BioMARIC

BioMARIC SARS-CoV-2 Total Ab ELISA (CE-IVD)

Reference

BM501-1.0

User friendly

Short assay

Ready-to-use diluents

Colour coded

Sample addition monitoring

Reliable

Superior performance

BioMARIC SARS-CoV-2 Total Ab ELISA is an Enzyme-Linked Immunosorbent Assay for the *in vitro* qualitative detection of IgM/IgA/IgG antibodies to the receptor binding domain (RBD) of SARS-CoV-2 spike protein in human serum and plasma (EDTA, heparin and citrate) samples.

It can be used, in conjunction with other diagnostic tests, for identifying patients with an adaptive immune response to SARS-CoV-2, indicating a prior infection with the virus.

Studies have demonstrated that RBD-specific antibody concentrations are directly correlated with SARS-CoV-2 neutralizing antibodies in patients[1]. Therefore, this assay can also be used as a screening tool for detecting the presence of anti-SARS-CoV-2 antibodies to determine the persons' immune status.

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CE IVD

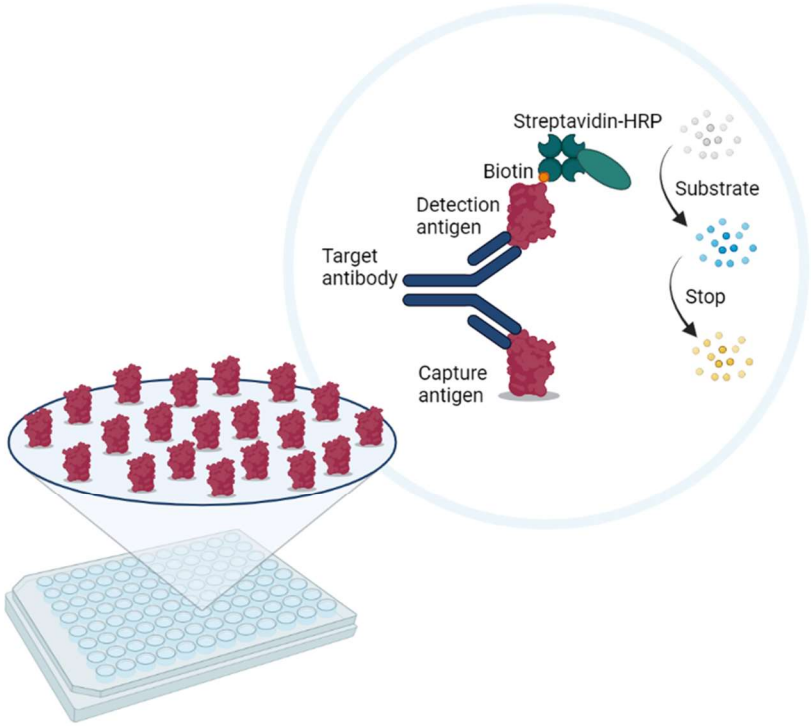
Assay Principle

Step 1 (30 minutes)
Coated RBD and biotinylated RBD form a sandwich-like immune complex with antibodies in the patient sample. Unbound biotinylated RBD is washed away.

Step 2 (30 minutes)
HRP-labelled streptavidin binds the immune complex through the interaction of biotin with streptavidin. Unbound streptavidin is washed away.

Step 3 (30 minutes)
Peroxidase metabolizes the substrate to develop a blue colour in proportion to the amount of antibodies present in the sample.

Step 4 (5 minutes)
Colour development is stopped by acidification, turning the blue colour of the solution to yellow. The absorbance is measured at 450 nm.



Assay Performance

Diagnostic Specificity *4 different countries (#352 samples)*	**100,0%*** *(95% CI: 99,0%-100,0%)*
Diagnostic sensitivity *>14 days after onset of symptoms (#126 samples)*	**99,2%*** *(95% CI: 95,7%-100,0%)*
Cross-reactivity *infections with common coronaviruses (HKU1, NL63, OC43 and 229E), other respiratory and other potentially cross-reacting pathogens (#34 samples)*	**no cross-reaction***
Interference *potentially interfering substances such as lipids, red blood cells, rheumatoid factor, bilirubin (#32 samples negative and 20 samples positive for SARS-CoV-2 Ab)*	**no interference***
Limit Of Detection (LoD) *SARS-CoV-2 Ab WHO International standard 20/136*	**1,64 IU/ml***
Agreement with Performance panels *Standard Performance Panels WHO 20/268, 20/B770 and EURM-017 +18*	**100,00%***

** Details can be found in the instructions for use of the BioMARIC SARS-CoV-2 Total Ab ELISA*

1 Gorbalenya, A.E., Baker, S.C. *et al.* The species Severe acute respiratory syndrome-related coronavirus: classifying 2019-nCoV and naming it SARS-CoV-2. Nat Microbiol 5, 536–544 (2020).

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