CORONAVIRUS AG RAPID TEST

PRODUCT CODE: COVAG010, COVAG020

COVAG010	COVAG020
10 TESTS	**20 TESTS**
STORE AT 2-30°C	
INSTRUCTIONS FOR USE	
FOR PROFESSIONAL USE ONLY	

IVD For In Vitro Diagnostics Use Only
LOT Lot Number
REF Catalogue Number
Storage Temperature
Expiry Date (Year / Month)
Warning, Read Enclosed Documents
Instructions For Use
Manufactured By

CORONAVIRUS AG RAPID TEST

The Fortress Coronavirus Ag Rapid Test is a single use in vitro immunochromatographic assay for the qualitative detection of nucleocapsid protein antigen from 2019 novel coronavirus (SARS-CoV-2) in nasopharyngeal swab specimens, directly from patients suspected for infection with SARS-CoV-2 by their healthcare provider. This test is intended to assist in the rapid diagnosis of the coronavirus disease 2019 (COVID-19). The Fortress Coronavirus Ag Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

SUMMARY AND EXPLANATION

Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), kidney failure and death. Those patients infected by COVID-19 are the main source of infection, whether they are showing symptoms or not.

The SARS-CoV-2 nucleocapsid protein antigen can be detected in upper respiratory specimens during the acute phase of infection. The rapid diagnosis of SARS-CoV-2 infection is aimed to help healthcare professionals in treatment of COVID-19 patients and in turn control the disease more efficiently and effectively.

PRINCIPLE OF THE TEST

The Fortress Coronavirus Ag Rapid Test is an immunochromatographic membrane assay that implements highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2 in nasopharyngeal (NP) swab. The test strip consists of the following sections: 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, whereas 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 patient sample is applied to the sample well, conjugates dried in the reagent pad are dissolved and travel along the strip along with the sample. If SARS-CoV-2 antigen is present in the sample, a complex formed between the anti-SARS-2 conjugate and the virus will be captured by the specific anti-SARS-2 monoclonal antibodies coated on the test line region (T). Absence of the T line indicates a negative result. As indication of a procedural control, a red line will always appear in the control line region (C) showing that the appropriate volume of sample has been applied and that the test reaction has been successful.

KIT CONTENTS

- Test cassette(s)
- Sterile swabs
- Extraction tubes and filtered nozzles
- Buffer(s)
- Tube Rack
- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Clock or timer

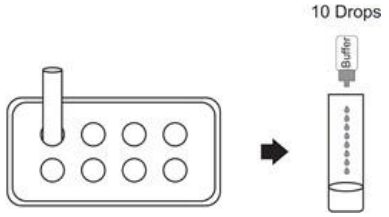
SPECIMEN COLLECTION

Use the nasopharyngeal swab supplied in the kit.

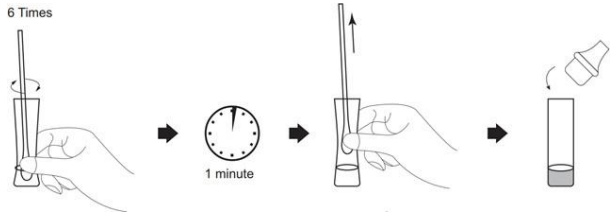
1. Carefully insert the swab into the nostril of the patient, reaching the surface of posterior nasopharynx that presents the most secretion under visual inspection.
2. Swab over the surface of the posterior nasopharynx. Rotate the swab several times.
3. Withdraw the swab from the nasal cavity.

SAMPLE PREPARATION PROCEDURE

1. Insert the test extraction tube into the tube rack provided. Ensure that the tube is standing firm and reaches the bottom of the tube rack.
2. Add 0.3 ml (about 10 drops) of the sample extraction buffer into the extraction tube.



3. Insert the swab into the extraction tube which contains 0.3 ml of the extraction buffer.
4. Rotate the swab approximately 6 times while pressing the head against the bottom and side of the extraction tube.
5. Leave the swab in the extraction tube for 1 minute.
6. Squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as testsample.
7. Insert the filtered nozzle provided into the extraction tube tightly.



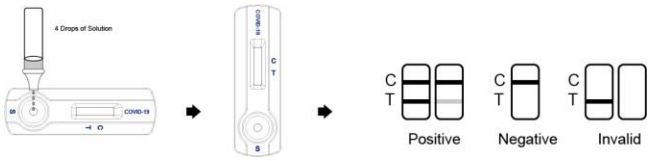
SPECIMEN TRANSPORT AND STORAGE

Nasopharyngeal swabs are for single use only, therefore it is important that the used swab is disposed of after specimen is removed during sample preparation, and not returned to the original packaging. **Specimens should be tested immediately after collection for best performance.** Where this is not possible, it is highly recommended that the nasopharyngeal swab containing patient specimen is placed in a clean, unused plastic tube labelled with the patient information and capped tightly at room temperature (15-30°C) for up to 1 hour prior to testing. If 1 hour is exceeded, dispose of the sample as this will no longer be valid and a new sample must then be collected for testing.

TEST PROCEDURE

Allow the test device, test sample and buffer to reach room temperature (15-30°C) prior to testing.

1. Remove test device from sealed pouch immediately before testing and lay flat on work bench.
2. Invert the sample extraction tube (with filtered nozzle affixed), and add 4 drops (approx. 100 µL) of test sample, by squeezing the extraction solution tube, into the sample window.



3. Wait for the coloured band(s) to appear. The result should be read within 15 minutes. Do not use results shown after 20 minutes.

INTERPRETATION OF RESULTS

1. POSITIVE:

The presence of two lines as control line (C) and test line (T) within the result window indicates a positive result.

2. NEGATIVE:

The presence of only the control line (C) within the result window indicates a negative result.

3. **INVALID:**

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Some causes of invalid results are due to incorrect testing procedure/application or the deterioration of the test device beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NOTE:

1. The intensity of colour in the test line region (T) may vary depending on the concentration of antigen present in the sample. For this reason, any trace of colour in the test line region (T) should be considered positive and further quantitative testing should be carried out on the patient sample. Please note that this is a qualitative test only, and cannot determine the concentration of antigen in the sample.
2. Insufficient specimen volume, incorrect test procedure/application or expired tests are the main reasons for control band absence.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control line region (C) is the internal procedural control. This confirms sufficient specimen volume and correct procedural technique has been applied. Control standards are not supplied with this test, however, it is recommended that positive and negative controls are sourced from a competent authority and tested as good laboratory practice, to confirm the test procedure and verify the test performance.

LIMITATIONS

1. The analysis of respiratory infection caused by microorganisms other than SARS-CoV-2 will not be determined with this test. The Fortress Coronavirus Ag Rapid Test is capable of detecting both viable and non-viable SARS-CoV-2. The performance of the test depends on antigen concentration and may not correlate with viral culture results performed on the same specimen.
2. Failure to follow the test procedure precisely may adversely affect test performance and/or invalidate the test result.
3. 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 rule out the presence of SARS-CoV-2 antigens in the sample, as they may be present below the minimum detection level of the test or in the case of the sample being collected or transported improperly.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Positive test results do not rule out co-infections with other pathogens.
6. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity, Specificity and Accuracy

The Fortress Coronavirus Ag Rapid Test has been evaluated with specimens obtained from patients. A commercialised molecular assay was used as the reference method. The results show that the Fortress Coronavirus Ag Rapid Test has a high overall relative accuracy.

Table 1: The Fortress Coronavirus Ag Rapid Test vs PCR

Method		PCR		Total Results
Fortress Coronavirus Ag Rapid Test	Results	Positive	Negative	
	Positive	68	0	68
	Negative	9	168	177
Total Results		77	168	245

Relative Sensitivity: 88.3%

Relative Specificity: 100%

Accuracy: 96.3%

STORAGE AND STABILITY

1. The kit can be stored at room temperature 2-30°C.
2. Do not freeze any of the test kit components.
3. Do not use test device and reagents after expiration date.
4. Reseal the sealable pouch immediately after removing a test device.
5. Test devices that have been outside of the sealed pouch for more than 1 hour should be discarded.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic use only.
2. The test device should remain in the sealed pouch until use.
3. Do not use kit past its expiration date.

4. Swabs, tubes and test devices are for single use only.
5. Extraction buffer contains a solution with a preservative (0.09% sodium azide). If solution comes in contact with the skin or eyes, flush with ample volumes of water.
6. Solutions that contain sodium azide may react explosively with lead or copper plumbing. Use large quantities of water to flush discarded solutions down the sink.
7. Do not interchange or mix components from different kit lots.
8. When collecting a nasopharyngeal swab sample, use the Nasopharyngeal Swab supplied in the kit.
9. To obtain accurate results, do not use visually bloody or overly viscous samples.
10. Wear suitable protective clothing, gloves, and eye/face protection when handling patient samples and the contents of this kit. New gloves should be worn each time a new patient sample is handled to avoid cross contamination.
11. Humidity and temperature can adversely affect results.
12. Used testing materials should be discarded in accordance with local disposal regulations.
13. All patient samples along with contaminated test materials should be treated as potentially infectious when handling.