FIND Evaluation of InTec PRODUCTS, INC.

Rapid SARS-CoV-2 Antigen Tests

External Report

Version 1.1, [6 May 2022]

Copyright and use of the report

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	26 January 2022	First release
1.1	6 May 2022	Addition of Omicron LOD results

1 Product Info:

Manufacturer name	InTec PRODUCTS, INC.
Test name	Rapid SARS-CoV-2 Antigen Tests
Product code(s)	ITP16010-TC25
Pack size(s)	25 tests per kit
Contents of kit	Buffer tube, cassette, disposable swab, instructions for use, tube holder
Equipment and consumables required, but not provided	Timer, PPE
Product storage (temperature range)	2-30° C, room temperature
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
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 Rapid SARS-CoV-2 Antigen Tests 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 Rapid SARS-CoV-2 Antigen Tests 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
Location of clinical site(s) (city, town)	• Mulago National Referral Hospital • Kiruddu National Referral Hospital • Mbarara Regional Referral Hospital • Masaka Regional Referral Hospital
Health care level of site(s)	National or regional referral hospitals
Study period (date to date)	16 November 2021 – 17 January 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 swab
Reference PCR method	cobas® SARS-CoV-2 Test (Roche Diagnostics)
Sample type, PCR test	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	**Uganda**
Total N (valid PCR results)	411
Age [mean (min-max), N]	36.8 (18-92), 411
Gender [%F, (n/N)]	47.1%, (193/410)
Symptoms present [%Yes, (n/N)]	100%, (411/411)

Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-5), 411
Days < 0-3 (n, %)	178, 43%
Days 4-7 (n, %)	199, 48%
Days 8+ (n, %)	34, 8%
Positivity [%, (n/N)]	26%, (107/411)
PCR Ct [median (Q1-Q3); N]	28.6 (24-33), 107
Ct > 33 (n, %)	26, 24%
Ct > 30 (n, %)	44, 41%
Ct > 25 (n, %)	74, 69%

4.2 Estimation of Clinical Performance

Country	**Uganda**
Clinical Sensitivity (95% CI), N	86% (78.2, 91.3), 107
Sensitivity days ≤7, N	86.1% (78.1, 91.6), 101
Sensitivity Ct ≤ 33, N	97.5% (91.4, 99.3), 81
Sensitivity Ct ≤ 25, N	100% (89.6, 100), 33
Clinical Specificity (95% CI), N	99.3% (97.6, 99.8), 304
Invalid rate (%, n/N)	0% (0/411)

4.3 Estimation of analytical performance

- Supplier-reported LOD = Supplier-reported LOD = 4.25 x10 ^{2} TCID50/ml ~ 2.98 x10 ^{2} pfu/ml (Wuhan wild type strain)

- 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 x 10^{3} $TCID_{50}$/ml	**1.0 x10^{3} pfu/ml**	**2.1 x10^{5} genome copies/ml** applied to test
Alpha (B.1.1.7)	**2.5 x10^{1} pfu/ml** ~ 3.525 x 10^{1} $TCID_{50}$/ml	**2.5 x10^{1} pfu/ml**	**9.5 x10^{3} genome copies/ml** applied to test
Gamma (P1)	**1.0 x10^{1} pfu/ml** ~ 1.41 x 10^{1} $TCID_{50}$/ml	**1.0 x10^{1} pfu/ml**	**3.1 x10^{3} genome copies/ml** applied to test
Delta (B.1617.2)	**2.5 x10^{2} pfu/ml** ~ 3.525 x 10^{2} $TCID_{50}$/ml	**2.5 x10^{2} pfu/ml**	**9.9 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**	**8.83 x10^{4} genome copies/ml** applied to test

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