Summary | LumiraDx SARS-CoV-2 Ag Test

Manufacturer: LumiraDx UK Ltd
Supplier: LumiraDx in Denmark, Norway, and Sweden

Summary of an evaluation provided by SKUP

Conclusion

The WHO suggested minimum performance requirements of ≥80 % sensitivity and ≥97 % specificity compared to a reference assay were met by LumiraDx SARS-CoV-2 Ag test both for the nasal and nasopharyngeal samples when used under real-life conditions by the intended users. The quality goal for user-friendliness was fulfilled.

Background
The LumiraDx system is an in vitro diagnostic point of care device for detection of Severe Acute Respiratory Syndrome Coronavirus 2 antigen (SARS-CoV-2 Ag) in nasal and nasopharyngeal swab specimens. The system is intended for professional use. LumiraDx is manufactured by LumiraDx UK Ltd. and the Ag test was launched into the Scandinavian market November 2020. This SKUP evaluation was carried out from October to December 2020 at the request of LumiraDx AS in Norway.

The aim of the evaluation
The aim of the evaluation was to assess the diagnostic performance and user-friendliness of LumiraDx SARS-CoV-2 Ag test when used under real life conditions by intended users in a dedicated Covid-19 testing centre.

Materials and methods
One nasal and two nasopharyngeal swab samples were taken at the same time from 450 subjects at Bergen Accident and Emergency Clinic. The subjects, 16 years or older, had been exposed to an individual who had previously tested positive for SARS-CoV-2. The nasal swab and one of the nasopharyngeal swabs were used for measurement with LumiraDx SARS-CoV-2 Ag Test, and the other nasopharyngeal swab was sent to the clinical microbiology laboratory at Haukeland University Hospital for measurement on an in-house RT-PCR comparison method. The diagnostic performance of the test was discussed related to present literature, mainly World Health Organization (WHO) recommendations. 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 among the participants in this evaluation was 18,5 %. The overall diagnostic sensitivity of LumiraDx SARS-CoV-2 Ag Test was 87 % for the nasal samples and 90 % for the nasopharyngeal samples. Of the 11 false negative nasal results and the eight false negative nasopharyngeal results, five and four participants, respectively, had ct values ≥33. The diagnostic specificity was 99,5 % for the nasal samples and 97,8 % for the nasopharyngeal samples. The positive predictive values of the test were 97 % for the nasal samples and 90 % for the nasopharyngeal samples. The negative predictive values of the test were 97,1 % for the nasal samples and 97,8 % for the nasopharyngeal samples. The user-friendliness was rated as satisfactory.

Comments from LumraDx AS
A letter with comments from LumiraDx AS is attached to the report.

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