Summary| CLINITEST Rapid COVID-19 Antigen Test

Manufacturer: Healgen Scientific LLC.
Supplier: Siemens Healthineers in Denmark, Norway and Sweden.

Summary of an evaluation provided by SKUP

Conclusion
In this evaluation, WHO's suggested minimum performance requirement of ≥80 % sensitivity compared to a reference assay was not met by CLINITEST COVID-19 Ag Test when used under real-life conditions and with a prevalence of 11 %. WHO's suggested minimum performance requirement of ≥97 % specificity was met. The quality goal for user-friendliness was fulfilled.

Background
The CLINITEST Rapid COVID-19 Antigen Test is an in vitro antigen-detecting rapid diagnostic test (Ag-RDT) for detection of Severe Acute Respiratory Syndrome Coronavirus 2 antigen (SARS-CoV-2 Ag) in nasopharyngeal and nasal swab specimens. The product is intended for professional use. The test is manufactured by Healgen Scientific LLC and was launched into the Scandinavian market in October 2020. This SKUP evaluation was carried out from March to June 2021 at the request of Siemens Healthineers in Norway.

The aim of the evaluation
The aim of the evaluation was to assess the diagnostic performance and user-friendliness of CLINITEST COVID-19 Ag Test when using nasopharyngeal swab specimens under real life conditions by intended users at a dedicated COVID-19 testing centre.

Materials and methods
The evaluation was carried out in a COVID-19 respiratory outpatient clinic in Oslo. 672 subjects (≥16 years) exposed to individuals with confirmed SARS-CoV-2 infection within 10 days of exposure were included. Two nasopharyngeal swab samples were taken from separate nostrils from each participant. One of the nasopharyngeal swabs was measured directly on the CLINITEST COVID-19 Ag Test and the other was sent to an in-house RT-PCR comparison method at Oslo University Hospital, Norway. The diagnostic sensitivity and specificity of the CLINITEST COVID-19 Ag Test were calculated by comparing the test results with the RT-PCR results, for the total population and stratified on clinical subgroups and relevant cycle threshold (ct) values. The overall diagnostic performance was compared with the World Health Organization (WHO) minimum performance requirements of ≥80% sensitivity and ≥97% specificity. User-friendliness was assessed using a questionnaire with three ratings: satisfactory, intermediate and unsatisfactory, and with the quality goal of a total rating of "satisfactory".

Results
The prevalence of SARS-CoV-2 infection among the participants was 11 % (73 out of 666). The overall diagnostic sensitivity of the CLINITEST COVID-19 Ag Test was 53 % with a 90 % confidence interval (CI) of 44-63 %. Out of 34 false negative results, 23 had ct values ≥30. When only the participants with ct values below 30 were considered, the sensitivity increased to 75 % (CI: 62-85 %). Symptoms were reported by 33 % of the participants. Of those with symptoms, the sensitivity was 65 % (CI: 46-69 %). For participants without symptoms the sensitivity was 44 % (CI: 29-60 %). The diagnostic specificity was 99,3 % (CI: 98,5-99,7 %). The positive predictive value of the test was 91 % and the negative predictive value was 94,5 %. The user-friendliness was rated as satisfactory.

Comments from Siemens Healthineers
A letter with comments from Siemens Healthineers is attached to the report.

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