FIND Evaluation of Abbott

Panbio COVID-19 Ag Rapid Test Device

External Report

Version 1.0, 02 November 2020

Copyright and use of the report

Evaluation Process – private sector engagement

FIND is a non-for-profit foundation, whose mission is to find diagnostic solutions to overcome diseases of poverty in lower- and middle-income countries. 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 webpage 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	1 November 2020	Interim version

2 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)	
Manufacturing Site (country)	South Korea

3 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 and/or the Institute of Virology, Charité-Universitätsmedizin Berlin in which standardized serial dilutions of cultured viral isolate were prepared. Dilutions were done 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 IgG/IgM 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 IgG/IgM 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.

4 Evaluation Details

Country of Collaborator	Switzerland
Location of clinical site(s) (city, town)	University Hospital of Geneva
Health care level of site(s)	Community Testing Clinic
Study period (date to date)	9-16 October 2020
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
Sample type, antigen test	Nasopharyngeal swab
Reference PCR Method	Cobas SARS-CoV-2 (Roche Diagnostics Inc)
Sample type, PCR test	Nasopharyngeal swab

5 Results

5.1 Study Cohort (NOTE: if multiple sites, one column per site/country)

Country	Switzerland
Total N (valid PCR results)	535
Age [mean (min-max), N]	38.5 (16-85), 535

Gender [%F, (n/N)]	53.6%, (287/534)
Symptoms present [%Yes, (n/N)]	99.8%, (534/535)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset* [median (Q1-Q3); N]	2 (1-3); 115
Days < 0-3 (n, %)	89, 77.4%
Days 4-7 (n, %)	23, 20%
Days 8+ (n, %)	3, 2.61%
Positivity [%, (n/N)]	21.5%, (124/535)
PCR Ct [median (Q1-Q3); N]	23.2% (18.4-25); 124
Ct > 33 (n, %)	8, 6.5%
Ct > 30 (n, %)	13, 10.5%
Ct > 25 (n, %)	31, 25%

**Note: data on symptom onset only available for individuals who test PCR positive.*

5.2 Estimations of Clinical and Analytical Performance

Country	Switzerland
Clinical Sensitivity (95% CI), N	85.5% (78.2, 90.6), 124
Sensitivity days ≤7, N	85.6% (77.9, 90.9), 111
Sensitivity Ct ≤ 33, N	89.7% (82.8, 94), 116
Sensitivity Ct ≤ 25, N	96.8% (90.9, 98.9), 93
Clinical Specificity (95% CI), N	100% (99.1-100), 411
Invalid rate (%, n/N)	0% (0/535)
Analytical Sensitivity (pfu/ml)	To be confirmed

5.3 Ease of Use

Panbio COVID-19 Ag	Pending [XX] out of 100	Pending [##] operators, [countr(ies)]