EN

SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) Package Insert

REF: HRK-6620

The SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab, oropharyngeal swab or nasopharyngeal swab specimen. The test is for in vitro diagnostic use only. For professional use only. Il is intended for clinical laboratories and healthcare professional use only for point-of-care testing. Not for at-home testing.

INTENDED USE

SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) is an *in vitro* diagnostic test for the qualitative detection of SARS-CoV-2 antigens in Nasal swab and Nasopharyngeal swab and Oropharyngeal swab, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the SARS-CoV-2 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 SARS-CoV-2 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

SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to SARS-CoV-2.
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 SARS-CoV-2; the reaction membrane contains the secondary antibodies for SARS-CoV-2, 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 SARS-CoV-2 is present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the virus will be caught by the specific anti-SARS-CoV-2 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.
SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) product can detect SARS-Cov-2 nucleo-protein (mainly) and spike protein.
More than 90% of the antibody used in the SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) is anti-nucleoprotein of SARS-Cov-2 and the target protein is the SARS-Cov-2 nucleoprotein.
The rest of the antibody used in SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) is anti-Spike protein and target protein is SARS-Cov-2 Constant fragment of Spike protein.
At present, whether the N501Y in the United Kingdom or the 501Y.V2 in South Africa, the variant fragments are mainly from the RBD fragment of the S protein, and the target fragments of the antibodies used in SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) have not been mutated. So, SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) can reliably detect the SARS-Cov-2 variants.

REAGENTS

The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against SARS-CoV-2; the reaction membrane contains the secondary antibodies for SARS-CoV-2, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

PRECAUTIONS

• For in vitro only.
• For professional 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 SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) 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 HANDLING

1）Specimen collection
• Nasal swab specimen (recommended)
It is important to obtain as much secretion as possible. Insert the sterile swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).

• Oropharyngeal swab specimen (optional)
It is important to obtain as much secretion as possible. Insert the sterile swab into throat that presents the most secretion from the red area of the throat wall and maxillary tonsils to collect throat swab specimen. Rub the bilateral throat tonsils and throat wall moderately to obtain the specimen. Please do not touch the tongue when remove the swab.

• Nasopharyngeal swab specimen (optional)
It is important to obtain as much secretion as possible. Insert the sterile swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab 5 times then remove it from the nasopharynx.

2）Specimen handling
Freshly collected specimens should be tested as soon as possible. It is essential that correct specimen collection and preparation methods are followed.

MATERIALS

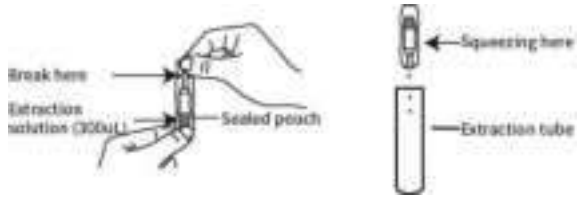
Materials provided

- 20*Test Cassette
- 20*Sterilized Swab
- 20*Extraction Tube
- 1*Package Insert
- 20*Nozzle
- 20*Sample Extraction Buffer
- Tube Stand*

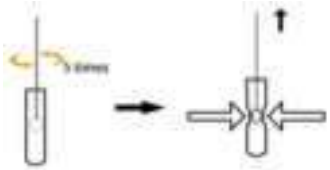
*The 20-test package contains the tube stand，the 5-test and 1-test package use the test box itself as tube stand.

DIRECTIONS FOR USE

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.
1.Hold the sealed pouch vertically and let all extraction solution flow into the bulb. Break the tip and squeeze the bulb to dispense all extraction solution into the extraction tube.



2. Collect specimen refer to Specimen Collection.
3. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the lube to extract the liquid from the swab. Try to release as much liquid as possible. Dispose the used swab as a biohazard waste.



4. Put on the tube tip.

5. Take out a test device from sealed foil pouch and put it on a clean and level surface.
6. Apply 3 drops (about 60 μL) of the extracted specimen into the specimen well. Please avoid bubbles during applying.

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.

Note:
• Do not interchange or mix extraction solution from different lots.
• Handle extraction solution with caution, do not contact with eyes or skjn. If spilled on eyes or skin, wash thoroughly with water.
• Please follow local regulations to handle the used materials.

INTERPRETATION OF RESULTS

1. Positive Result:
Both the quality control line C and the detection line T appear.
2. Negative Result:
Only the quality control line C appears, with no other line appearing on the detection line.
3. Invalid Result:
Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

• SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) 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 SARS-CoV-2
• SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) detects viable and non-viable SARS-CoV-2 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 SARS-CoV-2.
• 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 SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) and PCR. The results were summarized below:

Table: SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography) vs. PCR

Method		SARS-CoV-2 Nucleic Acid Test Kit (RT-PCR)		Total Results
SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography)	Results	Positive	Negative	
	Positive	98	0	100
	Negative	2	210	210
Total Results		100	210	310

Clinical sensitivity =2 /100=98.00 % (95%CI* 97.12% to 99.98%)
Clinical specificity = 210/210=100.00% (95%CI* 98.12% to 99.99%)
Accuracy: (98+210)/ (98+2+0+210) *100%=99.35% (95%CI* 98.78% to 99.89%)
*Confidence Interval

Limit of Detection (LoD)

SARS-CoV-2 Strain Tested	Huaree Tech product				
Stock SARS-CoV-2 Concentration	1 X 106 TCID50/mL				
Dilution	1/100	1/200	1/400	1/800	1/1600
Concentration in Dilution tested (TCID50/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	$1.25\ X\ 10^3\ TCID_{50}/mL$				

CROSS-REACTIVITY

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	$1.5 \times 10^6 TCID_{50}/mL$
	Type 3	$7.5 \times 10^6 TCID_{50}/mL$
	Type 5	$4.5 \times 10^6 TCID_{50}/mL$
	Type 7	$1.0 \times 10^6 TCID_{50}/mL$
	Type 8	$1.0 \times 10^6 TCID_{50}/mL$
	Type 11	$2.5 \times 10^6 TCID_{50}/mL$
	Type 18	$2.5 \times 10^6 TCID_{50}/mL$
	Type 23	$6.0 \times 10^6 TCID_{50}/mL$
	Type 55	$1.5 \times 10^6 TCID_{50}/mL$
Influenza A	H1N1 Denver	$3.0 \times 10^8 TCID_{50}/mL$
	H1N1 WS/33	$2.0 \times 10^8 TCID_{50}/mL$
	H1N1 A/Mal/302/54	$1.5 \times 10^8 TCID_{50}/mL$
	H1N1 New Caledonia	$7.6 \times 10^8 TCID_{50}/mL$
	H3N2 A/Hong Kong/8/68	$4.6 \times 10^8 TCID_{50}/mL$
Influenza B	Nevada/03/2011	$1.5 \times 10^8 TCID_{50}/mL$
	B/Lee/40	$8.5 \times 10^8 TCID_{50}/mL$
	B/Taiwan/2/62	$4.0 \times 10^8 TCID_{50}/mL$
Respiratory syncytial virus	N/A	$2.5 \times 10^6 TCID_{50}/mL$
Legionella pneumophila	Bloomington-2	1×10^5 PFU/mL
	Los Angeles-1	1×10^5 PFU/mL
	82A3105	1×10^5 PFU/mL
Rhinovirus A16	N/A	$1.5 \times 10^6 TCID_{50}/mL$
Mycobacterium tuberculosis	K	1×10^5PFU/mL
	Erdman	1×10^5PFU/mL
	HN878	1×10^5PFU/mL
	CDC1551	1×10^5PFU/mL
	H37Rv	1×10^5PFU/mL
Streptococcus pneumonia	4752-98 [Maryland (D1)6B-17]	1×10^5PFU/mL
	178 [Poland 23F-16]	1×10^5PFU/mL
	262 [CIP 104340]	1×10^5PFU/mL
	Slovakia 14-10 [29055]	1×10^5PFU/mL
Streptococcus pyrogens	Typing strain T1 [NCIB 11841, SF 130]	1×10^5PFU/ml
Mycoplasma pneumoniae	Mutant 22	1×10^5PFU/ml
	FHstrainofEatonAgent [NCTC10119]	1×10^5PFU/ml
	36M129-B7	1×10^5PFU/ml
Coronavirus	229E	$1.5 \times 10^6 TCID_{50}/ml$
	OC43	$1.5 \times 10^6 TCID_{50}/ml$
	NL63	$1.5 \times 10^6 TCID_{50}/ml$
	HKU1	$1.5 \times 10^6 TCID_{50}/ml$
Human etapneumovirus (hMPV) 3 Type B1	Peru2-2002	$1.5 \times 10^6 TCID_{50}/ml$
Human Metapneumovirus (hMPV) 16 Type A1	IA10-2003	$1.5 \times 10^6 TCID_{50}/ml$
Parainfluenza virus	Type 1	$1.5 \times 106 TCID_{50}/ml$
	Type 2	$1.5 \times 106 TCID_{50}/ml$
	Type 3	$1.5 \times 106 TCID_{50}/ml$
	Type 4A	$1.5 \times 106 TCID_{50}/ml$

Interfering Substances Reaction

When tested using the SARS-CoV-2 Antigen Rapid Test Kit (Immunochromatography), 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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CE

IVD

Number: 6600210322
Version: 2.0
Effective Date:2021-03-22