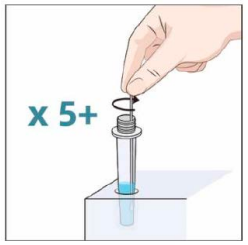
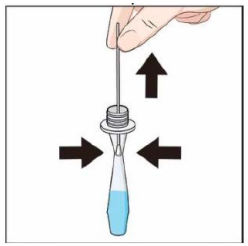


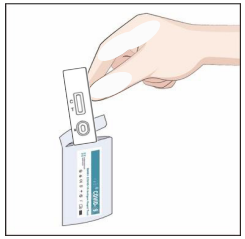
4. Immediately place the swab into the extraction tube. Be sure it is touching the bottom of the tube. Rotate the swab vigorously at least 5 times, rubbing the swab against the wall of the tube. Let the swab soak in the buffer liquid **for at least 1minute. Incorrect or invalid results may occur if the swab is soaked for too short or too long.**



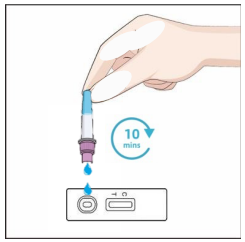
5. After one minute, carefully remove the swab from the tube. Squeeze the swab tip through the tube while removing the swab in order to remove as much liquid as possible from the swab. Do not touch the tip of the swab.

6. Screw the cap on to the extraction tube tightly, making sure that it is sealed tightly.

TEST PROCEDURE



7. Remove test device from the sealed pouch just prior to the testing. Set it on a flat surface.



8. Reverse the sample extraction tube and add 2 drops (about 70-80μl) of test sample by squeezing the extracted solution tube into the sample window. Wait 10 minutes. Do not handle or move the test device until the 10 minutes is complete.

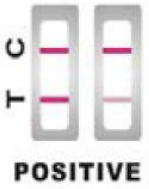
9. Read the result at 10-20 minutes. Do not interpret the result after 20 minutes. False positives, false negatives or invalid results may occur if the device is read beyond the recommended time period.

10. After interpretation of results, discard all biological components safely in the waste bag provided. Report test results to the local health authority. Sanitise the work space with 70% alcohol or household bleach, and wash hands with soap and water or use hand sanitiser.

INTERPRETATION OF RESULTS

Negative:
•One pink line appears at control line (C), and no T line (T) in test region. Which shows that no COVID-19 antigen was detected, and the result was negative.
•Even if the test is negative, there may be an infection, as the coronavirus cannot be accurately detected in all phases of an infection
•Repeat the test after 1~2 days if a positive result is expected.

A negative result does not exclude SARS-CoV-2 infection and may need to be confirmed with a molecular assay.



Positive:
•The presence of two pink lines, control line (C) and test line (T),indicates a positive result.
•Please contact a family doctor or the local health department immediately and follow local guidelines for self-isolation.

A negative result does not exclude SARS-CoV-2 infection and may need to be confirmed with a molecular assay.

Invalid:
•If the quality control line (C) is not observed, test results are invalid regardless of whether the test line (T) is displayed, and the specimen should be retested using a new strip.
•If the test results remain invalid, please contact a family doctor or visit a COVID-19 test center.
If the result is invalid, repeat the test with a new test kit.

SUMMARY

This product is used for in vitro qualitative detection of COVID-19 antigen in anterior nasal swabs. Coronavirus belongs to the Nestovirus, Coronaviridae, and is divided into three genera: α, β, and γ. Genera α, β are only pathogenic to mammals while genera γ mainly causes infections in birds. Coronavirus is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through the fecal-oral route. There are currently 7 known types of human coronavirus (HCoV) that cause human respiratory disease: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and 2019-nCoV, which are the important pathogens of human respiratory infections. 2019-nCoV may cause COVID-19, clinical manifestations are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, and acute breathing distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders and become life-threatening.

INTENDED USE

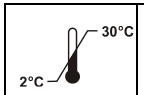
The BHM® COVID-19 Antigen Rapid Test is intended for the qualitative detection of the nucleocapsid protein antigen from 2019-nCoV from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19. The test is suitable to be performed by adults above the age of 18 as a self-test or performed on children above the age of 7 by an adult. Results are for the identification of 2019-nCoV nucleocapsid protein antigen. Antigen is generally detectable in anterior nasal specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with past medical history and other diagnostic information is necessary to determine infection status.

Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease. Individuals who test positive with the BHM® COVID-19 Antigen Rapid Test should self-isolate and seek follow-up care with their general practitioner or healthcare provider as additional testing may be necessary. Negative results should be treated as presumptive, do not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be confirmed with a molecular assay, if necessary, for patient management. Individuals who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have 2019-nCoV infection and should seek follow up care with their general practitioner or healthcare provider.

TEST PRINCIPLE

The reagent utilises the principle of the double antibody sandwich method combined with colloidal gold immunochromatography. The test card also contains a quality control line (C line), which should appear regardless of whether there is a T line. The C line is for the quality control of the antibody immune complex. If the C line does not appear, it indicates that the test result is invalid, and the sample should be retested with another test strip.

STORAGE AND STABILITY

	Store at 2°C to 30°C		Expires in 24 months (see package label)
	Keep away from sunlight		Keep dry
	Keep out of the reach of children		Do not use if package is damaged

WARNINGS AND PRECAUTIONS

1. People who are not able to perform the test alone should be tested by their legal guardians.
2. This product is applicable to nasal swab samples. Using other sample types may cause inaccurate or invalid test results.
3. Test within two hours after sample collection. Stale samples may cause inaccurate results.
4. Please wait 15 to 30 minutes after sample loading, and then read the test results. Incorrect waiting time may cause inaccurate results.
5. If the test line or control line is out of the test window, do not use the test card. The test result is invalid. Retest the sample with another test card.
6. This product is disposable. DO NOT recycle used components.
7. Disinfect used products, samples, and other consumables with a household bleach spray, or a 70% - 75% alcohol spray.
8. Wash the hands thoroughly before and after the test.
9. Do not touch swab tip when handling the swab.
10. Inadequate or inappropriate specimen collection may yield inaccurate test results.

PRODUCT PERFORMANCE

Limit of Detection (LoD): The BHM® COVID-19 Antigen Rapid Test performs to a standard whereby it can detect a viral load of 100 PFU/ml (equivalent to an ORF1ab Ct of 27.7 and N1 Ct of 30.7).

Cross-Reactivity with Other Pathogens
No cross-reactivity observed with the following pathogens: Influenza A (H1N1), Influenza A (H3N2), Influenza A (H5N1), Influenza A (H7N9), Influenza B, MERS-Coronavirus, Human Coronavirus (NL63), Human Coronavirus (229E), Human Coronavirus (OC43), Respiratory Syncytial Virus (Type A), Adenovirus Human Metapneumovirus (hMPV), Enterovirus/ Coxsackievirus B4, Parainfluenza, SARS-CoV-1 and Rhinovirus.

Interference Test
Mucin (2%), Blood (1%), Nasal Drops (15%), Nasal Spray (15%), Anti-viral Drugs (0.5%), Afrin-nasal spray (15%), Chloraseptic, Cepacol (1.5mg/ml), CVS throat spray (15%), Mupirocin Ointment (10mg/ml), Nasocort Allery (15%), Neilmed Sinuflow Ready Rinse (15%), NeilMed Sinufrin plus (15%), Neo-Synephrine (15%), Oseltamivir (2.5mg/ml), Mucin protein (2.5mg/ml), Rhinocort (15%), Saline Nasal spray (15%), Tobramycin (4.4ug/ml), and Zanamivir (282 ng/ml) were found not to affect test performance.

High Dose Hook Effect
No high dose hook effect was observed when tested with up to a concentration of 1.6 x 10^5 TCID50/ml of heat inactivated COVID-19 virus with the BHM® COVID-19 Antigen Rapid Test.

Intra-Assay
Within-run precision has been determined by using 10 replicates of three specimens: a negative, a low titer positive and a high titer positive. The three samples were correctly identified and consistent.

Inter-Assay
Between-run precision has been determined by 10 independent assays on the same three specimens: a negative, a low titer positive and a high titer positive. Three different lots of the BHM COVID-19 Antigen Rapid Test have been tested over a month period using the three samples. The specimens were correctly identified and consistent..

Sensitivity, Specificity & Total Accuracy
The product performance was evaluated with clinical specimens, using commercial RT-PCR kit as the reference method.
Overall Clinical Study Results for Nasal Swabs:

Method	PCR Positive	PCR Negative	Total Results
Positive Nasal Swab	54	0	54
Negative Nasal Swab	2	96	98
Total Results	56	96	152

Relative sensitivity = 96.4% (95%CI: 85.4%-98.9%)
Relative specificity = 100% (95%CI: 94.3%-100%)
Relative accuracy = 98.0% (95%CI: 93.4%-99.3%)

Overall Clinical Study Results for Oral Swabs:

Method	PCR Positive	PCR Negative	Total Results
Positive Oral Swab	55	1	56
Negative Oral Swab	2	94	96
Total Results	57	95	152

Relative sensitivity = 96.5% (95%CI: 85.4%-98.9%)
Relative specificity = 99.0% (95%CI: 94.3%-100%)
Relative accuracy = 98.2% (95%CI: 93.4%-99.3%)

LIMITATIONS

1. This product is intended for self-test diagnosis of COVID-19 only. The final diagnosis should not be determined solely on the result of a single test, but should be determined by a professional doctor after evaluating the clinical signs and the results of other examinations.

2. A negative result indicates that there is no virus in the sample, or the viral load is below the limit of detection of this product. It cannot completely exclude the possibility of viral infection of patient. Too early testing after exposure to the virus may also give a negative result. Please repeat the test after a few days if you suspect a virus infection
3. A positive result indicates that the tested sample has viral load higher than the limit of detection of this product.
4. Please follow the instructions strictly when storing and using the product. False negative results may also caused by abnormal storage conditions, or incorrect sampling.
5. DO NOT use the test if the packaging is damaged. The test may have inaccurate result.
6. Samples collected from asymptomatic COVID-19 people may have false negative results, if not enough viruses are collected.
7. The amount of viral antigens in the sample will decrease with the duration of disease. Samples taken one week after symptom onset are more prone to false negative results

INDEX OF SYMBOLS

	Manufacturer		Date of manufacture
	Authorized representative in the European Community		Consult instructions for use
	Contains sufficient for <*n*> tests		*In vitro* diagnostic medical device
	Batch Code		Use-by date
	Catalogue number		Store between 2-30°C
	Do not re-use		Do not use if package is damaged
	Keep away from sunlight		Keep dry

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