Automated checks of the correct functioning of the Instrument Standard nasopharyngeal swab collection equipment. Please
LumiraDx SARS-CoV-2 Ag Test Quick Reference Instructions
RFID (Radio frequency ID) Tag held inside the Test Strip carton < 0.01%
Authorized laboratories must collect information on the
Authorized laboratories using your product must have a process
If the differentiation of specific SARS viruses and strains is
Be careful to minimize the risks of cross-contamination when
Do not mix components from different kit lots.
Test results should be considered in the context of all available
For serial testing programs, additional confirmatory testing with a
recent exposures, history and presence of clinical signs and symptoms
and should not be used as the sole basis for treatment or patient
may not be the definite cause of disease. Laboratories within the
out bacterial infection or co-infection with other viruses. Additional

The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic
ONLY
used with the LumiraDx Platform. The LumiraDx Platform is a point of

Materials required but not provided with the Test Strip carton:

Performing a Test

Handling the Test Strips:

Instructions for sample collection:

Fig 2: Positive result for

Limitations

Comparison of the test results to the viral culture results performed on the same sample.
Viral culture results have the highest level of performance and may or may not correlate with
viral culture results on the same sample.

The LumiraDx Instrument and LumiraDx SARS-CoV-2 Ag Test Strips have
an error message will be shown
status or error and an instruction.

Alert messages
be displayed on the Instrument

The LumiraDx SAR-CoV-2 Ag Test is a single use fluorescence

Case reports indicate that this test may have an increased risk of false positive results when:

The test results are not to be used for the diagnosis or management of COVID-19.

Participants in the study were randomised using a 1:1 allocation to one of the two test methods.

The test results may be used to support the diagnosis or management of COVID-19.

The test results are not to be used for the diagnosis or management of COVID-19.

The test results may be used to support the diagnosis or management of COVID-19.

The test results may be used to support the diagnosis or management of COVID-19.

The test results are not to be used for the diagnosis or management of COVID-19.

The test results may be used to support the diagnosis or management of COVID-19.

The test results are not to be used for the diagnosis or management of COVID-19.
The performance of the SARS-CoV-2 Ag Test was established with 255 nasopharyngeal swabs prospectively collected from individual subgroups of 22 to 59 years, ≤ 5 years, and ≥ 60 years. Each subgroup was selected to ensure representative age distribution. Of all swabs, 67% were positive for SARS-CoV-2 RNA by RT-PCR. The positive results broken down by age of the patient:

- 22 to 59 years: 85% positive
- ≤ 5 years: 75% positive
- ≥ 60 years: 50% positive

The LoD of the LumiraDx SARS-CoV-2 Ag Test was then confirmed by testing 20 replicates with concentrations at the tentative Limit of Detection (LoD) and the tentative Limit of Quantitation (LoQ). The results showed that the test accurately detected SARS-CoV-2 RNA with high sensitivity and specificity. The results also showed that the test was robust against endogenous interference and high dose hook effect.

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2 at which 100% of all (true positive) results were observed. Final data analysis is presented below:

- LumiraDx: 0.35 mg/dL
- Zeptometrix: 3 mg/dL

The test was also evaluated for cross-reactivity with other respiratory viruses and bacteria, such as influenza A H3N2 (Wisconsin/67/05), Mycobacterium tuberculosis, Pseudomonas Aeruginosa, Parainfluenza virus Type 3, Legionella pneumophila, Mycoplasma pneumoniae, Streptococcus Salivarius, Staphylococcus aureus, Bordetella pertussis, and 100% of these organisms were tested in the absence or presence of heat inactivated SARS-CoV-2 at 3 x LoD.

Endogenous interference studies were conducted to evaluate the impact of interferons on test performance. No impact on test performance or high dose hook effect was observed up to 1.4 x 10^4 for interferons. The starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. The interference was ruled out.

The results showed 68 sequence IDs, mostly nucleocapsid protein, showing homology. Sequence ID AAR87518.1, had the highest alignment for the Wuhan-Hu-1 reference strain. The results also showed 30 sequence IDs, all nucleocapsid protein, showing homology. Sequence ID AGW27840.1 had the highest alignment for the B.1.1.529 variant. These comparative tests were conducted by the National Institutes of Health (NIH) as a part of Omicron Testing.

The LumiraDx Instrument, Test Strips and all provided LumiraDx documentation ('Products') are protected by law. The Intellectual Property Rights (IPRs) of the 'Products' are the property of their respective owners.

For more information, please visit www.who.int.