HEALGEN


HEALGEN®
COVID-19 IgG/IgM Rapid Test Cassette
(Whole Blood/Serum/Plasma)


HEALGEN®
One Step Rapid Test
For in vitro diagnostic use only

COVID-19 IgG/IgM Rapid Test Cassette

FDA Emergency Use Authorized (EUA)

Qualitative detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in human whole blood, serum and plasma. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.

Features

Time to Result: 10 minutes

Specimen Volume: 5 µL (Serum/Plasma) 10 µL (Whole Blood)

IgM and IgG isotypes reported separately

Storage: 2-30°C (36-86°F)

Stability: 24 months from date of manufacture

Performance

Sensitivity

IgM 100%; IgG 96.7%; Combined 100%

Specificity

IgM 100%; IgG 97.5%; Combined 97.5%

This test has not been FDA cleared or approved.

This test has been authorized by FDA under an EUA for use by authorized laboratories.

Emergency Use of this test is limited to CLIA laboratories certified to perform moderate or high complexity tests.

This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Not for the screening of donated blood.