Report from the evaluation SKUP/2022/125

organised by SKUP at the request of Nal von Minden GmbH

NADAL® COVID-19 Ag Test

A test for detection of SARS-CoV-2 Antigen
manufactured by Nal von Minden GmbH

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Table of contents

Attachments with raw data are included only in the copy to Nal von Minden Gm

1. 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

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

*CI for information only

This summary will also be published in Danish, Norwegian and Swedish at www.skup.org

2. Abbreviations and Acronyms

Ag	Antigen
Ag-RDT	Antigen-detecting Rapid Diagnostic Test
BLS	Biomedical laboratory scientist
C-NPU	Committee on Nomenclature, Properties and Units
CI	Confidence Interval
COVID-19	Coronavirus Disease 2019
Ct value	Cycle threshold-value
DEKS	Danish Institute of External Quality Assurance for Laboratories in the Health Sector
ECDC	European Centre for Disease Prevention and Control
EQA	External Quality Assessment
Equalis	External quality assessment in laboratory medicine in Sweden
NAATs	Nucleic Acid Amplification Tests
Noklus	Norwegian Organization for Quality Improvement of Laboratory Examinations
NPV	Negative Predictive Value
POC	Point of care
PPV	Positive Predictive Value
RNA	Ribonucleic acid
RT-PCR	Real Time Polymerase Chain reaction
SARS-CoV-2	Severe Acute Respiratory Syndrome Coronavirus 2
SKUP	Scandinavian evaluation of laboratory equipment for point of care testing
WHO	World Health Organization

3. Introduction

The purpose of Scandinavian evaluation of laboratory equipment for point of care testing (SKUP) is to improve the quality of near patient testing in Scandinavia by providing objective information about analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP evaluations in point of care (POC) settings.

3.1. The concept of SKUP evaluations

SKUP evaluations follow common guidelines and the results from various evaluations are comparable[1]. The evaluation set-up and details are described in an evaluation protocol and agreed upon in advance. The analytical results and user-friendliness are assessed according to pre-set quality goals. To fully demonstrate the quality of a product, the end-users should be involved in the evaluation. If possible, SKUP evaluations are carried out using three lot numbers of test cassettes from separate and time-spread productions.

3.2. Background for the evaluation

In December 2019, Wuhan city in Hubei Province, China, became the center of an outbreak of a severe pneumonia, later identified as caused by a novel Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) [1]. The virus causes coronavirus disease 2019 (COVID-19). Currently COVID-19 is mainly diagnosed by detection of ribonucleic acid (RNA) from SARS-CoV-2 using nucleic acid amplification tests (NAATs), such as real time polymerase chain reaction (RT-PCR) assays in a sample collected with a swab from the upper airways [2]. RT-PCR is performed in clinical microbiology laboratories, requiring advanced analytical instruments and trained personnel. The ease-of-use and rapid turnaround time of antigen-detecting rapid diagnostic tests (Ag-RDTs) offer decentralized testing that potentially can expand access to testing and decrease delays in diagnosis [3].

The NADAL COVID-19 Antigen Test is an in vitro diagnostic POC rapid test for detection of SARS-CoV-2 Antigen (Ag) in nasal, nasopharyngeal and oropharyngeal swab specimens. The product is intended for professional use. The test is manufactured by Nal von Minden GmbH and was launched into the Scandinavian market August 2020. This SKUP evaluation was carried out from December 2020 to October 2021 at the request of Nal von Minden GmbH in Norway.

3.3. The aim of the evaluation

The aim of the evaluation was to assess the diagnostic performance and user-friendliness of NADAL COVID-19 Ag Test when using nasal and nasopharyngeal swab specimens under real life conditions by intended users in dedicated COVID-19 test centres.

[1]SKUP evaluations are under continuous development. In some cases, it may be difficult to compare earlier protocols, results and reports with more recent ones.

3.4. The model for the evaluation of NADAL COVID-19 Ag Test

The evaluation was carried out in dedicated COVID-19 test centres, to evaluate the performance of NADAL COVID-19 Ag Test in the hands of the intended users, see flowchart in figure 1.

The evaluation included:

- Examination of the diagnostic performance (diagnostic sensitivity and specificity) of the NADAL COVID-19 Ag Test using nasal or nasopharyngeal swab specimens.
- Examination of the diagnostic performance related to different clinical subgroups and cycle threshold (ct) values from the RT-PCR results.
- Evaluation of the user-friendliness of the NADAL COVID-19 Ag Test and its manual.

In addition, the positive predictive value (PPV) and negative predictive value (NPV) were calculated.

Subjects exposed to a previously confirmed case of SARS-CoV-2 infection were included within 10 days of exposure e.g., targeted testing of household members or equivalent close contacts. Both symptomatic and asymptomatic participants were included. Household transmission of SARS-CoV-2 is reported to be high [4], and a prevalence of approximately 20 % was expected. Target number of participants was 100 positive results and 100 negative results, but maximum number included was initially set to 500. For comparison and assessment of the diagnostic sensitivity and specificity, a nasopharyngeal sample was measured on an RT-PCR comparison method.

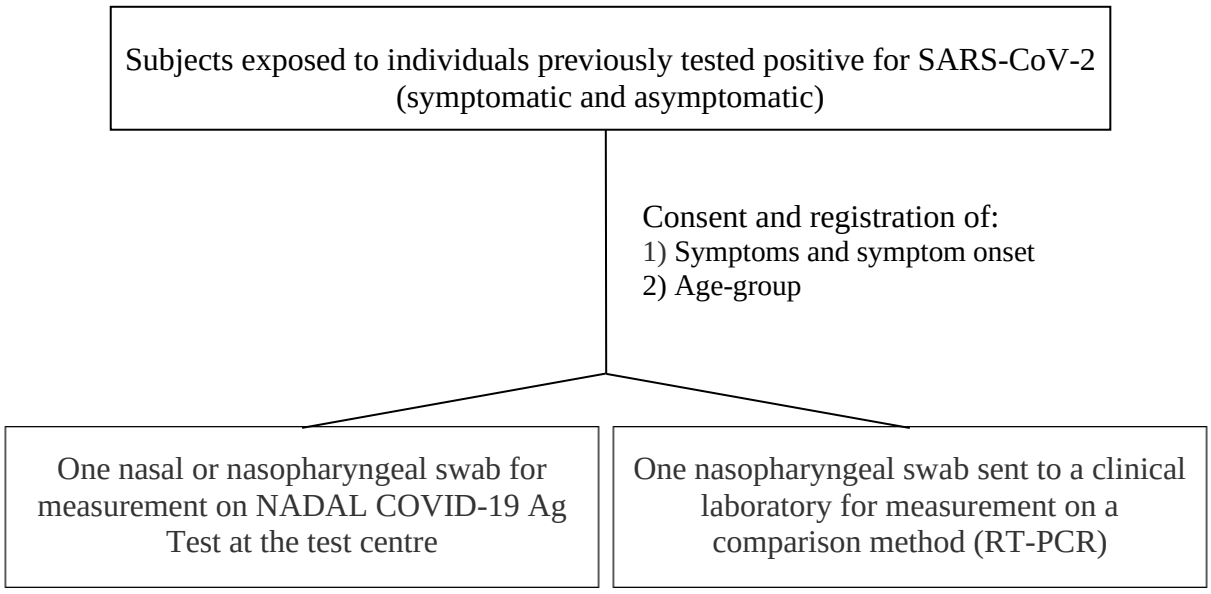

Figure 1. Flowchart illustrating the model of the evaluation. Enrolment of participants was planned to continue until at least 100 positive and at least 100 negative SARS-CoV-2 RT-PCR results were achieved in the clinical laboratory, but maximum number included was initially set to 500.

4. Quality goals

4.1. Analytical quality

Present recommendations for diagnostic SARS-CoV-2 tests

The World Health Organization (WHO) suggests that SARS-CoV-2 Ag-RDTs that meet the minimum performance requirements of ≥80 % sensitivity and ≥97 % specificity compared to a NAAT reference assay can be used to diagnose SARS-CoV-2 infection where NAAT is unavailable, or where prolonged turnaround times preclude clinical utility. In settings with low prevalence of active SARS-CoV-2 infections, specificity should ideally be ≥99 % to avoid many false-positive [3]. The European Centre for Disease Prevention and Control (ECDC) agrees with the minimum performance requirements set by WHO but suggests aiming to use tests with a performance closer to RT-PCR, i.e., ≥90 % sensitivity and ≥97 % specificity [5].

4.2. User-friendliness

The evaluation of user-friendliness was carried out by asking the employees in Lillestrøm municipal test centre to fill in a questionnaire, see section 5.5. The tested equipment must reach a total rating of "satisfactory" to fulfil the quality goal.

Technical errors

SKUP recommends that the fraction of tests wasted due to technical errors should not exceed 2 %.

4.3. Principles for the assessments

To qualify for an overall good assessment in a SKUP evaluation, the measuring system must show satisfactory analytical quality as well as satisfactory user-friendliness.

4.3.1. Assessment of the analytical quality

The analytical results are described and discussed related to literature. Statistical expressions and calculations used by SKUP are shown in attachment 5.

Diagnostic sensitivity

The diagnostic sensitivity was calculated as the fraction of the true positive NADAL COVID-19 Ag Test results in proportion to the positive RT-PCR results. The calculated result was given with a 90 % confidence interval (CI) (for information only).

Diagnostic specificity

The diagnostic specificity was calculated as the fraction of the true negative NADAL COVID-19 Ag Test results in proportion to the negative RT-PCR results. The calculated result was given with a 90 % CI (for information only).

Positive and negative predictive values

PPV and NPV were calculated given the prevalence in the tested population and the achieved diagnostic accuracy of the test.

Assessment of different lots
Six lots of test cassettes were used for the purpose of having an evaluation less sensitive to the risk of a poor batch. Separate lot-to-lot calculations were not performed.

Examination of different clinical subgroups
Sensitivity and specificity were calculated for results stratified on symptoms/no symptoms and days since symptom onset.

Examination of different ct values from the RT-PCR method
The ct value is defined as the number of cycles of amplification required with RT-PCR for the fluorescent signal of the RT-PCR method to reach a threshold above the background signal. The ct value is inversely proportional to the amount of target nucleic acid in the sample (i.e., the lower the ct value the greater the amount of target nucleic acid in the sample). Sensitivity was calculated for positive results stratified on ct values; ct <33, ct <30 and ct <25.

4.3.1.1. Assessment of user-friendliness

User-friendliness is assessed according to answers and comments given in the questionnaire (see section 6.5). For each question, the evaluator can choose between three given ratings: satisfactory, intermediate and unsatisfactory. To achieve the overall rating "satisfactory", the tested equipment must reach a total rating of "satisfactory" in all four subareas of characteristics described in section 6.5.

Technical errors
The evaluators registered failed measurements and technical errors during the evaluation. The proportion of tests wasted due to technical errors was calculated and taken into account in connection with the assessment of the user-friendliness. User errors related to the handling of the samples were excluded from the calculations.

4.4. SKUP's quality goals in this evaluation

For this evaluation, there were no pre-set quality goals for the diagnostic performance of the test. The results are nevertheless discussed related to present literature, specifically WHO recommendations.

For assessment of the user-friendliness:

User-friendliness, overall rating..... Satisfactory

5. Materials and methods

5.1. Definition of the measurand

The measurement systems intend to detect SARS-CoV-2 in secrete collected from the upper airways. The NADAL COVID-19 Ag Test detects the antigens specific for SARS-CoV-2 in nasal, nasopharyngeal and oropharyngeal specimens. For the comparison method, the RNA from SARS-CoV-2 was identified by RT-PCR in a nasopharyngeal specimen. The results were expressed on an ordinal scale (positive or negative) for both methods. The Committee on Nomenclature, Properties and Units (C-NPU) systematically describes clinical laboratory measurands in a database [6]. The NPU codes related to the evaluated method are NPU59312 (nasal) and NPU59310 (nasopharyngeal) The NPU code related to the comparison method is NPU59105. In this report the term SARS-CoV-2 will be used for the measurand.

5.2. The evaluated measurement system NADAL COVID-19 Ag Test

The information in this section derives from the company's information material.

NADAL COVID-19 Ag Test (figure 2) is a POC test intended for professional use for detection of SARS-CoV-2.

NADAL COVID-19 Ag Test kit includes:

- NADAL COVID-19 Ag Test cassettes
- Sterile nasal and nasopharyngeal swabs
- Extraction tubes including dropper caps
- Buffer bottles (à 7 mL) or buffer ampoules for single use (400 µl each)
- Reagent holder

Figure 2. NADAL COVID-19 Ag Test.

The NADAL COVID-19 Ag Test is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 viral nucleoprotein antigens in human nasopharyngeal, nasal, and oropharyngeal specimens. New kits are only available with pre-filled ampoules. The evaluated test kit is for medical trained personnel only, but a test kit is for self testing is also available.

The test procedure involves collecting nasal, nasopharyngeal or oropharyngeal specimen using a recommended swab which is eluted into a tube containing extraction buffer. Two drops of the specimen in extraction buffer are added to the test cassette using a dropper cap provided. The test result can be read visually after exactly 15 minutes. Any shade of colour in the test line region should be considered positive.

The formation of a coloured line in the control line region (C) of each test cassette serves as a procedural control, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

For technical details about the NADAL COVID-19 Ag Test, see table 1. For more information about the NADAL COVID-19 Ag Test, and name of the manufacturer and the suppliers in the Scandinavian countries, see attachments 2 and 3. For product specifications in this evaluation, see attachment 4.

Table 1. Technical details from the manufacturer

Technical details for NADAL COVID-19 Ag Test	
Sample material	Nasal, nasopharyngeal or oropharyngeal specimen
Stability of extraction buffer including specimen	Specimen should be tested immediately or placed in extraction buffer that should be tested within two hours of collection.
Measuring time	15 inutes

5.3. The selected comparison method

A selected comparison method is a fully specified method which, in the absence of a Reference method, serves as a common basis for the comparison of the evaluated method.

5.3.1. The selected comparison method in this evaluation

The selected comparison method in this evaluation was the routine RT-PCR method for SARS-CoV-2 at Fürst Medical Laboratory in Oslo, Norway, hereafter called "the comparison method". The laboratory is accredited according to NS-EN ISO/IEC 15189 (2012) (Norsk Standard_Europeisk Norm International Organization for Standardization). The division performing the RT-PCR measurements has approximately 23 employees.

Method for extraction: KingFisher Flex and MagMax (ThermoFisher Scientific), Viral/Pathogen Nucleic Acid Isolation Kit

Method for RT-PCR: 7500 SDS or Quantstudio 5 (Applied biosystems), RIDAGENE SARS-CoV-2 Realtime PCR kit

Principle: RT-PCR detection of the E-gene of the Sarbeco Betacorona virus, including SARS-CoV-2 [7].

Internal analytical quality control

Kit independent positive control (extraction control, locally produced) was included in each run. In addition, an internal control (R-biopharm) was added to each sample.

External analytical quality control

The hospital laboratory participates in the external quality assessment (EQA) scheme from INSTAND; Virus Genome Detection scheme (Coronaviruses including SARS-CoV-2) with six

samples in two challenges per year. They also participated in the one-time scheme from WHO with five samples.

5.3.1. Verification of the analytical quality of the comparison method

Trueness

The trueness of the RT-PCR method for detection of SARS-CoV-2 was verified with EQA results circumventing the evaluation period.

5.4. The evaluation

5.4.1. Planning of the evaluation

Inquiry about an evaluation

Nal von Minden GmbH via Scientific employee Tobias Roth, applied to SKUP in September 2020 for an evaluation of NADAL COVID-19 Ag Test.

Protocol, arrangements and contract

In November 2020, the protocol for the evaluation was approved, and Nal von Minden GmbH and SKUP signed a contract for the evaluation. Lillestrøm municipal test centre, and later Dr.Dropin test centre, agreed to represent the intended users in this evaluation. Fürst Medical Laboratory in Oslo, Norway agreed to perform the comparison measurements.

Training

Nal von Minden GmbH and a laboratory consultant at Noklus Lørenskog was responsible for the necessary training of the intended users at Lillestrøm municipal test centre. A SKUP-coordinator was responsible for the training at Dr.Dropin. The training reflected the training usually given to the end-users. Nal von Minden GmbH was not allowed to contact or supervise the evaluators during the evaluation period.

5.4.2. Evaluation sites and persons involved

At Lillestrøm and Dr.Dropin test centre, 13 and 8 professional health care workers, respectively, participated in the evaluation. They were all trained in collecting samples from upper airways and used nasopharyngeal and oropharyngeal swab specimens in the routine work. Biomedical laboratory scientists (BLS) from Fürst Medical Laboratory in Oslo were analysing the RT-PCR samples.

5.4.3. The evaluation procedure

Internal analytical quality control

To ensure proper test kit performance, internal analytical quality control samples for NADAL COVID-19 Ag Test should ideally have been measured each evaluation day. However, there was no internal analytical quality control available during the evaluation.

Recruitment of participants and ethical considerations

Subjects, 16 years or older, exposed to an individual who had previously tested positive for SARS-CoV-2 were invited to participate in the evaluation of NADAL COVID-19 Ag Test. Participation was voluntary and verbal informed consent was considered sufficient. Approval

from a regional ethical committee was not necessary because the evaluation was considered a quality assurance project. The project was approved by the Data protection officer at Haraldsplass Deaconess Hospital.

Handling of the samples and measurements
Tests, extraction buffer and specimens were brought to room temperature (15-30°C) prior to testing. Nasal or nasopharyngeal swab specimens were used for the measurements on the NADAL COVID-19 Ag Test. In the same sampling session, a separate nasopharyngeal swab was used to obtain a specimen for measurement on the comparison method.

The sampling from each patient was collected in the following order:
1. Nasopharyngeal swab specimen from one nostril for the comparison method
2. Nasopharyngeal swab specimen from the other nostril or nasal swab specimen collected from both nostrils for the NADAL COVID-19 Ag Test

Nasopharyngeal swab specimens were preferred, but nasal swab specimens were taken if participants were reluctant to participation due to the duplicate nasopharyngeal sampling. The samples were collected according to local guidelines and immediately placed into the test vial containing extraction buffer. The extracted samples were analysed in accordance with the instructions from the manufacturer. Any shade of colour in the test line region was considered a positive result. In case of technical errors and failed measurements, the test was repeated if possible until a result was obtained. Six lot numbers of test cassettes were used, alternating between the lot numbers.

The swabs for the comparison method were placed immediately into sterile tubes containing 2-3 mL of viral transport media. The tubes were kept at room temperature until transported to the clinical laboratory, where the samples were analysed on the comparison method. All samples were treated according to the internal procedures of the laboratory regarding potential interfering substances. For samples with ct values >35, repeated measurements were performed.

6. Results and discussion

Statistical expressions and calculations used by SKUP are shown in attachment 5.

6.1. Number of samples and study population characteristics

The practical work was performed from winter 2020 to fall 2021, during which Lillestrøm and Oslo experienced several outbreaks of COVID-19. In total, 690 participants provided samples for the evaluation, of which 679 results from the NADAL COVID-19 Ag Test were successfully matched to their corresponding RT-PCR result. Of these, 33 % (n=221) were nasal samples and 67 % (n=458) were nasopharyngeal samples. The vast majority of participants were exposed to individuals with confirmed SARS-CoV-2 infection, and 59 % (n=404) were in the age-group ≥30 years (table 2). 45 % (n=308) were symptomatic of whom 48 % (n=148) had a symptom duration of ≤5 days, however, 48 % (n=147) of the symptomatic did not state symptom onset. Among those with symptoms, 68 % (n=211) reported two or more symptoms, of which sore throat and headache were most commonly reported (not shown). 11 % (n=78) of the participants were RT-PCR positive. This was a substantially higher prevalence of SARS-CoV-2 infection than in the general population during the same time-period, and also much higher than in the total tested population in Norway. Investigation among exposed subjects is highly relevant for contact tracing in institutions, semi-closed communities and among household members or equivalent close contacts.

Table 2. Population characteristics

	Total successfully included n (% of all)	**PCR positive results n (% of subgroup)**	**PCR negative results n (% of subgroup)**
Total	679 (100)	78 (11)	601 (89)
Age			
≤19	85 (13)	16 (19)	69 (81)
20-29	190 (28)	20 (11)	170 (89)
≥30	404 (59)	42 (10)	362 (90)
Symptomatic			
No	371 (55)	8 (2)	363 (98)
Yes	308 (45)	70 (23)	238 (77)
Symptom duration	**n (% of symptomatic)**		
≤5 days	148 (48)	33 (22)	115 (78)
>5 days	13 (4)	2 (15)	11 (85)
Unknown	147 (48)	35 (24)	112 (76)

An account for the number of samples not included in the calculations, is given below.

Missing results

- ID 32, ID 533 and 577; no results from the comparison method available as the samples never arrived the clinical laboratory.
- ID 210; insufficient amount of sample material for the comparison method.
- ID 198 and ID 314; participant withdrew consent.

Omitted result

- ID 240, ID 327, ID 440, and ID 499; the results from the clinical laboratory were reported as inconclusive due to repeated measurements with ct values >35.
- ID 608; the evaluator reported an inconclusive result from the NADAL COVID-19 Ag Test.

6.2. Analytical quality of the selected comparison method

6.2.1. Internal analytical quality control

All results from the internal analytical quality controls were in accordance with the assigned values (data not shown).

6.2.2. The trueness of the comparison method

The trueness of the RT-PCR method for detection of SARS-CoV-2 was verified with EQA results for the period circumventing the evaluation period (table 3).

Table 3. EQA controls measured on the comparison method.

Time of measurements	EQA scheme	Sample id	Assigned value or SARS-CoV-2 GEq*/µL	Results from the RT-PCR method (ct value)
Week number 47 in 2020	INSTAND	75	positive	positive (25,8)
		76	negative	negative
		77	positive	positive (24,0)
		78	negative	negative
		79	positive	positive (28,4)
		80	positive	positive (27,8)
Week number 49 in 2020	WHO	WHO-SC-20-01	$4{,}5 \times 10^4$	positive (25,0)
		WHO-SC-20-02	$2{,}3 \times 10^6$	positive (19,2)
		WHO-SC-20-03	HCoV-OC43/negative	negative
		WHO-SC-20-04	MDCK cells/negative	negative
		WHO-SC-20-05	$4{,}5 \times 10^3$	positive (27,6)
Week number 24 in 2021	INSTAND	82	negative	negative
		83	positive	negative**
		84	negative	negative
		85	positive	positive (31,5)
		86	positive	positive (31,1)
		87	negative	negative

*GEq: Genome equivalent. **Repeated measurements also negative. Measures implemented.

Discussion

The trueness of the comparison method during the evaluation period was confirmed by the results from the INSTAND and WHO EQA schemes for SARS-CoV-2.

6.3. Analytical quality of NADAL COVID-19 Ag Test

The results below reflect the analytical quality of NADAL COVID-19 Ag Test under real-life conditions in the hands of intended users at dedicated testing centres.

6.3.1. Internal analytical quality control

Internal analytical quality controls for NADAL COVID-19 Ag Test were not available during the evaluation.

6.3.2. The diagnostic sensitivity of NADAL COVID-19 Ag Test

The diagnostic sensitivity of NADAL COVID-19 Ag Test was calculated as described in attachment 5 using the RT-PCR results as true values, both for the total population, stratified on clinical subgroups, relevant ct values, and with respect to sample type. The calculated results (tables 4-6) are given with a 90 % CI (for information only). Raw data is attached to the requesting company only (attachment 6).

Table 4. Diagnostic sensitivity of the NADAL COVID-19 Ag Test**.** Results achieved by intended users.
Overall results for both nasal and nasopharyngeal specimens and stratified on clinical subgroups and relevant ct values.

	Number of positive PCR results	Number of true positive results	Number of false negative results	Diagnostic sensitivity, % (90 % CI)
Total	78	58[1]	20[2]	74 (65-82)
Symptomatic				
No	8	4	4	50 (25-75)
Yes	70	54	16	77 (68-84)
≤5 days	33	26	7	79 (65-88)
>5 days	2	1	1	*
Unknown onset	35	27	8	77 (64-87)
Ct values				
<33	76	57	19	75 (66-82)
<30	70	56	14	80 (71-87)
<25	63	53	10	84 (75-90)

*n <8; not reported due to high degree of uncertainty in the estimated sensitivity.
[1]Median ct value for the true positive results = 17,0 (13,6-33,1).
[2]Median ct value for the false negative results = 25,8 (18,0-34,0). Unpaired t test (Excel) p-value <0,001 when comparing the means for the true positive and false negative results.

Table 5. Diagnostic sensitivity of the NADAL COVID-19 Ag Test measured in nasal specimens only. Results achieved by intended users. Overall results and stratified on clinical subgroups.

	Number of positive PCR results	Number of true positive results	Number of false negative results	Diagnostic sensitivity, % (90 % CI)
Total	27	23[1]	4[2]	85 (70-94)
Symptomatic				
No	1	1	0	*
Yes	26	22	4	85 (69-93)

*n <8; not reported due to high degree of uncertainty in the estimated sensitivity.
[1]Median ct value for the true positive results = 17,7 (14,5-33,0).
[2]Median ct value for the false negative results = 21,9 (21,3-34,0). Unpaired t test (Excel) p-value >0,05 when comparing the means for the true positive and false negative results.

Table 6. Diagnostic sensitivity of the NADAL COVID-19 Ag Test measured in nasopharyngeal specimens only. Results achieved by intended users. Overall results and stratified on clinical subgroups.

	Number of positive PCR results	Number of true positive results	Number of false negative results	Diagnostic sensitivity, % (90 % CI)
Total	51	35[1]	16[2]	69 (57-78)
Symptomatic				
No	7	3	4	*
Yes	44	32	12	73 (61-82)

*n <8; not reported due to high degree of uncertainty in the estimated sensitivity.
[1]Median ct value for the true positive results = 16,7 (13,6-26,6).
[2]Median ct value for the false negative results = 28,0 (18,0-32,9). Unpaired t test (Excel) p-value <0,001 when comparing the means for the true positive and false negative results.

6.3.3. The diagnostic specificity of NADAL COVID-19 Ag Test

The diagnostic specificity of NADAL COVID-19 Ag Test was calculated as described in attachment 5 using the RT-PCR results as true values, both for the total population and stratified on clinical subgroups. The calculated results (tables 7-9) are given with a 90 % (CI (for information only). Raw data is attached to the requesting company only (attachment 6).

Table 7. Diagnostic specificity of the NADAL COVID-19 Ag Test measured in both nasal and nasopharyngeal specimens. Results achieved by intended users. Overall results and stratified on clinical subgroups.

	Number of negative PCR results	Number of true negative results	Number of false positive results	Diagnostic specificity % (90 % CI)
Total	601	599	2	99,7 (99,0-99,9)
Symptomatic				
No	363	363	0	100 (99,5-100)
Yes	238	236	2	99,2 (97,4-99,9)
≤5 days	115	113	2	98,3 (94,6-99,7)
>5 days	11	11	0	100 (84,6-100)
Unknown onset	112	112	0	100 (98,3-100)

An account for the number of samples is given in section 6.1.

Table 8. Diagnostic specificity of the NADAL COVID-19 Ag Test measured in nasal specimens only. Results achieved by intended users. Overall results and stratified on clinical subgroup.

	Number of negative PCR results	Number of true negative results	Number of false positive results	Diagnostic specificity % (90 % CI)
Total	194	192	2	99,0 (96,8-99,8)
Symptomatic				
No	107	107	0	100 (98,2-100)
Yes	87	85	2	97,7 (93,0-99,6)

An account for the number of samples is given in section 6.1.

Table 9. Diagnostic specificity of the NADAL COVID-19 Ag Test measured in nasopharyngeal specimens only. Results achieved by intended users. Overall results and stratified on clinical subgroups.

	Number of negative PCR results	Number of true negative results	Number of false positive results	Diagnostic specificity % (90 % CI)
Total	407	407	0	100 (99,5-100)
Symptomatic				
No	256	256	0	100 (99,2-100)
Yes	151	151	0	100 (98,7-100)

An account for the number of samples is given in section 6.1.

6.3.4. The negative- and positive predictive value of NADAL COVID-19 Ag Test

Both the NPV and PPV, were 97 % for the NADAL COVID-19 Ag Test at a prevalence of 11 %. The calculations were performed as described in Attachment 5.

Discussion

The overall diagnostic sensitivity of the NADAL COVID-19 Ag Test was 74 %, with a 90 % CI of 65-82 % when compared to the results from the comparison method. PPV was 97 % at prevalence 11 %.

COVID-19 symptoms were reported by 45 % of the participants (table 2). Nearly half of the participant's symptom onset was unknown in this evaluation, but 48 % stated that the symptoms had lasted for five days or less and among these participants the sensitivity was 79 % (table 4). Participants tested more than 5-7 days since onset of symptoms are more likely to have lower viral loads, and the likelihood of false negative results with Ag-RDTs is higher [3]. For participants without symptoms (55 %), the sensitivity was 50 %. Although the number of results is small, this is still an indication that the test might have a lower sensitivity in asymptomatic than in symptomatic participants. This is consistent with findings generally on antigen test performance in asymptomatic individuals [8] and emphasizes the importance of careful evaluation of the target population before implementing Ag-RDTs for SARS-CoV-2.

The ct values from the comparison method are inversely proportional to the amount of target nucleic acid in the samples measured. The ct value can therefore give some indication of the viral load in the participant. When only the participants with ct values below 30 were considered, the sensitivity increased to 80 % (table 4). The median ct value for the false negative NADAL COVID-19 Ag Test results was higher than for the true positive results. Of the 20 false negative results, six had ct values ≥30. Thus, low viral load may have contributed to some of the false negative results. Low viral load suggests that the participants at the time of sampling either were in a pre-symptomatic phase or in a late phase of the infection, and probably non-infectious [9]. From an infection tracing perspective, however, they are still important.

The results stratified by ct values should be interpreted with caution. Due to differences in RT-PCR technology across laboratories, ct values may differ despite equal RNA concentrations in a sample. There is no universal ct value indicating contagiousness. In addition, the viral load in a sample may be affected by preanalytical conditions e.g., poor sampling can result in different viral loads in samples measured by the NADAL COVID-19 Ag Test and the comparison method even if collected from the same patient at the same time and by the same health care provider.

The sensitivity was 85 % for the nasal samples (table 5) and 69 % for the nasopharyngeal samples (table 6). For the nasal samples the most recent lots were used, and for the nasopharyngeal samples earlier manufactured lots were used, which may have had some influence on the performance although all test cassettes were used within their expiration dates. A more possible explanation to the difference in sensitivities can be the prevalence of symptoms in the tested population; a higher proportion of the true positive nasal samples were from symptomatic individuals (26 of 27) in contrast to the true positive nasopharyngeal samples (44 of 51). Additionally, a significant difference in ct values of the RT-PCR positive samples, could have resulted in the difference of sensitivity. Though, no major differences in ct-value were observed.

The overall diagnostic specificity for both nasal and nasopharyngeal samples was 99,7 % with a 90 % CI of 99,0-99,9 % (table 7). NPV was 97 % at prevalence 11 %. The specificity for the nasal swab specimens only, was 99,0 % (table 8) and for the nasopharyngeal samples 100 % (table 9). The main concern when using an Ag-RDTs instead of a RT-PCR method is the risk of false negative results, but if the disease prevalence is low (<1 %), the proportion of false positive results may still become noticeable [10]. WHO recommends a higher specificity (≥99 %) for the Ag-RDT tests if used in a low prevalence setting [3].

Conclusion

In this evaluation, the overall diagnostic sensitivity of NADAL COVID-19 Ag Test did not fulfill WHO's minimum performance requirement for diagnostic sensitivity (≥80 %), but it did fulfill the performance requirement for diagnostic specificity (≥97 %) when used under real life-conditions with a prevalence of 11 % by intended users.

6.4. Evaluation of user-friendliness

6.4.1. Questionnaire to the evaluators

The most important responses regarding user-friendliness come from the intended users themselves. The end-users often emphasise other aspects than those pointed out by more extensively trained laboratory personnel.

At the end of the evaluation period, the intended users filled in a questionnaire about the user-friendliness of the measurement system. SKUP has prepared detailed instructions for this.

The questionnaire is divided into four subareas:

Table A) Rating of operation facilities. Is the system easy to handle?
Table B) Rating of the information in the manual / insert / quick guide
Table C) Rating of time factors for the preparation and the measurement
Table D) Rating of performing internal and external analytical quality control

The intended users filled in table A and B. SKUP filled in table C and D and in addition, topics marked with grey colour in table A and B.

In the tables, the first column shows what property is evaluated. The second column in table A and B shows the rating by the users at the evaluation sites (one letter per evaluator). The rest of the columns show the rating options. The overall ratings from all the evaluating sites are marked in coloured and bold text. The total rating is an overall assessment by SKUP of the described property, and not necessarily the arithmetic mean of the rating in the rows. Consequently, a single poor rating can justify an overall poor rating, if this property seriously influences on the user-friendliness of the system.

Unsatisfactory and intermediate ratings are marked with a number and explained below the tables. The intermediate category covers neutral ratings assessed as neither good nor bad.

An assessment of the user-friendliness is subjective, and the topics in the questionnaire may be emphasised differently by different users. The assessment can therefore vary between different persons and between the countries. This will be discussed and taken into account in the overall assessment of the user-friendliness.

Comment
In this evaluation, the user-friendliness was assessed individually by four nurses.

Table A. Rating of operation facilities

Topic	Rating	Rating	Rating	Rating	Option
To prepare the test / instrument	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
To prepare the sample	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Application of specimen	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Specimen volume*	**S, I[1], S, S**	**Satisfactory**	**Intermediate**	Unsatisfactory	No opinion
Number of procedure step	**S, S, I[2], I[2]**	**Satisfactory**	**Intermediate**	Unsatisfactory	No opinion
Instrument / test design	**S, S, I[3], I[3]**	**Satisfactory**	**Intermediate**	Unsatisfactory	No opinion
Reading of the test result	**S, S, S, S**	**Easy**	Intermediate	Difficult	No opinion
Sources of errors	**S, S, S, N**	**Satisfactory**	Intermediate	Unsatisfactory	**No opinion**
Cleaning / Maintenance	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Hygiene, when using the test	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Size and weight of instrument	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Storage conditions for tests, unopened package	**S**	**+15 to +30°C**	+2 to +8°C	–20°C	
Storage conditions for tests, opened package	**S**	**+15 to +30°C or disposable**	+2 to +8°C	–20°C	
Environmental aspects: waste handling	**S**	**No precautions**	Sorted waste	Special precautions	
Intended users	**S**	**Health care personnel or patients**	Laboratory experience	Biomedical laboratory scientists	
Total rating by SKUP		**Satisfactory**			

*Assessed on whether the volume of extraction buffer was sufficient for repeated measurements.
[1]The nasal swabs had a long "brush" and uncertain if the buffer volume was enough to cover the "brush".
[2] There was a two-minute-delay before applying the processed specimen to the test cassette. Required two timers, making the test less suitable to use outside the test centre. Comment from SKUP: Kits with later production date does not require the two-minutes extraction time before measurement, and therefore SKUP will not include this rating in the final assessment of the test.
[3]The swabs were a bit long/ the tubes a bit short. Swab could fall out during relocation. Comment from SKUP: This problem is related to the two-minute extraction time, due to the removal of the extraction time, SKUP will not include this rating in the final assessment of the test.

Additional positive comments: Positive that the swab is removed from the extraction buffer before measurement, makes it easier to squeeze out sample material to the test cassette. Safe to work with, little risk of spilling. Small sample volume (two drops), easy to drip.

Additional negative comments: None

Table B. Rating of the information in the quick guide

Topic	Rating	Rating	Rating	Rating	Option
Table of contents/Index	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Preparations/Pre-analytic procedure	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Specimen collection	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Measurement procedure	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Reading of result	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Description of the sources of error	**S, S, S, N**	**Satisfactory**	Intermediate	Unsatisfactory	**No opinion**
Help for troubleshooting	**S[1], S, S, N**	**Satisfactory**	Intermediate	Unsatisfactory	**No opinion**
Readability / Clarity of presentation	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
General impression	**S, S, S, S**	**Satisfactory**	Intermediate	Unsatisfactory	No opinion
Measurement principle	**S**	**Satisfactory**	Intermediate	Unsatisfactory	
Available insert in Danish, Norwegian, Swedish	**S**	**Satisfactory**	Intermediate	Unsatisfactory	
Total rating by SKUP		**Satisfactory**			

Additional positive comments:
Informative, good quick guide. Good illustrations.

Additional negative comments:
An additional smaller “pocket edition” of the quick guide would be desirable.

Table C. Rating of time factors (filled in by SKUP)

Topic	Rating	Rating	Rating
Required training time	**<2 hours**	2 to 8 hours	>8 hours
Durations of preparations / Pre-analytical time	**<6 min.**	6 to 10 min.	>10 min.
Duration of measurement	**<20 min.**	20 to 30 min.	>30 min.
Stability of test, unopened package	**>5 months**	3 to 5 months	<3 months
Stability of test, opened package	**>30 day or disposable**	14 to 30 days	<14 days
Stability of quality control material, unopened*	>5 months	3 to 5 months	<3 months
Stability of quality control material, opened*	>6 days or disposable	2 to 6 days	≤1 day
Total rating by SKUP	**Satisfactory**		

*Not assessed since internal analytical controls were not developed at the time of the evaluation.
Comment from SKUP: COVID-19 Ag negative and positive control swabs were available from Nal von Minden when the report was published (Ref no. 243112).

Additional positive comments:
It is a great advantage that the extraction buffer including specimen is stable for up to at least two hours when contact tracing many people during a COVID-19 outbreak.

Table D. Rating of analytical quality control (filled in by SKUP)

Topic	Rating	Rating	Rating
Reading of the internal quality control*	Satisfactory	Intermediate	Unsatisfactory
Usefulness of the internal quality control*	Satisfactory	Intermediate	Unsatisfactory
External quality control	**Satisfactory**	Intermediate	Unsatisfactory
Total rating by SKUP	**Satisfactory**		

*Not assessed since internal analytical controls were not developed at the time of the evaluation.

6.4.2. Assessment of the user-friendliness

Assessment of the operation facilities (table A)
The operation facilities were overall assessed as satisfactory, but there were some intermediate ratings that should be addressed. The intermediate ratings mainly concerned the swabs and the test design.

Assessment of the information in the quick guide (table B)
The quick guide was assessed as satisfactory with comments on good illustrations.

Assessment of time factors (table C)
The time factors were assessed as satisfactory.

Assessment of analytical quality control possibilities (table D)
The external analytical quality control possibilities were assessed as satisfactory.

Conclusion
The user-friendliness of NADAL COVID-19 Ag Test and its manual was rated as satisfactory, with only some improvement potential pointed out. The quality goal for user-friendliness was fulfilled.

7. References

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6. The IFCC – IUPAC terminology for properties and units. http://www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch/ (accessed 2021-11-19).
7. Corman VM. *et al.* Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. 2020; **25**(3): 23 – 30.
8. Cochrane Database of Systematic Reviews (Dinnes *et al.*). Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection 2021. https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013705.pub2 (accessed 2021-11-19).
9. He X., Lau E.H.Y., Wu P. *et al.* Temporal dynamics in viral shedding and transmissibility of COVID-19. Nat Med 2020; **26**: 672 – 675.
10. Norwegian Directorate of Health. COVID-19 pandemic: Evaluation of Abbot's Panbio COVID-19 rapid antigen test in Norway, December 2020, https://www.helsedirektoratet.no/rapporter/evaluation-of-abbots-panbio-covid-19-rapid-antigen-test-in-norway/ (accessed 2021-11-19).

Attachments

1. The organisation of SKUP
2. Facts about NADAL COVID-19 Ag Test
3. Information about manufacturer, retailers and marketing
4. Product specifications for this evaluation, NADAL COVID-19 Ag Test
5. Statistical expressions and calculations
6. Raw data, NADAL COVID-19 Ag Test and the comparison method

Attachments with raw data are included only in the copy to Nal von Minden GmbH.

The organisation of SKUP

Scandinavian evaluation of laboratory equipment for point of care testing, SKUP, is a co-operative commitment of DEKS[1] in Denmark, Noklus[2] in Norway and Equalis[3] in Sweden. SKUP was established in 1997 at the initiative of laboratory medicine professionals in the three countries. SKUP is led by a Scandinavian *steering committee* and the secretariat is located at Noklus in Bergen, Norway.

The purpose of SKUP is to improve the quality of near patient testing in Scandinavia by providing objective and supplier-independent information about analytical quality and user-friendliness of laboratory equipment. This information is generated by organising SKUP *evaluations*.

SKUP offers manufacturers and suppliers evaluations of laboratory equipment for point of care testing. Provided the equipment is not launched onto the Scandinavian market, it is possible to have a confidential pre-marketing evaluation. The company requesting the evaluation pays the actual testing costs and receives in return an impartial evaluation.

There are *general guidelines* for all SKUP evaluations and for each evaluation a specific *SKUP protocol* is worked out in co-operation with the manufacturer or their representatives. SKUP signs *contracts* with the requesting company and the evaluating laboratories. The analytical results are assessed according to *pre-set quality goals*. To fully demonstrate the quality of a product, the *end-users* should be involved in the evaluations.

Each evaluation is presented in a *SKUP report* to which a unique *report code* is assigned. The code is composed of the acronym SKUP, the year the report was completed and a serial number. A report code, followed by an asterisk (*), indicates an evaluation with a more specific objective. The asterisk is explained on the front page of these protocols and reports.

SKUP reports are published at www.skup.org.

[1] DEKS (Danish Institute for External Quality Assurance for Laboratories in the Health Sector) is a non-profit organisation owned by the Capital Region of Denmark on behalf of all other Regions in Denmark.

[2] Noklus (Norwegian Organization for Quality Improvement of Laboratory Examinations) is a national not for profit organisation governed by a management committee consisting of representatives from the Norwegian Government, the Norwegian Medical Association and the Norwegian Society of Medical Biochemistry, with the Norwegian Association of Local and Regional Authorities (KS) as observer.

[3] Equalis AB (External quality assessment in laboratory medicine in Sweden) is a limited company in Uppsala, Sweden, owned by “Sveriges Kommuner och Regioner” (Swedish Association of Local Authorities and Regions), “Svenska Läkaresällskapet” (Swedish Society of Medicine) and IBL (Swedish Institute of Biomedical Laboratory Science).

Facts about NADAL COVID-19 Ag Test

This form is filled in by Nal von Minden.

Table 1. Basic facts

Name of the measurement system:	NADAL COVID-19 Ag Test
Dimensions and weight:	n.a.
Components of the measurement system:	Test cassette, tube and buffer for extraction of the measurand
Measurand:	SARS-CoV-2 Nucleoprotein
Sample material:	Nasal, nasopharyngeal swab and oropharyngeal swabs
Sample volume:	Two drops of extraction buffer including the sample material
Measuring principle:	Immunochromatography/ Lateral Flow
Traceability:	n.a.
Calibration:	n.a.
Measuring range:	Qualitative
Haematocrit range:	n.a.
Measurement time:	15 min after loading the sample onto the test cassette
Operating conditions:	For medical trained personnel only
Electrical power supply:	n.a.
Recommended regular maintenance:	n.a.
Package contents:	20 extraction tubes incl. dropper caps 2 buffer bottles (à 7 ml) or buffer ampoules for single use (400 µl each) 1 reagent holder 1 package insert
Necessary equipment not included in the package:	Transport media for sampled swabs, if necessary and timer

Table 2. Post analytical traceability

Is input of patient identification possible?	n.a.
Is input of operator identification possible?	n.a.
Can the instrument be connected to a bar-code reader?	n.a.
Can the instrument be connected to a printer?	n.a.
What can be printed?	n.a.
Can the instrument be connected to a PC?	n.a.
Can the instrument communicate with LIS (Laboratory Information System)? If yes, is the communication bidirectional?	n.a.
What is the storage capacity of the instrument and what is stored in the instrument?	n.a.
Is it possible to trace/search for measurement results?	n.a.

Table 3. Facts about the reagent/test strips/test cassettes

Name of the reagent/test strips/test cassettes:	NADAL COVID-19 Ag Test
Stability in unopened sealed vial:	2 years
Stability in opened vial:	Immediate testing is recommended in order to achieve best results

Table 4. Quality control*

Electronic self-check:	n.a.
Recommended control materials	Positive control swabs (REF: 243111) Negative control swabs (REF: 243112)
Stability in unopened sealed vial:	12 months
Stability in opened vial:	n.a.
Package contents:	20 pcs/ box

*An internal quality control material was developed before publication of this evaluation report. The information in this table was updated accordingly.

Information about manufacturer, retailers and marketing

This form is filled in by Nal von Minden.

Table 1. Marketing information

Manufacturer:	Nal von Minden GmbH
Retailers in Scandinavia:	Denmark: Nal von Minden GmbH Norway: Nal von Minden GmbH Sweden: Nal von Minden GmbH
In which countries is the system marketed:	Globally ☒ Scandinavia ☒ Europe ☒
Date for start of marketing the system in Scandinavia:	2020-08-30
Date for CE-marking:	2020-08-31
In which Scandinavian languages is the manual available:	Danish, Norwegian and Swedish.

Product specifications for this evaluation, NADAL COVID-19 Ag Test

NADAL COVID-19 Ag Test, REF. 243103N-20 with Jiangsu Swabs CE0197

Lot index used in evaluation	Lot no kit	Expiry date kit	Type of swab used	Lot no swab	Expiry date swab
a	175201	2022/08	Nasopharyngeal	20200710JZ	2023/07/09
b	175200	2022/08	Nasopharyngeal	20200710JZ	2023/07/09
c	175182	2022/08	Nasopharyngeal	20200710JZ	2023/07/09
d	175202	2022/09	Nasopharyngeal	20200710JZ	2023/07/09
e	SR2021010074	2022/12	Nasal	20210116JZ	2024/01/15
f	175354	2022/11	Nasal	20210206JZ	2024/02/05

Statistical expressions and calculations

This attachment is valid for evaluations of qualitative test methods with results on the ordinal scale.

Statistical terms and expressions

The definitions and formulas in this section originate from the Geigy document [a].

Statistical calculations

Diagnostic sensitivity is true positive/(true positive + false negative)

Diagnostic specificity is true negative/(false positive + true negative)

Positive predictive value (PPV) is true positive/(true positive + false positive)

Negative predictive value (NPV) is true negative/(true negative + false negative)

Prevalence is true positive/(true positive + true negative + false positive + false negative)

See table 1 for an illustration.

Table 1. Illustration of statistical calculations

	Truth		
	Positive	**Negative**	
Evaluated test positive	a	b	PPV = a/(a+b)
Evaluated test negative	c	d	NPV = d/(d+c)
	Diagnostic sensitivity = a/(a+c)	Diagnostic specificity = d/(b+d)	

Calculation of confidence intervals

Estimation of CI for fractions/proportions is performed according to Adjusted Walds [b]. The CIs are given for information only.

Relationship between PPV / NPV and prevalence

Contrary to diagnostic sensitivity and specificity, the PPV and NPV are related to the prevalence of the disease in a specific population (figure 1). PPV and NPV are also related to the diagnostic sensitivity and specificity of a diagnostic test.

a. Documenta Geigy. Mathematics and statistics. CIBA-GEIGY Limited, Basel, Switzerland 1971; p 186 formula # 772.
b. https://measuringu.com/calculators/wald/ (accessed 2021-11-22).

Raw data, NADAL COVID-19 Ag Test and the comparison method

Shown to the requesting company only.