Please carefully read the directions prior to use.

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COVID-19 Canea Rapid Test

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

INTENDED USE:

The COVID-19 Canea Rapid Test is intended for qualitative detection of IgM and IgG antibodies against COVID-19 in human serum, plasma or whole blood. The COVID-19 Canea Rapid test aids in diagnosing patients with suspected SARS-CoV-2 infection combined with a medical examination and the results of other laboratory tests. The results of the COVID-19 Canea Rapid Test should not be used as the sole basis for diagnosis.
Humans typically only begin forming antibodies one week after being infected with the novel coronavirus. In other words the positive detection rate during the first 5 days after exposure to the source of infection is very low. The positive detection rate after 2 weeks from first being infected is approximately 80%, and about 95% after 3 weeks. If antibody titers have decreased considerably during the recovery period, the test may return a negative result. The false positive rate in non-infected samples is about 2%.
Due to the complexity of the immune system and continuous variation of the virus's genes, the test results only serve as a reference and are not used as a basis for diagnosis. The T-lines may also turn grey instead of crimson.

TRANSMISSION AND ILLNESS:

SARS-CoV-2 is primarily transmitted through direct contact with secretions or aerosols and droplets. There are indications that faecal-oral transmission is also possible.
To date, 7 types of coronavirus causing respiratory diseases in humans have been identified: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and SARS-CoV-2. These are serious pathogens causing respiratory diseases in humans. SARS-CoV-2 is a pathogen that causes viral pneumonia. Symptoms include fever, a dry cough, loss of taste and smell, respiratory problems, etc. It can moreover cause serious lung inflammation, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, serious metabolic disorders, etc. and even quickly result in death.

TEST PRINCIPLE:

This test principle uses polyclonal anti-human IgM, IgG antibodies and polyclonal anti-mouse IgG antibodies, each immobilised on a nitrocellulose membrane. It uses colloidal gold to mark recombinant antigens of SARS-CoV-2 (COVID-19) and mouse IgG. This uses the technology of nano-colloidal gold and applies the principle of highly specific antibody-antigen reaction and the immunochromatographic analysis technique.
During the test, the SARS-CoV-2 (COVID-19) IgM antibody in the sample binds to the recombinant colloidal-gold marked SARS-CoV-2 (COVID-19) antigen to form a complex. This reacts with the monoclonal anti-human IgM antibody the T1 line is coated with during chromatography. In this case the T1 will show a red line. If the SARS-CoV-2 (COVID-19) IgG antibodies in the sample bind to the colloidal gold marked SARS-CoV-2 (COVID-19) antigen to form a complex which reacts with the monoclonal anti-human IgG antibodies that the T2 line is coated with during chromatography, T2 will show a red line.
If the samples do not contain SARS-CoV-2 (COVID-19) IgM and IgG antibodies, the recombinant colloidal gold marked SARS-CoV-2 (COVID-19) antibodies cannot bind to the anti-human IgM and IgG antibodies in the areas of the T1 and T2 lines and neither T1 nor T2 will show a red line.
Irrespective of the presence of SARS-CoV-2 (COVID-19) IgM and IgG antibodies in the sample, a red line will always appear as a control in the test. This line appears in control area C:
1. To verify sufficient volume was added.
2. To verify flow was achieved.
3. To check for reagents.

MATERIALS SUPPLIED:

The COVID-19 Canea Rapid Test includes the following items for testing:
1. COVID-19 Canea Rapid Test cartridge
2. Directions for use
3. Buffer solution
4. Pipette
5. Automatic blood lancet for drawing human capillary blood, pink, cap type, model XL II-2128, 21G needle (0.8 mm) with 2.8 mm puncture depth, consisting of spring, protective cap, release, back cap, needle, needle adapter and casing. Properties: The outside of the needle guide is smooth and free from defects. The point of the needle is sharp and free from folds, burrs and hooks. Self-destruction: The point of the needle retracts after being activated. Sterility: The lancet is sterile. The product was sterilised by radiation.

REQUIRED MATERIAL NOT SUPPLIED:

1. Clock or timer
2. Specimen collection container
3. Gloves
4. Alcohol pad for disinfection

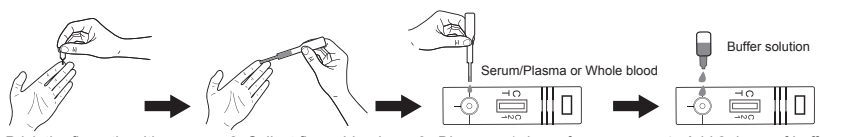
WARNINGS AND PRECAUTIONS:

1. Carefully read the directions for use before performing this test.
2. For in-vitro diagnosis and professional use only.
3. Do not use the test cartridge or blood lancet after the expiration date.
4. The test cartridge should be kept inside the sealed pouch until it is to be used.
   Do not use the test cartridge if the pouch is damaged or the seal has been broken.
5. Do not reuse the test cartridge or blood lancet.
6. Treat and handle the samples, the blood lancet and the used cartridge as if potentially contagious. Dispose of all samples, blood lancets and used cassettes in a suitable biohazard container. The hazardous materials should be handled and disposed of in compliance with local, national or regional regulations.
7. Do not mix or switch samples.
8. Wear disposable gloves, a lab coat and eye protection during the test and when handling potentially infectious materials. Thoroughly wash your hands afterwards.
9. Clean spilled materials thoroughly using a suitable disinfectant.
10. Ensure safety when conducting the test. Do not injure others or yourself.
11. Check the blood lancet before use. Do not use if damaged, the casing has been opened, or the protective cap has fallen off.
12. Verify that the blood lancet specification listed in the section "Materials supplied" meets your requirements.
13. When using the blood lancet, disinfect the tip of the middle finger or ring finger used as the puncture site with an alcohol pad. Do not touch once disinfected.

PREPARING THE SAMPLE:

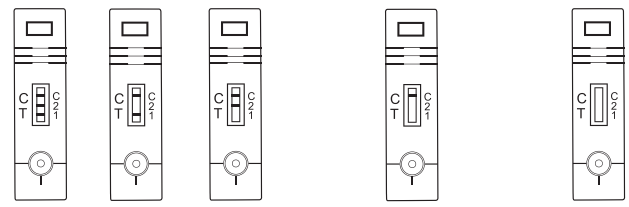
1. The sample is human serum/plasma or whole blood, including plasma or whole blood produced with clinical anticoagulants (EDTA, heparin, sodium citrate).
2. Blood samples from the fingertips should be tested immediately. Serum, plasma and anticoagulated whole blood can be stored. At room temperature, store for a maximum of 36 hours, at 2° to 8° no more than 3 months. Serum/plasma can be stored for longer at -20°. Handling the sample incorrectly can affect the results.
3. If previously refrigerated or frozen, only use the sample and test components at room temperature. Mix the thawed sample well before testing. Remove precipitate through centrifugation before testing if noticeable particles were present in the sample.
4. Do not use the test if the sample contains solid lipids, haemolysis or clouding. These can falsify results.

TEST PROCEDURE:



Read the directions prior to testing. Ensure the test inside the pouch is at room temperature before testing. Do not open the pouch until you are ready to start the test.
1. Remove the test from the sealed pouch. Place on a flat, clean and dry surface.
2. Disinfect the tip of the middle or ring finger with an alcohol pad. Allow the alcohol to evaporate before taking the sample. Do not touch the testing area after disinfecting!
3. Remove the cap from the sterile blood lancet and hold it against the tip of the ring or middle finger. Push the back of the blood lancet so a blood droplet forms. Carefully squeeze the area around the puncture site with your thumb and index finger to increase the blood flow and be able to draw enough blood with the pipette.
4. Use the included pipette to deposit 1 drop (about 10µl) of the sample in the well.
5. Open the plastic vial of buffer solution by unscrewing the cap. Hold the buffer bottle perpendicular and add 2 drops of buffers solution (about 70µl) to the well.
6. Read the results after 10-15 minutes.

INTERPRETATION OF RESULTS:



IgM (T1) and IgG (T2) POSITIVE:
Control line, T1 and T2 line appear in the test window.
IgM POSITIVE (T1):
Two coloured lines appear, one in the T1 region and the other in control region C.
IgG POSITIVE (T2):
Two coloured lines appear, one in the T2 region and the other in the control region. C.
Results NEGATIVE:
Only one line appears in control region C, no line appears in the T1/T2 region.
Results INVALID:
If no line appears in control region C, the test results are invalid regardless of whether or not there are lines in test region T1 or T2. The directions may not have been followed correctly or the test is defective. We recommend repeating the test with a new cartridge. If the problem continues, stop using the product and contact your local distributor.

STORAGE AND STABILITY

Storage: store at 2°C - 30°C.
Expiry date: see printed date.

LIMITATIONS

1. This test is a clinical in-vitro diagnostic agent. Positive test results require further investigation (to rule out false positives). Negative test results do not rule out possible infection (test performed too early or false negative).
2. If the SARS-CoV-2 (COVID-19) antibody is not detected at the time of sampling or the titer is below the minimum detection level of this test, a negative result will be shown which should be combined with extensive analysis of the clinical indicators and retested within 5 to 10 days.
3. A positive IgM antibody not only occurs in the primary infection stage but also in secondary infection.
4. A positive IgG antibody indicates current or prior infection.

PERFORMANCE CHARACTERISTICS

1. Analytical specificity
Results showed that the COVID-19 Canea IgG/IgM Rapid Test has no significant cross-reactivity with the following seromarkers:
Influenza A virus, influenza B virus, Hepatitis B surface antibodies, 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. Cross reactivity:
It was determined that the following substances and conditions do not affect the test.
List of potential interfering compounds and concentrations tested:

Cholesterol	200mg/ml	Rheumatoid Factor (RF)	80IU/ml
Triglyceride	15mmol/L	AMA	80U/ml
Haemoglobin	9g/L	HAMA	20ng/ml
Bilirubin	250µmol/l		

3. Diagnostic sensitivity and specificity
A clinical trial was conducted with a total of 609 blood samples. The results of the COVID-19 Rapid Test were compared with the clinical control standard and refer to the results of the nucleic acid amplification test. The diagnostic sensitivity and specificity of the IgM and IgG test are listed below:

Table 1 - Comparion of COVID-19 IgM test results

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

Results obtained:
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 IgG Test results

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

Results obtained:
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 - Compariosn of Covid-19 IgM + IgG test results

		Clinical reference standard		total result
		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 obtained:
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%)

SYMBOL INDEX:

	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 directions for use
			Do not use if the package is damaged

TRANSPORT:

Keep the product away from sunlight, rain or snow during transport. Do not transport the product together with toxic or hazardous materials.

MANUFACTURER CONTACT INFORMATION:

	MANUFACTURER:	EC REP AUTHORISED PERSON:
Test cartridge Buffer solution Pipette CE	Core Technology Co., Ltd. Room 100, C Building, No. 29 Life Park Road, Changping District, 102206 Beijing, China	WellKang Ltd. 16 Castle St, Dover, CT16 1PW UK
Automatic blood lancet CE 0123	Hebei Xingle Sci & Tech Co. Ltd. No 189 Nanhuan Road, 050700 XinleCity, Hebei Province, PEOPLE'S REPUPLIC OF CHINA	Shanghai International Holding Corp. GmbH (Europe), Eiffestraße 80, 20537 Hamburg, GERMANY
Kit assembly: Hebei Times Medical Technology Co., Ltd. TongXing Road 117, DingXing, HeBei Province, China		

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

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In-vitro diagnostic agent for professional use only!

Single test PZN 16615264 EAN 4031673101097

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