FIND Evaluation of CTK Biotech

OnSite COVID-19 Rapid Test

External Report

Version 2.1, [19 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	8 December 2021	First release
1.1	24 March 2022	BR Ct values corrected
2.0	13 April 2022	UK (LSTM) clinical data removed

2.1	19 May 2022	LOD data for new variants added

1 Product Info:

Manufacturer name	CTK Biotech, Inc.
Test name	OnSite COVID-19 Rapid Test
Product code(s)	R0182C
Pack size(s)	20 tests per kit
Contents of kit	Cassette device and desiccant in sealed foil pouches, sample extraction tubes, sample extraction tube rack, sample extraction buffer, nozzles, individually sealed pouches containing a sterile swab, IFU
Equipment and consumables required, but not provided	Positive and negative controls, timer, PPE
Product storage (temperature range)	2-30°C
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 OnSite COVID-19 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 OnSite COVID-19 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	**Brazil**
Location of clinical site(s) (city, town)	São Paulo, Brazil
Health care level of site(s)	Hospital das Clínicas da Universidade de São Paulo
Study period (date to date)	1 July – 17 October 2021
Study cohort inclusion/exclusion	Inclusion: • 18 years or older, who are undergoing testing for COVID-19 • Symptomatic for COVID-19 • Provided informed consent Exclusion: • Asymptomatic • Younger than 18 years
Sample type, antigen test	Combined nasopharyngeal and oropharyngeal swab (n=4) Oropharyngeal swab (n=1) Nasopharyngeal swab (n=491)
Reference PCR method	Abbott RealTime SARS-CoV-2 Assay (Abbott Molecular)
Sample type, PCR test	Combined nasopharyngeal and oropharyngeal swabs; oropharyngeal swabs; nasopharyngeal swabs

4 Results:

4.1 Study cohort

Country	Brazil
Total N (valid PCR results)	496
Age [mean (min-max), N]	38.1 (16-69), 496
Gender [%F, (n/N)]	71.5% (354/495)
Symptoms present [%Yes, (n/N)]	99.6% (494/496)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	3 (2-4), 494
Days < 0-3 (n, %)	294, 60%
Days 4-7 (n, %)	186, 38%
Days 8+ (n, %)	14, 3%
Positivity [%, (n/N)]	6%, (32/296)
PCR Ct [median (Q1-Q3); N]	29.6 (27.5-33.9), 32
Ct > 33 (n, %)	0, 0%
Ct > 30 (n, %)	1, 3%
Ct > 25 (n, %)	7, 22%

4.2 Estimation of Clinical Performance

Country	Brazil
Clinical Sensitivity (95% CI), N	90.3% (75.1, 96.7), 32
Sensitivity days ≤7, N	96.2% (81.1, 99.3), 26
Sensitivity Ct ≤ 33, N	90.3% (75.1, 96.7), 31
Sensitivity Ct ≤ 25, N	95.8% (78.8, 99.3), 24
Clinical Specificity (95% CI), N	99.4% (98.1, 99.8)
Invalid rate (%, n/N)	0.2% (1/496)

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

4.3 Estimation of analytical performance

- Supplier reported LOD 280 $TCID_{50}$/ml ~ 196 pfu/ml(isolate Gamma-Irradiated SARS-CoV-2 virus lysate (BEI Resources, NR-52287)
- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	**2.5 x10^2 pfu/ml ~** 3.525 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**5.9 x10^5 genome copies/ml** applied to test
Alpha (B.1.1.7)	**2.5 x10^2 pfu/ml** ~ 3.525 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**5.1 x10^3 genome copies/ml** applied to test
Gamma (P1)	**5.0 x10^2 pfu/ml** ~ 7.05 x 10^2 $TCID_{50}$/ml	**5.0 x10^2 pfu/ml**	**2.8 x10^5 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**	**1.64 x10^5 genome copies/ml** applied to test
Omicron (BA.1)	**2.50 x10^2 pfu/ml** ~ 3.525 x 10^2 $TCID_{50}$/ml	**2.5 x10^2 pfu/ml**	**4.42 x10^4 genome copies/ml** applied to test