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

Version 2.0, 3 March 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	27 February 2022	First release
2.0	3 March 2022	Data from South Africa added

1 Product Info:

Manufacturer name	Abbott Rapid Diagnostics
Test name	Panbio COVID-19 Ag (Nasopharyngeal and nasal swab kit)
Product code(s)	41FK10 (Nasopharyngeal swab kit) and 41FK11 (nasal swab kit)
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 (nasopharyngeal swabs for 41FK10 and nasal swabs for 41FK11), 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:

Clinical 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 97% 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 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 in order to assess the level of uncertainty introduced by sample size, using the Wilson's score method.
Ease of use	A System usability survey and ease of use questionnaire assessing the quality of the test, test preparation, ease of test execution, procedure time, ease of result interpretation, storage conditions and perceived settings of use was completed by operators and a final score out of 100 was calculated.

3 Evaluation details

Country of collaborator	Switzerland	South Africa
Location of clinical site(s) (city, town)	University Hospital of Geneva	Hilcrest and Durban central
Health care level of site(s)	Community Testing Clinic	Drive-through testing centers
Study period (date to date)	13 January – 9 February 2022	21 December 2021 to 3 February 2022
Study cohort inclusion/exclusion	Adults in community meeting Department of Public Health definition of a suspected COVID-19 case and being tested for SARS-CoV-2 part of routine medical care. Provided informed consent	Prospective, cohort with consecutive enrolment Inclusion criteria Residents of the selected communities falling under any of the following criteria: tested COVID-19 positive <7 days; presence of COVID-19 symptoms <7 days; Exposed to COVID-19 5-10 days ago; Heath care worker; Doctor referral for testing; Exclusion criteria:

		Anyone in the selected communities not willing to participate or unable to provide consent to participate.
Sample type, antigen test	Nasopharyngeal swab (NP), oropharyngeal swab (OP)*	Nasal swab (NA)
Reference PCR method	Cobas SARS-CoV-2 (Roche Diagnostics Inc)	Abbott RealTime SARS-CoV-2 (Abbott Molecular, Inc) Ct values adjusted to account for unread cycles (n=10) by the Abbott platform.
Sample type, PCR test	Nasopharyngeal swab	Nasopharyngeal swab

**Note: OP swab is an off-label sample type for this Ag RDT (Panbio COVID-19 Ag - 41FK10)*

4 Results

4.1 Study cohort

Country	**Switzerland**	**South Africa**
Total N (valid PCR results)	157	462
Age [mean (min-max), N]	38.5 (18-78), 157	40.6 (5-92), 462
Gender [%F, (n/N)]	52.9%, (83/157)	50.9%, (235/462)
Symptoms present* [%Yes, (n/N)]	99%, (100/101)	68.9%, (317/460)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset* [median (Q1-Q3); N]	2 (1-3), 96	2 (1-4), 317
Days < 0-3 (n, %)	82, 85%	217, 68%
Days 4-7 (n, %)	13, 14%	81, 26%
Days 8+ (n, %)	1, 1%	19, 6%
Positivity [%, (n/N)]	61%, (96/157)	40%, (184/462)
PCR Ct [median (Q1-Q3); N]	22.6 (20.2-26), 96	22.9 (19.5-28.7), 184
Ct > 33 (n, %)	7, 7%	25, 14%

Ct > 30 (n, %)	16, 17%	36, 20%
Ct > 25 (n, %)	30, 31%	73, 40%

**Note: data on symptom and onset for Switzerland only available for individuals who test PCR positive (using either NP, OP or saliva as sample – NP was used as reference test for this report).*

4.2 Estimations of clinical performance

Country	**Switzerland**		**South Africa**
	NP	**OP***	**NA**
Clinical Sensitivity (95% CI), N	84.2% (75.6, 90.2), 95[1]	84.4% (75.8, 90.3), 96	81.4% (75.2, 86.4), 183
Sensitivity days ≤7, N	85.6% (76.8, 91.4), 90	85.7% (77.1, 91.5), 91	87% (80.6, 91.5), 146
Sensitivity Ct ≤ 33, N	90.9% (83.1, 95.3), 88	87.6% (79.2, 93), 89	91.8% (86.4, 95.1), 158
Sensitivity Ct ≤ 25, N	92.3% (83.2, 96.7), 65	90.9% (81.6, 95.8), 66	99.1% (95, 99.8), 110
Clinical Specificity (95% CI), N	100% (94.1, 100), 61	96.7% (88.8, 99.1), 61	99.6% (98, 99.9), 278
Invalid rate (%, n/N)	0.6% (1/157)	0% (0/157)	0.2% (1/462)

[1] One PCR positive sample tested invalid with the RDT

** Note: OP swab is an off-label sample type for this Ag RDT (Panbio COVID-19 Ag - 41FK10)*