# MF-68 SARS-CoV-2 Antigen Test

A system for measurement of SARS-CoV-2 antigen manufactured by Shenzhen Microprofit Biotech Co., Ltd.

## Report from the evaluation SKUP/2022/131

***organised by SKUP at the request of Shenzhen Microprofit Biotech Co., Ltd.***

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Attachments with raw data are included only in the copy to Shenzhen Microprofit Biotech Co., Ltd.

## 1. Summary of an evaluation provided by SKUP | MF-68 SARS-CoV-2 Antigen Test

| | |
|---|---|
| *Manufacturer* | Shenzhen Microprofit Biotech Co., Ltd. |
| *Supplier* | Shenzhen Microprofit Biotech Co., Ltd. (requesting company) |
| *Launched in Scandinavia* | Not yet |

### Aim

To assess the diagnostic performance and user-friendliness of MF-68 SARS-CoV-2 Antigen Test when used under real life conditions by intended users in a dedicated COVID-19 test centre.

| Examination | Recommended Goals and Results |
|---|---|
| ***Overall diagnostic sensitivity*** | WHO recommends a minimum performance requirement of ≥80 % sensitivity compared to a nucleic acid-amplification test (NAAT) reference assay.<br>**Overall diagnostic sensitivity was not met: 70 % (90 % CI: 65-75 %)*** |
| ***Overall diagnostic specificity*** | WHO recommends a minimum performance requirement of ≥97 % specificity compared to a NAAT reference assay.<br>**Overall diagnostic specificity was met: 98,2 % (90 % CI: 94,4-99,7 %)*** |
| ***User-friendliness*** | **Quality goal;** a total rating of "Satisfactory" by SKUP<br>**The quality goal of user-friendliness was fulfilled** |

### Background

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

### Material and methods

| | |
|---|---|
| *Participants* | 321 persons with high probability of SARS-CoV-2 infection, of whom 211 (66 %) tested positive on the comparison method. |
| *Comparison method* | A real time polymerase chain reaction (RT-PCR) method, for detection of SARS-CoV-2 at the Department of Microbiology at Haukeland University hospital in Bergen. |
| *Analytical procedure* | Subjects who had booked a RT-PCR test at a COVID-19 test centre in Bergen, Norway, were invited to participate. The sampling procedure, performed by trained test personnel, included one oropharyngeal swab sample for RT-PCR detection, and one nasal swab sample from both nostrils for MF-68 SARS-CoV-2 Antigen Test.<br>The oropharyngeal 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.<br>The nasal swab was placed into the test vial containing extraction buffer and analysed in accordance with the instructions from the manufacturer. Three lots of MF-68 SARS-CoV-2 Antigen Tests were used. |
| *User-friendliness* | Assessed by the test personnel using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory |

### Additional results

| | |
|---|---|
| *Sensitivity stratified on cycle threshold (ct) values:* | <33: 72 %: (90 % CI: 67-77 %)*<br><30: 74 %: (90 % CI: 68-79 %)*<br><25: 73 %: (90 % CI: 65-80 %)* |
| *Prevalence:* | 66 % |
| *Positive predictive value (PPV):* | 99 % |
| *Negative predictive value (NPV):* | 63 % |

**Shenzhen Microprofit Biotech has accepted the report without further comments**

*Confidence interval (CI) for information only

*This summary is also 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 cards 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].

MF-68 SARS-CoV-2 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 produced by Shenzhen Microprofit Biotech Co., Ltd. The test is not launched into the Scandinavian market. The SKUP evaluation was carried out from February to March 2022 at the request of Shenzhen Microprofit Biotech in China.

## 3.3. The aim of the evaluation

The aim of the evaluation was to assess the diagnostic quality and user-friendliness of MF-68 SARS-CoV-2 Antigen Test when used under real-life conditions by intended users in one dedicated COVID-19 test centre.

[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 MF-68 SARS-CoV-2 Antigen Test

The evaluation was carried out in one dedicated COVID-19 test centre to evaluate the performance of MF-68 SARS-CoV-2 Antigen 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 MF-68 SARS-CoV-2 Antigen Test using nasal 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 MF-68 SARS-CoV-2 Antigen Test and its manual.
- Identification and examination of the diagnostic performance (diagnostic sensitivity) of 100 Omicron positive samples.

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

Subjects with high probability of a SARS-CoV-2 infection was included. Both symptomatic and asymptomatic participants were included. Target number of participants was 100 RT-PCR positive results and 100 RT-PCR negative results, but maximum number included was set to 500. For comparison and assessment of the diagnostic sensitivity and specificity, an oropharyngeal sample was measured on an RT-PCR comparison method.

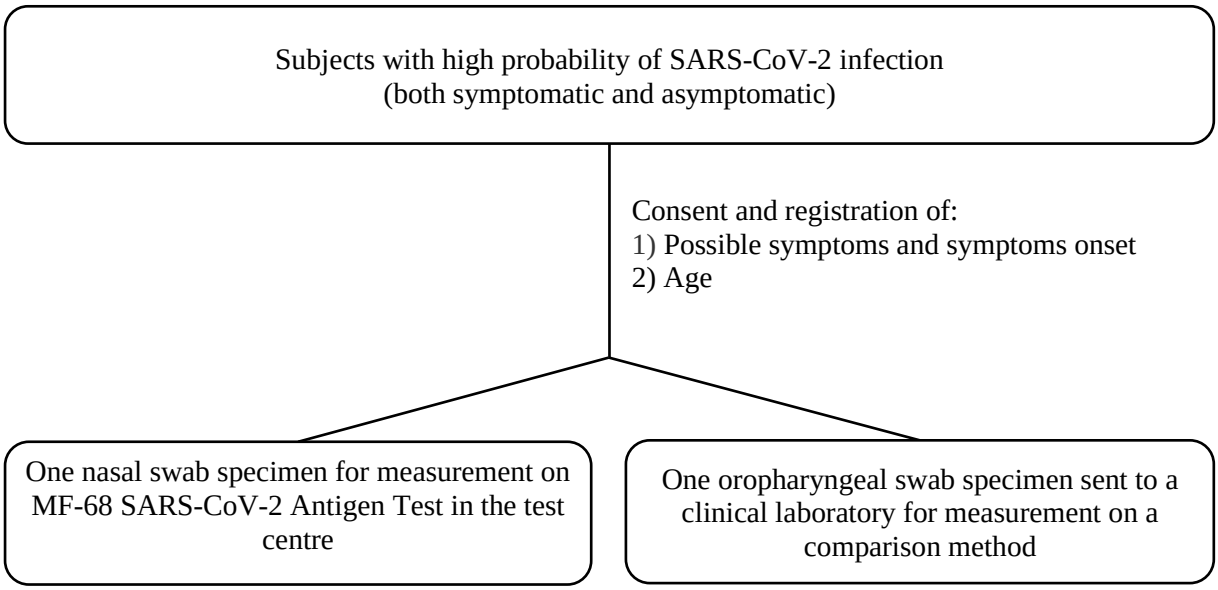


**Figure 1**. Flowchart illustrating the model for the evaluation of MF-68 SARS-CoV-2 Antigen Test.

# 4. Quality goals

## 4.1. Analytical quality

*Present recommendations for diagnostic* SARS-CoV-2 *tests*

The World Health Organization (WHO) offers advice on the potential role of Ag-RDTs in the diagnosis of COVID-19 [2]. WHO suggest 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. In settings with low prevalence of active SARS-CoV-2 infections the specificity should ideally be ≥99 % to avoid many false-positive results. 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 [4].

## 4.2. User-friendliness

The evaluation of user-friendliness was carried out by asking the evaluating persons at Bergen Municipality test centre Festplassen to fill in a questionnaire, see section 6.4. 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 test must show satisfactory diagnostic quality as well as satisfactory user-friendliness.

### 4.3.1. Assessment of the diagnostic quality

The 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 MF-68 SARS-CoV-2 Antigen 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 MF-68 SARS-CoV-2 Antigen 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*
Three lots of test cards 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.

### 4.3.2. Assessment of the user-friendliness

The user-friendliness is assessed according to the answers and comments given in the questionnaire (see section 6.4). For each question, the evaluator can choose between three given ratings; satisfactory, intermediate and unsatisfactory. The responses from the evaluators are reviewed and summed up. 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 6.4.

*Technical errors*
The evaluating persons register failed measurements and technical errors during the evaluation. The fraction of tests wasted due to technical errors is calculated and taken into account in connection with the assessment of the user-friendliness. User errors are not included in the calculation.

## 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. However, SKUP recommends the minimum performance requirements suggested by WHO and the results are discussed related to present literature.

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 nasopharynx, oropharynx or nostrils. MF-68 SARS-CoV-2 Antigen Test detects the presence or absence of antigens specific for SARS-CoV-2. For the comparison method the RNA from SARS-CoV-2 is identified by RT-PCR. The results are 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 [5]. The NPU code related to MF-68 SARS-CoV-2 Antigen Test is NPU59312. The NPU code related to the comparison method is NPU59178. In this report the term SARS-CoV-2 will be used for this measurand.

## 5.2. The evaluated measurement system MF-68 SARS-CoV-2 Antigen Test

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

MF-68 SARS-CoV-2 Antigen Test (figure 2) is a POC test intended for professional use for detection of SARS-CoV-2.

MF-68 SARS-CoV-2 Antigen Test kit includes:

- MF-68 SARS-CoV-2 Antigen Test cards
- Tubes prefilled with sample treatment solution
- Extra sample treatment solution (for back up use)
- Instruction of use
- Sterile swabs


**Figure 2.** MF-68 SARS-CoV-2 Antigen Test.

MF-68 SARS-CoV-2 Antigen Test is a colloidal gold chromatographic immunoassay for the qualitative detection of the SARS-CoV-2 antigen. When the processed specimen is added to the test card, the antigen, if present, is combined with SARS-CoV-2 colloidal gold labeled antibodies, to form a SARS-CoV-2 antigen-SARS-CoV-2 antibody-colloidal gold complex. The antigen-antibody gold complexes diffuse along the test card membrane and are captured by specific antibodies on the test line region resulting in a purple-red line. Further on, a red line in the control line region is formed when the colloidal gold labeled antibodies are captured by the sheep anti-mouse IgG antibodies. The result is interpreted visually based on the presence or absence of a test line.

The test procedure involves collecting nasopharyngeal, oropharyngeal or nasal specimen using a recommended swab, which is eluted into a sample treatment tube. Two drops of the specimen in extraction buffer are added to the test strip using a dropper cap provided. The test result can be read visually after exactly 15 minutes, but not after 20 minutes.

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

For technical details about MF-68 SARS-CoV-2 Antigen Test, see table 1. For more information about MF-68 SARS-CoV-2 Antigen Test, and name of the manufacturer and the suppliers in the Scandinavian countries, see attachment 2 and 3. For product specifications in this evaluation, see attachment 4.

**Table 1**. Technical details from the manufacturer

| **Technical details for MF-68 SARS-CoV-2 Antigen Test** | |
|---|---|
| Sample material | Nasal, nasopharyngeal or oropharyngeal specimen |
| Stability of extraction buffer including specimen | Specimen should be placed in extraction buffer and tested immediately or within one hour of collection* |
| Measuring time | 15 minutes |

*Based on information received from Shenzhen Microprofit Biotech Ltd., Co.

## 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 in the Department of Microbiology, Haukeland University Hospital in Bergen, 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 PCR measurements has approximately 30 employees.

| | |
|---|---|
| Instruments: | Lightcycler 480 (Roche) or Quantstudio 5 (Applied biosystems) |
| Reagent: | In-house RT-PCR. Mastermix: QuantiNova® Pathogen + IC Kit (Qiagen) |
| Principle: | RT-PCR detection of the E gene of the Sarbeco Betacorona virus, including SARS-CoV-2 |

*Internal analytical quality control*

Kit-independent positive (positive patient samples) and negative (transport medium) controls are included in the extraction step. In addition, an internal control (bacteriophage with RNA) is added to each sample.

*External analytical quality control*

The laboratory participates in the external quality assessment (EQA) scheme Quality Control for Molecular Diagnostics (QCMD, United Kingdom) for SARS-CoV-2 with five samples in two challenges per year.

### 5.3.2. 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 for a period circumventing the evaluation period.

### 5.3.3. Variant detection of Omicron

The method for detection of Omicron variant in this evaluation was RT-PCR and melting curve analysis. Two mutations in the gene which codes for the spike protein (ES371L and S373P) was identified. All SARS-CoV-2 positive samples that had either one or both of these mutations in the spike protein were designated to be the Omicron variant [6].

## 5.4. The evaluation

### 5.4.1. Planning of the evaluation

*Inquiry about an evaluation*

Shenzhen Microprofit Biotech Co., Ltd. via Mary Chen, Regulatory Affairs Specialist, applied to SKUP in November 2021 for an evaluation of MF-68 SARS-CoV-2 Antigen Test.

*Protocol, arrangements and contract*

In February 2022, the protocol for the evaluation was approved, and Shenzhen Microprofit Biotech Co., Ltd. and SKUP signed a contract for the evaluation. Bergen Municipals dedicated COVID-19 test centre at Festplassen agreed to represent the intended users in this evaluation and the Department of Microbiology, Haukeland University Hospital agreed to perform the comparison method.

*Training*

To optimize performance, WHO recommend that testing with Ag-RDTs should be conducted by trained operators in strict accordance with the manufacturer's instructions. Shenzhen Microprofit Biotech does not have a local representative in Norway, SKUP was therefore responsible for the necessary training in use of MF-68 SARS-CoV-2 Antigen Test. The training in the test centre reflected the training usually given to the end-users. Shenzhen Microprofit Biotech was not allowed to contact or supervise the evaluators during the evaluation period.

### 5.4.2. Evaluation sites and persons involved

The practical work was carried out over two weeks in the dedicated COVID-19 test centre, ending in March 2022. In the test centre sixteen trained test personnel participated in the evaluation. They were all trained in collecting samples from upper airways and use both nasal and oropharyngeal swab specimens in the routine work. They were also trained in use of rapid antigen tests for SARS-CoV-2. Biomedical laboratory scientists (BLSs) from the Department of Microbiology, Haukeland University Hospital in Bergen analysed the RT-PCR samples and performed the variant detection of Omicron.

### 5.4.3. The evaluation procedure

*Internal analytical quality control*
No internal quality control was available for the test kit during the evaluation.

*Recruitment of participants and ethical considerations*
Subjects, 16 years or older, with high risk of COVID-19 infection were invited to participate in the evaluation of MF-68 SARS-CoV-2 Antigen Test. Due to the high prevalence of COVID-19 infection in Bergen during the evaluation, everyone who booked a RT-PCR test at the test centre and accepted to join the evaluation was recruited. 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.

*Handling of the samples and measurements*
Test cards and extraction buffer were brought to room temperature (15-25°C) prior to testing. Nasal swab specimens were used for the measurements on MF-68 SARS-CoV-2 Antigen Test. In the same sampling session, an oropharyngeal swab was collected for measurement on the comparison method.

The sampling from each patient was collected in the following order:
1. Oropharyngeal swab specimen for the comparison method
2. Nasal swab specimen collected from both nostrils for MF-68 SARS-CoV-2 Antigen Test

Nasal swab specimens were collected according to local guidelines and immediately placed into the test vials containing extraction buffer. The extracted samples were analysed within one hour of collection, and 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. Three lot numbers of test cards were used, alternating between the lot numbers.

The oropharyngeal swab specimens 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 measured on the comparison method. All samples were treated according to the internal procedures of the laboratory regarding potential interfering substances.

*Additional experiments*
Variant detection for Omicron was performed on 110 of the positive RT-PCR samples in the evaluation. The variant analysis was performed according to internal procedures of the laboratory.

# 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 over two weeks in February and March 2022, during which Bergen city experienced a major outbreak of COVID-19.

In total, 326 participants provided samples for the evaluation (table 2), of which 321 were successfully matched to their corresponding RT-PCR result. Of these, 59 % (n=191) were ≥30 years old. The vast majority of the participants, 90 % (n=288), reported having symptoms at the point of the testing, of which 43 % (n=125) reported having symptoms for 2-5 days prior to testing. The most common symptom was sore throat, in which 59% of the symptomatic population reported this symptom. A positive RT-PCR result was achieved for 66 % (n=212) of the participants, this high number was expected due to the ongoing outbreak.

**Table 2.** Population characteristics

| | **Total successfully included, n (% of all)** | **RT-PCR positive results, n (% of subgroup)** | **RT-PCR negative results, n (% of subgroup)** |
|---|---|---|---|
| **Total** | 321 (100) | 211 (66) | 110 (34) |
| **Age** | | | |
| ≤19 | 8 (3) | 4 (2) | 4 (4) |
| 20-29 | 122 (38) | 80 (38) | 42 (38) |
| ≥30 | 191 (59) | 127 (60) | 64 (58) |
| **Symptomatic** | | | |
| No | 33 (10) | 10 (5) | 23 (21) |
| Yes | 288 (90) | 201 (95) | 87 (79) |
| **Symptom duration** | **n (% of symptomatic)** | | |
| ≤1 days | 109 (38) | 76 (38) | 33 (38) |
| 2-5 days | 125 (43) | 89 (44) | 36 (41) |
| >5 days | 33 (12) | 21 (10) | 12 (14) |
| Unknown | 21 (7) | 15 (8) | 6 (7) |

*Missing results*

ID 35; no result from the comparison method as the sample never arrived at the clinical laboratory.

*Omitted results*

ID 274; the result from the clinical laboratory was reported as inconclusive and therefore the results were not included in the calculations of diagnostic sensitivity and specificity.

*Recorded error codes, technical errors and failed measurements*

There was one failed measurement on MF-68 SARS-CoV-2 Antigen Test due to no extraction buffer in the test tube.

The fraction of tests wasted due to technical error was 0,3 % (1 out of 326).
The SKUP recommendation of a fraction of ≤2 % tests wasted due to technical errors was achieved.

*Detection of Omicron positive samples*
To determine the diagnostic sensitivity of MF-68 SARS-CoV-2 Antigen Test in Omicron-positive samples, 110 of the RT-PCR positive samples were typed, all of which were identified as the Omicron variant.

## 6.2. Analytical quality of the selected comparison method

### 6.2.1. Internal analytical quality control

All results from the internal analytical quality controls (negative, positive, internal control) were in the 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 | Assigned value (SARS-CoV-2 dPCR Log10 Copies/ml) | Results from the RT-PCR method (ct value) |
|---|---|---|---|
| Nov. 2021 | QCMD | Positive (3,3) | Positive (33,62) |
| | | Positive (3,2) | Positive (34,14) |
| | | Positive (4,4) | Positive (29,86) |
| | | Positive (3,4) | Positive (32,92) |
| | | Positive (3,4) | Positive (33,60) |
| March 2022 | QCMD | Positive (3)<br>Delta Variant B.1.617.2 | Positive (29,91) |
| | | Positive (4)<br>Lineage B.1 | Positive (28,46) |
| | | Positive (3)<br>Delta Variant B.1.617.2 | Positive (30,04) |
| | | Positive (4)<br>Delta Variant B.1.617.2 | Positive (26,89) |
| | | Positive (3)<br>Lineage B.1 | Positive (30,94) |

*Discussion*
The trueness of the comparison method was confirmed during the evaluation period by the results from the QCMD EQA scheme for SARS-CoV-2.

## 6.3. Analytical quality of MF-68 SARS-CoV-2 Antigen Test

The results below reflect the analytical quality of MF-68 SARS-CoV-2 Antigen Test under real-life conditions in the hands of intended users at a dedicated COVID-19 test centre.

### 6.3.1. Internal analytical quality control

Internal analytical quality controls for MF-68 SARS CoV-2 Antigen Test are only available for separate purchase and was not provided by Microprofit Biotech for this evaluation.

### 6.3.2. The diagnostic sensitivity of MF-68 SARS-Cov-2 Antigen Test

The diagnostic sensitivity of MF-68 SARS-CoV-2 Antigen Test was calculated as described in attachment 5 using the RT-PCR values as true values, both for the total population, stratified on clinical subgroups and on relevant ct values. The calculated results (table 4) 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 MF-68 SARS CoV-2 Antigen Test measured in nasal specimen**.** Results achieved by intended users. Overall results and stratified on clinical subgroups and relevant ct values.

| | **Number of positive RT-PCR results** | **Number of true positive results** | **Number of false negative results** | **Diagnostic sensitivity, % (90 % CI)** |
|---|---|---|---|---|
| **Total** | 211 | 148[1] | 63[2] | 70 (65-75) |
| **Symptomatic** | | | | |
| No | 10 | 6 | 4 | 60 (35-81) |
| Yes | 201 | 142 | 59 | 71 (65-76) |
| ≤1 days | 76 | 52 | 24 | 68 (59-76) |
| 2-5 days | 89 | 70 | 19 | 79 (71-85) |
| >5 days | 21 | 12 | 9 | 57 (40-73) |
| Unknown onset | 15 | 8 | 7 | 53 (33-72) |
| **Ct values** | | | | |
| <33 | 192 | 139 | 53 | 72 (67-77) |
| <30 | 174 | 129 | 45 | 74 (68-79) |
| <25 | 100 | 73 | 27 | 73 (65-80) |

[1]Median ct value for the true positive results = 25,6 (17,2 – 37,9).
[2]Median ct value for the false negative results = 26,9 (19,44 – 36,9).
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 MF-68 SARS CoV-2 Antigen Test

The diagnostic specificity of MF-68 SARS-CoV-2 Antigen 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 (table 5) are given with a 90 % CI (for information only). Raw data is attached to the requesting company only (attachment 6).

**Table 5**. Diagnostic specificity of MF-68 SARS CoV-2 Antigen Test measured in nasal specimens. Results achieved by intended users. Overall results and stratified on clinical subgroups.

| | Number of negative RT-PCR results | Number of true negative results | Number of false positive results | Diagnostic specificity % (90 % CI) |
|---|---|---|---|---|
| **Total** | 110 | 108 | 2 | 98,2 (94,4-99,7) |
| **Symptomatic** | | | | |
| No | 23 | 23 | 0 | 100 (92-100) |
| Yes | 87 | 85 | 2 | 97,7 (93,0-99,6) |
| ≤1 days | 33 | 32 | 1 | 97,0 (86,6-100) |
| 2-5 days | 36 | 35 | 1 | 97,2 (87,6-100) |
| >5 days | 12 | 12 | 0 | 100 (85,7-100) |
| Unknown onset | 6 | 6 | 0 | * |

* n <8; not reported due to high degree of uncertainty in the estimated sensitivity.
An account for the number of samples is given in section 6.1.

### 6.3.4. The diagnostic sensitivity of SARS-CoV-2 Antigen Test in Omicron positive samples

The diagnostic sensitivity of MF-68 SARS-CoV-2 Antigen Test in 110 Omicron positive samples was calculated as described in attachment 5 using the RT-PCR values as true values. The calculated results (table 6) are given with a 90 % CI (for information only). Raw data is attached to the requesting company only (attachment 6).

**Table 6:** Overall diagnostic sensitivity of MF-68 SARS-CoV-2 Antigen Test measured in Omicron positive results. Results achieved by intended users.

| | Number of positive RT-PCR results | Number of true positive results | Number of false negative results | Diagnostic sensitivity % (90 % CI) |
|---|---|---|---|---|
| **Total** | 110 | 81 | 29 | 74 (66-80) |

### 6.3.5. The negative and positive predictive value of MF-68 SARS-CoV-2 Antigen Test

The PPV was 99 % and NPV was 63 % for MF-68 SARS-CoV-2 Antigen Test at a prevalence of
66 %. The calculations were performed as described in Attachment 5.

### 6.3.6. Discussion and conclusion

The overall diagnostic sensitivity of MF-68 SARS-CoV-2 Antigen Test was 70 % with a 90 % CI of 65-75 % when compared to the results from the comparison method. PPV was 99 % at prevalence 66 %.

COVID-19 symptoms were reported by 90 % of the participants (table 2). Of them, 43 % stated that the symptoms had lasted for two to five days, and among these participants the sensitivity was 79 % (table 4). Among the participants whose symptoms lasted for more than 5 days (12 %) the sensitivity was 57 %, and among the participants that reported symptoms for less than 2 days (38 %) the sensitivity was 68 %. Participants tested more than 5-7 days and less than 2 days after onset of symptoms are more likely to have lower viral loads, and the likelihood of false negative results with Ag-RDTs is higher [3]. It has also been reported that in a vaccinated population the first symptoms will originate from immune system reaction to

the virus and not from the virus itself, which could lead to a lower sensitivity in participants tested early in the symptomatic phase [7]

Very few participants reported no symptoms (10 %), and among these the sensitivity was 60 %. This indicates that the test might have lower sensitivity in asymptomatic than in symptomatic participants, although the 90 % CIs were overlapping. This is consistent with findings generally on antigen test performance in asymptomatic individuals [8] and emphasises 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. The results stratified on ct values were similar with overlapping 90 % CIs (table 4). The median ct values for the false negative MF-68 SARS-CoV-2 Antigen Test results were slightly higher than for the true positive results. Of the 69 false negative results, 18 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 MF-68 SARS-CoV-2 Antigen Test and the comparison method even if collected from the same patient at the same time and by the same health care provider.

It is reported that the main variant of SARS-CoV-2 in Norway, at the time of the evaluation, was the Omicron variant [10]. This is also in accordance with the results from this evaluation, showing that all the samples tested for the variant on RT-PCR (n=110) were Omicron positive. A study on viral load has shown that the overall viral load is higher in nasal samples for the Omicron variant, but that the viral load reaches higher levels earlier in oropharyngeal samples, when measured with RT-PCR [11]. This leads to a slightly higher sensitivity when collecting the sample in oropharynx versus in the nostrils for the Omicron variant [12]. Since the sample for the comparison method was collected in oropharynx, and the sample for MF-68 SARS-CoV-2 Antigen Test was collected in the nostrils, this could have affected the sensitivity of MF-68 SARS-CoV-2 Antigen Test, especially in the early symptomatic participants.

The diagnostic sensitivity in the Omicron positive samples was 74 % with a 90 % CI of 66-80 % when compared to the results from the comparison method (table 6). The diagnostic sensitivity of the Omicron positive samples reflected the overall diagnostic sensitivity of MF-68 SARS-CoV-2 Antigen Test.

The overall diagnostic specificity was 98,2 % with a 90 % CI of 94,4-99,7 % (table 5). NPV was 63 % at prevalence 66 %. The main concern when using an Ag-RDTs instead of a RT-PCR method is the risk of false negative results, which is why WHO recommends a higher specificity (≥99 %) for the Ag-RDT tests if used in a low prevalence setting [3]. The risk has been demonstrated in settings with down to 1 % prevalence [13].

*Conclusion*

In this evaluation, the overall diagnostic sensitivity of MF-68 SARS-CoV-2 Antigen Test did not meet WHO's minimum performance requirement for diagnostic sensitivity (≥80 %), but it did meet the performance requirement for diagnostic specificity (≥97 %) when used under real life-conditions by intended users and at a prevalence of 66 %.

## 6.4. Evaluation of user-friendliness

### 6.4.1. Questionnaire to the evaluators

The most important response regarding user-friendliness comes 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 is up for consideration. The second column in table A and B shows the rating by the users at the evaluation sites. 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 six evaluating personnel at Bergen Municipal dedicated COVID-19 test centre at Festplassen.

**Table A.** Rating of operation facilities

| Topic | Rating | Rating | Rating | Rating | Option |
|---|---|---|---|---|---|
| To prepare the test | **S, S, S, S, S, I[1]** | **Satisfactory** | **Intermediate** | Unsatisfactory | No opinion |
| To prepare the sample | **S, S, S, S, S, I[1]** | **Satisfactory** | **Intermediate** | Unsatisfactory | No opinion |
| Application of specimen | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Specimen volume* | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Number of procedure step | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Instrument / test design | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Reading of the test result | **S, S, S, S, S, S** | **Easy** | Intermediate | Difficult | No opinion |
| Sources of errors | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Hygiene, when using the test | **S, S, S, S, S, I[1]** | **Satisfactory** | **Intermediate** | Unsatisfactory | No opinion |
| Size and weight of test kit | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Storage conditions for tests, unopened package | **S** | **+15 to +30°C (+2-30°C)** | +2 to +8°C | –20°C | |
| Storage conditions for tests, opened package | **S** | **+15 to +30°C or disposable (20-25°C)** | +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]Not happy about how the test kits are packed in general, not just this test kit. I feel that you must touch many parts of the test kit that you might not have to use right now, which is not hygienic.

Additional positive comments: The dropper caps on the extraction buffer tube, makes it easy to use. Logic test process.

Additional negative comments: None

**Table B.** Rating of the information in the insert

| Topic | Rating | Rating | Rating | Rating | Option |
|---|---|---|---|---|---|
| Table of contents/Index | **S, S, S, S, S, N** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Preparations/Pre-analytic procedure | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Specimen collection | **S, S, S, S, S, I**[1] | **Satisfactory** | **Intermediate** | Unsatisfactory | No opinion |
| Measurement procedure | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Reading of result | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Description of the sources of error | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Help for troubleshooting | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| Readability / Clarity of presentation | **S, S, S, S, S, S** | **Satisfactory** | Intermediate | Unsatisfactory | No opinion |
| General impression | **S, S, 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** | | | |

*Not available in Danish or Swedish yet. Will be available if the test in launched.
[1]Not easy to understand if you don't know what "pharyngeal" or "fagene" is. Comment from SKUP: MF-68 SARS-CoV-2 Antigen Test is a test for professional use, the comment is therefore not included in the total assessment.

Additional positive comments: Clear procedure. Clear explanation of the test procedure.

Additional negative comments: None

**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 analysis | **<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 days 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** | | |

*The test card should be used as soon as possible after opening the foil pouch and within 1 hour.
**When stored in +2 to +8 °C. 14 days when stored in -20 to -80 °C.

**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 quality control material was not available for the test kit during the evaluation.

### 6.4.2. Assessment of the user-friendliness

*Assessment of the operation facilities (table A)*
The operation facilities were in total assessed as satisfactory, but there were a few intermediate ratings. The motivations for the lower ratings were how the test kit was packed.

*Assessment of the information in the manual (table B)*
The package insert was assessed as satisfactory with positive comments that it was easy to understand.

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

*Assessment of analytical quality control possibilities (table D)*
Internal quality controls are available for separate purchase but were not included in this evaluation. The external analytical quality control possibilities were assessed as satisfactory.

*Conclusion*
The user-friendliness of MF-68 SARS-CoV-2 Antigen Test and its package insert was rated as satisfactory, although there is improvement potential pointed out. The quality goal for user-friendliness was fulfilled.

# 7. References


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# Attachments

1. The organisation of SKUP
2. Facts about MF-68 SARS-CoV-2 Antigen Test
3. Information about manufacturer, retailers and marketing
4. Product specifications for this evaluation, MF-68 SARS CoV-2 Antigen Test
5. Statistical expressions and calculations
6. Raw data MF-68 SARS CoV-2 Antigen Test and comparison method
7. Raw data for Omicron-positive samples, from MF-68 SARS-CoV-2 Antigen Test and comparison method results

Attachments with raw data are included only in the copy to Shenzhen Microprofit Biotech Co., Ltd.

# 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.

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[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 MF-68 SARS-CoV-2 Antigen Test
This form is filled in by Shenzhen Microprofit Biotech Co., Ltd. in China.

**Table 1. Basic facts**

| | |
|---|---|
| Name of the measurement system: | SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) |
| Dimensions and weight: | Width:68mm Depth:50mm Height:50mm length:135mm Weight:322g/box |
| Components of the measurement system: | Test Card, sample treatment solution, instruction of use, sterile swabs, sample treatment tube |
| Measurand: | SARS-CoV-2 N protein |
| Sample material: | Nasal swab, nasopharyngeal swab, oropharyngeal swab |
| Sample volume: | Vertically drop 2 drops (about 60 μL) of the treated sample solution into the sample hole of the test card. Only 2 drops of the treated sample solution can be added! Adding too much or too little of the treated sample solution may result in invalid test results. |
| Measuring principle: | MF-68 SARS-CoV-2 Antigen Test is a colloidal gold chromatographic immunoassay for the qualitative detection by of the novel Coronavirus (SARS-CoV-2) antigen. When the processed specimen is added to the test card, the antigen, if present, is combined with novel coronavirus (SARS-CoV-2) colloidal gold labeled antibodies, to form a SARS-CoV-2 Antigen-SARS-CoV-2 antibody-colloidal gold complex. Positive result is shown as a visual purple-red line. |
| Traceability: | NA |
| Calibration: | NA |
| Measuring range: | NA |
| Haematocrit range: | NA |
| Measurement time: | The test card is kept at room temperature for 15 minutes to observe the test results, but observation results over 20 minutes are invalid. |
| Operating conditions: | Room temperature (20- 25°C) |
| Electrical power supply: | NA |
| Recommended regular maintenance: | NA |
| Package contents: | 25×Test Card (including desiccant), 1×Extra sample treatment solution, 1×instruction of use, 25×Sterile swabs, 25×prefilled sample treatment tube |
| Necessary equipment not included in the package: | Timer |

**Table 2. Post analytical traceability**

| | |
|---|---|
| Is input of patient identification possible? | No instrument, need to record manually |
| Is input of operator identification possible? | NA |
| Can the instrument be connected to a bar-code reader? | NA |
| Can the instrument be connected to a printer? | NA |
| What can be printed? | NA |
| Can the instrument be connected to a PC? | NA |
| Can the instrument communicate with LIS (Laboratory Information System)?<br>If yes, is the communication bidirectional? | NA |
| What is the storage capacity of the instrument and what is stored in the instrument? | NA |
| Is it possible to trace/search for measurement results? | NA |

**Table 3. Facts about the reagent/test strips/test cards**

| | |
|---|---|
| Name of the reagent/test strips/test cards: | SARS-CoV-2 Antigen Test Kit (Colloidal Gold Chromatographic Immunoassay) |
| Stability<br>in unopened sealed vial: | Test kit is valid for 18 months at 2-30℃ in dry place |
| Stability<br>in opened vial: | After opening the foil bag, the test card should be used as soon as possible within 1 hour. |
| Package contents: | One Test Card with one desiccant |

**Table 4. Quality control**

| | |
|---|---|
| Electronic self check: | NA |
| Recommended control materials and volume: | NA |
| Stability<br>in unopened sealed vial: | NA |
| Stability<br>in opened vial: | NA |
| Package contents: | NA |

Information about manufacturer, retailers and marketing

This form is filled in by Shenzhen Microprofit Biotech Co., Ltd. in China.

**Table 1. Marketing information**

| | |
|---|---|
| Manufacturer: | Shenzhen Microprofit Biotech Co., Ltd |
| Retailers in Scandinavia: | Denmark: Not decided yet<br>Norway: Not decided yet<br>Sweden: Not decided yet |
| In which countries is the system marketed: | Globally ☐ Scandinavia ☐ Europe ☒ |
| Date for start of marketing the system in Scandinavia: | Not decided yet |
| Date for CE-marking: | 2021.11.22 |
| In which Scandinavian languages is the manual available: | Norwegian |

# Product specifications of this evaluation

*MF-68 SARS-CoV-2 Antigen Test Kit (REF: MF-68)*

| Lot name in evaluation | Lot no. | Expiry date |
|---|---|---|
| A | 22007 | 10.07.2023 |
| B | 22008 | 11.07.2023 |
| C | 22009 | 12.07.2023 |

*Other equipment used in the evaluation*

| Equipment | Name | Lot no. | Expiry date |
|---|---|---|---|
| Nasal specimen swab (included in the test kit)<br>REF: 2123-1003 | CITOSWAB Collection Swab | 211211 | 2024.12 |

# 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. 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 2021-08-04).

Raw data, MF-68 SARS-CoV-2 Antigen Test and comparison method results

*Shown to requesting company only.*

# Raw data for Omicron-positive samples, from MF-68 SARS-CoV-2 Antigen Test and comparison method results

*Shown to requesting company only.*