



COVID-19 Antibody Test

Realy Tech Rapid Test Device

Serological testing for the presence of IgG and IgM antibodies against SARS-CoV-2 is an important step to determine if an individual has had prior exposure to the virus which causes Covid-19.¹

The Realy Tech Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of IgG & IgM antibodies specifically against SARS-CoV-2 in human whole blood, serum or plasma.



Product Features

- Point-of-care finger prick test
- CE marked
- Manufactured by Hangzhou Realy Tech, China
- Independently validated using positive & negative blood samples against CMI reference method
- **Sensitivity** IgG 99%, IgM 98%
- **Specificity** IgG 100%, IgM 99%
- 10-15 minute result
- Virus Tracing App included
- €32 per test ex VAT (volume based discounts available)

**Virus
Tracing App
Included**

Clinical Evidence

The Realy Tech Rapid Test Device has been independently clinically validated and has shown very high levels of Sensitivity, (IgG 99%, IgM 98%)² and Specificity (IgG 100%, IgM 99%)³ indicating it's suitability as a reliable test method.

The test has also been analytically validated with favourable results for precision, stability, robustness and cross reactivity, among others.⁴ The test has been produced in an ISO13485 approved factory and carries the CE mark of approval. In accordance with the European Commission working document on the performance of Covid-19 test methods, (16th April 2020) the most critical performance parameter for identifying persons who have developed an immune response against SARS CoV-2 is diagnostic specificity.⁵ The Realy Tech Rapid Test Device performs strongly against the European guideline with Specificities of 99% IgM and 100% IgG, thereby minimising the possibility of false positive test results.⁶

References:

1. NPHET Subgroup – Diagnostic Testing Approaches: A Strategic Framework (May 22nd 2020)
- 2,3,6. Clinical validation report of COVID-19 IgG/IgM Rapid Test (Colloidal Gold) by the Shijiazhuang Municipal Centre For Disease Control And Prevention. (March 4th 2020)
4. Analytical validation study on Realy Tech COVID-19 IgG/IgM Rapid Test
5. Current performance of COVID-19 test methods and devices and proposed performance criteria. (European Commission 16th April 2020 working document)