FIND Evaluation of NADAL COVID-19 Ag Rapid Test External Report

Version 1.0, 26 April 2021

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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	26 April 2021	Initial release

1 Product Info:

Manufacturer Name	NADAL
Test name	COVID-19 Ag Rapid Test
Product Code(s)	243103N-20
Pack size(s)	20 tests/kit
Contents of kit	Test cassettes, extraction tubes, dropper caps, buffer, sterile swabs, reagent holder, package insert
Equipment and consumables required, but not provided	PPE, timer, biohazard container
Product Storage (temperature range)	2-30°C
Shelf-life (months)	24 months after date of production
Manufacturing Site (country)	Subcontracting manufacturing site of Nal von minden, Hangzhou, China

2 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:	Verification of 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 NADAL COVID-19 Ag Rapid 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 NADAL COVID-19 Ag Rapid Test 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.

3 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)	24 November 2020 – 20 January 2021
Study cohort inclusion/exclusion	Individuals (age 16+) 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) (n=217) Cobas SARS-CoV-2 & Influenza A/B (Roche Diagnostics Inc) (n=72) TaqPath™ COVID-19 CE IVD RT PCR Kit (Thermo Fisher Scientific) (with Nimbus Presto Extraction instrument) (n=173)
Sample type, PCR test	Nasopharyngeal swab

4 Results

4.1 Study Cohort

Country	Switzerland
Total N (valid PCR results)	462
Age [mean (min-max), N]	38.7 (16-82), 462

Gender [%F, (n/N)]	55.4%, (256/462)
Symptoms present[1] [%Yes, (n/N)]	94.2%, (65/69)
Hospitalized (n, % Yes)	Not applicable
Days from symptom onset [median (Q1-Q3); N]	2 (1-3), 54
Days < 0-3 (n, %)	45, 83%
Days 4-7 (n, %)	7, 13%
Days 8+ (n, %)	2, 4%
Positivity [%, (n/N)]	14.9%, (69/462)
PCR Ct [median (Q1-Q3); N]	22.7 (20.25-26.7); 68
Ct > 33 (n, %)	2, 3%
Ct > 30 (n, %)	9, 13%
Ct > 25 (n, %)	23, 34%

[1]Note: data on symptom onset only available for individuals who tested PCR positive.

4.2 Estimation of Clinical Performance

Country	Switzerland
Clinical Sensitivity (95% CI), N	88.4% (78.8, 94), 69
Sensitivity days ≤7, N	88.5% (77, 94.6), 52
Sensitivity Ct ≤ 33, N	92.4% (83.5, 96.7), 66
Sensitivity Ct ≤ 25, N	97.8% (88.4, 99.6), 45
Clinical Specificity (95% CI), N	99.2% (97.8, 99.7), 393
Invalid rate (%, n/N)	0% (0/462)

4.2.1 Estimation of Analytical Performance

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	**2.5×10^2 pfu/ml** ~ 3.55×10^2 $TCID_{50}$/ml	**2.5×10^2** pfu/ml	**3.4×10^4 copies/ml** applied to test	**$2 \times 10^{2.4}$** TCID50/ml ~ **$1.4 \times 10^{2.4}$ pfu/ml**

Note: viral dilution was applied directly to the test cassette, not to the provided swab