Summary of an evaluation provided by SKUP | NADAL COVID-19 Ag Test

Manufacturer	Nal von Minden GmbH
Supplier	Nal von Minden GmbH (requesting company)
Launched in Scandinavia	August 2020

SKUP
www.skup.org
SKUP/2022/125

Aim

To assess the diagnostic performance and user-friendliness of NADAL COVID-19 Ag Test (Coronavirus disease 2019 Antigen) when used under real life conditions by intended users in dedicated COVID-19 test centres.

Examination	Recommended Goals and Results
Overall Sensitivity	WHO recommends a minimum performance requirement of ≥80 % sensitivity compared to a nucleic acid-amplification test (NAAT) reference assay. **Overall Diagnostic Sensitivity was not met: 74 % (90 % CI: 65-82 %)***
Overall Specificity	WHO recommends a minimum performance requirement of ≥97 % specificity compared to a NAAT reference assay. **Overall Diagnostic Specificity was met: 99,7 % (90 % CI: 99,0-99,9 %)***
User-friendliness	**Quality goal;** a total rating of "Satisfactory" by SKUP **User-friendliness was fulfilled**

Background

Measurement system	*In vitro* device, rapid test, for qualitative detection of SARS-CoV-2
Intended users	Health care professionals
Sample material	Nasal, nasopharyngeal or oropharyngeal specimen, of which the two first were evaluated by SKUP.

Material and methods

Participants	679 persons exposed to individuals with confirmed SARS-CoV-2 infection, of whom 78 (11 %) tested positive on the comparison method.
Comparison method	A real time polymerase chain reaction (RT-PCR) method, for detection of SARS-CoV-2 at Fürst Medical Laboratory in Oslo.
Analytical procedure	Subjects exposed to an individual with confirmed SARS-CoV-2 infection were invited to participate in the evaluation. The sampling procedure, performed by trained health care professionals, included one nasopharyngeal swab sample from one nostril for RT-PCR detection, and a second nasopharyngeal swab sample from the other nostril, or a nasal swab sample from both nostrils, for the NADAL COVID-19 Ag Test. The nasopharyngeal swab for RT-PCR detection was immediately placed into sterile tubes, containing 2-3 mL of viral transport media, until transported to the clinical laboratory. The nasopharyngeal or nasal swab was placed into the test vial containing extraction buffer and analysed in accordance with the instructions from the manufacturer. Six lots of NADAL COVID-19 Ag Test were used.
User-friendliness	Assessed using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory

Additional results

Sensitivity stratified on ct-values:	<33: 75 %: (90 % CI: 66-82 %)* <30: 80 %: (90 % CI: 71-87 %)* <25: 84 %: (90 % CI: 75-90 %)*
Prevalence:	11 %
Positive predictive value (PPV):	97 %
Negative predictive value (NPV):	97 %

Nal von Minden GmbH has accepted the report without further comments

* 90 % CI included for information only