# HMPV Rapid Test (Nasopharyngeal Swab) Package Insert

| REF IHMPV-502 | English |
|---|---|

*A rapid test for the qualitative detection of metapneumovirus antigens in human nasopharyngeal swab specimen.*
*For professional in vitro diagnostic use only.*

**【INTENDED USE】**

The HMPV Rapid Test (Nasopharyngeal Swab) is a rapid chromatographic immunoassay for the qualitative detection of human metapneumovirus antigens in human nasopharyngeal swab as an aid in the diagnosis of HMPV infection.

**【SUMMARY】**

Human metapneumovirus (HMPV) can cause upper and lower respiratory disease in people of all ages, especially among young children, older adults, and people with weakened immune systems. 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 HMPV Rapid Test (Nasopharyngeal Swab) is a rapid test to qualitatively detect the presence of human metapneumovirus antigens in nasopharyngeal swab. The test uses antibodies specific for human metapneumovirus virus to selectively detect human metapneumovirus Virus antigens in nasopharyngeal swab specimens.

**【PRINCIPLE】**

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

**【REAGENTS】**

The test contains anti-human metapneumovirus antibodies coated particles and anti-human metapneumovirus antibodies coated on the membrane.

**【PRECAUTIONS】**

**Please read all the information in this package insert before performing the test.**

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.

**【STORAGE AND STABILITY】**

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use after the expiration date.

**【MATERIALS】**

**Materials provided**

• Test cassettes • Package insert • Sterile swabs • Procedure card
• Extraction buffer • Workstation • Extraction tubes and tips (Optional)

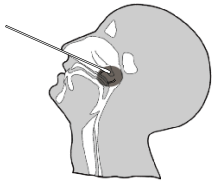
**Materials required but not provided**

• Timer

**【SPECIMEN COLLECTION, TRANSPORT AND STORAGE】**

**Nasopharyngeal Swab Specimen Collection**

1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx 5-10 times.
3. Withdraw the sterile swab from the nasal cavity and avoid excess volume and highly-viscous nasopharyngeal discharge.



Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

**Specimen Transport and Storage**

Specimens should be tested as soon as possible after collection. If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 24 hours at 2-8°C.

**【SPECIMEN PREPARATION】**

Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation. Please refer to the Procedure Card for detailed information of Specimen Extraction.

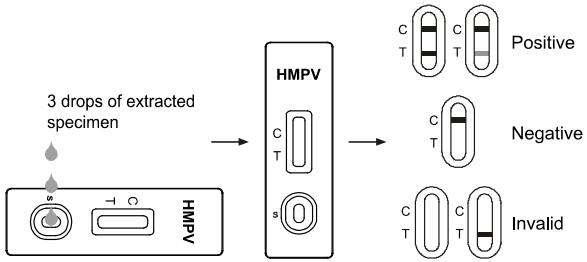
1. Place the swab specimen in the extraction tube with extraction buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
2. Remove the swab while squeezing the swab head against the inside of the extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

***NOTE:** The storage of the specimen after extraction is stable for 2 hours at room temperature or 24 hours at 2-8°C.

**【DIRECTIONS FOR USE】**

**Allow the test, specimen swab, buffer and/or controls to reach room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Invert the specimen extraction tube and add **3 drops of extracted specimen** (approx.75-100 µL) to the sample well (S) and then start the timer.
3. Wait for the colored line(s) to appear. Read the result at **15 minutes**. Do not interpret the result after 20 minutes.




**【INTERPRETATION OF RESULTS】**

(Please refer to the illustration above)

**POSITIVE: Two colored lines appear.** One colored line should be in the control line region (C) and another colored line should be in the test line region (T).

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of HMPV antigens present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE: One colored line appears in the control line region (C).** No line appears in the test line region (T).

**INVALID: Control line fails to appear.** Insufficient specimen 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 cassette immediately and contact your local distributor.

**【QUALITY CONTROL】**

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards 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.

**【LIMITATIONS】**

1. The HMPV Rapid Test (Nasopharyngeal Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of HMPV antigens in swab specimens. Neither the quantitative value nor the rate of increase in HMPV antigens can be determined by this qualitative test.
2. The HMPV Rapid Test (Nasopharyngeal Swab) will only indicate the presence of HMPV antigens in the specimen and should not be used as the sole criteria for the diagnosis of HMPV infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information 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.

**【PERFORMANCE CHARACTERISTICS】**

**Sensitivity and Specificity**

The HMPV Rapid Test (Nasopharyngeal Swab) was evaluated with clinical swab specimens whose status was confirmed using RT-PCR. The results are presented in the following tables.

| Method | | RT-PCR | | Total Results |
|---|---|---|---|---|
| HMPV Rapid Test (Nasopharyngeal Swab) | 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%);
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 | $1\times10^7$ $TCID_{50}$/mL |
| Influenza A H3N2 | $1\times10^7$ $TCID_{50}$/mL |
| SARS-CoV-2 Culture Fluid | $3.8\times10^6$ $TCID_{50}$/mL |
| Respiratory syncytial virus | $1\times10^7$ $TCID_{50}$/mL |
| Human Rhinovirus | $1.41\times10^5$ $TCID_{50}$/mL |
| *Streptococcus group F* | $1.0\times10^8$ org/mL |
| *Staphylococcus epidermidis* | $6.07\times10^8$ CFU/mL |
| *Escherichia coli* | $1.0\times10^8$ org/mL |
| *Streptococcus pyogenes* | $2.39\times10^8$ CFU/mL |
| *Neisseria subflava* | $1.0\times10^8$ org/mL |
| *Moraxella catarrhalis* | $1.0\times10^8$ org/mL |
| *Candida albicans* | $4.76\times10^7$ CFU/mL |
| *Pseudomonas aeruginosa* | $1.0\times10^8$ org/mL |
| *Streptococcus pneumoniae* | $1.34\times10^8$ CFU/mL |
| *Neisseria lactamica* | $1.0\times10^8$ org/mL |
| *Staphylococcus aureus* | $8.35\times10^8$ CFU/mL |

**Interfering Substances**

Test results were interfered by following substances at certain concentrations:

| Substance | Concentration |
|---|---|
| Mucin | 50 µg/mL |
| Dexamethasone | 0.8 mg/mL |
| Mupirocin | 12 mg/mL |
| Oxymethazoline Hydrochloride Spray | 12 mg/mL |
| Whole Blood | 5 µL/mL |

**【BIBLIOGRAPHY】**


1. American Academy of Pediatrics. Human metapneumovirus. Red Book 2018 Report of the Committee on Infectious Diseases [online edition].
2. Edwards KM, Zhu Y, Griffin MR, Weinberg, GA, Hall CB, Szilagyi PG, Staat MA, Iwane MK, Prill MM, Williams JV, for the New Vaccine Surveillance Network (NVSN).Burden of Human Metapneumovirus Infection in Young Children.N Engl J Med. 2013;368:633-643


**Index of Symbols**

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| | Consult instructions for use or consult electronic instructions for use | Σ | Contains sufficient for <n> tests | 2°C 30°C | Temperature limit |
| IVD | *In vitro* diagnostic medical device | LOT | Batch code | REF | Catalogue number |
| EC REP | Authorized representative in the European Community/European Union | | Use-by date | | Do not re-use |
| | Do not use if package is damaged and consult instructions for use | | Manufacturer | | Caution |


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