SARS-CoV-2 Antigen Test Cassette
Instruction for Use

CE IVD

For professional use only.
For *in vitro* diagnostic use only.

INTENDED USE

The SARS-CoV-2 Antigen Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) antigens in nasopharyngeal specimen from human. The test is intended to aid in the rapid differential diagnosis of SARS-CoV-2 viral infection.

TEST PRINCIPLE

The SARS-CoV-2 Antigen Test Cassette is an immunoassay based on the principle of Immunochromatography sandwich for determination of SARS-CoV-2 antigen extracted from the nasopharyngeal specimen. The test strip is composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibodies against the nucleocapsid protein of SARS-CoV-2. The reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, the specimen is absorbed into the device by capillary action, mixes with the SARS-CoV-2 antibody-colloidal gold conjugate and flows across the pre-coated membrane. When the SARS-CoV-2 antigen level in the specimen is at or above the limit of detection of the test (LOD), the antigen bound to the antibody-colloidal conjugate are combined by SARS-CoV-2 antibody immobilized in the Test Region(T) of the device, and this produces a colored test band that indicates a positive result. When the SARS-CoV-2 antigen level in the specimen is zero or below the LOD, there will be no visible colored band in the Test Region(T) of the device. This indicates a negative result. To serve as a procedure control, a colored line will appear at the Control Region(C), if the test has been performed properly.
Swab specimens require a sample preparation step, in which the sample is eluted off the swab into buffer solution. When the sample is added to the sample well, the test results are interpreted at 15 minutes based on the presence or absence of colored Sample Lines.

MATERIALS

Materials Provided

Test Cassette……...…....20	Extraction Buffer……...1
Disposable Swab……...……...…...20	Instruction for Use……...…1
Extraction Tube with dropping tip……...……20	Work Station……...1

Materials Required but Not Provided
Timer, containers and personal protection objects such as coat, gloves, glasses etc.

STORAGE AND STABILITY

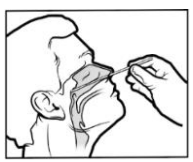
1. Store at 4-30°C in the sealed pouch until the expiration date printed on the package. Do not freeze.
2. The test cassette should be used within 1 hour after opening the sealed pouch.
3. Kit contents are stable until the expiration date printed on the package.
4. Keep away from sunlight, moisture and heat.

PRECAUTIONS

1. For *in vitro* diagnostic use only. Not for self-testing. Do not use after expiration date. Do not reuse the used test card.
2. Do not eat, drink, or smoke in the area where the specimens or kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Follow standard biosafety guidelines for handling and disposal of potential infective materials.
6. The test cassette should remain in a sealed foil pouch until use. Do not use the test cassette if the pouch is damaged or opened.
7. Humidity and temperature can adversely affect the results.
8. The used test strip should be discarded according to national, state and local regulations.

SPECIMEN COLLECTION

Nasopharyngeal Specimen Collection and Preparation

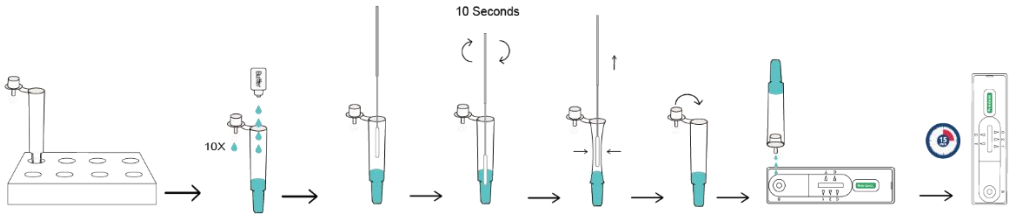


- Tilt patient's head back 70 degrees.
- Gently and slowly insert the swab provided through the nostril parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx.
- Gently rub and roll the swab for at least 5 times to absorb secretions, then slowly remove swab while rotating it.
- Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection.
- The swab collected with the specimen should be tested as soon as possible. If immediate testing is not possible, the swab should be placed in a sterile plastic tube labeled with patient's information and closed tightly at room temperature (15-30℃) for up to 1 hour before testing.

TEST PROCEDURE

Nasopharyngeal Specimen Test Procedure

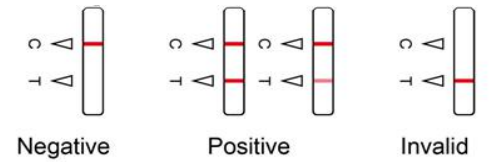
1. Allow the test cassette, specimen, buffer and/or controls to reach room temperature 15-30℃ (59-86℉) prior to testing.
2. Place the extraction tube in the workstation. Add 10 drops of extraction buffer solutions into the extraction tube.
3. After the specimen collection, insert the swab into the extraction tube which contains buffer, and rotate the swab for approximately 10 seconds to dissolve the sufficient specimen in the buffer.
4. Remove the swab while squeezing the swab head to screw the remaining specimen out.
5. Discard the swab according to your biohazard waste disposal protocol.
6. Remove a test cassette from the foiled pouch by tearing at the notch and place it on a clean and horizontal surface.
7. Cover the extraction tube with the dropping tip and add 3 drops of the specimen vertically into the specimen well of the cassette.
8. Read the result after 15 minutes. The test result should not be read and interpreted after 20 minutes.



INTERPRETATION OF RESULTS

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking, and correct procedural technique. Quality Control materials (positive control swab and negative control swab) are not included in the kit and can be purchased separately.

1. **Positive:** Two colored Lines appear in the result window: Test line (T) and Control line (C), which are considered positive for SARS-CoV-2 antigen.
2. **Negative:** If only Control line (C) appears in the result window, which is considered negative for SARS-CoV-2 antigen.
3. **Invalid:** If the Control line fails to appear, whatever if the test line appears in the test line region, it is considered as an invalid result, review the procedure and retest with a new test cassette. If the problem still exists, stop using the test kit immediately and contact your local distributor.



***NOTE:** The intensity of the color in the test line regions may vary depends on the concentration of SARS-CoV-2 antigen. Therefore, any shade of color in the test line region should be considered positive.

QUALITY CONTRAOL

There are internal procedural controls in the test. A colored line displayed in the control area (C) is an internal procedural control. It confirms the presence of a sufficient amount of sample and correct procedure.

LIMITATIONS OF THE TEST METHOD

1. The test is for qualitative detection of SARS-CoV-2 antigen in human nasopharyngeal swab.
2. This test detects both viable (live) and non-viable, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the specimen and may or may not correlate with viral culture results performed on the same specimen.
3. A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test.
4. False negative results may occur if a specimen is improperly collected, transported, or handled.
5. False results may occur if specimens are tested after 1 hour of collection.
6. Positive test results can't exclude co-infections with other pathogens.
7. SARS-CoV may produce a positive result. SARS-CoV can be detected as a cross-reaction.
8. As with all diagnostic tests, all results must be interpreted in conjunction with clinical data available to the physician.
9. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time excludes the possibility of a SARS-Cov-2 infection.
10. The potential effects of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressive drugs have not been evaluated with regard to the test.
11. Performance has only been established with the specimen types listed in the Intended Use. Other specimen types have not been evaluated and should not be used with this assay.

PERFORMANCE CHARACTERISTICS

1. Sensitivity, Specificity and accuracy
The SARS-CoV-2 Antigen Test Cassette was compared with a commercially available gold standard reagent (PCR), the results showed that the clinical sensitivity and specificity.
Nasopharyngeal swab

Assessment reagent	PCR (gold standard reagent)		Total
	Positive	Negative	

SARS-CoV-2 Antigen Test Cassette	Positive	116	1	117
	Negative	2	120	122
Total		118	121	239

Clinical Sensitivity (Positive coincidence rate):98.31% (95% CI: 94.00% ~99.50%)

Clinical Specificity (Negative coincidence rate):99.17% (95% CI: 95.50%~99.90%)

2. Limit of Detection (LOD)

The detection limit of SARS-CoV-2 Antigen Test Cassette has been examined. The LOD of the test for the NP-protein of SARS-CoV-2 is approximately 100pg/ml. The LOD of the test for the SARS-CoV-2 virus (inactivated) is approximately 50 $TCID_{50}$/ml.

Concentration	Positive/result	Agreement rate
100pg/ml NP-protein	30/30	100%
50 $TCID_{50}$/ml	10/10	100%

3. Cross-reactivity

The SARS-CoV-2 Antigen Test Cassette was tested with various microorganisms for possible cross-reactivity. No cross-reactivity was seen with the following microorganisms when tested at the concentration presented in the table below.

Substance	Concentration	Substance	Concentration
Arcanobacterium	1×10^8 org/ml	Coronavirus NL63	$1\times10^{5.07}$ U/ml
Candida albicans	1×10^8 org/ml	Influenza A H1N1	3.16×10^5 $TCID_{50}$/ml
Corynebacterium	1×10^8 org/ml	Influenza A H3N2	1×10^5 $TCID_{50}$/ml
Escherichia coli	1×10^8 org/ml	Influenza B (Yamagata and Victoria) virus	3.16×10^6 $TCID_{50}$/ml
Moraxella catarrhalis	1×10^8 org/ml	Human Rhinovirus 2	$2.81\times10^4$$TCID_{50}$/ml
Neisseria lactamica	1×10^8 org/ml	Human Rhinovirus 14	$1.58\times10^6$$TCID_{50}$/ml
Nesseria subflava	1×10^8 org/ml	Human Rhinovirus 16	$8.89\times10^6$$TCID_{50}$/ml
Pseudomonas aeruginosa	1×10^8 org/ml	Measles virus	1.58×10^4 $TCID_{50}$/ml
Staphylococcus aureus subspaureus	1×10^8 org/ml	Adenovirus 3	$1.58\times10^4$$TCID_{50}$/ml
Staphylococcus epidermidis	1×10^8 org/ml	Parainfluenza virus 2	$1.58\times10^7$$TCID_{50}$/ml
Streptococcus pneumoniae	1×10^8 org/ml	Parainfluenza virus 3	1.58×10^8 $TCID_{50}$/ml
Streptococcus pygenes	1×10^8 org/ml	Respiratory syncytial virus	$8.89\times10^4$$TCID_{50}$/ml
Streptococcus salivarius	1×10^8 org/ml	MERS-coronavirus	10^5 PFU/ml
Streptococcus sp. group F	1×10^8 org/ml	EB virus	10^5 PFU/ml
Human Coronavirus OC43	2.45×10^6 LD_{50}/ml		

4. Interfering Substances

The following compounds have been tested using the SARS-CoV-2 Antigen Test Cassette and no interference was observed.

Analytes	Conc.	Analytes	Conc.
Whole Blood	20μl/ml	Oxymetazoline	0.6mg/ml
Mucin	50μg/ml	Phenylephrine	12mg/ml
Budesonide Nasal Spray	200μl/ml	Rebetol	4.5μg/ml
Dexamethasone	0.8mg/ml	Relenza	282ng/ml
Flunisolide	6.8ng/ml	Tamiflu	1.1μg/ml
Mupirocin	12mg/ml	Tobramycin	2.43mg/ml

5. Precision

Intra-assay

The intra-assay precision was determined by testing the three batches of products for 10 times with the same negative solution and positive solution. The color results of the same batch of products were consistent, and the coincidence rate was 100%.

Inter-assay

The inter-assay precision was determined by testing the three batches of products with the same negative solution and positive solution. The color results of the different batches of products were consistent, and the coincidence rate was 100%.

Manufacturing Date and Expiration Date: view on label

INDEX OF SYMBOL

	Consult Instructions for Use		Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
	Do not use if package is damaged	LOT	Lot Number	4 30	Temperature limit 4-30℃
REF	Catalog #		Manufacturer	CE	CE mark

Jiangsu Mole Bioscience Co., Ltd
6-7th Floor, G116 Building, No.805, Jiankang Avenue,
Medical New& Hi-Tech District,
Taizhou, Jiangsu Province, China
info@molechina.com
www.molechina.com

EC REP

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
E-mail: peter@ lotusnl.com

REF: R220T001B0C0
Number: BMA5682301
Effective Date: 2021-06-30

Revision Date: 2021-12-21
Packing Size: 20 Tests/ Pack
EN version 0.0