Shenzhen Aivd Biotech Inc.

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COVID-19 (SARS-CoV-2) Antigen Detection Rapid Lateral Flow Test (latex bead-based)

AIVD Biotech's COVID-19 Ag test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein (NP) antigen from SARS-CoV-2 in direct nasal swabs from individuals suspected of COVID-19.

Description:

This kit utilizes the principle of latex bead immunochromatography to qualitatively detect the new coronavirus (COVID-19) Np antigen in human nasal swabs. Lateral flow immunochromatographic assay provides an easy workflow, short turnaround time, and rapid diagnosis of COVID-19 suspected patients.

The test contains latex bead conjugate pad and a membrane strip pre-coated with antibodies specific to SARS-CoV-2 antigen on the test lines (T). If SARS-CoV-2 antigen is present in the specimen, a visible band appears on the test lines (T) as antibody-antigen-antibody latex bead complex forms. The control line (C) is used for procedural control and should always appear if the test is performed correctly.

This method does not require expensive medical instruments and consumables. Just take the specimen and add it to the sample well. If sample contains the antigen, it will interact with the latex bead-labeled COVID-19 anti-SARS-COV-2 NP antibodies on the conjugate pad. Then a visible red band appears on the test line (T) as antigen-antibody conjugate complex forms. If test line not appear, the result considered negative. The control line (C) is used for procedure control and should always appear if the test is performed correctly, indicating that the proper volume of specimen has been added and membrane wicking has occurred. **If the control line C does not appear, it indicates that the test result is invalid, and this sample needs to be tested again with another test cassette.**

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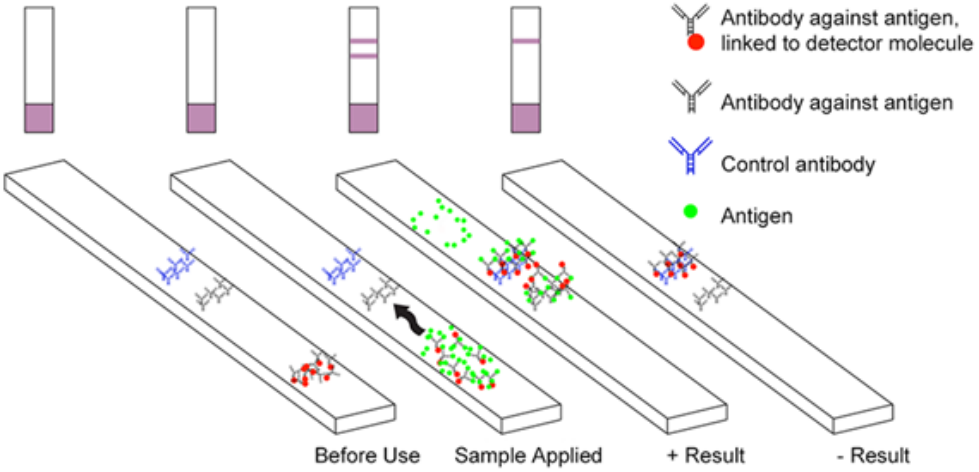

Figure 1 Test principle

Required components

1. A foil pouch with a desiccant and a single use test card, 1 piece

3. Sterile swab, 1 piece

3. Extraction buffer tube (1 ml), 1 tube.

4. Instructions for use, 1 piece.

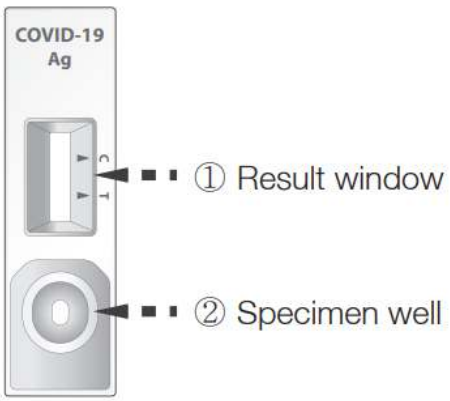

Figure 2 Single use test card

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Storage conditions

1. Store at the dark place, room temperature 18~28C with low humidity.

2. After opening the foil bag, please use the test cassette within 30 mins.

3. Expiration period 12 month

Specimen requirements:

1. Nasopharyngeal swab specimen.

2.Specimen should be tested as soon as possible upon collection. If the sample has to be stored, store the swab sample at room temperature for up to 1 hours or 2~8℃ for up to 4 hours prior to testing.

Specimen collection

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinate. Rotate the swab 5 times or more against the nasal wall then slowly remove from the nostril.

Specimen preparation

1. Insert the extraction buffer tube into the tube rack, make sure that the sample tube is firmly upright and touches the bottom of the rack.

2. Insert the swab into an extraction buffer tube.

3. Gently stir the swab in the tube, and then left swab inside the tube for 1 minute or Mix on the vortex mixer for about 30 seconds,

4. The sample should be tested immediately after collection.

If it cannot be tested in time, it should be stored in the virus transport matrix. The specimens can be stored at 2-8°C for 4 hours。

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Basic Protocol：

Step 1: If the sample is refrigerated, remove the sample to be tested and the required reagents from the storage conditions, equilibrate to room temperature (15~30°C)

Step 2: When preparing to test, open the aluminum foil bag, take out the test card, and lay it flat on a table.

Step 3: Mark the sample number on the test card,

Step 4: Using pipette add 50ul of the sample into a sample well on the device,

Step 5: Read the result within 15 minutes,

Please read the result after 15 minutes. After observing and recording the result, please discard the test card to avoid affecting the result judgment.

Do not read test results after 30 minutes. It may give false results.

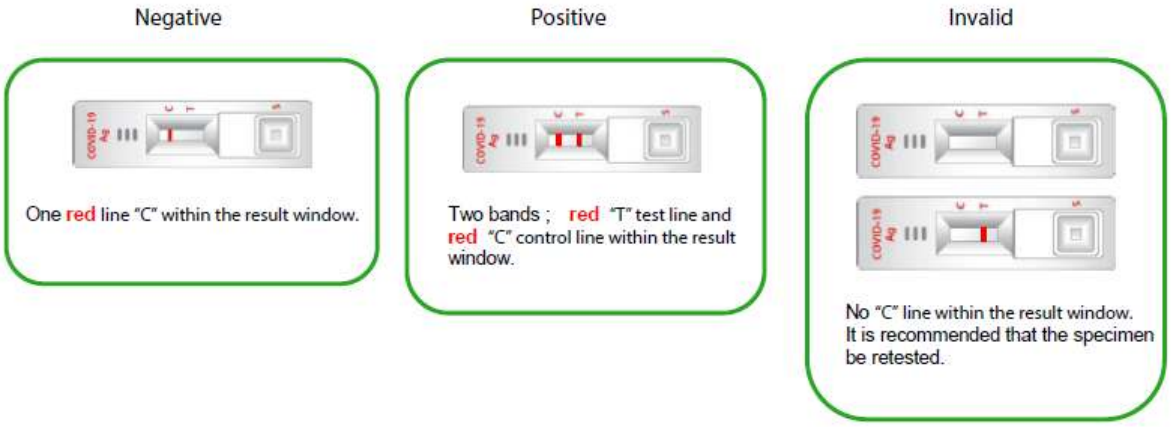
Results Judgment

1. Negative result: If only the control line C appears and the test line T does not show color, it means that no new coronavirus antigen have been detected;

2. Positive result:

If both the quality control line C and the test line T appear, it means that the new coronavirus antigen is detected;

3. Invalid result: If the line C is not observed, the test is considered invalid regardless of whether there is a test line appeared or not, the test should be repeated using another test cassette.



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Performance Characteristics

A total of 365 samples from suspected patient were tested by the RT-qPCR test. Testing results are shown in the following table:

	PCR	
AIVD SARS-Cov-2 Antigen Rapid Test Kit	Positive	Negative
Positive	59	8
Negative	6	292
Total:	65	300

Sensitivity: 90.7%;

Specificity: 97.3%.