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ORIGINAL ARTICLE

Accuracy of the serological detection of IgG and IgM to SARS-Cov-2: a prospective, cross-sectional study

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Abstract

In response to the rapidly evolving of SARS-CoV-2 infection, numerous serological tests have been developed but their sensitivity and specificity are unclear. We collected serum samples of patients and health-care professionals to assess the accuracy of chemiluminescent (CLIA) and two lateral flow immunochromatographic assays (LFIA) to determine IgG and IgM antibodies to SARS-CoV-2 virus. We calculated the φ correlation for qualitative results and test accuracy, adopting the following case definition: either real-time-PCR positivity or serological positivity with at least two different tests. We analyzed 259 samples, obtaining strong correlation between CLIA and both LFIA for IgG (φ=0.9), and moderate correlation for IgM (φ=0.6). For patients, the sensitivity was suboptimal for all methods (CLIA 81%, LFIA A 85%, LFIA B 78%), while it was poor in asymptomatic health-care workers (CLIA 50%, LFIA A 50%, LFIA B 33%). Overall, CLIA is more sensitive and specific for the determination of both IgG and IgM, whilst both LFIA methods reported good sensitivity and specificity for IgG, but scarce sensitivity for the IgM determination. The determination of SARS-CoV-2-specific IgG is useful to detect infection 6 days from symptom onset.

Keywords SARS-CoV-2 · COVID-19 · Accuracy · IgG to SARS-CoV-2 · IgM to SARS-CoV-2

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