FIND Evaluation of Bionote, Inc.

NowCheck COVID-19 Ag Test, nasal swab

External Report

Version 1.0, 30 March 2021

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	30 March 2021	Initial release

1 Product info:

Manufacturer name	Bionote, Inc.
Test name	NowCheck COVID-19 Ag Test
Product code(s)	**RG1901DGN (Nasal)**, RG1901DG (NP)
Pack size(s)	25 tests per kit
Contents of kit	**RG1901DGN (Nasal)** Test device, Extraction buffer tube, Nozzle cap, Nasal swab, Paper stand, Film, Instructions for us RG1901DG (NP) Test device, Extraction buffer tube, Nozzle cap, Nasopharyngeal swab, Paper stand, Film, Instructions for use
Equipment and consumables required, but not provided	Equipment: Timer, refrigerator - optional (for storage of specimens prior to testing, if applicable). Consumables: PPE
Product storage (temperature range)	2-30°C
Shelf-life (months)	24 months
Manufacturing site (country)	Republic of 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 NowCheck COVID-19 Ag Test, nasopharyngeal swab report.*
Clinical performance:	Sensitivity was calculated as the proportion of true positive results detected by NowCheck COVID-19 Ag Test 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 NowCheck COVID-19 Ag Test 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 NowCheck COVID-19 Ag Test, 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 NowCheck COVID-19 Ag Test, nasopharyngeal swab report.*

3 Evaluation details

Country of collaborator	**Brazil**
Location of clinical site(s) (city, town)	Marica and Guapimirim, state of Rio de Janeiro
Health care level of site(s)	Community testing clinic
Study period (date to date)	21 to 27 January 2021; 23 to 26 February 2021
Study cohort inclusion/exclusion	Adults in community meeting national suspect definition. Provided informed consent
Sample type, antigen test	Nasal mid-turbinate (Nasal) and Nasopharyngeal (NP)
Reference PCR method	Lab-developed assay based on the US CDC protocol, which targets two regions (N1 and N2) of the nucleocapsid (N) gene of SARS-CoV-2 (https://www.fda.gov/media/134922/download)
Sample type, PCR test	Nasopharyngeal (NP)

4 Results

4.1 Study cohort

Country	**Brazil**
Total N (valid PCR results)	218
Age [mean (min-max), N]	42.3 (18-90)

Gender [%F, (n/N)]	57.8%, (126/218)
Symptoms present [%Yes, (n/N)]	100%, (218/218)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	4 (3-6); 218
Days < 0-3 (n, %)	72, 33%
Days 4-7 (n, %)	123, 56%
Days 8+ (n, %)	23, 11%
Positivity [%, (n/N)]	36.2%, (79/218)
PCR Ct [median (Q1-Q3); N]	24 (20.9-28); 79
Ct > 33 (n, %)	7, 9%
Ct > 30 (n, %)	12, 15%
Ct > 25 (n, %)	33, 42%

4.2 Estimation of clinical performance

Country	**Brazil**	
	Nasal swab	**Nasopharyngeal swab**
Clinical Sensitivity (95% CI), N	89.9% (81.3, 94.8), 79	89.9% (81.3, 94.8), 79
Sensitivity days ≤7, N	92.5% (83.7, 96.8),67	92.5% (83.7, 96.8),67
Sensitivity Ct ≤ 33, N	97.2% (90.4, 99.2), 72	97.2% (90.4, 99.2), 72
Sensitivity Ct ≤ 25, N	100% (92.3, 100), 46	100% (92.3, 100), 46
Clinical Specificity (95% CI), N	98.6% (94.9, 99.6), 139	98.6% (94.9, 99.6), 139
Invalid rate (%, n/N)	0% (0/218)	0% (0/218)
Positive percent agreement – nasal/NP (95% CI), N	100% (95, 100), 73	NA
Negative percent agreement – nasal/NP (95% CI), N	100% (97.4, 100), 145	NA