FIND Evaluation of Abbott

Panbio COVID-19 Ag Rapid Test Device (NASAL)

External Report

Version 1.0, 11 February 2021

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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	11 February 2021	Initial release

1 Product info:

Manufacturer name	Abbott Rapid Diagnostics Jena GmbH
Test name	Panbio COVID-19 Ag Rapid Test Device Nasal
Product code(s)	41FK11 (nasal *version evaluated*), 41FK21 (nasal, contains 2D barcode), 41FK10 (nasopharyngeal)
Pack size(s)	25 tests per kit
Contents of kit	**41FK11** Test device (individually in a foil pouch with desiccant), buffer, extraction tubes, extraction tube caps, positive control swab, negative control swab, sample collection swab (**Nasal swab**), quick reference guide, Instructions for Use 41FK10 Test device (individually in a foil pouch with desiccant), buffer, extraction tubes, extraction tube caps, positive control swab, negative control swab, sample collection swab (**Nasopharyngeal swab**), quick reference guide, Instructions for Use
Equipment and consumables required, but not provided	Personal Protective Equipment per local recommendations (i.e. gown/lab coat, face mask, face shield/eye goggles and gloves), 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:	Prospective diagnostic accuracy study to demonstrate the equivalency of nasal swab to nasopharyngeal swab for COVID-19 antigen RDTs, using consecutive enrolment.
Index assays:	Novel lateral flow format tests that detect recombinant SARS-CoV-2 antigens used with nasal swab as sample type.
Reference method:	Results of the index test are compared to the routine, diagnostic RT-PCR result, which is used for clinical management. Comparability between nasal swab Ag RDT results and nasopharyngeal swab Ag RDT results was also analysed.

Limit of detection:	*Not conducted. See Panbio COVID-19 Ag, nasopharyngeal swab report.*
Clinical Performance:	Sensitivity was calculated as the proportion of true positive results detected by Panbio COVID-19 RDT nasal 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 RDT nasal among all negatives by the reference method, and reported as a percentage. Positive and negative percent agreement between the two sample types was also calculated as the proportion of nasal swab positive/negative among all positive/negative by nasopharyngeal swab by Panbio COVID-19 RDT, 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	*Not conducted. See Panbio COVID-19 Ag, nasopharyngeal swab report.*

3 Evaluation details

Country of collaborator	**Germany**
Location of clinical site(s) (city, town)	Heidelberg
Health care level of site(s)	Drive-in testing Center
Study period (date to date)	15 December 2020 to 19 January 2021
Study cohort inclusion/exclusion	Adults able to ambulate, at high risk for SARS-CoV-2 according to clinical suspicion, and meeting suspect definition of the Department of Public Health Provided informed consent
Sample type, antigen test	Nasal Mid-Turbinate (NMT, Nasal) and Nasopharyngeal (NP)

Reference PCR method	• LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol)
	  ○ N = 266
	• Allplex 2019-nCov Assay (Seegene Inc)
	  ○ N = 13
	• Abbott *RealTime* SARS-CoV-2 (Abbott Molecular, Inc)
	  ○ N = 3

Sample type, PCR test	Nasopharyngeal (NP)

4 Results

4.1 Study cohort

Country	Germany
Total N (valid PCR results)	281
Age [mean (min-max), N]	42.92 (18-81)
Gender [%F, (n/N)]	52.1%, (146/280)
Symptoms present [%Yes, (n/N)]	46.2%, (130/279)
Hospitalized (n, % Yes)	Not available
Days from symptom onset [median (Q1-Q3); N]	3 (1-5); 126
Days < 0-3 (n, %)	86, 68%
Days 4-7 (n, %)	290, 23%
Days 8+ (n, %)	11, 9%
Positivity [%, (n/N)]	16% (44/281)
PCR Ct [median (Q1-Q3); N]	21.7 (18.5-25.9); 44
Ct > 33 (n, %)	2, 5%
Ct > 30 (n, %)	6, 14%
Ct > 25 (n, %)	13, 30%

4.2 Estimation of clinical performance

Country	Germany	
	Nasal swab	**Nasopharyngeal swab**
Clinical Sensitivity (95% CI), N	86.4% (73.3, 93.9), 44*	90.9% (78.8, 96.4), 44*
Sensitivity days ≤7, N	97% (84.7, 99.5), 33	93.9% (80.4, 98.3), 33
Sensitivity Ct ≤ 33, N	90.5% (77.9, 96.2), 42	92.9% (81, 97.5); 42
Sensitivity Ct ≤ 25, N	96.8% (83.8, 99.4), 31	96.8% (83.9, 99.4); 31
Clinical Specificity (95% CI), N	99.2% (97, 99.8), 237	99.2% (97, 99.8), 237
Invalid rate (%, n/N)	0%, 0/281	0%, 0/281

Positive percent agreement – nasal/NP (95% CI), N	88.1% (75, 94.8), 42	NA
Negative percent agreement – nasal/NP (95% CI), N	99.2% (97, 99.8), 239	NA

[*]Note:44/44 positives were tested using TibMolbiol.