LumiraDx SARS-CoV-2 Ag Test: asymptomatic specificity

The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in nasal swab and nasopharyngeal swab samples. Samples are collected from individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals. The Test aids in the diagnosis of current SARS-CoV-2 infection by detection of SARS-CoV-2 antigen.

Presented below is a summary of studies on asymptomatic subjects and the specificity (negative agreement vs PCR) of the LumiraDx SARS-CoV-2 Ag Test in these populations.

Asymptomatic at-risk key workers

A study of 98 key workers was conducted in the UK during the COVID-19 pandemic in July 2020. Subjects aged 19-63 (46 female, 52 male), were recruited and nasal swab samples collected and extracted in extraction buffer[1]. Samples were tested fresh within 1 hour of collection and tested according to the Product Insert. The performance of the LumiraDx SARS-CoV-2 Ag Test was compared to the results from nasal swab samples, collected into 3ml universal transport medium (UTM) and tested with an Emergency Use Authorization (EUA) PCR method, Roche Cobas 6800. Of the 98 samples tested, one false positive was detected. The resulting negative percent agreement (NPA) versus the PCR method was 99.0 %.

Asymptomatic subjects

A study of 256 asymptomatic subjects was conducted during September-November 2020 in the USA, during the COVID-19 pandemic[1]. Subjects reported no symptoms, and had been in contact with COVID-19 positive family member or co-worker. Samples were tested fresh within 4 hours of collection and tested according to the Product Insert. The performance of the LumiraDx SARS-COV-2 Ag Test was compared to the results from nasal swab samples, collected into 3ml universal transport medium (UTM) and tested with an EUA method – Thermo Fisher. Of the 244 samples tested negative by PCR, there were no false positive results detected. The resulting negative percent agreement (NPA) versus the PCR method was 100 %.

Asymptomatic and symptomatic subject cohort

404 subjects were included in a Quality Improvement Study conducted by the University of Edinburgh/ Edinburgh Royal Infirmary during October 2020[1,2]. Subjects were symptomatic staff or asymptomatic pre-surgery patients who attended a drive-in testing centre. Nasal throat samples were taken for reference PCR analysis (Seegene, Abbott or Altona SARS-CoV-2 RT-PCR) and nasal swab specimens were collected for analysis with the LumiraDx SARS-CoV-2 Ag Test. There were 369 negative subjects in this study, and statistical analysis demonstrated 99 % NPA versus the PCR reference methods.

1. S-CLIN-REP-00014. LumiraDx SARS-CoV-2 Antigen Clinical Study Report.
2. S-CLIN-REP-00031. Lothian Drive Through Study with SARS-CoV-2 Ag Test