Summary of an evaluation provided by SKUP | Flowflex SARS-CoV-2 Ag Rapid Test

Manufacturer	Acon Biotech Hangzhou Co. Ltd.
Supplier	Acon Biotech Hangzhou Co. Ltd. (requesting company)
Launched in Scandinavia	2020

SKUP
www.skup.org
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Aim

To assess the diagnostic performance and user-friendliness of Flowflex SARS-CoV-2 Ag Rapid Test when used under real life conditions by intended users in dedicated COVID-19 test centres.

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: 75 % (90 % CI: 68-82 %)***
Overall diagnostic specificity	WHO recommends a minimum performance requirement of ≥97 % specificity compared to a NAAT reference assay **Overall diagnostic specificity was met: 99,6 % (90 % CI: 98,6-99,9 %)***
User-friendliness	**Quality goal;** a total rating of 'Satisfactory' by SKUP **The quality goal of user-friendliness was fulfilled**

Background

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

Material and methods

Participants	564 persons exposed to individuals with confirmed SARS-CoV-2 infection, of whom 121 (21 %) tested positive on of the comparison methods.
Comparison method	A real time polymerase chain reaction (RT-PCR) method for detection of SARS-CoV-2 at the Clinical Diagnostic Department at the Hospital of South West Jutland in Esbjerg and the Department of Clinical Biochemistry at Bispebjerg Hospital in Copenhagen NV.
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 oropharyngeal swab sample for RT-PCR detection and one nasal swab sample from both nostrils, for the Flowflex SARS-CoV-2 Ag Rapid 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. Tree lots of Flowflex SARS-CoV-2 Ag Rapid Test were used.
User-friendliness	Assessed by trained health care professionals using a questionnaire with three given ratings; satisfactory, intermediate and unsatisfactory.

Additional results

Sensitivity stratified on cycle threshold (ct) values for the E-gene:	<33: 78 %: (90 % CI: 70-84 %)* <30: 82 %: (90 % CI: 75-88 %)* <25: 83 %: (90 % CI: 76-89 %)*
Prevalence:	21 %
Positive predictive value (PPV):	95 %
Negative predictive value (NPV):	97 %

Acon Biotech Hangzhou Co. Ltd. has accepted the report without further comments

**Confidence interval (CI) is for information only*