SARS-CoV2 serology assays: utility and limits of different antigen based tests through the evaluation and the comparison of four commercial tests

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Abstract

Introduction: SARS-CoV2 serology testing is multipurpose provided to choose an efficient test. We evaluated and compared 4 different commercial serology tests, three of them had the Food and Drug Administration (FDA) approval. Our goal was to provide new data to help to guide the interpretation and the choice of the serological tests. Methods: Four commercial tests were evaluated: Cobas®Roche®(total anti-N antibodies), VIDAS®Biomerieux®(IgM and IgG anti-RBD antibodies), Mindray®(IgM and IgG anti-N and anti-RBD antibodies) and Access®Beckman Coulter®(IgG anti-RBD antibodies). Were tested: a positive panel (n=72 sera) obtained from COVID-19 confirmed patients and a negative panel (n=119) of pre-pandemic sera. Were determined the analytical performances and was drawn the ROC curve to assess the manufacturer's threshold. Results: A large range of variability between the tests was found. Mindray®IgG and Cobas® tests showed the best overall sensitivity 79,2%CI95%[67,9-87,8]. Cobas® showed the best sensitivity after D14; 85,4%CI95%[72,2-93,9]. The best specificity was noted for Cobas®, VIDAS®IgG and Access® IgG(100%CI95%[96,9-100]). Access® had the lower sensitivity even after D14 (55,5% CI95%[43,4-67,3]). VIDAS®IgM and Mindray®IgM tests showed the lowest specificity and sensitivity rates. Overall, only 43 out of 72 sera gave concordant results (59,7%). Retained cut-offs for a significantly better sensitivity and accuracy, without altering significantly the specificity, were: 0,87 for Vidas®IgM(p=0,01), 0,55 for Vidas®IgG(p=0,05) and 0,14 for Access®(p<10-4). Conclusion: Although FDA approved, each laboratory should realize its own evaluation for commercial tests. Tests variability may raise some concerns that seroprevalence studies may vary significantly based on the used serology test.

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