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

LOTEST ON THE QUALITATIVE DETECTION OF ANTIGENS OF THE NEW CORONAVIR **IN HUMAN SALT.**

By way of exception, the antigen test is intended for use by a lay person

INTENDED USE

The new coronavirus antigen test device (saliva) (SARS-CoV-2) is a diagnostic test for the qualitative detection of new coronavirus antigens in human saliva using a rapid immunochromatographic method. The identification is based on monoclonal antibodies specific for the new coronavirus antigen. Provides clinicians with information on prescribing the right drugs.

OVERVIEW

New coronaviruses belong to the ÿgenus. COVID-19 is an acute respiratory infectious disease. People are generally more prone. Currently, patients infected under the new coronavirus are a major source of infection; asymptomatic infected people can also be a source of infection. Based on the current epidemiological inquiry, the incubation period is 1 to 14 days, usually 3 to 7 days. The main symptoms include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, muscle aches and diarrhea occur in a few cases.

Severe Acute Respiratory Syndrome - Coronavirus - 2 (SARS-CoV-2) is an envelope, non-segmented positive sense RNA virus. The cause of the disease Coronavirus-0 (COVID-19) common in humans is contagious. SARS-CoV-2 has several structural proteins, including a tip (S), a shell (E), a membrane (M), and a nucleocapsid (N).

There are currently many variants of the new coronavirus (SARS-CoV-2) and the N501Y mutation and its approximate variants are attracting attention because their mutation position is located in the spike glycoprotein binding domain for the virus receptor, thereby altering the efficacy of the infected virus. In silico analysis showed that the N501Y mutation did not alter the primary and tertiary protein structure of the RBD domain of the spike protein. Its antigenicity therefore remains unchanged.

PRINCIPLE

The new coronavirus antigen test (SARS-CoV-2) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to the new coronavirus.

The test strip consists of the following three parts, namely the sample pad, the reagent pad, and the reaction membranes. The membrane reagent contains colloidal gold-conjugated monoclonal antibodies against Novel coronavirus; the reaction membrane contains secondary antibodies against the new coronavirus and polyclonal antibodies against mouse globulin, which are pre-immobilized on the membrane.

If the sample is received by the test, the conjugated solution from said reagent pad gets dissolved and migrates along with the nasal sample. If a new coronavirus is present in the sample, a complex will form between the anti-new coronavirus conjugate and the virus will be captured / detected by a specific T-coated monovlonal anti-novel coronavirus. Whether the sample contains virus or not, the solution continues to migrate and encounters another reagent (anti-mouse IgG antibody) that binds the remaining conjugates, creating a red line in region C.

The new coronavirus (SARS-CoV-2) antigen-rapid test device can detect both the SARS-Cov-2 nucleoprotein and the top SARS-Cov-2 protein. Using an ELISA, we found that the antibody we were using bound to amino acids 511-531 of the SARS Cov-2 protein.
The detectability of SARS-CoV-2 genetic variants was tested by examining the susceptibility to recombinant SARS-Cov-2 spike proteins (319-541aa). In these tests, the Novel Coronavirus antigen test (SARS-Cov-2) reached the same values in the detection of variants B.1.1.7 (UK) and B.1.351 (SA) as in the detection of the standard variant.

REACTION

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

NOTICE

• The antigen test is, by way of exception, intended for use by a lay person.
• Do not use after the expiration date.
• Before opening, inspect the foil bag containing the test device for damage.
• Perform the test at room temperature 15 to 30 ° C.
• Wear gloves when hanging specimens, do not touch the reagent membrane and specimen window.
• All specimens and accessories used should be considered infectious and disposed of in accordance with local regulations.

• Do not use blood samples.

STORAGE AND STABILITY

Store the new coronavirus (SARS-CoV-2) antigenic rapid test device (saliva) at room temperature or refrigerated (2-30 ° C). Protect from frost. All reagents are stable until the expiration date indicated on their outer carton and buffer vial.

SAMPLING AND PREPARATION

1. Sampling:

An oral fluid sample should be taken using the collection tools provided with the kit.
Follow the detailed instructions for use below. No other sampling tools should be used in this test. Oral fluid collected at any time of the day may be used.

2. Sample preparation:

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

MATERIAL

Supplied material

- Testing device
- Plastic bag
- Extraction buffer
- Package leaflet
- Nozzle
- Extraction tube
- Test tube rack * Cup / saliva pocket Dropper

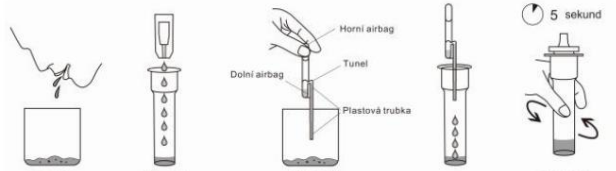
* Pack of 20 tests contains test tube rack, package with 1 test and 5 tests uses the test box itself as a test tube rack.

Required material not included in the kit: Timer

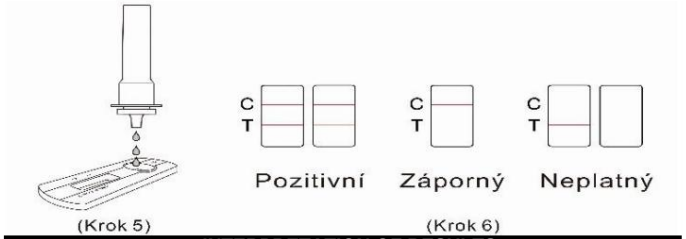
INSTRUCTIONS FOR USE

Allow the assay, sample, and extraction buffer to reach room temperature (15-30 ° C) before testing. Keep nothing, including food, drink, chewing gum, tobacco, water, and mouthwash, in your mouth for at least 10 minutes before sampling.

1. Pour enough saliva into the saliva bowl / pocket.
2. Remove the extraction tube and extraction buffer, remove the extraction buffer cap, add all extraction from the buffer to the extraction tube.
3. Use a dropper to drain enough saliva. Make sure that the fluid level does not exceed the tunnel between the lower airbag and the plastic tube, transfer all saliva in the plastic tube to the extraction tube.
4. Remove the dropper, close the extraction tube and gently shake the extraction tube vertically for about 5 seconds to mix the saliva well with the extraction buffer. Fold the used cup / bag in half and dispose of it in a plastic bag as medical waste in accordance with local regulations.



5. Remove the test device from the sealed foil pouch and use as soon as possible. For best results, perform the test immediately after opening the foil pouch. Place the test equipment on a clean and level surface. Transfer 3 drops of sample to the test well of the test device in a vertical direction, run
timer.
6. Read the result in 10 ~ 20 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(See image above)

POSITIVE: Two red lines appear. One red line appears in the control area (C) and one red line in the test area (T). The color shade may vary, but the test should be considered positive whenever only a faint line is present. If the result of the antigen test is positive, the user must contact their healthcare provider to perform a confirmatory PCR test.

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 that the number of viral particles is below a detectable range. If the result of the antigen test is negative, the user must continue to observe all hygienic measures of the Ministry of Health of the Czech Republic.
NOT VALID: No red line appears in the control area (C). The test is invalid even if there is a line (T) in the test area. 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 a new test device. If the problem persists, stop using the test kit immediately and contact your local distributor. If the result of the antigen test is unclear / invalid, the user should perform a new test according to the above procedure. If the test is repeatedly found to be invalid, the supplier / new manufacturer / State Institute for Drug Control must be informed.

Instruction: The patient can only change the treatment if he has been properly trained in this regard.
The user should not make any conclusions about the health impact of the results obtained without first consulting the physician.

LIMITATIONS

• The new coronavirus antigen test (via saliva) (SARS-CoV-2) is an acute phase screening test for qualitative detection. The sample taken may contain antigen concentrations below the reagent susceptibility threshold, so a negative test result does not rule out infection with a new coronavirus.
• The new coronavirus (SARS-CoV-2) antigenic rapid test device (via saliva) detects viable and non-viable antigens against the new coronavirus. The performance of the assay depends on the amount of antigen in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present, therefore 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 lower than the sensitivity of the test or if the sample is of poor quality.
• Efficacy of the test has not been established in monitoring antiviral therapy for new coronavirus.
• Positive test results do not rule out 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 sensitivity between adults and children.

• The concentration of the virus in saliva is greatly affected by factors such as food, diet, smoking, breath fresheners, etc. Therefore, strictly follow these instructions 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 rule out the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

Clinical evaluation

The clinical trial was performed to compare the results obtained with an antigenic rapid test device (via saliva) for a new coronavirus (SARS-CoV-2) and PCR. The results are summarized below:

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

Method		Nucleic acid testing kit 2019-nCoV (RT-PCR)		Overall the results
Antigen rapid test device (via saliva) for a new coronavirus (SARS-CoV-2)	The results	Positive	Negative	
	Positive	157 1 12 235 169		158
	Negative	236		247
Overall results				405

Clinical sensitivity = 157/169 = 92.9% (95% CI *: 87.89% to 96.00%)
Clinical specificity = 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 TCID 50 / mL 1 X 10 TCID / gl					
dilution	1/100	1/200	1/400	1/800	1/1600
Test concentration at dilution (TCID50 / Ml)	1x10 3 5x10 2 100		2,5x 10 2 1,25X10 5		
Rates of 20 replications near cut-o ff	(20/20) 1 00 (20/20) / ml		1 00 (20/20) 95 (19/20) 10 (2/20)		
Detection limit (LOD) per virus strain	1,25 X 10 TCID 50				

cross reaction

The test results are below the corresponding concentrations of the substances in the table below, which has no effect on the negative and positive test results of this reagent and does not cross-react.

Virus / Bacteria / Parasite	Strain	Concentration
MERS coronavirus	Not specified	72 micrograms / ml
adenovirus	Type 1 Type	1,5 x 10 5 TCID 50 / ml
	3 Type 5	7,5 x 10 4 TCID 50 / ml
	Type 7? type	4,5 x 10 5 TCID 50 / ml
	8 Type 11	1,0 x 10 6 TCID 50 / ml
	Type 18 Type	1,0 x 10 5 TCID 50 / ml
	23 Type 55	2,5 x 10 6 TCID 50 / ml
	H1N1 Denver	2,5 x 10 5 TCID 50 / ml
		6,0 x 10 5 TCID 50 / ml
		1,5 x 10 5 TCID 50 / ml
Influence A		3,0 x 10 6 TCID 50 / ml
	H1N1 WS / 33	2,0 x 10 6 TCID 50 / ml
	H1N1 A / Mÿl / 302/54	1,5 x 10 5 TCID 50 / ml
	H1N1 New Caledonia	7.6 x 10 6 TCID 50 / ml
	H3N2 A / Hong Kong / 8/68	4,6 x 10 5 TCID 50 / ml
In fl Enza B	Nevada / 03/2011	1,5 x 10 6 TCID 50 / ml
	B / Lee / 40	8,5 x 10 5 TCID 50 / ml
	B / Taiwan / 2/62	4,0 x 10 6 TCID 50 / ml
Respiratory syncytial virus	Not specified	2,5 x 10 5 TCID 50 / ml
Legionella pneumophila	Bloomington-2	5 1 x 10 PFU / ml
	Los Angeles-1	1 x 10 5 PFU / ml
	82A3105	1 x 10 5 PFU / ml
Rhinovirus A16	Not specified	1,5 x 10 5 TCID 50 / ml
Mycobacterium tuberculosis	K	1 x 10 5 PFU / ml
	Erdman	1 x 10 5 PFU / ml
	HN878	5 1 x 10 PFU / ml
	CDC1551	5 1 x 10 PFU / ml
	H37Rv	5 1 x 10 PFU / ml
Streptococcal pneumonia	4752-98 [Maryland (D1) 6B-17]	5 1 x 10 PFU / ml
	178 [Poland 23F-16]	5 1 x 10 PFU / ml
	262 [CIP 104340]	1 x 10 5 PFU / ml
	Slovakia 14-10 [29055]	1 x 10 5 PFU / ml
Streptococcus pyrogens	Typical strain T1 [NCIB 11841, SF 130]	1 x 10 5 PFU / ml
Mycoplasma pneumoniae	mutant 22	1 x 10 4 PFU / ml
	FH kmen 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
	NL63	1,5 x 10 4 TCID 50 / ml

	HKU1	1,5 x 10 ^{6} TCID 50 / ml
Human etapneumovirus (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
Virus parachÿipky	Type 1	7,5 x 10 ^{5} 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 ^{5} TCID 50 / ml

Reactions of interfering substances

When tested with the new coronavirus (SARS-CoV-2) antigen rapid test device (saliva), there was no interference between the device reagents and the potential interfering substances listed in the table below, which would cause false positive or negative results for SARS-CoV. -2
antigen.

Fabric	Concentration	Fabric	Concentration
Mucin	100ÿg / mL	Acetylsalicylic acid	3,0 mM
Whole	5% (v / v)	Ibuprofen	2,5 mM
Blood Biotin	100ÿg / mL	Mupirocin	10 mg/mL
Neosynefrín (fenylefrin)	5% (v / v) 5%	Tobramycin	10ÿg/mL
Afrin nasal spray (oxymetazoline)	(v / v) 5% (v /	Erythromycin	50uM
Salt nasal spray	v) 5% (v / v)	Ciprofloxacin	50uM
Homeopathy	10 mg / mL 10	Ceftriaxone	110mg/mL
Sodium cromoglycate	mg / mL 5 mg /	Meropenem	3.7ÿg/mL
Olopatadin hydrochlorid	mL 10 mg / mL	Tobramycin	100ÿg/mL
Zanamivir		Histamin hydrochlorid	100ÿg/mL
Oseltamivir		peramivir	1mmol / mL
Artemeter / lumefantrin	50uM	Flunisolid	100ÿg/mL
Doxycycline hyclate	50uM	Budesonide	0,64nmol/ L
quinine	150uM	fFutikazon	0,3ng/mL
Lamivudin	1 mg/mL	Lopinavir	6ÿg/mL
Ribavirin	1 mg/mL	Ritonavir	8.2mg/mL
Daclatasvir	1 mg/mL	Abidor	1mmol / mL
Acetaminofen	150uM	Collected nasal swabs with people	Not specified

SYMBOL

Mark	Meaning	Mark	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Producer	EC REP	Authorized representative for European Community
	Date of manufacture		Expiration date
	Do not reuse		Read the instructions for use
LOT	Batch code	CE	Meets the requirements of the EC directive 98/79 / EN

ALFI Corp., sro.
Operating 5492/3
722 00, Ostrava Trebovice
Website: www.4toilet.cz

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

Number: 1100003207
Version: 2.1
Revision date: 29.4.2021

CE