Instructions for use

ZandCell COVID-19 Antigen Test
(hypersensitive colloidal gold)

[Product Name]
ZandCell COVID-19 Antigen Test (hypersensitive colloidal gold)
[Model]
One test per bag for one person, 6 tests/kit

[Intended Use]
This product is used for qualitative detection of coronavirus-19 antigen in saliva, sputum or nasopharyngeal swab samples.

[Summary]
Coronavirus, as a large virus family, is a single positive stranded RNA virus with envelope. The virus is known to cause major illnesses such as colds, Middle East Respiratory Syndrome (MERS), and Severe Acute Respiratory Syndrome (SARS). The core protein of SARS-CoV-2 is the N protein (nucleocapsid), which is a protein component located inside the virus. It is relatively conserved among β-coronaviruses and is often used as a tool for the diagnosis of coronaviruses.

[Principle]
The kit works with the principle of antigen-antibody reaction and immunochromatography. The device includes monoclonal antibody 1 against sars-cov-2 surface protein labeled by hypersensitive colloidal gold; monoclonal antibody 2 against sars-cov-2 surface protein is coated at T line of reaction zone; Goat anti chicken antibody is coated at position of quality control line (C).
In the process of the test, when the level of coronavirus-19 in the sample reaches or exceeds the detection threshold, the antigen of coronavirus-19 in the sample binds with the monoclonal antibody 1 precoated on the gold pad. The conjugates migrated upward through capillary effect, and then bound to the coated mcab-2 at the T-line. If there is no coronavirus-19 in the sample, there will be no purple red band on the T line. No matter whether there is coronavirus-19 in the sample, purple red band will appear at the position of quality control line (C). The purplish red band of quality control line (C) can be used as the standard to judge whether the sample is sufficient and whether the chromatographic process is normal or not. It can also be used as the internal control standard of reagents.

[Components]
The products of different specifications contain one or six test cassettes, one instruction manual and 1ml sample diluent. Each kit contains a test cassette and a bag of desiccant, a set of saliva collector (including a saliva funnel and a collection tube containing 1 ml diluent), and a dropper.
The test cassette consists of gold label pad, sample pad, nitrocellulose membrane, absorbent paper, PVC board and plastic card.

[Storage and Stability]
It should be stored at 2℃~ 30℃, be kept dry and away from sunlight.
The shelf life is 18 months.
For per test, it should be used within 30 minutes after unsealing.
Production date and expiration date are shown in the package label.

[Sample Requirements]
The test cassette is suitable for detecting coronavirus-19 antigen in saliva, blood, sputum, feces, sewage, food, seafood, aerosol and other samples.
Samples should be used as soon as possible after collection and should not be stored for a long time at room temperature. If the sample can not be detected in time, the sample can be stored for 48 hours at 2 ℃ - 8 ℃. Long term storage should be frozen at - 20 ℃, avoid repeated freezing and thawing.

[Test Method]
Please read the instructions carefully before testing.
1. Open the aluminum foil bag of the test cassette, take out the test cassette, and mark the inspected person or sample number on the cassette. Use within 30 minutes, especially at room temperature above 30 ° C or high humidity, as soon as possible.
2. Put the kit on a clean platform, open the cover of the diluent tube, screw on the saliva funnel, and collect the saliva to 2ml; screw off the saliva funnel, cover it, turn upside down and mix well, then screw off the cover, suck a tube of liquid with a dropper, drop 2-3 drops into the sample hole, and start to count for 10-15 minutes.
3. Wait for the purple stripe to appear. The test results should be read within 10-15 minutes, after more than 15 minutes, the reading results are invalid.

[The Explanation of the Testing Results]
Positive (+): As Fig.1 showed, there should be purple-red bands in C and T areas ;
Negative (-): As Fig.2 showed, there should be purple-red band only in C areas.

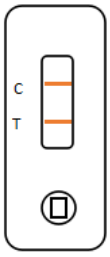

Figure 1 positive (+)

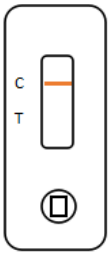

Figure 2 negative (-)

Invalid results: no matter whether there is purple red band at T line position, if there is no purple red band at quality control line (C), it indicates that the operation procedure is incorrect or the test kit has been invalid. In this case, you must read the instruction manual carefully, and then test again with a new test kit. If the problem persists, stop using this batch number and contact your local supplier immediately.

[Limitation of Procedure]
1. This reagent is a qualitative and preliminary screening

method, which can not determine the content of coronavirus-19 in saliva. This reagent provides only one preliminary analysis result, and a second analysis method must be used to determine the result.
2. The possible causes of negative results of this product include:
1) There is no virus in the sample, or the virus content in the sample is very low, which is lower than the critical detection concentration of reagent, and the low concentration sample cannot be detected.
2) The virus may have been inactivated in the sample. Although the nucleic acid fragment may still exist, the virus antigen may have been destroyed and inactivated.
3) Incorrect operation or other factors that may affect the detection, such as improper transportation and storage, leading to reagent failure.
3. When the epidemic degree of the disease decreases, the positive predictive value decreases, so the interpretation of positive results of low-risk population should be cautious.

[Product Performance Index]
1. Physical Property
1.1 Appearance
The test cassette should be clean and integral, no burrs, no damage, no pollution; the label should be clear and not damaged. The sample dilution should be clear without impurities and flocs.
1.2 Liquid migration speed
The liquid migration speed should be no less than 10mm/min.
1.3 Strip width
The membrane strip width of the testing strip should be≥2.5mm.
1.4 Sample dilution volume
The sample dilution volume should be no less than the indicated value.
2. Detection Limit
For the detection of the manufacturer's sensitivity reference materials, the results should meet its requirements.
3. Negative reference material compliance rate
For the detection of the manufacturer's negative reference materials, the negative detection rate should be 100%.
4. Positive reference material compliance rate
For the detection of the manufacturer's positive reference materials, the positive detection rate should be 98,1%.
5. Precision
For the detection of the manufacturer's precision reference materials, the results should all be positive and the color rendering should be uniform.
6. Analysis Specificity
6.1 Cross-reactivity: The test device has no cross reactivity with endemic human coronavirus OC43 antibody ⩽ 10^3 cfu/ml, influenza A virus antibody⩽$5X10^4$ TCID50/0.1 ml, influenza B virus antibody⩽$2X10^5$ TCID50/0.1ml, respiratory syncytial virus antibody ⩽ 1 TCID50/0.1 ml, adenovirus antibody ⩽ 4.85 × 10^8IFU/mL, EB virus antibody, measles virus antibody ⩽ 48.2Units/ml, cytomegalovirus antibody, rotavirus antibody, norovirus antibody⩽1.36g/cm^3, mumps virus antibody, varicella-zoster virus antibody, and mycoplasma pneumoniae antibody⩽ 5mg/(kg • d).
6.2 The test results do not be interfered with the substance at the following concentration: bilirubin concentration≤250μmol/L; triglycerides concentration ≤15mmol/L; hemoglobin concentration ≤10g/dL.
The test results do not be influenced by the following substance: α-interferon, zanamivir, ribavirin, oseltamivir, and paramivir, Lopinavir, ritonavir, abidol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride (containing Preservatives), beclomethasone, dexamethasone, flunisolide, triamcinolone, budesonide, mometasone and fluticasone.

[Precautions]
1. Do not use expired products.
2. Do not freeze. Avoid excessive temperature and humidity in the experimental environment. The reaction temperature should be 15℃~30℃ and the humidity should be below 70%.
3. The package bag contains desiccant, and it should not be taking orally.
4. When testing, please wear protective clothing, gloves and eye shields.
5. Do not use the test cassette with broken single packaging, unclear marks, and past the expiration date.
6. Dispose of used specimens, test kit and other waste in accordance with relevant local laws and regulations.

[References]
1. Regulations on registration of IVD Reagents, October 1, 2014.
2. Guidelines for the Preparation of IVD Reagent Specifications, September 11, 2014
3. Guidelines for Technical Review of Pathogen specific M immunoglobulin Qualitative Detection Reagent Registration, May 17,2013.

[Explanation of Symbols]

IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		CONSULT INSTRUCTIONS FOR USE
	EXPIRY DATE		DO NOT REUSE
	DATE OF MANUFACTURER		MANUFACTURER
2℃-30℃	TEMPERATURE LIMIT	LOT	BATCH CODE
EC REP	EC REPRESENTATIVE	CE	CE Symbol

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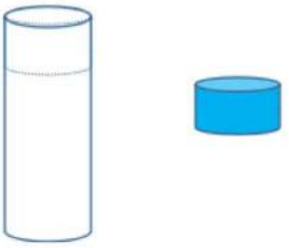
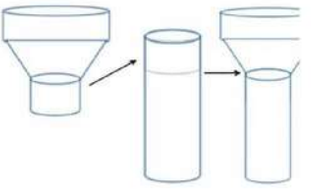


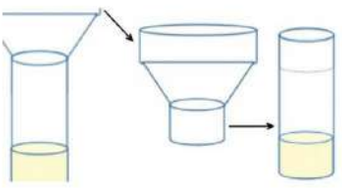
1. Open the cover of the sample tube



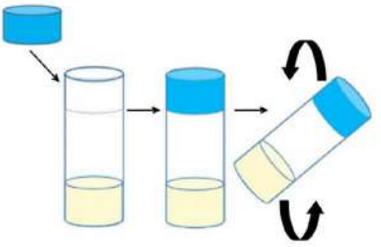
2. Screw on the salivary funnel

2. Odhrkajte se, da odstranite slino iz grla.

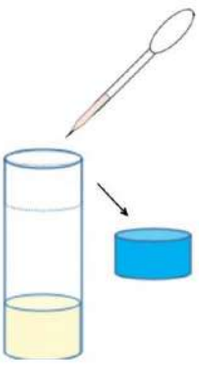
4. Collect saliva to 2 ml



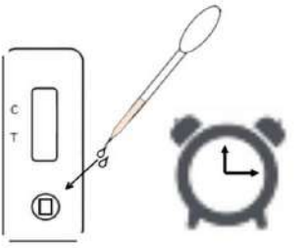
5. Remove the salivary funnel



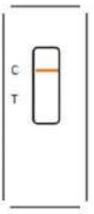
6. Cover and mix well upside down



7. Open the lid and suck a tube of liquid with a dropper

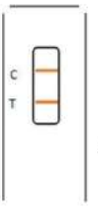


8. Add 2–3 drops into the sample hole and wait for 10–15 minutes for the result



9.

Figure 1: If only C line is shown, it is negative. There is no SARS-CoV-2 in saliva



10.

Figure 2: If both C and T lines are shown, it is positive. Saliva contains SARS-CoV-2

11. If there is no C line, no matter whether T line is shown, the reaction is invalid and needs to be retested