



Biotech for Medicine

BioMARIC SARS-CoV-2 Anti-NP ELISA (CE-IVD)

Reference

BM502-1.0

User friendly

Short assay

Ready-to-use diluents

Colour coded

Sample addition monitoring

Reliable

Superior performance

BioMARIC SARS-CoV-2 Anti-NP ELISA is an Enzyme-Linked Immunosorbent Assay for the semi-quantitative detection of IgM/IgA/IgG antibodies to Nucleoprotein (NP) of SARS-CoV-2 in human serum and plasma (EDTA, heparin and citrate) samples.

It can be used, in conjunction with other diagnostic tests, to identify patients with an adaptive immune response to SARS-CoV-2 upon infection.

As the majority of the currently available vaccines induce an anti-S protein neutralizing antibody response, the BioMARIC SARS-CoV-2 Anti-NP ELISA can be used to discriminate between infection-induced and vaccination-induced immunity¹.





Assay Principle

Step 1 (30 minutes)

Coated NP and biotinylated NP form a sandwich-like immune complex with antibodies in the patient sample. Unbound biotinylated NP is washed away.

Step 2 (30 minutes)

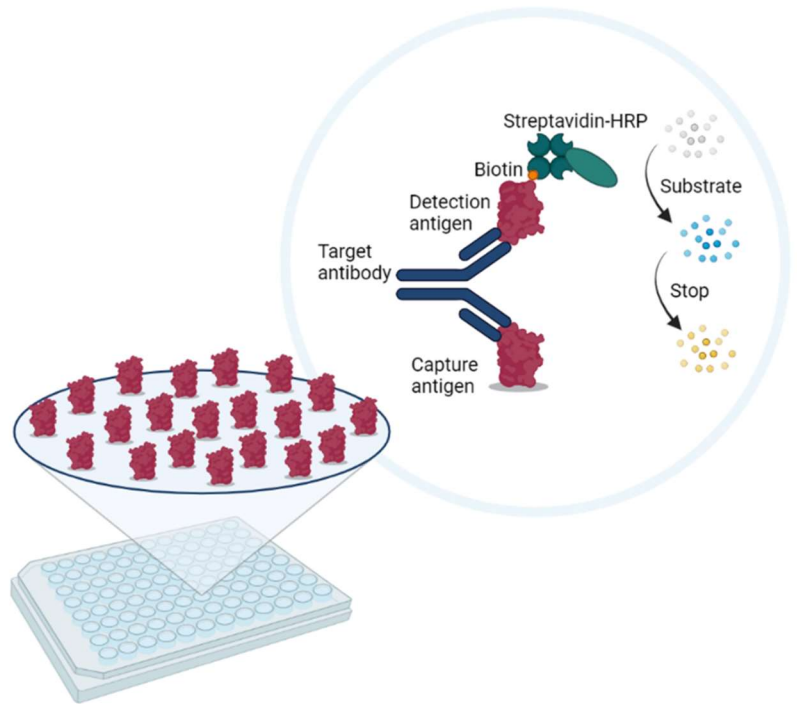
HRP-labelled streptavidin binds the immune complex through the interaction of biotin with streptavidin. Unbound streptavidin is washed away.

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	98,9%* (95% CI: 99,0%-100,0%)
4 different countries (#448 samples)	
Diagnostic sensitivity	100%* (95% CI:95,7%-100,0%)
>14 days after onset of symptoms (#127 samples)	
Cross-reactivity	no cross-reaction*
common coronaviruses (HKU1, NL63, OC43 and 229E), other respiratory and other potentially cross-reacting pathogens (#38 samples)	
Interference	no interference*
potentially interfering substances such as lipids, red blood cells, rheumatoid factor, bilirubin (#31 samples negative and 30 samples positive for SARS-CoV-2 Ab)	
Limit Of Detection (LoD)	1,2 IU/ml*
SARS-CoV-2 Immunoglobulin Working Reagent NIBSC 21/234	
Agreement with Performance panels	100,00%*
Standard Performance Panels WHO 20/268, 20/B770 and EURM-017 +18	

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

1 Ong DSY, Fragkou PC, Schweitzer VA, Chemaly RF, Moschopoulos CD, Skevaki C; European Society of Clinical Microbiology and Infectious Diseases (ESCMID) Study Group for Respiratory Viruses (ESGREV). How to interpret and use COVID-19 serology and immunology tests. Clin Microbiol Infect. 2021 Jul;27(7):981-986. doi: 10.1016/j.cmi.2021.05.001. Epub 2021 May 8. PMID: 33975005; PMCID: PMC8106522.

