Antigen rapid test device (via saliva) for a new coronavirus (SARS-CoV-2)
Packaging information

LOTEST FOR QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS **IN HUMAN SALIVA.**
For professional in vitro diagnostic use only.

INTENDED USES

The Antigen Rapid Test Device (via saliva) for a novel coronavirus (SARS-CoV-2) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in human saliva using a rapid immunochromatographic method. Identification is based on monoclonal antibodies specific for the novel coronavirus antigen. It will provide clinicians with information on prescribing the correct medication.

OVERVIEW

The new coronaviruses belong to the genus βgenus. COVID-19 is an acute respiratory infectious disease. Humans are generally susceptible. Currently, patients infected with the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on current epidemiological investigations, the incubation period is 1 to 14 days, usually 3 to 7 days. The main manifestations include fever, fatigue and dry cough. In a few cases, nasal congestion, rhinorrhea, sore throat, myalgia and diarrhea may occur.

PRINCIPLE

The Antigen Rapid Test Device (via saliva) for the novel coronavirus (SARS-CoV-2) is an immunochromatographic membrane test that uses highly sensitive monoclonal antibodies against the novel coronavirus.
The test strip consists of three parts, namely the sample pad, the reagent pad and the reaction membrane. The reagent membrane contains colloidal gold conjugated with monoclonal and antibodies to the novel coronavirus; the reaction membrane contains secondary antibodies to the novel coronavirus and polyclonal antibodies to mouse globulin which are pre-immobilised on the membrane.
When the test device is inserted into the saliva sample, the conjugates dried in the reagent cartridge dissolve and migrate with the sample. If a novel coronavirus is present in the sample, the complex formed between the antibody conjugate against the novel coronavirus and the viruses will be captured by the specific monoclonal antibody against the novel coronavirus that coats the T region.
Regardless of whether the sample contains virus or not, the solution continues to migrate and encounters another reagent (anti-mouse IgG antibody) that binds to the remaining conjugates, forming a red line in the C region.
Products Antigenic rapid testing devices (via saliva) for a novel coronavirus (SARS -CoV-2) can recognize SARS -COV-2 nucleoprotein (major) and spike protein.
More than 90% of the antibodies used in the Antigen Rapid Test Facility (via saliva) for the novel coronavirus (SARS-CoV-2) are SARS-COV-2 antinucleoprotein and the target protein is SARS -COV-2 nucleoprotein.
The remainder of the antibodies used in the Antigen Rapid Test Facility (via saliva) to the novel coronavirus (SARS-CoV-2) are anti-spike protein and the target protein is a constantfragment of the SARS -COV-2 spike protein. Whether it is currently N501Y in the UK or 501Y.V2 in South Africa, the mutant fragment is primarily the RBD fragment of the S protein, whereas the target fragment of the antibody Antigenic rapid testing device (via saliva) for a novel coronavirus (SARS-CoV-2) has not mutated. Therefore, the antigenic rapid test device (via saliva) for the novel coronavirus (SARS-COV-2) can reliably detect SARS-COV-2 variants.
Therefore, the Antigen Rapid Testing Device (via saliva) for the novel coronavirus (SARS -CoV-2) can reliably detect the nucleoprotein and the peak protein of the SARS -COV-2 mutagen.

RESPONSE

The reaction membrane contains colloidal gold conjugated with monoclonal antibodies to the novel coronavirus; the reaction membrane contains secondary antibodies to the novel coronavirus and polyclonal antibodies to mouse globulin that are pre-immobilized on the membrane.

NOTICE

• *In vitro* diagnostic use only.
• Do not use after the expiry date.
• Check the foil bag containing the test device for damage before opening it for use.
• Carry out the test at room temperature between 15 and 30 °C.
• Wear gloves when hanging samples, do not touch the reagent membrane and sample window.
• All samples and used accessories should be considered infectious and disposed of in accordance with local regulations.
• Do not use blood samples.

STORAGE AND STABILITY

Store the antigen rapid test device (via saliva) for the new coronavirus (SARS-CoV-2) at room temperature or in a cool place (2-30 °C). Protect from freezing. All reagents are stable until the expiry date marked on their outer packaging and buffer bottle.

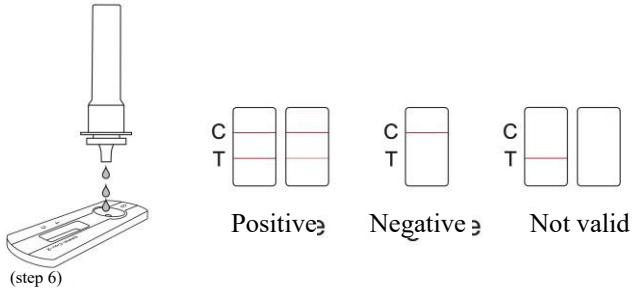
SAMPLING AND SAMPLE PREPARATION

1. Sampling:
The oral fluid sample should be collected using the sampling tools provided with the kit. Follow the detailed instructions for use below. No other sampling tools should be used for this test. Oral fluid collected at any time during the day may be used.

When saliva is collected, follow the instructions for sample preparation with the buffer provided with the kit.

MATERIAL

Material supplied



(step 6)

INTERPRETATION OF RESULTS

(See picture above)
POSITIVE: Two red lines appear. One red line appears in the control area (C) and one red line appears in the test area (T). The shade of colour may vary but the test should be considered positive whenever even a faint line is present.
NEGATIVE: Only one red line appears in the control area (C) and none in the test area (T). A negative result indicates that there are no new coronavirus particles in the sample or the number of virus particles is below the detectable range.
NOT APPLICABLE: No red line appears in control area (C). The test is invalid even if there is a red line in the test area (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control area failure. Check the test procedure and repeat the test with new test equipment. If the problem persists, stop using the test set immediately and
contact your distributor.

RESTRIC

• The antigen rapid test device (via saliva) for a novel coronavirus (SARS-CoV-2) is a screening test for qualitative detection of acute phase. The specimen collected may contain antigen concentrations below the sensitivity threshold of the reagent, so a negative test result does not exclude infection with a novel coronavirus.
• The antigen rapid test device (via saliva) for the new coronavirus (SARS-CoV-2) detects both viable and nonviable antigen against the new coronavirus. The performance of the test depends on the amount of

* The 20-test pack contains a tube rack, the 1-test and 5-test pack uses the test box itself as a tube rack.

Necessary material not included in the kit

● Timer

Allow the test device, sample and extraction buffer to come to room temperature (15-30°C) before testing. Do not insert anything into the mouth 10 minutes before taking the oral fluid sample, including food, beverages, gum, tobacco, water and mouthwash products.
1. Fill enough saliva into the cup/spittoon.
2. Using a dropper, remove saliva from the cup, transfer 4 drops of saliva into the extraction tube.
3. Remove the extraction tube and extraction buffer bottle, remove the cap of the buffer bottle and add all the extraction buffer to the extraction tube.
4. Remove the nozzle and attach it to the extraction tube, gently shake it vertically for about 5 seconds to mix the saliva well with the extraction buffer.
5. Fold the used cup/cup in half and dispose of in a plastic bag as medical waste in accordance with local regulations

(krok 1) (krok 2) (krok 3) (krok 4)

6. Remove the test device from the sealed foil bag and use it as soon as possible. For best results, test immediately after opening the foil pouch. Place the test device on a clean and level surface.
7. Transfer 3 vertical drops of sample into the well of the test device and start the timer.
8. The result will be in 10 to 20 minutes. Do not interpret the result after more than 20 minutes.

antigen in the sample and may not correlate with a cell culture performed on the same sample. A positive test does not exclude the possibility that other pathogens may be present, so it is necessary to compare the results with all other available clinical and laboratory information for an accurate diagnosis.
• A negative test result may occur if the level of extracted antigen in the sample is below the sensitivity of the test or if the sample is of poor quality.
• The efficacy of the test has not been established in monitoring antiviral treatment of the new coronavirus.
• Positive test results do not exclude co-infection with other pathogens.
• Negative test results are not intended to detect coronavirus infection other than SARS-CoV-2.
• Children tend to spread the virus longer than adults, which can lead to differences in susceptibility between adults and children.
• Factors such as food, diet, smoking, breath fresheners, etc. greatly influence the concentration of the virus in saliva. Therefore, please follow these instructions carefully before sampling

A negative result may occur if the antigen concentration in the sample is below the detection limit of the test or if the sample was collected or transported incorrectly, therefore a negative test result does not exclude the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

ClinicalEvaluation

A clinical trial was conducted to compare the results obtained using an antigen rapid test device (via saliva) for a novel coronavirus (SARS -CoV-2) and PCR. The results are summarized below:

Antigen rapid test device (via saliva) for a novel coronavirus (SARS-CoV-2) vs. PCR

Method		Nucleic Acid Test Kit 2019-nCoV (RT-PCR)		Overall results
Antigen testing device (via saliva) for new coronavirus (SARS-CoV-2)	Results	Positive	Negative	
	Positive	157	1	158
	Negative	12	235	247
Overall results		169	236	405

Clinical sensitivity =157/169= 92.9% (95% CI *:87.89% to 96.00%)
Clinical sensitivity = 235/236=99.58% (95% CI * 97.39% to >99.99%)
Accuracy: (157+235)/(157+1+12+235) *100%=96.79% (95% CI *94.53% to 98.17%)
Confidence interval

detection limit

Strain 2019-nCoV tested	Really Tech product				
Concentration 2019-nCoV1 X 10^5 TCID 50/mL	1 X 10^5 TCID 50/ml				
dilution	1. 100	1 000 1 000 1 200 1 400	1. 400	1. 800	1/1600
Tested concentration in dilution (TCID50/Ml)	1x10^3	5x10^2	2,5x 10^2	1,25X102	5.
M20 replicationblz ko cut -o ff	100 (20/20)	1 00 (20/20)	1 00 (20/20)	95 (19/20)	10 (2/20)
Limit of detection (LOD) per virus strain	1.25 X 10^2 TCID 50/ml				

cross-reaction

The test results are below the corresponding concentration of the substances in the table below, which has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Virus / Bacteria / Parasite	The Strain	Concentration
MERS-coronavirus	N/A	72 micrograms/ml
adenovirus	Type 1	1.5 x 10^6 TCID 50/ml
	Type 3	7.5 x 10^6 TCID 50/ml
	Type 5	4.5 x 10^6 TCID 50/ml
	Type 7?	1.0 x 10^6 TCID 50/ml
	type 8	1.0 x 10^6 TCID 50/ml
	Type 11	2.5 x 10^6 TCID 50/ml
	Type 18	2.5 x 10^6 TCID 50/ml
	Type 23	6.0 x 10^6 TCID 50/ml
	Type 55	1.5 x 10^6 TCID 50/ml
In fl uenza A	H1N1 Denver	3.0 x 10^8 TCID 50/ml
	H1N1 WS/33	2.0 x 10^8 TCID 50/ml
	H1N1 A/Mel/302/54	1.5 x 10^8 TCID 50/ml
	H1N1 New Caledonia	7.6 x 10^8 TCID 50/ml
	H3N2 A / Hong Kong / 8/68	4.6 x 10^8 TCID 50/ml
In fl Enza B	Nevada / 03/2011	1.5 x 10^8 TCID 50/ml
	B / Lee / 40	8.5 x 10^8 TCID 50/ml
	B / Taiwan / 2/62	4.0 x 10^8 TCID 50/ml
Respiratory syncytial virus	N/A	2.5 x 10^6 TCID 50/ml
Legionella pneumophila	Bloomington-2	1 x 10^5 PFU/ml
	Los Angeles-1	1 x 10^5 PFU/ml
	82A3105	1 x 10^5 PFU/ml
Rhinovirus A16	N/A	1.5 x 10^6 TCID 50/ml
Mycobacterium tuberculosis	K	1 x 10^5 PFU/ml
	Erdman	1 x 10^5 PFU/ml
	HN878	1 x 10^5 PFU/ml
	CDC1551	1 x 10^5 PFU/ml
	H37Rv	1 x 10^5 PFU/ml
Streptococcalpneumonia	4752-98 [Maryland (D1) 6B-17]	1 x 10^5 PFU/ml
	178 [Poland 23F-16]	1 x 10^5 PFU/ml
	262 [CIP 104340]	1 x 10^5 PFU/ml
	Slovakia 14-10 [29055]	1 x 10^5 PFU/ml
Streptococcus pyrogens	Typical T1 strain [NCIB 11841, SF 130]	1 x 10^5 PFU/ml
Mycoplasma pneumoniae	mutant 22	1 x 10^5 PFU/ml
	FH strain Eaton Agent [NCTC 10119]	1 x 10^5 PFU/ml
	36M129-B7	1 x 10^5 PFU/ml
Coronavirus	229E	1.5 x10^6 TCID 50 / ml
	OC43	1.5 x10^6 TCID 50 / ml

Human stage neumovirus (hmpv) 3, type B1	Peru2-2002	1.5 x 10^6 TCID 50/ml
Human metapneumovirus (hmpv) 16, type A1	IA10-2003	1.5 x 10^6 TCID 50/ml
The parainfluenza virus	Type 1	7.5 x 10^6 TCID 50/ml
	Type 2	4.5 x 10^6 TCID 50/ml
	Type 3	1.0 x 10^6 TCID 50/ml
	Type 4A	1.0 x 10^6 TCID 50/ml

Reaction of interfering substances

When tested using the new coronavirus (SARS-CoV-2) antigen rapid test device (saliva), there were no interferences between the device reagents and the potential interfering substances listed in the table below that would have caused false positive or negative results for the SARS -CoV-2 antigen.

Substance	Concentration	Substance	Concentration
Mucin	100 µg/mL	Acetylsalicylic acid	3,0 mM
Platypus	5% (v/v)	Ibuprofen	2,5 mM
Biotin	100 µg/mL	Mupirocin	10 mg/mL
Neosynephrine (phenylephrine)	5%(v/v)	Tobramycin	10µg/mL
Afrin nasal spray (oxymetazoline)	5%(v/v)	Erythromycin	50uM
Saline nasal spray	5%(v/v)	Ciprofloxac	50uM
Homeopathy	5%(v/v)	Ceftriaxone	110mg/mL
Sodium cromoglycate	10 mg/mL	Meropenem	3.7µg/mL
Olopatadine hydrochloride	10 mg/mL	Tobramycin	100 µg/mL
Zanamivir	5 mg/mL	Histamine hydrochloride	100 µg/mL
Oseltamivir	10 mg/mL	Peramivir	1mmol/mL
Artemeter / lumefantrine	50uM	Flunisolide	100 µg/mL
Doxycycline Hyclate	50uM	Budesonide	0.64nmol/L
Quinine	150uM	fFutikazone	0.3ng/mL
Lamivudine	1 mg/mL	Lopinavir	6 µg/mL
Ribavirin	1 mg/mL	Ritonavir	8.2mg/mL
Daclatasvir	1 mg/mL	Abidor	1mmol/mL
Acetaminophen	150uM	Collected nasal swabs in humans	N/A

SYMBOL	Meaning of	Brand	Meaning of
IVD	Diagnosticin vitro medical device		Storage temperature limit
	Producer	EC REP	Authorised representative for the European Community
	Date of manufacture		Expiry date
	Do not reuse		Read the instructions for use
LOT	Batch code	CE	Meets the requirements of EC Directive 98/79/EC

HANGZHOU REAL TECH CO., LTD.
4th Floor, Building #12, Eastern Medicine Town, Xiasha Economic and Technological Development,
310018 Hangzhou, Zhejiang, People's Republic of China
Website: www.realytech.com

EC REP **Luxus Lebenswelt GmbH**
Kochstr.1 47877, Willich, Germany

Number: 1100003201
Version: 1.5
Effective date: 22 January 2021

CE