HMPV Rapid Test

Catalogue Number: RAPG-HMPV-001

Please read this manual carefully before operating to ensure proper use.

TEST KIT DESCRIPTION AND INTENDED USE

The Biopanda HMPV Rapid Test is a lateral flow immunochromatographic assay for the qualitative detection of human metapneumovirus antigens present in nasopharyngeal swab samples.
It is intended to assist in the diagnosis of HMPV infection, in conjunction with other tests.
This test is for *in vitro* diagnostic use only.

BACKGROUND

Human metapneumovirus (HMPV) can cause upper and lower respiratory disease in people of all ages, especially among young children, older adults, and people with a weakened immune system. Discovered in 2001, HMPV is in the Pneumoviridae family.[1]
Symptoms commonly associated with HMPV include cough, fever, nasal congestion, and shortness of breath. Clinical symptoms of HMPV infection may progress to bronchitis or pneumonia and are similar to other viruses that cause upper and lower respiratory infections. The estimated incubation period is 3 to 6 days, and the median duration of illness can vary depending upon severity but is similar to other respiratory infections caused by viruses.[2]
The Biopanda HMPV Rapid Test uses antibodies specific for human metapneumovirus to selectively detect human metapneumovirus antigens in nasopharyngeal swab samples.

TEST PRINCIPLE

The Biopanda HMPV Rapid Test is a qualitative, membrane based immunoassay for the detection of antigens to HMPV in nasopharyngeal swab samples. The membrane is pre-coated with anti-human metapneumovirus antibodies. During testing, the HMPV antigen in swab sample reacts with HMPV antibody particles in the test. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with the anti-human metapneumovirus antibodies on the membrane in the test line region. If the sample contains HMPV antigen, a coloured line will appear in the test line region, indicating a positive result. If the sample does not contain HMPV antigen, a coloured line will not appear in the test line region, indicating a negative result.
To serve as a procedural control, a coloured line will always appear in the control line region, indicating that proper volume of sample has been added and membrane wicking has occurred.

KIT CONTENTS

- 20 x Foil wrapped test cassettes
- 20 x Sample collection tubes with extraction buffer
- 20 x Sterile swabs
- 1 x Package insert

STORAGE AND HANDLING

Store the kit at between 2-30°C in a cool, dry place away from direct sunlight. **DO NOT FREEZE**. Refrigeration is not necessary. The test cassettes are stable up until the expiry date printed on the foil pouch as long as the pouch has not been opened.
Do not open the foil pouch until you are ready to run the test. Do not touch the sample well or results window of the test cassette.

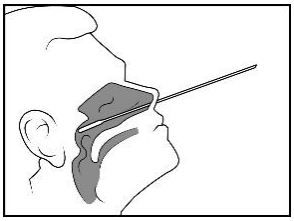
PRECAUTIONS

- This kit is for *in vitro* diagnostic use only and should only be used by trained health professionals.
- Keep the test inside the foil wrapper until it is needed.
- Ensure each test is used only once.
- All samples should be considered as potentially infectious and handled accordingly. Disposable gloves and a laboratory coat should be worn.
- Dispose of used tests in a safe manner according to local regulations.
- Ensure the test kit is at room temperature (15-30°C) before running any tests. Extremes of humidity and temperatures can adversely affect results.
- Tests that have reached their expiry date should not be used.
- Only use reagents from this kit when performing the test.

SAMPLE COLLECTION AND PREPARATION

With Nasopharyngeal swab

- Carefully insert the sterile swab into the nostril, parallel to the palate (and not upwards) until resistance is encountered where it has reached the surface of the nasopharynx.
- Gently rub and roll the swab head over against the nasopharynx. Leave the swab in place for several seconds, then slowly withdraw the swab while rotating it.
- If the head of the swab has not been saturated with fluid from the first collection, it can be re-inserted into the other nostril to collect samples from the other side.



Nasopharyngeal Swab

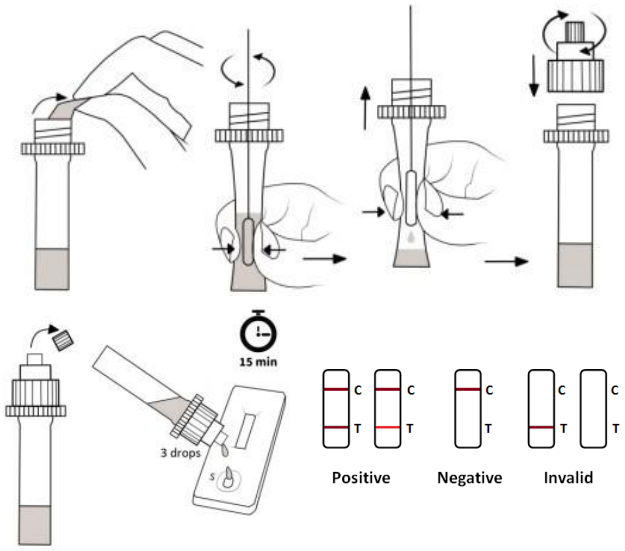
- Freshly collected swab samples should be tested as soon as possible after collection. If it is not possible to process immediately, the swab should be placed into a dry, sterile, and tightly sealed plastic tube for storage. The sample may be stored at 2-8°C for up to 24 hours.

TEST PROCEDURE

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

Refer to the illustration below.

1. Carefully peel off the sealing film from the sample collection tube.
2. Place the swab sample into the sample collection tube, immersing the swab head in the buffer by gently squeezing the bottom of the tube. **Rotate the swab for approximately 10 seconds**.
3. Remove the swab while squeezing the swab head against sides of the extraction tube as you remove it to expel as much liquid as possible. Discard the swab in accordance with your biohazard waste disposal protocol.
4. Tighten the cap onto the sample collection tube.
5. Remove the test cassette from the sealed foil pouch and place it on a clean, level surface. Run test immediately.
6. Hold the sample collection tube upright and unscrew the tip of the tube. Invert the tube and **add 3 drops of solution** (approx. 75-100 µl) to the sample well (S) of the test cassette. Start the timer.
7. Wait for the coloured line(s) to appear. **Interpret results at 15 minutes**. Results read after 20 minutes are considered invalid.



INTERPRETATION OF TEST RESULTS

POSITIVE:* Two coloured lines appear. One coloured line should appear in the control line region (C) and the other coloured line should appear in the test line region (T).
***NOTE:** The intensity of the colour in test line region (T) may vary depending on the concentration of HMPV antigens present in the sample. Therefore,

any shade of colour in the test region should be considered positive.
NEGATIVE: One coloured line appears in the control line region (C). No line appears in the test line region (T).
INVALID: Control line fails to appear. Insufficient sample 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.

INTERNAL QUALITY CONTROL

Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal procedural control. It confirms sufficient sample volume and correct procedural technique. If the test is working properly, the strip background in the results area should be white to light pink and not interfere with the ability to read the test result.
It is also recommended to test with external positive and negative quality controls to ensure the correct test procedure is being followed and to verify the test performance.

PERFORMANCE CHARACTERISTICS

Clinical Sensitivity and Specificity

The Biopanda HMPV Rapid Test was evaluated with clinical swab samples whose status was confirmed using RT-PCR. The results are presented in the following table:

Method		Other Rapid Test		Total Results
Biopanda HMPV Rapid Test	**Results**	Positive	Negative	
	Positive	55	1	56
	Negative	5	109	114
Total Results		60	110	170

Relative Sensitivity: 91.7% (95%CI*: 81.6% - 97.2%)
Relative Specificity: 99.1% (95%CI*: 95.0% - 100%)
Overall Accuracy: 96.5% (95%CI*: 92.5% - 98.7%) *Confidence Intervals

Cross-Reactivity

Test results were affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below at certain concentrations.

Description	Test Level
Influenza A H1N1	1 x 10^7 $TCID_{50}$/ml
Influenza A H3N2	1 x 10^7 $TCID_{50}$/ml
SARS-CoV-2 Culture Fluid	3.8 x 10^6 $TCID_{50}$/ml
Respiratory Syncytial Virus	1 x 10^7 $TCID_{50}$/ml
Human Rhinovirus	1.41 x 10^5 $TCID_{50}$/ml
Streptococcus group F	1 x 10^8 org/ml
Staphylococcus epidermidis	6.07 x 10^8 CFU/ml
Escherichia coli	1 x 10^8 org/ml
Streptococcus pyogenes	2.39 x 10^8 CFU/ml
Neisseria subflava	1 x 10^8 org/ml
Moraxella catarrhalis	1 x 10^8 org/ml
Candida albicans	4.76 x 10^8 CFU/ml
Pseudomonas aeruginosa	1 x 10^8 org/ml
Streptococcus pneumoniae	1.34 x 10^8 CFU/ml
Neisseria lactamica	1 x 10^8 org/ml
Staphylococcus aureus	8.35 x 10^8 CFU/ml

Interfering Substances

Test results were interfered by the following substances at certain concentrations:

Substances	Concentration
Mucin	50 µg/ml
Dexamethasone	0.8 mg/ml
Mupirocin	12 mg/ml
Oxymetazoline Hydrochloride Spray	12 mg/ml
Whole Blood	5 µg/ml

LIMITATIONS OF THE TEST PROCEDURE

1. The Biopanda HMPV Rapid Test is for in vitro diagnostic use only. The test should be used for the detection of HMPV antigens in swab samples. Neither the quantitative value nor the rate of increase in HMPV antigens can be determined by this qualitative test.
2. The test will only indicate the presence of HMPV antigens in the sample and should not be used as the sole criteria for the diagnosis of HMPV infection.
3. A definitive diagnosis should not be based on results from this test alone. The results must be considered with other clinical information such as the patient's exposure history, symptoms or lack thereof, and other test results available to the physician.
4. 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 HMPV infection.

REFERENCES

1. Kimberlin, D. W. (2018). *Red Book: 2018-2021 report of the committee on infectious diseases* (No. Ed. 31). American academy of pediatrics.
2. Edwards, K. M., Zhu, Y., Griffin, M. R., Weinberg, G. A., Hall, C. B., Szilagyi, P. G., ... & Williams, J. V. (2013). Burden of human metapneumovirus infection in young children. *New England Journal of Medicine*, *368*(7), 633-643.

SYMBOLS USED

The following symbols are used on the packaging and labelling. They are presented here along with their meaning.

	Manufacturer		Expiration date
	Do not re-use test	IVD	*in vitro* diagnostic medical device
	Consult instructions for use	LOT	Batch code
	Storage temperature	Σ	Contains sufficient for <*n*> tests
REF	Catalogue number	STERILE EO	Sterilised using ethylene oxide

Thank you for purchasing Biopanda's HMPV Rapid Test kit. Please read this manual carefully before operating to ensure proper use.

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