GENESIS

Prolab 40 Años Trabajando por las personas

CE IVD

Dec 2021, Ver. 01

P213115 EZER™ Human Metapneumovirus Antigen Rapid Test

This kit is designed for testing freshly collected swab samples.

INTENDED USE

The EZER™ Human Metapneumovirus Antigen Rapid Test is intended to be used to detect Human Metapneumovirus antigen in nasopharyngeal swab, or pharyngeal swab to support the diagnosis of Human Metapneumovirus infection.

BACKGROUND

Human metapneumovirus (hMPV), first identified in the Netherlands in 2001, is an RNA virus that belongs to the Metapneumovirus genus within the Pneumovirinae subfamily of the Paramyxoviridae family.

hMPV is a virus that can cause respiratory infection. hMPV infection is a typical respiratory infection in infants. It is similar to respiratory syncytial (RS) virus infection and differentiation from each other is difficult. hMPV infection is an important factor for inducing bronchiolitis.

The majority experience primary hMPV infection during infancy, and reinfection occurs frequently. As hMPV infection may become prevalent in infants and the elderly and increase in severity, early detection is important.

Conventionally, genetic testing is used for the detection of hMPV, but it has some disadvantages, for instance, requiring complicated manipulation, special equipment and instruments, and a certain period of time to obtain the test results.

Compared to genetic testing, this product allows rapid detection of hMPV, without requiring special skills or instruments.

The EZER™ Human Metapneumovirus antigen rapid test, a lateral flow immunochromatographic assay permits the early diagnosis of Human Metapneumovirus infection by simple and rapidly detecting the antigen in nasopharyngeal swab, or pharyngeal swab.

PRINCIPLE

This product is a test plate consisting of three parts: the lower part of the sample, the reagent part and the expansion part, and has a long square-shaped carrier. The reagent part comprises a labeled anti Human Metapneumovirus monoclonal antibody A (mouse) (hereinafter referred to as labeled antibody A); and the expanded part comprises an immobilized monoclonal antibody B (rat) of Human Metapneumovirus (hereinafter referred to as Anti-Human Metapneumovirus antibody B) and murine IgG polyclonal antibody (hereinafter referred to as anti-mouse immunoglobulin antibody).

After the sample is dropped from the lower portion of the sample plate of the test plate, the labeled antibody A is dissolved to form an immune complex with the Human Metapneumovirus antigen in the sample. The immune complex moves due to the capillary phenomenon of the developing portion, and is captured by the anti-Human Metapneumovirus antibody B immobilized in the Testing portion [T], so that the Testing portion [T] forms a red band due to the action of the practical. This red band of the kit can be visually determined to determine the presence of hMPV in the on the other hand, regardless of whether or not hMPV is present in the sample, the remaining labeled antibody A continues to move in the developing portion, and is captured by the anti-mouse immunoglobulin antibody immobilized in the Control portion [C], and red band is formed by practical. This shows the normal movement of the practical marker antibody.

CONTENTS

Test devices (20), Sterilized swabs (20), Extraction tubes (20), Nozzles (20), Tube stand (1), Package insert (1).

STORAGE CONDITIONS

Test devices must be stored at 2~30°C. DO NOT FREEZE. Devices must be brought back to room temperature at time of testing.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only.
2. Use the swab supplied in the kit for collection nasopharyngeal or pharyngeal sample.
3. Proper specimen collection, storage and transport are critical to the performance of this test.
4. Do not use kit components beyond the expiration date.
5. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
6. Please do not touch the sample drop and the judgment part of the test board directly by hand.
7. Do not reuse the device.
8. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device ensuring that the test procedure has been followed accurately.
9. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the

measurement, the reaction and color development may slightly continue and progress even after 15 minutes.

10. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present.
11. If the line is not red at all (e.g. black), the test result is invalid and another test should be performed.
12. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.

SAMPLE COLLECTION AND PREPARATION

DOs and DON'Ts of Sample Collection

- Do use freshly collected samples of nasopharyngeal or pharyngeal swabs for optimum test performance.
- Do test sample immediately.
- Use only swabs provided with the kit.

Prepare test samples with sample extraction buffer for immediate testing after collection. If immediate testing is not possible, collected samples can be held refrigerated (2~8°C) for up to 48 hours prior to testing. Inadequate sample collection or improper sample handling may yield a false-negative result.

Nasopharyngeal Swabbing
Insert sterilized swab into nostril parallel to the palate and leave in place for a few second to absorb secretions. Collect samples with nasopharyngeal (NP) swabs for optimum results.

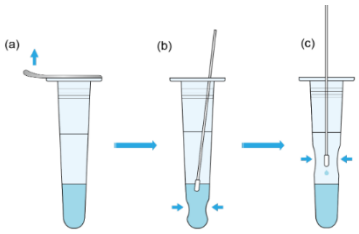
Pharyngeal swabbing
Firmly insert a pharyngeal swab into the pharynx through the oral cavity, and collect the mucosal epithelium by swabbing the posterior wall of the pharynx and the palatine tonsil several times, centering around the rubefacient portion. **Avoid touching saliva.** If the specimen is mixed with saliva, the test result lines may become fainter on the test plate.

PROCEDURE

Reagents, specimens and devices must be at room temperature (15~30 °C) for testing. Please read the instruction completely before beginning to test specimens.

1. Sample Extraction

Insert swab with collected sample into extraction tube containing 0.5 ml of sample extraction buffer. Squeeze the swab several times by compressing the outside walls of the tube end against the swab to mix well. Finally squeeze the swab to make most of the solution stays in the extraction tube and remove the swab. Use extraction solution as test sample. （step a~c）

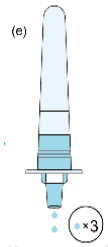


2. Test Reaction

(1) Remove test device from sealed foil pouch prior to testing and lay flat on work bench.

(2) Insert filtered nozzle into the extraction tube with test sample. (step d)

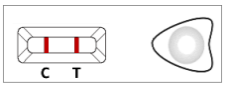
(3) Invert extraction tube and add 3 drops of test sample into the sample well by gently squeezing extraction tube. (step e)



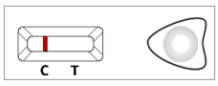
(4) Read results at 15 minutes and disregard after 30 minutes. A positive result may be visible at 3 minutes. However, the complete reaction time of 15 minutes is required to confirm a negative result.

INTERPRETATION OF RESULTS

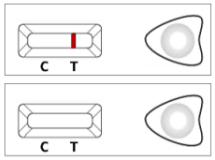
Allow the samples to react according to the procedure and read the red purple lines that appear in the reading area.



Positive
Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T). This indicates that the specimen contains detectable amount of Human Metapneumovirus antigen. The shade of color may vary, but it should be considered positive whenever there is even a faint line.



Negative
Only one reddish band appears on control region of the device. No reddish line is visible next to the Test "T". This indicates that there is no detectable Human Metapneumovirus antigen in the sample.



Invalid Result

No red line appears in the control region (C). The test is invalid even if there is a line in the region (T).

Review testing procedures and repeat the test using a new rapid test device.

PRECAUTIONS FOR ASSESSMENT

1. Assessment must be conducted exactly 15 minutes after starting the reaction. Given the nature of the measurement (immunochromatography), the reaction and color development may slightly continue and progress even after 15 minutes.
2. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present. Occasionally, broken lines may appear, but the test result is valid as long as a red line is present.
3. If the line is not red at all (e.g., black), the test result is invalid and another test should be performed.
4. If the specimen is dark-colored, it may stain the membrane and affect the assessment.
5. A highly viscous specimen may affect sample migration and/or the reaction, resulting in weak coloration, delayed or no formation of the line, or a nonspecific reaction because of specimen retention.
6. If invalid results are repeatedly obtained for the same specimen, centrifuge the specimen (15,000g, 10 minutes) and use 100 µL of its supernatant as the sample.This may facilitate obtaining valid test results.

REPORTING OF RESULTS

Positive Test Positive for the presence of Human Metapneumovirus antigen.

Negative Test Negative for the presence of Human Metapneumovirus antigen. Infection due to Human Metapneumovirus cannot be ruled-out because the antigen present in the sample may be below the detection limit of the test. Culture confirmation of negative samples is recommended.

Invalid Test Test result is inconclusive. Do not report results.

QUALITY CONTROL

Internal control：

Each EZER™ Human Metapneumovirus antigen rapid test devices contains internal/procedural controls. The appearance of a control line at the Control “C” position validates the proper reagent function and assures that the correct test procedure was followed.

PERFORMANCE CHARACTERISTICS

Minimum detection limit

The minimum detection limit of this product is as follows.
Genotype A: 4.5×10^3 $TCID_{50}$/mL
Genotype B: 3.0×10^3 $TCID_{50}$/mL

Cross-reactivity evaluation

1. Bacteria and Yeast
   The EZER™ Human Metapneumovirus Antigen Rapid Test was found no cross reactivity with the following bacteria：
   Bordetella pertussis, Candida albicans, Chlamydia pneumoniae, Haemophilus infiuenzae, Legionella pneumophila, Mycobacteria tuberculosis, Mycoplasma pneumoniae, Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes.
2. Virus
   The EZER™ Human Metapneumovirus Antigen Rapid Test was found no cross reaction with the following virus pathogens：
   Adenovirus, Enterovirus, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Influenza A H1N1, Influenza A H3N2, Influenza B, Parainfluenza virus Type 1, Parainfluenza virus Type 2, Parainfluenza virus Type 3, Parainfluenza virus Type 4, Respiratory Syncytial Virus, Rhinovirus
3. Endogenous/Exogenous Interference Substances
   The EZER™ Human Metapneumovirus Antigen Rapid Test was found no interference reaction with the following substances：

Substance	Concentration
Whole Blood	4%
Mucin	0.3%
Chloraseptic (Menthol/Benzocaine)	1.5 mg/mL
Naso GEL (NeilMed)	5% v/v
OTC Nasal Drops (Phenylephrine)	15% v/v
Afrin (Oxymetazoline)	15% v/v
OTC Nasal Spray (Cromolyn)	15% v/v
Zicam	5% v/v
Homeopathic (Alkalol)	1:10 dilution
Sore Throat Phenol Spray	15% v/v
Tobramycin	4 µg/mL
Mupirocin	10 mg/mL
Fluticasone Propionate	1% v/v
Tamiflu (Oseltamivir Phosphate)	5 mg/mL

Clinical Studies

The performance of the EZER™ Human Metapneumovirus test was compared to PCR method at one clinical site.

(1) Table 1: Performance Summary of the EZER™ Human Metapneumovirus test compared to PCR with Nasopharyngeal swab.

		PCR		
		+	-	Total
EZER™ Human Metapneumovirus	+	80	0	80
	-	7	104	111
	Total	87	104	191

Relative Sensitivity : 92.0%
Relative Specificity : 100%
Accuracy : 96.3%

(2) Table 2: Performance Summary of the EZER™ Human Metapneumovirus test compared to PCR with Pharyngeal swab.

		PCR		
		+	-	Total
EZER™ Human Metapneumovirus	+	107	0	107
	-	10	54	64
	Total	117	54	171

Relative Sensitivity : 91.5%
Relative Specificity : 100%
Accuracy : 94.2%

LIMITATIONS OF THE PROCEDURE

1. This kit is a qualitative test and cannot determine the amount of antigen in the sample.
2. Users should test specimens as quickly as possible after specimen collection.
3. Positive test results do not rule out co-infections with other pathogens.
4. A false-negative test result may occur if the Sample collected may contain antigen titles below the reagent's sensitivity threshold or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of the virus infection.
5. Specimen obtained early with sudden onset of symptoms will contain the highest viral titers, the amount of antigen in a sample may decrease as the duration of illness increases.
6. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
7. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for clinical management.

AVAILABILITY

Product	Cat. No.	Contents
EZER™ Human Metapneumovirus	P213115	20 Tests

REFERENCES

1. Kikuta H, Sakata C, Gamo R, Ishizaka A, Koga Y, Konno M, Ogasawara Y, Sawada H, Taguchi Y, Takahashi Y, Yasuda K, Ishiguro N, Hayashi A, Ishiko H, Kobayashi K. Comparison of a lateral-flow immunochromatography assay with real-time reverse transcription-PCR for detection of human metapneumovirus. *J Clin Microbiol.* 2008;46(3):928-932.
2. Kaida A, Iritani N, K ubo H, Shiomi M, Kohdera U, Murakami T. Seasonal distribution and phylogenetic analysis of human metapneumovirus among children in Osaka City, Japan. *J Clin Virol.* 2006;35(4):394-399.
3. Montes M, Vicente D, Esnal O, Cilla G, Pérez-Trallero E. A PCR–restriction fragment length polymorphism assay to genotype human metapneumovirus. *Clin Microbiol Infect.* 2008;14(1):91-93.

Index of Symbols

	Attention, see instructions for use		Manufacturer/ Manufactured by		Keep away from sunlight
CE	CE Marking		Tests per kit	EC REP	Authorized Representative
STERILE EO	Sterilized using ethylene oxide		Use by		Do not reuse
	Store between 2~30℃	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Caution		Upward

EC REP **Lotus NL B.V.**
Koningin Julianaplein 10, le Verd, 2595AA,
The Hague, Netherlands.

Hangzhou Genesis Biodetection and Biocontrol Co., Ltd.
ADD : No.139, St.10th (East), Hangzhou Economic & Technological Development Zone.
Hangzhou, Zhejiang Province, China, 310018
TEL : +86-571-87818163
FAX : +86-571-8782-4695
Web : www.genesis-ivd.com