Quantitative point-of-care device for serological testing of anti-SARS-CoV-2 IgM

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The pandemic caused by SARS-CoV-2 has originated a boom in the research and development of in-vitro diagnostic tests, of both virological and serological nature. Among the different solutions in the market, point-of-care (PoC) tests are becoming essential tools in expedite patient management. Current PoC technologies for antibody testing such as lateral flow immunoassays (LFIA) are mostly qualitative or semi-quantitative and suffer from lower sensitivities (66.0%) in comparison with central laboratory methods, such as enzyme-linked immunosorbent assays (ELISA) and chemiluminescence immunoassays (CLIA) (84.3% and 97.8%, respectively) [1]. We propose a portable device with disposable chips for diagnosis and monitorization of the serological response to Covid-19. The device is composed of a portable electronic reader and disposable biochips with an array of magnetic sensors. Magnetic markers coupled to on-chip magnetic attraction were used to allow an increased sensitivity (below µg/mL) of assays in short times [2]. The proposed technology has been validated for various clinical applications [2,3]. Major assets include, low cost (< 10€/test), multiplex (6 probes/test) and fast time to results (< 1 h). A sandwich immunoassay format was implemented with SARS-CoV-2 spike1 glycoprotein immobilized on the surface of the biochip, while magnetic particles conjugated with secondary anti-human IgM antibodies were used to label and capture the target IgM. A calibration curve was obtained for commercially acquired human anti-SARS-CoV-2 IgM antibodies with a sensitivity down to 1 ng/mL. A linear range between 1 ng/ml and 10 µg/ml was obtained, which is in the clinically relevant range of IgM prevalence (<10 µg/ml). The proven high sensitivity when compared with LFIAs, combined with portability, user-friendliness and wider dynamic range when compared to ELISA and CLIA makes it a promising alternative. Validation of the portable detection system for clinical use will be performed using serum samples provided by infected patients. IgG and IgA calibration curves are also being obtained to allow for the full range evaluation of the serological panel.

REFERENCES

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FIGURE

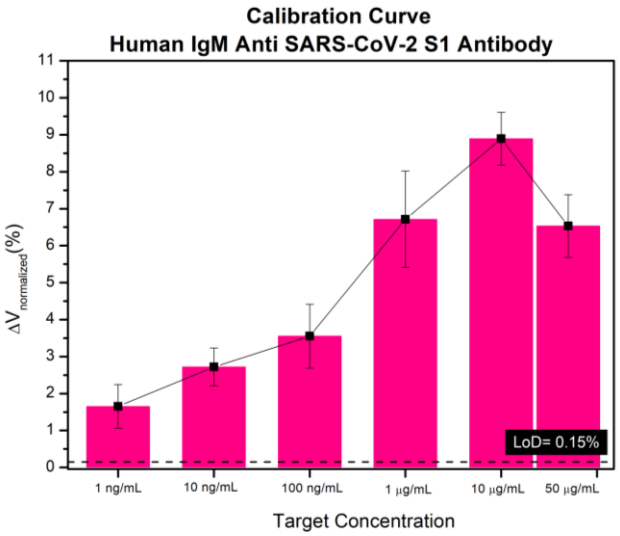

Figure 1: Calibration obtained in the MR-platform for human IgM anti-SARS-CoV-2 S1 antibody.