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. **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. **Overall diagnostic specificity was met: 98,2 % (90 % CI: 94,4-99,7 %)***
User-friendliness	**Quality goal;** a total rating of "Satisfactory" by SKUP **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. 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. 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 %)* <30: 74 %: (90 % CI: 68-79 %)* <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