ISO 13485:2016

CE IVD

camtech biomedical

Camtech COVID-19 Viral Antigen Test Kit

Fluorescent 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.

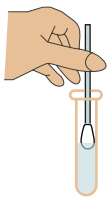
The kit uses a sandwich immunoassay to detect nucleocapsid (N) antigen from the SARS-CoV-2 virus, present during infection with COVID-19. As the test detects the viral particles themselves, it allows early detection and, therefore, screening of COVID-19. In contrast, detection of antibodies can only occur after the body has mounted a response to the virus and has to be performed several days after symptom onset.

FAST • RELIABLE • ACCURATE

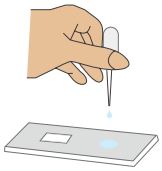
- Direct viral protein detection from oropharyngeal (throat) swab
- Results in less than 20 minutes including sample preparation
- High sensitivity (100 ng/ml)
- No cross-reaction with other coronaviruses
- Early alert of the infection, before antibody testing could be effective
- Manufactured under ISO 13485

ASSAY PROCEDURE & INTERPRETATION

Sample collection (oropharyngeal swab)



Rinse the swabbed sample into the buffer solution. This extract serves as test sample.



Transfer 5 drops (100 µl) of sample on the test card.

Wait 15 minutes and evaluate the result under UV light.

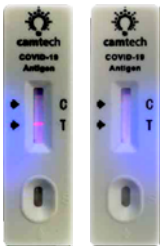
Negative result

Only control line (C) appears.

Positive result

Both control line (C) and test line (T) appear.

Test line, weaker in intensity compared to control line, is also considered positive.



Invalid result

Discard the test if no control line (C) or only test line (T) is visible.

Repeat the test with a new kit.

LIMITATIONS & PRECAUTIONS

1. The test kit is intended to be used by a medical professional.
2. Sample collection and processing methods have great impact on virus detection. Negative test results do not exclude the possibility of virus infection. If the test result is negative and the patient has clinical symptoms, it is recommended to use virus isolation and culture for confirmation, and a comprehensive diagnosis by the attending physician.
3. Avoid collecting saliva during sample taking.
4. The collected samples may be contagious, and the processing and testing operations of the samples should be performed in compliance with local relevant biosafety regulations.
5. The kit should be stored between 10°C to 25°C for a maximum of 12 months from the date of manufacturing.

COMPARISON WITH OTHER TESTING METHODS

	NUCLEIC ACID TESTING (PCR)	ANTIBODY DETECTION	ANTIGEN DETECTION
Assay time	> 1 hour	15 minutes	15 minutes
Specificity and sensitivity	good specificity, high sensitivity	lower specificity and sensitivity	good specificity, high sensitivity
Experimental complexity	difficult, trained personnel needed	easy, simple to operate	easy, simple to operate
Detection window from infection	early	late	early
Sample type	oro- or nasopharyngeal swab	whole blood, serum, plasma	oropharyngeal swab

PERFORMANCE DATA

PARAMETERS	PERFORMANCE
Diagnostic sensitivity and specificity - consistency with nucleic acid (PCR) test results	Positive coincidence rate (sensitivity): **88.66%** Negative coincidence rate (specificity): **94.55%**
Consistency coefficient (Kappa)	0.824
Cross-reactivity	No cross-reactivity with other tested human coronaviruses (OC43, 229E, NL63, HKU1). Minimal cross-reaction with the N protein of SARS-CoV.

BOX CONTENTS

- 50 pieces of foil-pouched test kits
- Sterile swab sticks
- Pre-filled vials with buffer solution
- Transfer pipette
- UV light source
- Instruction manual

ORDERING INFORMATION

PRODUCT ID	PACKAGE	BOX SIZE (mm)	WEIGHT (kg)
RTSVT	50 tests / box	L 290 x W 200 x H 150	2.2

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