FIND Evaluation of Abbott

Panbio COVID-19 Ag Rapid Test Device

External Report

Version 2.1, 10 December 2020

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	01 November 2020	Interim version
1.1	12 November 2020	Corrected test name in text
2.0	15 November 2020	Added data for Germany
2.1	10 December 2020	Updated LOD Methodology; Added Shelf-life and EoU results

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:

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	Germany
Location of clinical site(s) (city, town)	University Hospital of Geneva	1. Heidelberg 2. Berlin
Health care level of site(s)	Community Testing Clinic	1. Heidelberg: Drive-in testing Center 2. Berlin: Ambulatory testing clinic of Charité – University Hospital
Study period (date to date)	9-16 October 2020	1. Heidelberg: 28 September - 30 October 2020 2. Berlin19 October – 30 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	Adults able to ambulate and meeting suspect definition of the Department of public health Provided informed consent
Sample type, antigen test	Nasopharyngeal swab	Nasopharyngeal swab
Reference PCR method	Cobas SARS-CoV-2 (Roche Diagnostics Inc)	• Cobas SARS-CoV-2 (Roche Diagnostics Inc) ○ N = 236 • Abbott *RealTime* SARS-CoV-2 (Abbott Molecular, Inc) ○ N = 45

		• Allplex 2019-nCov Assay (Seegene Inc) ○ N = 725 • LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol) ○ N = 15 • RealStar® SARS-CoV-2 RT-PCR Kit (altona Diagnostics) ○ N = 88
Sample type, PCR test	Nasopharyngeal swab	Nasopharyngeal swab

4 Results

4.1 Study cohort

Country	**Switzerland**	**Germany**
Total N (valid PCR results)	535	1108
Age [mean (min-max), N]	38.5 (16-85), 535	38.7 (18-86), 1108
Gender [%F, (n/N)]	53.6%, (287/534)	50.7%, (557/1099)
Symptoms present [%Yes, (n/N)]	99.8%, (534/535)	64.5%, (709/1100)
Hospitalized (n, % Yes)	Not applicable	Not applicable
Days from symptom onset* [median (Q1-Q3); N]	2 (1-3); 115	3 (2-5); 692
Days < 0-3 (n, %)	89, 77.4%	380, 55%
Days 4-7 (n, %)	23, 20%	230, 33%
Days 8+ (n, %)	3, 2.61%	82, 12%
Positivity [%, (n/N)]	21.5%, (124/535)	9.6%, (106/1108)
PCR Ct [median (Q1-Q3); N]	23.2% (18.4-25); 124	21.7 (19.5-26.2); 105
Ct > 33 (n, %)	8, 6.5%	2, 1.9%
Ct > 30 (n, %)	13, 10.5%	12, 11.4%
Ct > 25 (n, %)	31, 25%	33, 31.4%

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

4.2 Estimations of clinical performance

Country	Switzerland	Germany
Clinical Sensitivity (95% CI), N	85.5% (78.2, 90.6), 124	86.8% (79, 92), 106[§]
Sensitivity days ≤7, N	85.6% (77.9, 90.9), 111	90.8% (82.2, 95.5), 76
Sensitivity Ct ≤ 33, N	89.7% (82.8, 94), 116	88.3% (80.7, 93.2), 103
Sensitivity Ct ≤ 25, N	96.8% (90.9, 98.9), 93	95.8% (88.5, 98.6), 72
Clinical Specificity (95% CI), N	100% (99.1,100), 411	99.9% (99.4, 100), 1002
Invalid rate (%, n/N)	0% (0/535)	0% (0/1108)

[§] *44/106 positives were tested using Roche Cobas, 42/106 using Seegene Allplex, 5/106 using Altona and 15/106 using TibMolbiol*

4.2.1 Estimation of analytical performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	**5.0×10^3 pfu/ml** ~ 7.14×10^3 $TCID_{50}$/ml	**4.55×10^2** pfu/ml	**6.88×10^5 copies/ml** applied to test	2.5 x 101.8 $TCID_{50}$/ml ~ **1.1×10^2 pfu/ml**

Note: verified concentration accounts for volume of dilution that is absorbed onto the swab and then diluted into the proprietary extraction buffer.

4.3 Ease of use

Panbio COVID-19 Ag	86 out of 100	7 operators, Germany