ISO
13485:2016

camtech
diagnostics

Camtech COVID-19 IgM/IgG Rapid Test Kit

Rapid Immunoassay for COVID-19 Infection
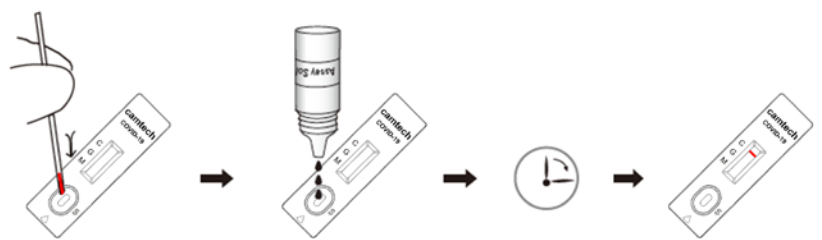
covid19-test.com

COVID-19 testing

The coronavirus outbreak has swept across the Globe evolving into a pandemic as declared by the WHO on the 12 March 2020. Diagnosis has been at the forefront of monitoring the spread of the disease and ensuring timely treatment, especially, for those who are most at risk.

The currently employed method for diagnosis relies on RT-PCR to identify viral-specific nucleotides. Although accurate, this approach is both time and labour intensive, moreover, requiring specialist training and equipment. Therefore, there is a need for an easy to use, rapid testing approach to provide timely treatment and identification of post-infection immunity in mild or asymptomatic cases.

FAST • RELIABLE • ACCURATE

- ◆ IgG and IgM in whole blood, serum and plasma

- ◆ Results in less than 20 minutes including sample preparation

- ◆ High sensitivity & specificity

- ◆ Only small amount of blood needed

- ◆ Manufactured under ISO 13485

ASSAY PROCEDURE & INTERPRETATION

Add 10 μl of serum / plasma or load 20 μl of whole blood

Add 2 drops (~60 μl) of assay buffer

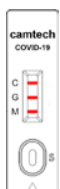Wait 15 minutes

Read and interpret the results

Negative | IgM positive | IgG positive | IgM/IgG positive | Invalid

Note: Please read under bright light. Even a faint line in the test region is noted to be positive.

LIMITATIONS & PRECAUTIONS

1. The test kit is intended to be used by a medical professional.

2. This test detects the presence of COVID-19 antibodies (IgM/IgG) in blood samples. As there may be a few days' delay between the viral infection and development of antibodies in an individual, any negative result from this test should not be used as sole basis to rule out COVID-19 infection. The negative results have to be carefully considered together with clinical presentations. Any positive result from this test should be confirmed with supplemental laboratory testing (e.g. RT-PCR).

3. Dispose gloves, swabs, test tubes, and the used strips properly after the test, in accordance with GLP.

4. Do not use the kit after the expiration date or more than 30 minutes after removing it from the sealed package. Do not re-use the test device.

5. The kit should be stored between 2°C to 30°C (36°F to 86°F).

COMPARISON WITH MOLECULAR TESTING

	MOLECULAR TESTING (RT-PCR)	CAMTECH COVID-19 IgM/IgG RAPID TEST KIT
Principle	Nucleic acid test of SARS-CoV-2	Antibody IgM/IgG detection in blood
Test time (incl. sample prep.)	> 2 hours	15-30 minutes
Test cost	Very expensive	Highly economical
Experimental complexity	Difficult, highly complex	Easy, simple to operate
Specimen	Throat, nasopharyngeal swab, sputum	Whole blood, serum, plasma
Advantages / Disadvantages	- Accurate at early stage - Difficult to detect latent stages of infection or post-infection. - Appropriate for early stage with limited cases of patients up to 100 patient load	- Possible to detect latent stages of infection or post-infection. - Appropriate 7 days after the onset of symptoms - Suitable for testing a large number of patients

PERFORMANCE DATA

PARAMETERS	PERFORMANCE
Analytical sensitivity (ELISA)	1.85 s/CO for IgM; 1.48 s/CO for IgG
Diagnostic sensitivity (Overall for IgM&IgG)	After Day 7 from symptoms onset: 87.5% After Day 10 from symptoms onset: 95% After Day 13 from symptoms onset: 100%
Diagnostic specificity	100% (using pre-pandemic samples)
Cross-reactivity	no cross-reactivity with other tested human coronaviruses (OC43, 229E, NL63, HKU1)

BOX CONTENTS

♦ 100 pieces of foil-pouched test devices

♦ 4 dropping bottles of assay solution

♦ Instruction manual

ORDERING INFORMATION

PRODUCT ID	PACKAGE	BOX SIZE (mm)
RTMG	100 tests / box	L 290 x W 200 x H 150

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