**REF: 20261**

# Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate)

## Package Insert

*A rapid test for the qualitative detection of Influenza type A, type B and A (H1N1) antigen in nasopharyngeal swab, throat swab or nasal aspirate specimens.*
*For professional in vitro diagnostic use only.*

**【INTENDED USE】**

The Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate) is a rapid chromatographic immunoassay for the qualitative detection of influenza type A, type B and A (H1N1) antigen in nasopharyngeal swab, throat swab or nasal aspirate specimens. It is intended to aid in the rapid differential diagnosis of influenza A, B viral infections.

**【SUMMARY】**

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus.[1] Influenza outbreaks occur each year during the fall and winter months. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder.

The gold standard of laboratory diagnosis is 14-day cell culture with one of a variety of cell lines that can support the growth of influenza virus.[2] Cell culture has limited clinical utility, as results are obtained too late in the clinical course for effective patient intervention. Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) is a newer method that is generally more sensitive than culture with improved detection rates over culture of 2-23%.[3] However, RT-PCR is expensive, complex and must be performed in specialized laboratories.

The Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate) qualitatively detects the presence of Influenza type A, type B and/or A (H1N1) antigen in nasopharyngeal swab or throat swab or nasal aspirate specimens, providing results within 15 minutes. The test uses antibodies specific for Influenza type A, type B and A (H1N1) to selectively detect Influenza type A, type B and A (H1N1) antigen in nasopharyngeal swab, throat swab or nasal aspirate specimens.

**【PRINCIPLE】**

The Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate) is a qualitative, lateral flow immunoassay for the detection of Influenza type A, type B and A (H1N1) nucleoproteins in nasopharyngeal swab, throat swab or nasal aspirate specimens. In this test, antibodies specific to the Influenza type A, type B and A (H1N1) nucleoproteins is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibodies to Influenza type A, type B and/or A (H1N1) that are coated onto particles. The mixture migrates up the membrane to react with the antibodies to Influenza type A, type B and/or A (H1N1) on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

**【REAGENTS】**

The test cassette contains anti-Influenza type A, type B and A (H1N1) particles and anti-Influenza type A, type B and A (H1N1) 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 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 beyond the expiration date.

**【SPECIMEN COLLECTION AND PREPARATION】**

• Nasopharyngeal swab sample

Insert a sterilized swab into a nasal cavity securely from a nostril and collect mucoepidermis wiping turbinate several times.

• Throat swab sample

Insert a sterilized swab into pharynx and collect mucoepidermis mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times, and be careful not to make saliva attach to the swab.

• Nasal aspirate

Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasal cavity from a nostril, start the aspiration device and then collect nasal aspirate sample. Dip a sterilized swab into the collected nasal aspirate sample and make the specimen cling to the swab.

**【MATERIALS】**

**Materials provided**

- Test Cassettes
- Extraction Reagent
- Extraction Tubes
- Sterile Swabs
- Package Insert
- Workstation
- Extraction Tube Tips

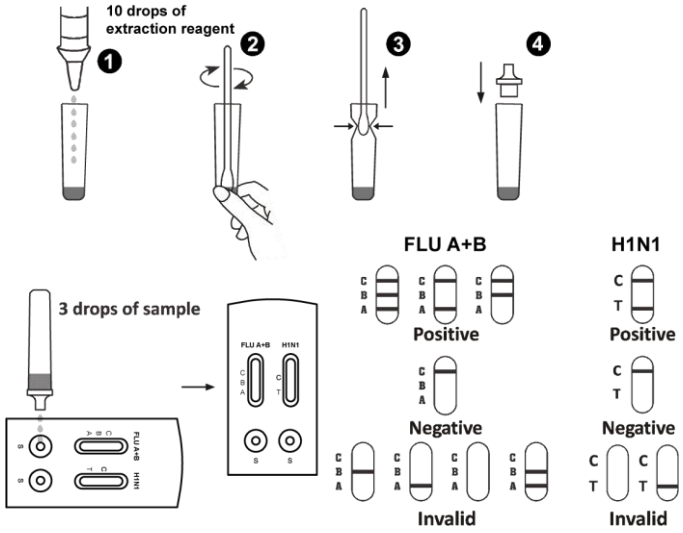
**Materials required but not provided**

- Timer
- Aspiration Device

**【DIRECTIONS FOR USE】**

**Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.**

1. Remove the test cassette from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add **10 drops of extraction reagent** (Approx. 400ul) to the Extraction Tube. See illustration 1.
3. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. See illustration 2.
4. 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. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. See illustration 4
6. Add **3 drops of the solution** (approx.120ul) to each sample well separately and then start the timer.
7. 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 Influenza A:* Two distinct colored lines appear in the left window**. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

**POSITIVE Influenza B:* Two distinct colored lines appear in the left window**. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

**POSITIVE Influenza A and Influenza B:* Three distinct colored lines appear in the left window**. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

**POSITIVE Influenza A (H1N1):* Two distinct colored lines appear in the left window and two distinct colored lines appear in the right window**. Colored line should be in the control region (C) and colored line should be in the Influenza A region (A) and H1N1 region (T in the right window). A positive result in the Influenza A region and H1N1 region indicates that Influenza A (H1N1) antigen was detected in the sample.

***NOTE**: The intensity of the color in the test line regions (A, B or H1N1) will vary based on the amount of Flu A or B or A (H1N1) antigen present in the sample. So any shade of color in the test regions (A or B or H1N1) should be considered positive.

**NEGATIVE: One colored line appears in the control region (C).** No apparent colored line appears in the test line region(s) (A or B or H1N1).

**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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**【QUALITY CONTROL】**

**Internal Quality Control**

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

**External Quality Control**

Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.

**【LIMITATIONS】**

1. The Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate) is for professional in vitro diagnostic use only. The test should be used for the detection of Influenza type A, type B and A (H1N1) virus in nasopharyngeal swab, throat swab or nasal aspirate specimens. Neither the quantitative value nor the rate of increase in Influenza type A, type B and/or A (H1N1) virus concentration can be determined by this qualitative test.
2. The Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate) will only indicate the presence of Influenza type A, type B and/or A (H1N1) virus in the specimen from both viable and non-viable Influenza A and B strains.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Influenza A and/or B virus present in the nasopharyngeal swab is not adequate or is below the detectable level of the test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

**【EXPECTED VALUES】**

The Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate) has been compared with a leading commercial RT-PCR test. The correlation between these two systems is over 97%.

**【PERFORMANCE CHARACTERISTICS】**

**Sensitivity, Specificity and Accuracy**

The Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate) has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate). Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result

**Nasopharyngeal Swab Specimen**

| | | Type A | | | Type B | | |
|---|---|---|---|---|---|---|---|
| | | RT-PCR | | Total | RT-PCR | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Flu A+B | Positive | 52 | 1 | 53 | 31 | 1 | 32 |
| | Negative | 1 | 102 | 103 | 1 | 102 | 103 |
| Total | | 53 | 103 | 156 | 32 | 103 | 135 |
| Relative Sensitivity | | 98.1% | | | 96.9% | | |
| Relative Specificity | | 99.0% | | | 99.0% | | |
| Accuracy | | 98.7% | | | 98.5% | | |

| | Type A (H1N1) | | |
|---|---|---|---|
| | RT-PCR | | Total |
| | Positive | Negative | |

| | | | | |
|---|---|---|---|---|
| Flu A (H1N1) | Positive | 21 | 1 | 22 |
| | Negative | 1 | 102 | 103 |
| Total | | 22 | 103 | 125 |
| Relative Sensitivity | | 95.5% | | |
| Relative Specificity | | 99.0% | | |
| Accuracy | | 98.4% | | |

**Throat Swab Specimen**

| | | Type A | | | Type B | | |
|---|---|---|---|---|---|---|---|
| | | RT-PCR | | Total | RT-PCR | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Flu A+B | Positive | 52 | 1 | 53 | 31 | 1 | 32 |
| | Negative | 1 | 102 | 103 | 1 | 102 | 103 |
| Total | | 53 | 103 | 156 | 32 | 103 | 135 |
| Relative Sensitivity | | 98.1% | | | 96.9% | | |
| Relative Specificity | | 99.0% | | | 99.0% | | |
| Accuracy | | 98.7% | | | 98.5% | | |

| | | Type A (H1N1) | | |
|---|---|---|---|---|
| | | RT-PCR | | Total |
| | | Positive | Negative | |
| Flu A (H1N1) | Positive | 21 | 1 | 22 |
| | Negative | 1 | 102 | 103 |
| Total | | 22 | 103 | 125 |
| Relative Sensitivity | | 95.5% | | |
| Relative Specificity | | 99.0% | | |
| Accuracy | | 98.4% | | |

**Nasal Aspirate Specimen**

| | | Type A | | | Type B | | |
|---|---|---|---|---|---|---|---|
| | | RT-PCR | | Total | RT-PCR | | Total |
| | | Positive | Negative | | Positive | Negative | |
| Flu A+B | Positive | 52 | 1 | 53 | 31 | 1 | 32 |
| | Negative | 1 | 102 | 103 | 1 | 102 | 103 |
| Total | | 53 | 103 | 156 | 32 | 103 | 135 |
| Relative Sensitivity | | 98.1% | | | 96.9% | | |
| Relative Specificity | | 99.0% | | | 99.0% | | |
| Accuracy | | 98.7% | | | 98.5% | | |

| | | Type A (H1N1) | | |
|---|---|---|---|---|
| | | RT-PCR | | Total |
| | | Positive | Negative | |
| Flu A (H1N1) | Positive | 21 | 1 | 22 |
| | Negative | 1 | 102 | 103 |
| Total | | 22 | 103 | 125 |
| Relative Sensitivity | | 95.5% | | |
| Relative Specificity | | 99.0% | | |
| Accuracy | | 98.4% | | |

**Precision**

**Intra-Assay & Inter-Assay**

Within-run and Between-run precision has been determined by using five specimens of Influenza standard control. Three different lots of the Influenza Combo Rapid Test Cassette (Swab/Nasal Aspirate) have been tested using negative, Influenza A weak, Influenza A strong, Influenza B weak, Influenza B strong, H1N1 weak and H1N1 strong. Three replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

**Cross-reactivity**

The following organisms were tested at $1.0x10^8$org/ml and all found to be negative when tested with the Influenza A/B/H1N1 Combo Rapid Test Cassette (Swab/Nasal Aspirate):

| | |
|---|---|
| *Arcanobacterium* | *Pseudomonas aeruginosa* |
| *Candida albicans* | *Staphylococcus aureus subspaureus* |
| *Corynebacterium* | *Staphylococcus epidermidis* |
| *Enterococcus faecalis* | *Staphylococcus saprophylicus* |
| *Enterococcus faecium* | *Streptococcus agalactiae* |
| *Escherichia coli* | *Streptococcus bovis* |
| *Haemophilus* | *Streptococcus dysgalatiae / subsp.dysgalatiae* |
| *Moraxella catarrhalis* | *Streptococcus oralis formerly Streptococcus* |
| *Neisseria gonorrhoeae* | *Streptococcus pneumoniae* |
| *Neisseria lactamica* | *Streptococcus pygenes* |
| *Nesseria subllava* | *Streptococcus salivarius* |
| *Proleus vulgaris* | *Streptococcus sp group F.type 2* |

**【BIBLIOGRAPHY】**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3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.



**IBS International Biomedical Supplies INC**

**460 West Hunt Club Road, Suite 202 Ottawa ON K2F OB8,Canada**

**Website:www.ibsbiomedical.com**