FIND Evaluation of Abbott Panbio COVID-19 Ag Rapid Test Device Country Specific External Report

Version 1.0, 28 April 2021

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	28 April 2021	Initial version

1 Product Info:

Manufacturer name	Abbott Rapid Diagnostics
Test name	Panbio COVID-19 Ag
Product code(s)	41FK10
Pack size(s)	25 tests / kit
Contents of kit	Tests with desiccant in individual foil pouch, Buffer, Extraction tubes, Extraction tube caps, positive control swab, negative control swab, sample collection swabs, quick reference guide, IFU
Equipment and consumables required, but not provided	PPE, Timer, Biohazard container
Product storage (temperature range)	2-30°C
Shelf-life (months)	12 months
Manufacturing site (country)	South Korea

2 Study details:

Study design:	**THSTI site**: 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 97% specificity. Presence of symptoms, date of symptom onset and hospitalization status is collected for all enrolled participants. **KGMU site**: Prospective diagnostic evaluation study to determine the accuracy of COVID-19 antigen RDTs using a **case-control design** with enrolment of confirmed COVID-19 PCR positive individuals (cases) and a matched number of randomly selected COVID-19 PCR negative patients (controls). Dedicated PCR and Antigen samples were collected at the time of enrolment. The operators of both PCR and Ag RDTs are blinded to the results of the other test.
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:	*See Panbio COVID-19 Ag Rapid Test Device report*
Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by Panbio COVID-19 Ag 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 Panbio COVID-19 Ag 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.
Ease of use	*See Panbio COVID-19 Ag Rapid Test Device report*

3 Evaluation details:

Country of collaborator	India (THSTI)	India (KGMU)
Location of clinical site(s) (city, town)	ESIC Medical College and Hospital, Faridabad	King George's Medical University, Lucknow, Uttar Pradesh
Health care level of site(s)	Tertiary care Hospital	Tertiary Care hospital
Study period (date to date)	10 November 2020 - 24 November 2020	1-24 December 2020
Study cohort inclusion/exclusion	Inclusion: • Any person > 6 years of age presenting to ESIC volunteering for study (parents or guardians provided consent for <18). Exclusion: • Hemodynamic instability as determined by the treating physician. • Patient unable to cooperate with respiratory sample collection. • Patient unable to give informed consent	Cases: Symptomatic and asymptomatic patients hospitalized at KGMU and tested positive for COVID-19 by PCR Controls: Outpatients consulting for COVID-19 testing (symptomatic cases as well as contacts of confirmed cases) at KGMU and tested negative for COVID-19 by PCR Inclusion: • Adult age (≥ 18 years) • Voluntarily given written consent and the willing

	Recent history of excessive nose bleeds.	to participate in this study Exclusion: • Hemodynamic instability as determined by the treating physician. • Patient unable to cooperate with respiratory sample collection. • Patient unable to give informed consent. Recent history of excessive nose bleeds.
Sample type, antigen test	Nasopharyngeal swab	Nasopharyngeal swab
Reference PCR method	RealStar SARS-CoV-2 RT-PCR Kit (Altona)	RealStar® SARS-CoV-2 RT-PCR Kit (Altona Diagnostic)
Sample type, PCR test	Nasopharyngeal and oropharyngeal swab (combined)	Nasopharyngeal swab (n=2), combined oropharyngeal and nasopharyngeal swab (n=296)

4 Results:

4.1 Study cohort

Country	**India (THSTI)**
Total N (valid PCR results)	228
Age [mean (min-max), N]	38.8 (8-88); 228
Gender [%F, (n/N)]	64.9% (100/228)
Symptoms present [%Yes, (n/N)]	100% (228/228)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	3 (2-4); 228
Days < 0-3 (n, %)	151, 66%

Days 4-7 (n, %)	62, 27%
Days 8+ (n, %)	15, 7%
Positivity [%, (n/N)]	52%, (118/228)
PCR Ct [median (Q1-Q3); N]	27.7 (23.6-31.4); 118
Ct > 33 (n, %)	25, 21%
Ct > 30 (n, %)	44, 37%
Ct > 25 (n, %)	81, 69%

Country	**India (KGMU)**		
	Overall	**Cases**	**Controls**
Total N (valid PCR results)	298	97	201
Age [mean (min-max), N]	45.5 (14-87); 298	48.7 (14-86); 97	44 (15-87); 201
Gender [%F, (n/N)]	33.6% (99/295)[1]	30.9% (30/97)	34.8% (69/198)
Symptoms present [%Yes, (n/N)]	29.5% (88/298)	20.6% (20/97)	33.8% (68/201)
Hospitalized (n, % Yes)	Not applicable		
Days from symptom onset [median (Q1-Q3); N]	5 (3-7); 88	5.5 (3.8-8); 20	4 (2.8-7); 68
Days < 0-3 (n, %)	33, 38%	5, 25%	28, 41%
Days 4-7 (n, %)	34, 39%	9, 45%	25, 37%
Days 8+ (n, %)	21, 24%	6, 30%	15, 22%
Positivity [%, (n/N)]		32.5%, (97/298)	
PCR Ct [median (Q1-Q3); N]	Not applicable	24 (20-28); 96	Not applicable
Ct > 33 (n, %)	Not applicable	6, 6%	Not applicable
Ct > 30 (n, %)	Not applicable	15, 16%	Not applicable
Ct > 25 (n, %)	Not applicable	38, 40%	Not applicable

[1] Gender data not available for n=3; [2] PCR Ct value not available for n=1

4.2 Estimation of Clinical Performance

Country	**India (THSTI)**	**India (KGMU)**
Clinical Sensitivity (95% CI), N	61% (52, 69.3), 118	84.5% (76, 90.4), 97
Sensitivity days ≤7, N	61.3% (52, 69.8), 111	100% (78.5, 100), 14
Sensitivity Ct ≤ 33, N	74.2% (64.5, 82), 93	86.7% (78.1, 92.2), 90
Sensitivity Ct ≤ 25, N	91.9% (78.7, 97.2), 37	100% (93.8, 100), 58

Clinical Specificity (95% CI), N	100% (96.6, 100), 109	100% (98.1, 100), 201
Invalid rate (%, n/N)	0% (0/227)	0% (0/298)