IVD

SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag)

Instructions for use

A rapid test for the qualitative detection of antigens to the novel coronavirus SARS-CoV-2 in nasopharyngeal or oropharynx swab, nasal swab and saliva specimen.
For professional in vitro diagnostic use only.

PACKING SPECIFICATIONS

40 T/kit, 20 T/kit, 10 T/kit, 5T/kit, 1 T/kit.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) is a rapid chromatographic immunoassay for the qualitative detection of novel coronavirus SARS-CoV-2 in human throat and nasal secretions, and saliva specimen.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test is for detection of SARS-CoV-2 antigens. Anti-SARS-CoV-2 monoclonal antibodies are coated in the test line and conjugated with the colloidal gold. During testing, the specimen reacts with the anti-SARS-CoV-2 antibodies conjugate in the test strip. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with another Anti-SARS-CoV-2 monoclonal antibodies in the test region. The complex is captured and forming a colored line in the Test line region. The SARS-CoV-2 Antigen Rapid Test contains anti-SARS-CoV-2 monoclonal antibodies conjugated particles and another anti-SARS-CoV-2 monoclonal antibodies are coated in the test line regions.

PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after expiration date.
- The Test cassette should remain in the sealed pouch until use.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- The used Test Strip should be discarded according to national, state and local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated (2-30°C). The Test Strip is stable through the expiration date printed on the sealed pouch. The Test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date. The stability of the kit under these storage conditions is 18 months

SPECIMEN COLLECTION AND PREPARATION

The SARS-CoV-2 Antigen Rapid Test (COVID- 19 Ag) can be performed using nasopharyngeal or oropharynx swab, nasal swab and saliva.

Nasopharyngeal Swab: Insert the sterile swab into the deep nasal cavity until the nasopharynx. Gently rub and rotate the swab against wall of turbinate for several times.

Oropharynx Swab: Insert the sterile swab into the throat. Gently scrape the secretions around the wall of pharynx and tonsil.

Nasal Swab: Insert the sterile swab into one of the nostrils around 2.5cm. Gentally rub against the anterior nasal wall and repeat the actions into the other nostril.

Saliva: Prepare a specimen collection container. Make a “Kruuua” noise from the throat, to get out the saliva or sputum from the deep throat. Then spit saliva (about 1-2ml) into the container. Morning saliva is optimal for saliva collection. Do not brush the teeth, eat food or drink before collection the saliva specimen.

Take out of an assay buffer tube, and tear off the head of the tube. Extrude all the liquid (around 0.5ml) into a specimen collection tube.Insert the swab into the tube and squeeze the flexible tube to extrude the specimen from the head of the swab. Make the specimen resolved in the assay buffer sufficiently. Add the tip onto the specimen collection tube. If saliva specimen, suck the saliva from the container and place 5 drops (approx.200ul) of the saliva into the sample collection tube.
The assay should be performed immediately in 2 hours after the specimen preparation. If the assay could not be carried immediately, the prepared specimen should be kept no more than 24 hours at 2-8°C or 7 days at -20°C.
Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly for more than two times.
If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

COMPONENTS

Materials Provided

1) Foil pouches, each contains one test cassettes, one disposable dropper and one desiccant bag
2) Assay buffer tubes (0.5ml each)
3) Sterile swabs (each bag contains one nasopharyngeal swab and one oropharynx swab)
4) Specimen collection tubes with tips
5) Instruction for use

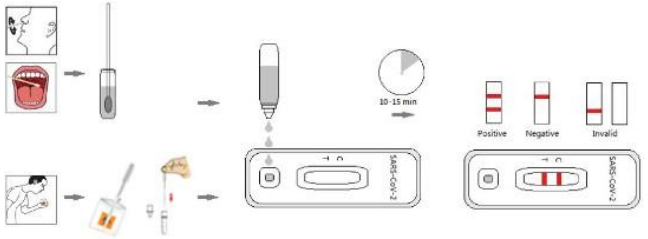
Materials Required But Not Provided

1) Specimen collection container
2) Timer

TEST PROCEDURE

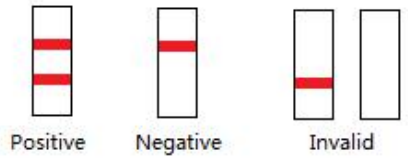
Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and horizontal surface. Reverse the specimen collection tube, extrude 3 drops of the prepared specimen into the specimen well (S) of the test cassette and start the timer.
   See illustration below.



3. Wait for the colored line(s) to appear. Read results at 10 minutes. Do not interpret the result after 15 minutes.

INTERPRETATION OF RESULTS



- **Positive (+):** Two colored lines appear. One colored line should always appear in the control line region (C) and another line should be in the T line region.
  **NOTE: The intensity of the color in the test line regions may vary depending on the concentration of SARS-CoV-2 present in the specimen. Therefore, any shade of color in the test line region should be considered positive and recorded as such.*
- **Negative (-)**: One colored line appears in the control line region (C). No line appears in the T line region.
- **Invalid**: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an 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

1. The SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) is for *in vitro* diagnostic use only. This test should be used for the detection of SARS-CoV-2 antigens in human throat and nasal secretions. If saliva specimen, the loading of virus is usually lower. If negative found in saliva but symptoms like COVID-19, it is suggested to repeat the assay by throat or nasal swab.
2. The SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) will only indicate the presence to SARS-CoV-2 in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
3. If the symptom persists, while the result from COVID-19 Rapid Test is negative or non-reactive result, it is recommended to re-sample the patient few days late or test with PCR.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. 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 preclude the possibility of COVID-19 infection.
6. The potential impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated in the test.
7. Due to inherent differences between methodologies, it is highly recommended that, prior to switching from one technology to the next, method correlation studies are undertaken to qualify technology differences. One hundred percent agreement between the results should not be expected due to differences between technologies.
8. 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 Rapid Test (COVID-19 Ag) has been compared with a commercial gold standard reagent (PCR). The result showed the relative sensitivity and specificity

Nasopharyngeal or oropharynx swab

Method		Gold standard reagent (PCR)		Total Results
SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag)	Results	Positive	Negative	
	Positive	105	0	105
	Negative	2	200	202
Total Result		107	200	307

Relative Sensitivity: 98.13% （95%CI: 93.02%～99.90%）

Relative Specificity: 100% （95%CI：97.73%～100.00%）

Accuracy: 99.35% （95%CI：97.50%～99.98%）

Nasal Swab

Method		Gold standard reagent (PCR)		Total Results
SARS-CoV-2 Antigen Rapid Test	Results	Positive	Negative	
	Positive	103	0	103
(COVID-19 Ag)	Negative	7	100	107
Total Result		110	100	210

Relative Sensitivity: 93.64% （95%CI: 87.23%～97.10%）

Relative Specificity: 100% （95%CI：95.56%～100.00%）

Accuracy: 96.67% （95%CI：93.15%～98.51%）

Saliva

Method		Gold standard reagent (PCR)		Total Results
SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag)	Results	Positive	Negative	
	Positive	112	1	113
	Negative	11	99	110
Total Result		123	100	223

Relative Sensitivity: 91.06% （95%CI: 84.55%～95.08%）

Relative Specificity: 99.00% （95%CI：94.01%～99.99%）

Accuracy: 94.62% （95%CI：90.74%～96.99%）

2. Limit of Detection (LOD)

The limit of detection of the SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) has been studied. The LOD of the test to the SARS-CoV-2 N protein is around 0.2-0.5ng/mL. The LOD of the test to the SARS-CoV-2 virus (inactivated) is about 2-5X10^2 $TCID_{50}$/mL

Concentration	Positive/Result	Agreement Rate
0.5ng/mL N protein	100/100	100%
5X10^2 $TCID_{50}$/mL	100/100	100%

3. Cross-reactivity:

The SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) is associated with a panel of proteins of other human coronavirus recombinant antigens and virus. The results showed in below sheet.

Substance	Concentration	Result
SARS-CoV-2 N protein	0.001 μg/mL	positive
SARS-CoV N protein	1 μg/mL	negative
MERS-CoV N protein	1 μg/mL	negative
HCoV-NL63 N protein	1 μg/mL	negative
HCoV-229E N protein	1 μg/mL	negative
HCoV-HKU1 N protein	1 μg/mL	negative
HCoV-NL63 virus	1X$10^6$$TCID_{50}$/mL	negative
HCoV-229E virus	1X$10^6$$TCID_{50}$/mL	negative

4. Interfering Substances:

The following compounds and other respiratory symptoms relative virus have been tested using the SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) and no interference was observed.

substance	concentration	result
alpha-interferon	3millionIU	No interference
Purified Mucin	1000ng/mL	No interference
Parainfluenza virus	1X$10^5$$TCID_{50}$/mL	negative
Influenza A virus	1X$10^5$$TCID_{50}$/mL	negative
Influenza B virus	1X$10^5$$TCID_{50}$/mL	negative
Chlamydia pneumoniae	1X$10^5$$TCID_{50}$/mL	negative
Adenovirus	1X$10^5$$TCID_{50}$/mL	negative
Mycoplasma pneumoniae	1X$10^5$$TCID_{50}$/mL	negative
Respiratory syncytial virus	1X$10^5$$TCID_{50}$/mL	negative

PRECISION

Intra-Assay

Within-run precision has been determined by using 15 replicates of two specimens: a negative, and an N protein (1ng/ml) as positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same two specimens: a negative, an N protein (1mg/ml) as positive. Three different lots of the SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) have been tested using these specimens. The specimens were correctly identified >99% of the time.

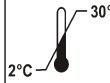
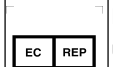
CAUTIONS

1.For in-vitro diagnostic use only.
2.Must not use kit beyond the expiration date.
3.Do not mix components from kits with different lot number.
4.Avoid microbial contamination of reagents.
5.Use the test as soon as possible after opening to protect it from moisture.

INSTRUCTION APPROVAL AND REVISION DATE

Approval Date: 2020-09-01, Revision Date: 2021-04-06
Date of Issue: 2020-04-06

INDEX OF SYMBOLS

	Consult instructions for use		Store between 2-30°C		Use by
	For *in vitro* diagnostic use only		Do not reuse		Lot Number
	Manufacturer		Tests per kit	REF	Catalog No
	European union authorized		Keep dry		Don't use the product
	Biological risks		The product meets the basic requirements of European in vitro.		

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