LumiraDx SARS-CoV-2 Antigen (Ag) Test: Superior analytical sensitivity compared to several lateral flow tests

Background:

Since COVID-19 significantly affects global health and public life, reliable detection of SARS-CoV-2 infections is of major importance. The LumiraDx SARS-CoV-2 Ag Test is a microfluidic immunofluorescence assay for the direct and qualitative detection of nucleocapsid protein (antigen) in nasal and nasopharyngeal swab specimens from individuals suspected of COVID-19 or asymptomatic individuals. Presented below is a summary of four publications that verified the superior analytical performance of the LumiraDx SARS-CoV-2 Ag Test compared to lateral flow antigen tests in independent laboratory studies and one meta-analysis.

Independent technical validation conducted by the Swiss Society for Microbiology [1]

This study analysed 300 (200 SARS-CoV-2 negative, 100 positive) nasopharyngeal samples collected into Amies buffer, on the Roche Cobas 6800 rt-PCR, the LumiraDx SARS-CoV-2 Ag Test, and the Standard Q COVID-19 Rapid Antigen Test from SD Biosensor/ Roche. To analyse the same sample with each of the tests, the experimental procedure was adjusted consequently resulting in an off-label methodology for the LumiraDx SARS-CoV-2 Ag Test.

The analysis revealed a higher analytical sensitivity of the LumiraDx SARS-CoV-2 Ag Test compared to the SD Biosensor/ Roche test at higher Ct values (which correlate with lower viral loads). E. g. at Ct ≤ 29 the sensitivity was 98.7% for the LumiraDx Ag Test and 92.0% for the SD Biosensor/ Roche test. The specificity was 99% for both antigen tests compared in the study. Furthermore, the superior performance of the LumiraDx SARS-CoV-2 Ag Test was confirmed by the analysis of serially diluted samples, where the LumiraDx SARS-CoV-2 Ag Test detected samples, diluted 2-titer higher than those detected by the reference method.

Comparative clinical performance of four SARS-CoV-2 rapid antigen tests [2]

This study compared the LumiraDx SARS-CoV-2 Ag Test in an off-label methodology with 3 other SARS-CoV-2 antigen tests (RIDA® QUICK SARS-CoV-2 Antigen (R-Biopharm), SARS-CoV-2 Rapid Antigen Test (Roche), and NADAL® COVID-19 Ag Test (Nal von Minden GmbH)). This was a laboratory validation using nasopharyngeal swabs collected into phosphate buffered saline (PBS) from subjects at any stage of infection status, regardless of symptom onset day. In addition, viral culture samples were tested using samples diluted with test extraction buffer.

The study demonstrated that the LumiraDx SARS-CoV-2 Ag Test was the most sensitive test using these samples when compared to rt-PCR (Roche Cobas 6800 SARS-CoV-2), and that the sensitivity and specificity of the test in the proposed infectivity range (>6 $\log_{10}$ RNA copies/ml) was 100%. The limit of detection for infective virus was the lowest determined for the 4 tests (5.979 $\log_{10}$ RNA copies/ml). The study further states that antigen tests are better aligned with cell culture-based testing for infectivity than rt-PCR and indicated that LumiraDx SARS-CoV-2 Ag Test detected more of the cell culture positive samples compared to the other tests.

LumiraDx SARS-CoV-2 Antigen Test shows superior analytical sensitivity to competitors [3]

In this study a head-to-head comparison of the LumiraDx SARS-CoV-2 Ag Test to the Abbott PanBio and the SD Biosensor Standard Q lateral flow antigen tests was performed, using off-label methodology. Serial dilutions of isolates from three different SARS-CoV-2 viral cultures were further diluted 1:1 with the supplied extraction buffers of the tests and analysed. The viral content of the samples was determined by a Plaque-Forming-Assay, giving the results in Plaque-Forming-Units (PFU).

The study demonstrated that LumiraDx SARS-CoV-2 Ag Test had superior analytical sensitivity than Abbott PanBio or SD Biosensor (2.1-55.6 PFU vs. 52.9-1428.6 PFU and 8.8-238.1 PFU, respectively).

Systematic review and meta-analysis revealed that the LumiraDx SARS-CoV-2 Ag Test performed best among 61 antigen rapid diagnostic tests (RDT's) [4]

The authors conducted a systematic review and meta-analysis, based on the search results up until 30 April 2021, including a total of 133 clinical and analytical accuracy studies. This meta-analysis was performed to create an up-to-date summary of the performance of RDT's in order to inform decision makers about the best test to choose. In this meta-analysis, the overall performance based on all published datasets was calculated per RDT.

Out of all 61 assessed tests, the LumiraDx SARS-CoV-2 Ag Test showed the highest overall sensitivity.

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References:

(1) Report of the „Bundesamt für Gesundheit" Switzerland 2020 (available upon request)

(2) Kohmer et al.,J Clin Med. 2021 Jan; 10(2): 328.(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7830733/)

(3) Krüger et al., Infection. 2021 Aug 12 : 1–12. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8358901/)

(4) Brümmer et al., PLoS Med. 2021 Aug; 18(8): e1003735. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8389849/)

Regulatory status of the LumiraDx SARS-CoV-2 Ag Test in the US:

In the USA, the SARS-CoV-2 Antigen Test product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.