

New aspects and possible applications for antibody detection with Mikrogen's *recomLine* SARS-CoV-2 IgG test

Dear partner,

The novel coronavirus SARS-CoV-2 has been dominating our scientific and social life for more than a year. The significance of serology in SARS-CoV-2, outside of the epidemiological perspective, is not clearly understood at present, which is why the humoral immune response is of central interest in numerous studies. The resulting information will allow us to review and expand the potential applications for serological testing. For this reason, please find enclosed a short summary of interesting aspects from recent publications concerning the *recomLine* SARS-CoV-2 IgG from MIKROGEN.

Antigen-specific detection of SARS-CoV-2 IgG antibodies – Enables very good test performance and differentiated assessment of the immune response

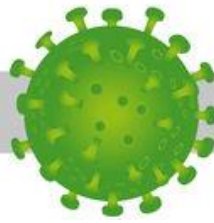
The *recomLine* SARS-CoV-2 IgG immunoassay uses different immunodominant diagnostic markers (nucleocapsid protein (NP) and subunits (S1 and RBD) of the spike protein). The layout of the assay thus allows the identification of specific antibodies against each of the SARS-CoV-2 specific antigens.

The test was extensively validated in a study and compared with NP- and S1-based screening assays. It showed excellent agreement with respect to the overall result and also with respect to reactivity to the specific SARS-CoV-2 antigens (1). Thus, the test is a useful tool for clarifying borderline or discrepant screening results and for antigen-specific detection of SARS-CoV-2 IgG antibodies. In another large comparative study using numerous commercial SARS-CoV-2 antibody tests, the *recomLine* SARS-CoV-2 IgG also showed very good correlation with the other systems as well as with a neutralization assay (2). Another article confirmed the test to have higher specificity and also better sensitivity than mono-antigenic screening assays (3). In addition, the simultaneous detection of antibodies to multiple antigens allows a better and more detailed assessment of the competence of the humoral immune response. The test can be used both for confirmation and directly as an entry test. The combination of a highly specific IgG antibody test (line assay) and a cellular test system is recommended here to assess the immunity situation against SARS-CoV-2.

Detection of antibodies against seasonal coronaviruses (HCoV) – Influence of HCoV-specific antibodies on the severity of COVID-19 disease and potential applications

In addition to SARS-CoV-2 specific antibodies, the *recomLine* SARS-CoV-2 IgG detects antibodies directed against the NP antigen of seasonal coronaviruses (HCoV: 229E, NL63, OC43, HKU1).

In a pilot study from Muenster, Germany (4), using the assay, it was shown that patients with critical COVID-19 disease had significantly lower titers of OC43- and HKU1-specific antibodies than patients with milder courses. This correlation of severity of COVID-19 disease and HCoV antibody titers was confirmed in a larger follow-up study with samples from different centers in Germany and France (5). Prior infection with seasonal coronaviruses, specifically OC43, may therefore be protective against a severe course of COVID-19. For this reason, the authors recommend the detection of anti-OC43 antibodies in hospitalized COVID-19 patients as part of risk assessment or, if necessary, for determining prioritization for vaccination.



Significance of avidity maturation of SARS-CoV-2 specific antibodies – correlation with severity of COVID-19 disease and possible relevance for immunity

Avidity determination of SARS-CoV-2 and HCoV-specific antibodies is possible with the *recomLine* SARS-CoV-2 IgG for research purposes. Corresponding instructions and evaluation software are available from MIKROGEN.

Due to the highly variable immune response, the establishment of avidity determination for SARS-CoV-2 infection has been recommended (6). In addition to improving serologic diagnosis, this could allow differentiation between cross-reacting coronaviruses, analysis of reinfection with SARS-CoV-2, and determination of the quality of immune status after future immunization programs. In a study on the kinetics of neutralizing and antigen-specific IgG antibodies, avidity maturation of progression sera was determined using the *recomLine* SARS-CoV-2 IgG (2). Only a subset of patients showed classical maturation to high-avidity IgG antibodies against different SARS-CoV-2 specific antigens. This is supported by another study, which was able to show that during the course of infection there is often a discontinuation of avidity maturation. (7). The development of high-avidity IgG antibodies also usually correlates with high IgG titers and a more severe COVID-19 disease. Based on the resulting hypothesis that only individuals who develop high-avidity antibodies to SARS-CoV-2 are protected from reinfection, avidity determination may be of critical importance in verifying vaccination success in the wake of immunization initiatives currently being launched worldwide.

References

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