VISION
BIOTECHNOLOGY

COVID-19 RAPID ANTIGEN

CE-IVD TEST

REF
V2005Y190

CE
IVD

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COVID-19 RAPID ANTIGEN CE-IVD TEST

User Manual

REF : V2005Y190

Antigen Lateral Flow Assay Kit

(Nasopharyngeal Swab)

This manual must be read attentively and completely before using this product.

If you have any problems, please contact our Technical Service Center for help.

VISION Biotechnology Ltd.

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Context

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1. Intended Use

“COVID-19 RAPID ANTIGEN CE-IVD TEST” This kit is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein in nasopharyngeal swab as an aid in the scientific research of primary and secondary COVID-19 infections.

2. Product Description

Vision Covid19 Rapid Diagnostic Antigen Test is a qualitative test that detects SARS-CoV-2 nucleocapsid protein in nasopharyngeal swab specimen. After applying the sample, SARS-CoV-2 nucleocapsid protein bind to capture antibody-coated particles in the test cassette. The sample then moves chromatographically through the membrane. In the T test line

region, it reacts with locally bound SARS-CoV-2 nucleocapsid protein, respectively, resulting in a colored line. If the specimen does not contain COVID-19 antigens, no colored line will appear in any of the test line areas, indicating a negative result.

As a positive control for the correct performance of the procedure and operation of the cassette, a colored line should always appear in the control line area. If the control line area is blank the test is invalid.

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3. Kit Content

Item	Specification	Storage
Test Casette		**2-30℃, 18 months**
VTM		
Swab		
Product Description	**1 copy**	

Note: It is suggested to use the vtm within 6 months after opening the vial.

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4. Specimen Collection, Handling, And Storage

Inadequate or inappropriate specimen collection, storage, and transport are likely to yield false test results. Training in specimen collection is highly recommended due to the importance of specimen quality. CLSI MM13-A may be referenced as an appropriate resource.

4.1 Collecting The Specimen

- Follow specimen collection device manufacturer instructions for proper collection methods.
- This kit can be performed with Nasopharyngeal Swab Specimen.
- Nasopharyngeal Swab Specimen: Collect specimen from nasal by using swab.

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- Remove the swab from the packaging.
- Tilt the patient's head back slightly, so that the nasal passages become more accessible.
- Gently insert the swab along the nasal septum, just above the floor of the nasal passage, to the nasopharynx, until resistance is felt.
- Insert the swab into the nostril, parallel to the palate. If you detect resistance to the passage of the swab, back off and try reinserting it at a different angle, closer to the floor of the nasal canal.
- The swab should reach a depth equal to the distance from the nostrils to the outer opening of the ear.
- The CDC recommends leaving the swab in place for several seconds to absorb secretions and then slowly removing the swab while rotating it.
- Rotate the swab in place several times before removing it.

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- Open the collection tube and insert the swab into the tube. Break the swab at the groove and discard what remains of the swab.

Note for sample

1. Bring samples to room temperature prior to testing. Frozen samples must be completely thawed and mixed well prior to testing. Samples should not be frozen and thawed repeatedly.
2. If samples are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.

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5. Procedure

1. The swab clinical specimen is added to the well.
2. The sample flows down to the sample pad.
3. Capillary action/lateral flow will move the sample across the test.
4. Next, the sample/conjugate complex moves to the nitrocellulose membrane. Here, it comes in contact with two test lines: antibody and control.

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5. The antibody line, which contains an immobilised capture antibody that recognises SARS-CoV-2 nucleocapsid protein will bind here. However, only antibody/COVID-19 antigen/gold nanoparticle complexes will produce a visible coloured line.

6. The control line is the last line the sample will encounter. The control line contains an immobilised antibody that recognises Rabbit IgG, the control antibody. To serve as a procedural control, a coloured line should always appear in the control line region, indicating that the proper volume of specimen has been added and membrane wicking has occurred.
7. Finally, any excess will flow through to the absorption pad.
8. After 10- 15 minutes, the results of the test can be read.

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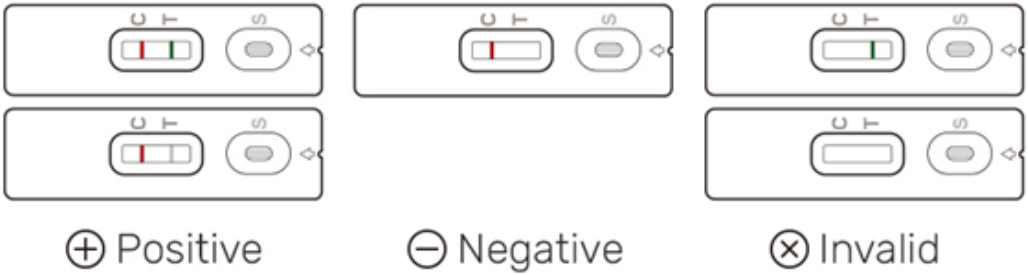
6. Results



T Positive: Two lines appear

Two colored line should appear in the test line(T) and control line region (C).

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Negative: One line appears

One colored line should appear in the control line region (C). No line appears in T test line region.

Invalid: Control line fails to appear

Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. of the problem persists, is continue using the test kit immediately and contact Vision Biotechnology Technical Service.

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7. Disclaimer and use limitations

Vision Covid19 Rapid Diagnostic Test Antigen kit is a qualitative test that detects SARS-CoV-2 nucleocapsid protein in nasopharyngeal swab. After applying the sample, antigen bind to COVID detection antibodies-coated particles in the test cassette. The mixture then moves chromatographically through the membrane. In the T test line region, it reacts with locally bound capture antibodies, respectively, resulting in a colored line.

If the specimen does not contain SARS-CoV-2 nucleocapsid protein, no colored line will appear in any of the test line areas, indicating a negative result. As a positive control for the correct performance of the procedure and operation of the cassette, a colored line should always appear in the control line area. If the control line area is blank the test is invalid.

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8. Sensivity and Specifity

The 2019-nCoV Antigen Rapid Test Cassette was compared with a leading commercial PCR. The results show that 2019-nCoV Antigen Rapid Test Cassette has a high sensitivity and specificity.

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Relative Specificity: 98.0% (89.4%-99.9%)*

Accuracy: 98.6% (92.3%-99.96%)*

9. Quality Control

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal valid procedural control, it confirming adequate membrane wicking. Control standards

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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.

Note

1. This product is for scientific research only.
2. Please read the manual carefully before use. All kinds of reagents provided in this kit are only for this experiment.
3. Do not use expired products or products with a broken aluminum foil.
4. Handle all samples cautiously as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of samples.

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5. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when samples are assayed.

6. Do not eat, drink or smoke in the area where samples or kits are handled.

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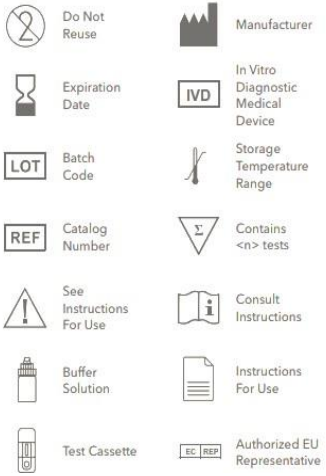

7.The used tests, samples and potentially contaminated should be discarded according to the local regulation.

8.Humidity and temperature could adversely affect results.

9. Do not use components from different batches of kits.

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