

Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) Package Insert

A RAPID TEST FOR THE QUALITATIVE DETECTION OF NOVEL CORONAVIRUS ANTIGENS IN NASOPHARYNGEAL SWAB AND OROPHARYNGEAL SWAB. For professional In Vitro Diagnostic Use Only.

INTENDED USE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an *in vitro* diagnostic test for the qualitative detection of novel coronavirus antigens in Nasopharyngeal swab and Oropharyngeal swab, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the novel coronavirus antigen. It will provide information for clinical doctors to prescribe correct medications.

SUMMARY

COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coronavirus. The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coronavirus; the reaction membrane contains the secondary antibodies for Novel coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coronavirus is present in the sample, a complex formed between the anti- Novel coronavirus conjugate and the virus will be caught by the specific anti- Novel coronavirus monoclonal coated on the T region.

Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Novel coronavirus; the reaction membrane contains the secondary antibodies for Novel coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

PRECAUTIONS

- For *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform test at room temperature 15 to 30°C.
- Wear gloves when handling the samples, avoid touching the reagent membrane and sample window.
- All samples and used accessories should be treated as infectious and discarded according to local regulations.
- Avoid using bloody samples.

STORAGE AND STABILITY

Store the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) at room temperature or refrigerated (2-30°C). Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

SPECIMEN COLLECTION AND PREPARATION

1. Specimen collection:

It is applicable to the diagnosis of the Novel coronavirus from the samples of Nasopharyngeal swab. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

For nasopharyngeal swab completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus.

For oropharyngeal swab completely insert the sterilized swab supplied in this kit into the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.

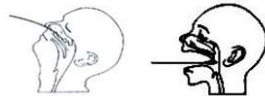
It is recommended to collect sample from Nasopharyngeal for more accurate results.

2. Specimen preparation:

1) Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.

2) Nasopharyngeal and oropharyngeal Swabbing

Insert the swab into the extraction tube which contains Sample Extraction Buffer. Rotate the swab inside the tube using a circular motion to roll the side of the extraction tube so that liquid is expressed and reabsorbed from the swab, remove the swab. The extracted solution will be used as test sample.



MATERIALS

Materials provided

- Test Device
- Sterilized Swab
- Extraction Tube
- Package Insert
- Nozzle with Filter
- Sample Extraction Buffer
- Tube Stand

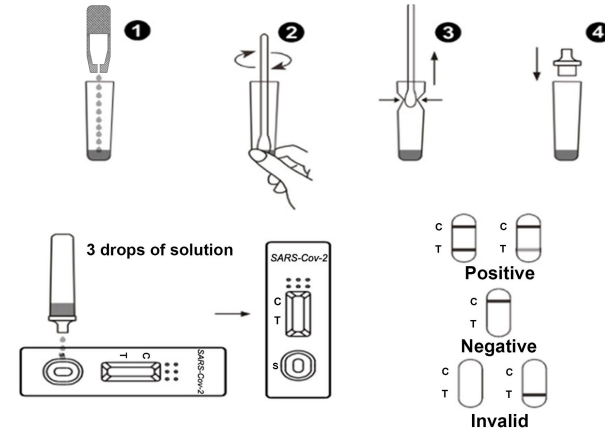
Materials required but not provided

- Timer

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Unscrew the whole cap of the specimen collection tube,
3. Take out 1 bottle of Sample Extraction Buffer, remove the bottle cap, add all the extraction buffer into the extraction tube.
4. Place the sterilized swab specimen in the sample extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
5. Remove the sterilized swab while squeezing the sterilized swab head against the inside of Buffer as you remove it to expel as much liquid as possible from the swab. Discard the sterilized swab in accordance with your biohazard waste disposal protocol.
6. Screw on and tighten the cap onto the specimen collection tube, then **shake the specimen collection tube vigorously** to mix the specimen and the sample extraction buffer. See illustration 4.
7. Add 3 drops of the solution (approx 80ul) to the sample well and then start the timer. Read the result at 10-20 minutes. Don't interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.

NEGATIVE: Only one red line appears in the control region (C), and no line in the test region (T). The negative result indicates that there are no Novel coronavirus particles in the sample or the number of viral particles is below the detectable range.

INVALID: No red line appears in the control region (C). The test is invalid even if there is a line on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection with novel coronavirus
- The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load 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, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- A negative test result may occur if the level of extracted antigen in a specimen is below the

sensitivity of the test or if poor quality specimen is obtained

- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results are not intended to rule in other coronavirus infection except the SARS-Cov-2.
- Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
- A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-Cov-2 infection, and should be confirmed by viral culture or PCR.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Clinical evaluation was performed to compare the results obtained by Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) and PCR. The results were summarized below:

Table: Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab) vs. PCR

Method	2019-nCoV Nucleic Acid Test Kit (RT-PCR)		Total Results	
	Results	Positive		Negative
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)	Positive	56	0	56
	Negative	6	200	206
Total Results		62	200	262

Clinical sensitivity = 56/62=90.32% (95%CI*75.51% to 92.77%)

Clinical specificity = 200/200 > 99.9% (95%CI*97.73% to 100%)

Accuracy: (56+200)/(56+0+6+200) *100%=97.71% (95%CI*94.98% to 99.06%)

*Confidence Interval

Limit of Detection (LoD)

2019-nCoV Strain Tested	Realy Tech product				
Stock 2019-nCoV Concentration	1 X 10 ⁸ TCID ₅₀ /mL				
Dilution	1/100	1/200	1/400	1/800	1/1600
Concentration in Dilution tested (TCID ₅₀ /ml)	1X10 ⁶	5X10 ⁵	2.5X 10 ⁴	1.25X10 ³	6.25X10 ²
Call rates of 20 replicates near cut-off	100(20/20)	100(20/20)	100(20/20)	95(19/20)	10(2/20)
Limit of detection (LoD) per Virus Strain	1.25 X 10 ³ 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	Strain	Concentration
MERS-coronavirus	N/A	72 µg/mL
	Type 1	1.5 x 10 ⁸ TCID ₅₀ /mL
Adenovirus	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
	Influenza A	H1N1 Denver
H1N1 WS/33		2.0 x 10 ⁶ TCID ₅₀ /mL
H1N1 A/Mal/302/54		1.5 x 10 ⁶ TCID ₅₀ /mL
H1N1 New Caledonia		7.6 x 10 ⁶ TCID ₅₀ /mL
H3N2 A/Hong Kong/8/68		4.6 x 10 ⁶ TCID ₅₀ /mL
Influenza B	Nevada/03/2011	1.5 x 10 ⁶ TCID ₅₀ /mL
	B/Lee/40	8.5 x 10 ⁶ TCID ₅₀ /mL
	B/Taiwan/2/62	4.0 x 10 ⁶ 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 ⁵ TCID ₅₀ /mL
	K	1 x 10 ⁵ PFU/mL
Mycobacterium tuberculosis	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
	4752-98 [Maryland (D1)6B-17]	1 x 10 ⁵ PFU/mL
Streptococcus pneumonia	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	Typing strain T1 [NCIB 11841, SF 130]	1 x 10 ⁵ PFU/ml
Mycoplasma pneumoniae	Mutant 22	1 x 10 ⁵ PFU/ml
	FH strain of Eaton Agent [NCTC 10119]	1 x 10 ⁵ PFU/ml
	36M129-B7	1 x 10 ⁵ PFU/ml
Coronavirus	229E	1.5 x 10 ⁶ TCID ₅₀ /ml
	OC43	1.5 x 10 ⁶ TCID ₅₀ /ml
	NL63	1.5 x 10 ⁶ 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
Parainfluenza virus	Type 1	1.5 x 10 ⁶ TCID ₅₀ /ml
	Type 2	1.5 x 10 ⁶ TCID ₅₀ /ml
	Type 3	1.5 x 10 ⁶ TCID ₅₀ /ml
	Type 4A	1.5 x 10 ⁶ TCID ₅₀ /ml

Interfering Substances Reaction

When tested using the Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (swab), there was no interference between the device reagents and the Potential interference substances listed in below table that would create false positive or negative results for SARS-Cov-2 antigen.

Substance	Concentration	Substance	Concentration
Mucin	100µg/mL	Acetylsalicylic acid	3,0 mM
Whole Blood	5% (v/v)	Ibuprofen	2,5 mM
Biotin	100µg/mL	Mupirocin	10 mg/mL
Neo-Syneprine (Phenylephrine)	5%(v/v)	Tobramycin	10µg/mL
Afrin Nasal Spray (Oxymetazoline)	5%(v/v)	Erythromycin	50µM
Saline Nasal Spray	5%(v/v)	Ciprofloxacin	50µM
Homeopathic	5%(v/v)	Ceftriaxone	110mg/mL
Sodium Cromoglycate	10 mg/mL	Meropenem	3,7µg/mL
Olopatadine Hydrochloride	10 mg/mL	Tobramycin	100µg/mL
Zanamivir	5 mg/mL	Histamine Hydrochloride	100µg/mL
Oseltamivir	10 mg/mL	Peramivir	1mmol/mL
Artemether-lumefantrine	50µM	Flunisolide	100µg/mL
Doxycycline hyclate	50µM	Budesonide	0,64nmol/ L
Quinine	150µM	Fluticasone	0,3ng/mL
Lamivudine	1 mg/mL	Lopinavir	6µg/mL
Ribavirin	1 mg/mL	Ritonavir	8,2mg/mL
Daclatasvir	1 mg/mL	Abidor	417,8ng/mL
Acetaminophen	150µM	Pooled human nasal wash	N/A

SYMBOLS

Symbol	Meaning	Symbol	Meaning
	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer		Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction for use
	Batch code		Meet the requirements of EC Directive 98/79/EC



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