Please read the instructions carefully before use.

COVID-19 Canea Rapid Test

CE

COVID-19 IgM/IgG Ab Rapid Test (Whole Blood, Serum, Plasma)
For In-vitro-diagnostic and professional use only!
In vitro rapid cassette for the qualitative detection of IgM and IgG antibodies against SARS-CoV-2 in human serum/plasma or whole blood.

INTENDED USE:

COVID-19 IgM/IgG Ab Test is used for qualitative detection of the IgM and IgG antibodies of COVID-19 in human serum/plasma or whole blood. The COVID-19 Ab Rapid Test is an aid in the diagnosis of patients with suspected COVID-19 infection in conjunction with clinical presentation and the results of other laboratory tests. Results of the COVID-19 Canea Rapid Test should not be used as the sole basis for diagnosis.
Normally, humans begin to produce antibodies about 1 week after being infected with novel coronavirus, that is, the positive rate of detection within 5 days after exposure to the source of infection is extremely low, the positive rate is about 80% at 2 weeks after infection and about 95% at 3 weeks, Antibody titers decreased significantly during the rehabilitation period, and there may be negative results. The false positive rate of uninfected samples is about 2%. Most of the coloration belongs to the grey area, that is, the T line is not obvious purplish red colour. Due to the complex immune system and the continuous variation of viral genes, the test results are for reference only and are not used as the basis for diagnosis.

INTRODUCTION:

CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. Evidence suggests transmission via fecal-oral route. 7 kinds of HCoVs caused humans respiratory diseases are found by now: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and 2019-nCoV which are the serious pathogens for human respiratory diseases. 2019-nCoV was found as the viral pneumonia. Its clinical manifestations are fever, enervate and systemic symptoms, with dry cough, difficult breathing etc. and it may aggravate severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolic disorders etc. and even life threatening rapidly.

PRINCIPLE:

This test kit uses anti-human IgM, IgG antibodies and goat anti-mouse IgG polyclonal antibodies that are respectively immobilized on a nitrocellulose membrane. It uses colloidal gold to label recombinant antigens of the SARS-CoV-2 (COVID-19) and mouse IgG. Using nano-colloidal gold technology and applying highly specific antibody-antigen reaction and immunochromatographic analysis technology principle.
When testing, the SARS-CoV-2 (COVID-19) IgM antibody in the sample combined with the colloidal gold-labelled SARS-CoV-2 (COVID-19) recombinant antigen to form a complex, which was then combined with the anti-human IgM monoclonal antibody coated in the T1 line during chromatography, at this time there is one red line in the T1. When the SARS-CoV-2 (COVID-19) IgG antibody in the sample combined with the colloidal gold-labelled SARS-CoV-2 (COVID-19) race antigen to form a complex, which is then combined with the anti-human IgG monoclonal antibody coated in the T2 line during the chromatography process. At this time there is one red line in the T2. When the samples do not contain SARS-CoV-2 (COVID-19) IgM and IgG antibodies, colloidal gold-labelled SARS-CoV-2 (COVID-19) recombinant antibodies cannot combine with anti-human IgM and IgG antibodies in the T1 and T2 line regions, so there is no red coloured line in the T1 and T2 lines. Regardless of the presence of SARS-CoV-2 (COVID-19) IgM and IgG antibodies in the sample, a red line will form in the control area (C). The red line appears in the control area (C) serves as:
1. Verification that sufficient volume is added.
2. That proper flow is obtained
3. And as a control for the reagents.

MATERIALS PROVIDED:

COVID-19 IgM/IgG Ab Test contains the following items to perform the assay:
1. COVID-19 IgM/IgG Test Cassette
2. Instruction for use
3. Buffer
4. Pipette

MATERIALS REQUIRED BUT NOT PROVIDED:

1. Clock or Timer
2. Sample container
3. Glove
4. Sterile lancet

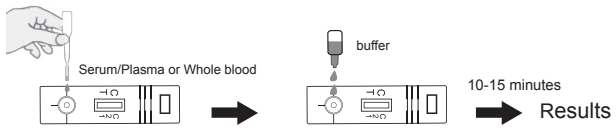
WARNING AND PRECAUTIONS:

1. Read instruction for use carefully before performing this test.
2. For in vitro diagnostic and professional use only.
3. Do not use the test cassette beyond the expiration date.
4. The test cassette should remain in the sealed pouch until use. Do not use the test cassette if the pouch is damaged or the seal is broken.
5. Do not reuse the cassette.
6. Treat and properly handle the specimens and used cassette as if they were potentially infectious. Dispose all specimens and used cassettes in a proper bio-hazard container. The handling and disposal of the hazardous materials should follow local, national or regional regulations.
7. Do not mix and interchange different specimens.
8. Wear disposable gloves, lab coat and eye protection while handling potentially infectious material and performing the assay. Wash hands thoroughly afterwards.
9. Clean spills thoroughly using an appropriate disinfectant.

SPECIMEN PREPARATION:

1. The specimen is human serum/plasma or whole blood, including clinical anticoagulants (EDTA, heparin, sodium citrate) origin prepared plasma or whole blood.
2. Fingertip blood samples should be tested immediately, serum, plasma, and anticoagulated whole blood are collected, stored at room temperature for no more than 36 hours, at 2° to 8° for no more than 3 months, serum/plasma can be stored at -20° for a long time. Deteriorated samples may affect the results.
3. Bring the specimen and test components to room temperature if refrigerated or frozen. Mix the specimen well prior to assay once thawed. The precipitate should be removed by centrifugation prior to the test if clearly visible particles existed in the specimen.
4. Do not perform the test if specimen includes massive lipid, hemolysis or turbidity against invalid test result.

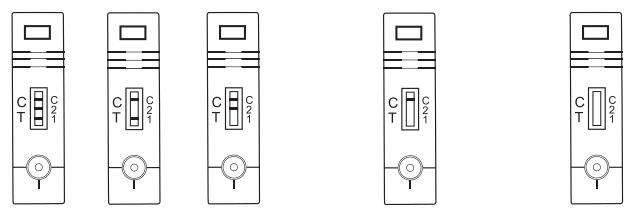
TEST PROCEDURE:



1. Dispense 1 drop of specimen to the sample well
2. Add 2 drops of buffer to sample well

Read the instruction first prior to testing. Bring the pouched test to room temperature prior to testing. Do not open the pouch until ready to begin testing.
1. Remove the test from the sealed pouch. Lay it on a flat, clean and dry surface.
2. Use the pipette provided to add 1 drop (about 10μL) of specimen to the sample well.
3. Hold the buffer bottle vertically and add 2 drops of buffer (approximate 70μL) to sample well.
4. Read results in 10-15 minutes.

INTERPRETATION OF RESULTS:



IgG & IgM Positive:
Control line and T1 line & T2 line appear in the test window.
IgM Positive:
Two coloured lines appear, one is in T1 area and the other line is in control area.
IgG Positive:
Two coloured lines appear, one is in T2 area and the other line is in control area. Negative: Only one line appears in control area, no line appears in T1/T2 area.
Invalid:
No line appears in the control area, the test results are invalid regardless of the presence or absence of line in the test area. The direction may not been followed correctly or the test may be deteriorated. It is recommended that repeat the test using a new device. If the problem persist, please stop to use the product and contact local distributor.

STORAGE AND STABILITY:

Storage: store at 2°C - 30°C.
Shelf life: 12 months.

LIMITATION OF THE TEST

1. This kit is a clinical auxiliary test product. Positive test results need to be further confirmed (excluding false positives). Negative test results cannot exclude the possibility of infection (window period or false negative).
2. When the SARS-CoV-2 (COVID-19) antibody does not appear at the time of sample collection or when the titer is lower than the minimum detection limit of this kit, a negative result will appear, which should be combined with comprehensive analysis of clinical indicators and retested within 5 to 10 days.
3. IgM antibody positive doesn't only occurs in the primary infection period, but also in the secondary infection.
4. IgG antibody positive indicates infection or previous infection.

PERFORMANCE CHARACTERISTICS

1. Analytic Specificity
Results demonstrated that COVID-19 Canea Rapid Test has no significant cross-reactivity with the seromarkers listed following:
Influenza A virus, Influenza B virus, Hepatitis B surface antibody, Hepatitis C virus, Parainfluenza virus, Human immunodeficiency virus, Adenovirus, Respiratory syncytial virus, EB virus, Mumps virus, Varicella zoster virus, Enterovirus 71, Measles virus, Cytomegalovirus, Chlamydia pneumoniae, Mycoplasma pneumoniae, Treponema pallidum.
2. Interference
The following substances and conditions were found not to interfere with the test.
List of potentially interfering compounds and concentrations tested are as follows:

Chemical analytes	Concentrations	Chemical analytes	Concentrations
Cholesterol	200mg/mL	Rheumatoid factor (RF)	80IU/mL
Triglyceride	15mmol/L	AMA	80U/mL
Hemoglobin	9g/L	HAMA	20ng/mL
Bilirubin	250μmol/L		

3. Diagnostic sensitivity and specificity
A clinical study using a total 609 blood samples was conducted. The results of the COVID-19 Canea Rapid Test were compared with clinical reference standard and refer to the results of nucleic acid detection test. The diagnostic sensitivity and specificity of the IgM and IgG test results are given as below:

Table 1 - Comparison of COVID-19 Test-IgM

		Clinical reference standard		total results
		positive	negative	
Results of COVID-19 IgM Ab rapid test	positive	219	6	225
	negative	26	358	384
total result		245	364	609

Results gave
sensivity: 219/245 = 89.4% (95%CI:84.8%~93%)
specificity: 358/364 = 98.4% (95%CI:96.5%~99.4%%)
accuracy: 577/609 = 94.8% (95%CI:92.7%~96.4%)

Table 2 - Comparison of COVID-19 Test-IgG

		Clinical reference standard		total results
		positive	negative	
Results of COVID-19 IgG Ab rapid test	positive	224	5	229
	negative	21	359	380
total result		245	364	609

Results gave
sensivity: 224/245=91.4% (95%CI:87.2%~94.6%)
specificity: 359/364 = 98.6% (95%CI:96.8%~99.6%)
accuracy: 583/609 = 95.7% (95%CI:93.8%~97.2%)

Table 3 - Comparison of COVID-19 Test-IgM&IgG

		Clinical reference standard		total results
		positive	negative	
Results of COVID-19 IgM/IgG Ab rapid test	positive	230	7	237
	negative	15	357	372
total result		245	364	609

Results gave
sensivity: 230/245 = 93.9% (95%CI:90.1%~96.5%)
specificity: 357/364 = 98.1% (95%CI:96.1%~99.2%)
accuracy: 587/609 = 96.4% (95%CI:94.6%~97.7%)

INDEX OF SYMBOLS:

	Do not re-use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use-by date
2°C 30°C	Store at 2°C - 30°C	REF	Catalogue number
	Manufacturer		Consult instructions for use
EC REP	Authorized representative in the European Community		Do not use if the package is damaged

MANUFACTURER CONTACT INFORMATION:

Core Technology Co.,Ltd.
Room 100, C Building, No.29 Life Park Rd.,
Changping District,Beijing, 102206 China

EC REP WellKang Ltd.
16 Castle St,Dover, Kent, CT16 1PW,England,UK

DISTRIBUTOR:
Canea Pharma Chemisch Pharmazeutische Vertriebsgesellschaft mbH
Tarpenring 12
D-22419 Hamburg
Germany

COVID-19 IgM/IgG Ab Rapid Test (Whole Blood, Serum, Plasma)
For-In-vitro-diagnostic and Professional use only!

5 tests	PZN 16702230	EAN 4031673101158
10 tests	PZN 16615270	EAN 4031673101103
25 tests	PZN 16622608	EAN 4031673101141

Release Date: 25th of May 2020 / Version: 004