensitivity values in both studies may have been impacted by the higher proportion of samples with low viral loads (high Ct values) compared to previous studies conducted as part of the FIND independent test evaluations.

4.3 Estimation of analytical performance

- Supplier-reported LOD = 5.0 x10$_2$ TCID50/ml~ 3.5 x10$_2$ pfu/ml (isolate UK wild type (B1))

- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	5.0 x10^2 pfu/ml ~ 7.05 x 10^2 $TCID_{50}$/ml	5.0 x10^2 pfu/ml	1.18 x10^6 copies/ml applied to test
Alpha (B.1.1.7)	1.0 x10^3 pfu/ml ~ 1.41 x 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 x 10^3 $TCID_{50}$/ml	1.0 x10^3 pfu/ml	5.6 x10^5 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	1.64 x10^5 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	4.42 x10^4 copies/ml applied to test

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