Performance evaluation of a rapid point-of-care microfluidic immunofluorescence assay for the detection of SARS-CoV-2 antibodies

The LumiraDx SARS-CoV-2 Antibody (Ab) Test is a point-of-care (POC) test that uses a rapid, high sensitivity microfluidic immunofluorescence assay to qualitatively detect total antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The test was evaluated for clinical agreement using samples with real-time polymerase chain reaction (RT-PCR)-confirmed SARS-CoV-2 infection status across POC settings.

Methods

Plasma samples from participants (≥18 years) were collected from clinical studies and commercial suppliers for positive and negative agreement analysis. Matrix equivalency was determined using donor whole blood, plasma and serum samples spiked with immunoglobulin (Ig) M and IgG. Cross-reactivity was analysed using samples with known related and high-prevalence pathogens. Fingerstick application with capillary blood (applied directly or using transfer tube) from participants (≥18 years) was analysed following RT-PCR testing. Application was performed by untrained users and ease of use of the LumiraDx SARS-CoV-2 Ab Test was investigated.

Results

An overall positive agreement of 97.2% (95% confidence interval (CI): 90.4, 99.2%; n=72) was determined in samples obtained ≤118 days following RT-PCR testing, and 100% (n=59) in a subset obtained ≥7 days following RT-PCR testing. Samples from participants without a history of SARS-CoV-2 infection (endemic symptomatic, asymptomatic and non-endemic participants) showed an overall negative agreement of 100% (95% CI: 98.7, 100%; n=290) with RT-PCR testing. Matrix equivalency demonstrated 100% agreement and no cross-reactivity with any of the tested pathogens; 100% agreement was observed between capillary fingerstick application and RT-PCR results, as well as between sample application methods. Test operators indicated that the LumiraDx SARS-CoV-2 Ab Test was easy to use.

Conclusion

The LumiraDx SARS-CoV-2 Ab Test demonstrated excellent agreement when compared with RT-PCR test results, using capillary and venous whole blood, plasma and serum. This study reported 97.2% positive and 100% negative agreement overall in samples collected after RT-PCR testing, and 100% positive agreement in samples obtained at least 7 days after RT-PCR confirmation when using the LumiraDx SARS-CoV-2 Ab Test.

The LumiraDx SARS-CoV-2 Ab Test has achieved CE mark. The data represented in this document is only applicable to the CE marked product.

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