

EZER™ HPIVs Antigen Rapid Test

This kit is designed for testing freshly collected swab or nasal aspiration samples.

INTENDED USE

The *EZER*™ HPIVs Antigen Rapid Test is an in vitro diagnostic test for the qualitative detection of Human parainfluenza virus type 1, 2, 3 nucleoprotein antigens in nasopharyngeal (NP) swab and nasal aspirate samples, using the rapid immunochromatographic method. The detection is based on the monoclonal antibodies specific for the nucleoprotein of either Human parainfluenza virus. It is intended to aid in the rapid diagnosis of Human parainfluenza virus type 1, 2, 3 infection.

BACKGROUND

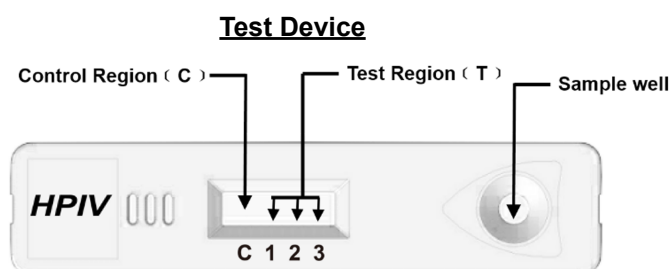
This kit is developed for immunochromatographic assay detection of Human parainfluenza virus using monoclonal antibodies against the antigen of Human parainfluenza virus type 1, 2, 3, which specifically react with and recognize the Human parainfluenza virus subtypes that can cause respiratory infection in the sample. As shown in the illustration, the test device, which is the key part of the kit, consists of four parts from right to left, the sample well, the reagent part, the development part, and a long square-shaped absorbent paper.

The reagent part comprises a color microsphere-labeled anti-Parainfluenza I virus monoclonal antibody A1 (mouse) and a color microsphere-labeled anti-Parainfluenza II virus monoclonal antibody A2 (mouse), a color microsphere-labeled anti-Parainfluenza III virus monoclonal antibody A3 (mouse) (hereinafter referred to as color microsphere-labeled antibody A1, A2 and A3); the T1 in the development part contains the immobilized Parainfluenza I monoclonal antibody B1 (mouse), and the T2 contains the immobilized Parainfluenza II monoclonal antibody B2 (mouse), and the T3 contains the immobilized Parainfluenza III monoclonal antibody B3 (mouse) (hereinafter referred to as The anti-Parainfluenza I antibody B1 and the anti-Parainfluenza II antibody B2, and the anti-Parainfluenza III antibody B3), and the immobilized anti-mouse IgG polyclonal antibody (hereinafter referred to as an anti-mouse immunoglobulin antibody) are contained at C1.

After the sample is dropped from the lower portion of the sample plate of the test plate, the microsphere-labeled antibody A1, the color microsphere-labeled antibody A2, and the color microsphere-labeled antibody A3 are dissolved, respectively, and the parainfluenza virus type

I antigen and the accessory are specific to the sample. The parainfluenza virus II antigen and the parainfluenza virus III antigen form an immune complex. The immune complex moves by the capillary phenomenon of the development part, the parainfluenza virus type I antigen is captured by the anti-parainfluenza virus type I antibody B1 immobilized in the determination unit T1, and the parainfluenza virus type II antigen is immobilized in the determination unit T2. The anti-parainfluenza virus type II antibody B2 is captured, and the parainfluenza virus type III antigen is captured by the anti-parainfluenza virus type III antibody B3 immobilized in the determination unit T3, and is excited at the determination units T1, T2, and T3, respectively. This red bands of the kit can be visually determined to whether there is a parainfluenza virus type I antigen, parainfluenza type II antigen and parainfluenza type III antigen in the sample.

On the other hand, regardless of whether the parainfluenza virus type I, parainfluenza virus type II and parainfluenza virus type III are present in the sample, the remaining color microsphere-labeled antibody A1, color microsphere-labeled antibody A2, and color microsphere-labeled antibody A3 The movement of the anti-mouse immunoglobulin antibody immobilized in the determination unit C1 is continued, and red band is formed by practical. This shows the normal movement of the color microsphere-labeled antibody



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STORAGE CONDITIONS

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

Warnings and Precautions

1. For *in vitro* Diagnostic Use
2. Pathogenic microorganisms may be present in clinical specimens. All specimen and the related contaminated items need to be handled, stored and disposed following "Standard Precautions" and institutional guidelines.
3. Use the swab supplied in the kit for collection nasopharyngeal sample.
4. Proper specimen collection, storage and transport are critical to the performance of this test.
5. Do not use kit components beyond the expiration date.
6. Apply universal precaution when performing the test.
7. 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.
8. Please do not touch the sample drop and the judgment part of the test board directly by hand.
9. Do not reuse the device.
10. 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.
11. 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.
12. 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.
13. If the line is not red at all (e.g. black), the test result is invalid and another test should be performed.
14. 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

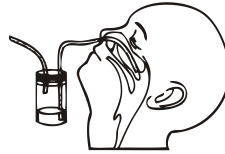
Use freshly collected samples of nasopharyngeal swabs and nasal aspirates for optimum test performance.

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.



Nasal Aspiration

Collect nasal aspirate fluids using the specific aspirator as instructed.

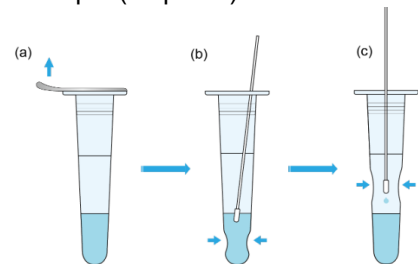
PROCEDURE

Allow the EZERT™ HPIVS Rapid Test and collected samples to equilibrate to room temperature (15~30°C) prior to testing.

1. Sample Extraction

(1) Nasopharyngeal swabs

Insert swab with collected sample into extraction tube containing 0.5ml 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).

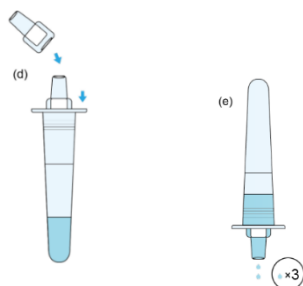


(2) Nasal Aspirate Fluids

When using a nasal aspirate sampling, add 500µL of the sample to the extraction tube containing 0.5 ml of sample extraction buffer and mix well. Use extraction solution as test sample.

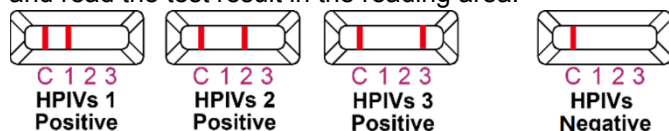
2. Test Reaction

- (1) Remove test device from sealed foil pouch prior to testing and lay flat on work bench.
- (2) Insert nozzle into the extraction tube with test sample (d).
- (3) Invert the extraction tube and add 3 drops (100µl) of test sample into sample well by gently squeezing the extraction tube (e).
- (4) Read results at 15 minutes. Do not read test result 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 run according to the instruction and read the test result in the reading area.



HPIVs 1 Positive:

One red line appears in the control region (C), and one red line in the T1 region (T). The shade of color may vary, but it should be considered positive result whenever there is even a faint line.

HPIVs 2 Positive:

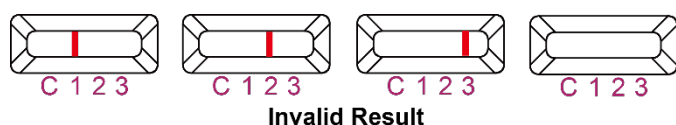
One red line appears in the control region (C), and one red line in the T2 region (T). The shade of color may vary, but it should be considered positive result whenever there is even a faint line.

HPIVs 3 Positive:

One red line appears in the control region (C), and one red line in the T3 region (T). The shade of color may vary, but it should be considered positive result whenever there is even a faint line.

Negative:

One red line appears in the control region (C), and no line in the Test region (T). The negative result indicates that there are no Human parainfluenza virus type 1, 2, 3 in the samples or the number of viral particles is below the detection limit.



Invalid:

No red line appears in the control region (C). The test is invalid even if there is a line in the Test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review testing procedures and repeat the test using a new rapid test device.

QUALITY CONTROL

Internal control

Each EZER™ HPIVs rapid test device 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

1. Limit of Detection

The limit of detection (LOD) for the EZER™ HPIVs Antigen Rapid Test was established for a total of 3 Human parainfluenza virus strains:

Strain	TCID ₅₀ /mL
Human Parainfluenza virus type 1	2.0×10 ⁵
Human Parainfluenza virus type 2	9.78×10 ⁴
Human Parainfluenza virus type 3	5.4×10 ⁶

TCID₅₀/mL = 50% Tissue Culture Infectious Dose

2. Cross Reactivity

(1) Bacteria

No cross reactivity with the following bacteria, *Bordetella pertussis*, *Candida albicans*, *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Legionella pneumophila*, *Mycobacteria tuberculosis*, *Mycoplasma pneumoniae*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*.

(2) Virus

No cross reaction with the following pathogens, Adenovirus, Human metapneumovirus, Enterovirus, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, Influenza A H1N1, Influenza A H3N2, Influenza B, Parainfluenza virus Type 4, Respiratory Syncytial Virus, Rhinovirus.

3. Interference substances

The EZER™ HPIVs 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

4. Clinical Studies

The performance of the *EZER*TM HPIVs Antigen Rapid Test was compared to cell culture method at one clinical site.

(1) Table 1: The performance comparison of Human Parainfluenza virus type 1 detection of the HPIVs Antigen Rapid Test vs cell culture in Nasopharyngeal swab

		Cell culture		
		+	-	Total
<i>EZER</i> TM HPIVs Antigen Rapid Test	+	21	0	21
	-	2	33	35
	Total	23	33	56

Sensitivity: 91.3%

Specificity: 100.0%

Overall result consistency: 96.4%

(2) Table 2: The performance comparison of Human Parainfluenza virus type 2 detection of the HPIVs Antigen Rapid Test vs cell culture in Nasopharyngeal swab

		Cell culture		
		+	-	Total
<i>EZER</i> TM HPIVs Antigen Rapid Test	+	19	0	19
	-	1	33	34
	Total	20	33	53

Sensitivity: 95.0%

Specificity: 100.0%

Overall result consistency: 98.1%

(3) Table 3: The performance comparison of Human Parainfluenza virus type 3 detection of the HPIVs Antigen Rapid Test vs cell culture in Nasopharyngeal swab

		Cell culture		
		+	-	Total
<i>EZER</i> TM HPIVs Antigen Rapid Test	+	35	0	35
	-	4	33	37
	Total	39	33	72

Sensitivity: 89.7%

Specificity: 100.0%

Overall result consistency: 94.4%

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
<i>EZER</i> TM HPIVs Antigen	P213114	20 Tests

Index of Symbols

	Attention, see instructions for use		Tests per kit		Authorized Representative
	For in vitro diagnostic use only		Use by		Do not reuse
	Store between 2~30°C		Lot Number		Catalog #

EC REP **Lotus NL B.V.**
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