

**FIND Evaluation of PerkinElmer
 COVID-19 Antigen Test (NS, NP)
 External Report**
Version 1.1, [03 June 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	9 December 2021	First release
1.1	03 June 2022	LOD results for new variants added

1 Product Info:

Manufacturer name	Zephyr Biomedicals, A Division of Tulip Diagnostics (P) Ltd., A Perkinelmer Company
Test name	PerkinElmer COVID-19 Antigen Test (NS, NP)
Product code(s)	502120025
Pack size(s)	25 tests per kit
Contents of kit	Individual pouches containing a cassette and desiccant pouch, sterile nasal/nasopharyngeal swabs, extraction buffer tubes, nozzles for extraction buffer tubes, stand for extraction tubes, extraction buffer bottle, instructions for use
Equipment and consumables required, but not provided	PPE, Timer, Biohazard container
Product storage (temperature range)	4°C to 30°C
Shelf-life (months)	15 months
Manufacturing site (country)	India

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:	<p>Sensitivity was calculated as the proportion of true positive results detected by PerkinElmer COVID-19 Antigen Test among all positives by the reference method, and reported as a percentage</p> <p>Specificity was calculated as the proportion of true negative specimens, identified as negative by PerkinElmer COVID-19 Antigen Test among all negatives by the reference method and reported as a percentage.</p> <p>The 95% confidence intervals were calculated to assess the level of uncertainty introduced by sample size, using the Wilson’s score method.</p>
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3 Evaluation details:

Country of collaborator	Brazil
Location of clinical site(s) (city, town)	1. Rio de Janeiro 2. Guapimirim State of Rio de Janeiro
Health care level of site(s)	1. Tertiary hospital Community testing clinics
Study period (date to date)	2 October – 16 November 2021
Study cohort inclusion/exclusion	Children over 12 years old and adults in community meeting national suspect definition Provided informed consent or assent
Sample type, antigen test	Anterior nasal (Nasal)
Reference PCR method	Lab-developed assay based on the US CDC protocol, which targets two regions (N1 and N2) of the nucleocapsid (N) gene of SARS-CoV-2 (https://www.fda.gov/media/134922/download)
Sample type, PCR test	Nasopharyngeal swab

4 Results:

4.1 Study cohort

Country	Brazil
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Total N (valid PCR results)	497
Age [mean (min-max), N]	36.6 (12-87), 497
Gender [%F, (n/N)]	60.7% (301/296)
Symptoms present [%Yes, (n/N)]	99%, (492/497)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-5), 492
Days < 0-3 (n, %)	204, 41%
Days 4-7 (n, %)	259, 53%
Days 8+ (n, %)	29, 6%
Positivity [%, (n/N)]	10%, (49/497)
PCR Ct [median (Q1-Q3); N]	21.2 (18.3-25), 49
Ct > 33 (n, %)	2, 4%
Ct > 30 (n, %)	8, 16%
Ct > 25 (n, %)	12, 24%

4.2 Estimation of Clinical Performance

Country	Brazil
Clinical Sensitivity (95% CI), N	84.4% (71.8, 92.4), 46 ¹
Sensitivity days ≤7, N	83.7% (70, 91.9), 43
Sensitivity Ct ≤ 33, N	86.4 (73.7, 93.6), 44
Sensitivity Ct ≤ 25, N	94.3 (81.4, 98.4), 35
Clinical Specificity (95% CI), N	97.3% (95.1, 98.5), 365 ²
Invalid rate (% , n/N)	0% (0/497)
Non-actionable rate (% , n/N)	15.5% (77/497) ³

¹ n=3: PCR positive samples with non-actionable RDT results

² n=74: PCR negative samples with non-actionable RDT results

³ n=77: Ag RDTs with a high level of background were observed as the buffer ran through the cassette. This background prevented an accurate interpretation of the test result and therefore these test results were deemed not actionable.

4.3 Estimation of analytical performance

- Supplier-reported LOD = 1.15×10^4 TCID₅₀/ml ~ 8.0×10^3 pfu/ml (isolate USA-WA1/2020, NR-52281)
- Verified LOD

Variant (lineage)	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent
UK wild type (B1)	1.0×10^3 pfu/ml ~ 1.41×10^3 TCID ₅₀ /ml	1.0×10^3 pfu/ml	3.0×10^6 genome copies/ml applied to test
Alpha (B.1.1.7)	5.0×10^2 pfu/ml ~ 7.05×10^2 TCID ₅₀ /ml	5.0×10^2 pfu/ml	1.8×10^4 genome copies/ml applied to test
Gamma (P1)	5.0×10^2 pfu/ml ~ 7.05×10^2 TCID ₅₀ /ml	5.0×10^2 pfu/ml	2.8×10^5 genome copies/ml applied to test
Delta (B.1617.2)	5.0×10^2 pfu/ml ~ 7.05×10^2 TCID ₅₀ /ml	5.0×10^2 pfu/ml	1.9×10^6 genome copies/ml applied to test
Omicron (BA.1)	5.0×10^3 pfu/ml ~ 7.05×10^3 TCID ₅₀ /ml	5.0×10^3 pfu/ml	8.8×10^5 genome copies/ml applied to test

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