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

IVD **REF: IN4658I**

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 coronvirus 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 coroinavirus .

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 coroinavirus;the reaction membrane contains the secondary antibodies for Novel coroinavirus, 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 coroinavirus is present in the sample, a complex formed between the anti- Novel coroinavirus conjugate and the virus will be caught by the specific anti- Novel coroinavirus 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 coroinavirus; the reaction membrane contains the secondary antibodies for Novel coroinavirus,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 hanging 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.

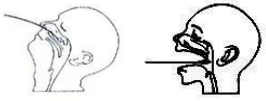
STORAGE AND STABILITY

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

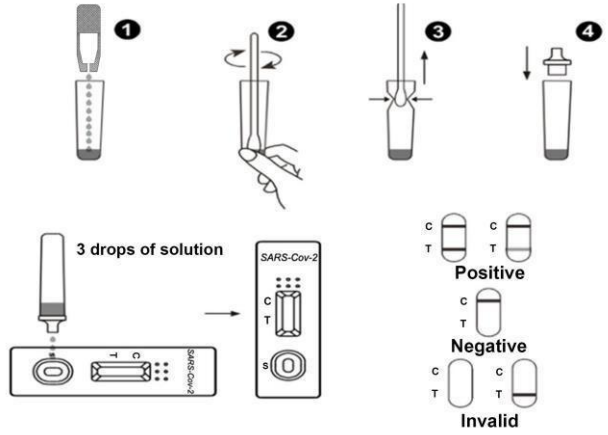
Materials required but not provided

- 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 coroinavirus 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
The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test Cassette (Swab)	Results	Positive	Negative	
	Positive	201	0	201
	Negative	8	450	458
Total Results		209	450	659

Clinical sensitivity = 201/209=96.17 % (95%CI* 92.51% to 98.17%)
Clinical specificity = 450/450＞99.9% (95%CI* 98.98% to 100%)
Accuracy: (201+450)/ (201+0+8+450) *100%=98.79% (95%CI* 97.58% to 99.43%)
*Confidence Interval

Limit of Detection (LoD)

2019-nCoV Strain Tested	INVBIO product				
Stock 2019-nCoV Concentration	1 X 10 $TCID_{50}$/mL				
Dilution	1/100	1/200	1/400	1/800	1/1600
Concentration in Dilution tested ($TCID_{50}$/ml)	$1X10^4$	$5X10^3$	$2.5X\ 10^3$	$1.25X10^3$	$6.25X10^2$
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 $TCID_{50}$/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
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 $10^5$$TCID_{50}$/mL
	Type 7	1.0 x $10^6$$TCID_{50}$/mL
	Type 8	1.0 x $10^6$$TCID_{50}$/mL
	Type 11	2.5 x $10^5$$TCID_{50}$/mL
	Type 18	2.5 x $10^5$$TCID_{50}$/mL
	Type 23	6.0 x $10^5$$TCID_{50}$/mL
	Type 55	1.5 x $10^5$$TCID_{50}$/mL
Influenza A	H1N1 Denver	3.0 x $10^3$$TCID_{50}$/mL
	H1N1 WS/33	2.0 x $10^3$$TCID_{50}$/mL
	H1N1 A/Mal/302/54	1.5 x $10^3$$TCID_{50}$/mL
	H1N1 New Caledonia	7.6 x $10^3$$TCID_{50}$/mL
	H3N2 A/Hong Kong/8/68	4.6 x $10^3$$TCID_{50}$/mL
Influenza B	Nevada/03/2011	1.5 x $10^3$$TCID_{50}$/mL
	B/Lee/40	8.5 x $10^3$$TCID_{50}$/mL
	B/Taiwan/2/62	4.0 x $10^3$$TCID_{50}$/mL
Respiratory syncytial virus	N/A	2.5 x $10^5$$TCID_{50}$/mL
Legionella pneumophila	Bloomington-2	1 x 10 PFU/mL
	Los Angeles-1	1 x 10^7 PFU/mL
	82A3105	1 x 10^7 PFU/mL
Rhinovirus A16	N/A	1.5 x 10^5 $TCID_{50}$/mL
Mycobacterium tuberculosis	K	1 x 10^7PFU/mL
	Erdman	1 x 10^7PFU/mL
	HN878	1 x 10^7PFU/mL
	CDC1551	1 x 10^7PFU/mL
	H37Rv	1 x 10^7PFU/mL
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	1 x 10^7PFU/mL
	178 [Poland 23F-16]	1 x 10^7PFU/mL
	262 [CIP 104340]	1 x 10^7PFU/mL
	Slovakia 14-10 [29055]	1 x 10^7PFU/mL

Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	1 x 10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	1 x 10^5PFU/ml
	FHstrainofEatonAgent [NCTC 10119]	1 x 10^5PFU/ml
	36M129-B7	1 x 10^5PFU/ml
Coronavirus	229E	1.5 x10^6TCID $_{50}$/ml
	OC43	1.5 x10^6TCID $_{50}$/ml
	NL63	1.5 x 10^6TCID $_{50}$/ml
	HKU1	1.5 x 10^6TCID $_{50}$/ml
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	1.5 x 10^6TCID $_{50}$/ml
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	1.5 x 10^6TCID $_{50}$/ml
Parainfluenza virus	Type 1	1.5 x 106TCID$_{50}$/ml
	Type 2	1.5 x 106TCID$_{50}$/ml
	Type 3	1.5 x 106TCID$_{50}$/ml
	Type 4A	1.5 x 106TCID$_{50}$/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-Synephrine (Phenylephrine)	5%(v/v)	Tobramycin	10μg/mL
Afrin Nasal Spray (Oxymetazoline)	5%(v/v)	Erythromycin	50uM
Saline Nasal Spray	5%(v/v)	Ciprofloxacin	50uM
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	50uM	Flunisolide	100μg/mL
Doxycycline hyclate	50uM	Budesonide	0.64nmol/ L
Quinine	150uM	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	150uM	Pooled human nasal wash	N/A

SYMBOLS

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

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