ADVAITE BGI

CLIA Waived

RapCov™ Rapid COVID-19 Test

Test is manufactured in FDA approved GMP facilities in USA.

For Emergency Use Authorization Only | For in vitro diagnostic use | Rx Only

Product Overview

The RapCov™ Rapid COVID-19 Test is a lateral flow immunoassay intended for the qualitative detection of immunoglobin G (IgG) antibodies to the SARS-CoV-2 virus in human fingerstick whole blood samples. The Test is intended for use to identify individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Samples should only be tested from individuals that are 15 days or more post symptom onset. Each box includes individually packaged test cassettes and individually sample collector pouches for 25 tests.

Testing of fingerstick whole blood specimens is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a that meet the requirements to perform high, moderate, or waived complexity tests. Testing of fingerstick whole blood specimens is also authorized for use at the Point of Care (POC), i.e., inpatient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Benefits

- Highly accurate: 93% overall test sensitivity and 100% test specificity
- Fast: Results in 15 minutes at the Point-of-Care (PoC)
- Know the status: Help determine recent or prior infection even when patients do not know it
- Understand disease prevalence: Aid investigation of ongoing outbreak
- No shipment delay: Manufactured in the USA and stocked locally

Request for Information or Quotation

Contact your BGI account representative for more information including product pricing.
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MADE IN USA

In the United States:
- This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
- This test has been authorized only for detecting the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of 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 Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated, or authorization is revoked sooner.

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