OnSite Influenza A/B Rapid Test-Dip Strip (Swab)

CE

CTK BIOTECH SIMPLIFYING DIAGNOSTICS

REF

Catalog Number R0187S

IVD

In Vitro Diagnostic

INTENDED USE

The *OnSite* Influenza A/B Rapid Test is a lateral flow immunoassay for the qualitative detection and differentiation of Influenza A virus, including the H1N5 and H1N1, and Influenza B virus in nasal/throat/ nasopharyngeal swab or nasopharyngeal aspirate/wash specimens. It is intended to be used as a screening test and aid in the diagnosis of Influenza A and B viral infections. Any reactive specimen with the *OnSite* Influenza A/B Rapid Test must be confirmed with alternative testing method(s).

SUMMARY AND EXPLANATION OF THE TEST

Influenza A and B is a contagious infection attributed to a filterable virus. The viral infection affects mainly the nose, throat, bronchi, and occasionally lungs, causing fever, cough, sore throat, headache, pain in the back and limbs. The virus is transmitted easily from person to person via droplets and small particles produced when infected people cough or sneeze. Influenza spreads around the world in seasonal epidemics, resulting in hundreds of thousands of deaths worldwide annually, and millions in pandemic years.

Influenza A and B is mainly diagnosed by clinical symptoms. Collection of clinical specimens for viral culture remains critical to provide information regarding circulating influenza subtypes and strains. Since there is a trend of more global outbreaks of Influenza A, the laboratory rapid test has become an urgent need for screening patients.

The *OnSite* Influenza A/B Rapid Test is an immunological antigen test, which provides an instant test result without special instrumentation or requiring a skilled lab technician.

TEST PRINCIPLE

The *OnSite* Influenza A/B Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing anti-Influenza A and B antibody conjugated with colloidal gold (antibody conjugates), 2) a nitrocellulose membrane strip containing two test bands (T1 and T2 bands) and a control band (C band). The T1 band is pre-coated with unconjugated anti-Influenza A antibody, the T2 band is pre-coated unconjugated anti-Influenza B antibody, and the C band is pre-coated with goat anti-mouse IgG antibody.

Test (T) Lines

The Influenza antigen is first extracted from the swab specimen with extraction buffer. The antigen extracts contact the test strip and then migrate by capillary action across the test strip. Influenza A antigen if present in the extract will bind to the antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Influenza A antibodies, forming a burgundy colored T1 band, indicating an Influenza A positive test result.

Influenza B antigen if present in the extract will bind to the antibody conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-Influenza B antibodies, forming a burgundy colored T2 band, indicating Influenza B positive test result.

Absence of the T band suggests a negative result. The test contains an internal control (C band) which should exhibit a burgundy colored band of the immunocomplex goat anti-mouse IgG/antibody-gold conjugates regardless of the color development on the T band. Otherwise, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Each kit contains 20 test devices, each sealed in a foil pouch with two items inside:
   a. One strip device.
   b. One desiccant.
2. 20 sample extraction tubes, each containing 0.3ml of extraction buffer
3. 20 sterile swabs, each sealed in a plastic-paper pouch
4. One package insert (instruction for use).

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

For *in Vitro* Diagnostic Use

1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15℃ -30℃) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
8. Dispose of all specimens and materials used to perform the test as biohazardous waste.
9. Handle the Negative and Positive Control in the same manner as patient specimens.
10. The testing results should be read within 10 minutes after a specimen is applied to the sample well. Results read after 10 minutes may give erroneous results.
11. Do not perform the test in a room with strong air flow, ie. an electric fan or strong air-conditioning.

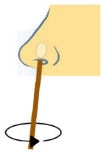
REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2℃-30℃. The positive and negative controls should be kept at 2℃-8℃**.** If stored at 2℃-8℃, ensure that the test device is brought to 15℃-30℃ before opening. The test device is stable through the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit over 30℃.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard biosafety procedures.

1. Specimen collection



Nasal swab

Throat swab

1.1 Nasal swab specimens
To collect a nasal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation push the swab until resistance is met, which is at the level of the turbinate(less than one inch into the nostril). Rotate the swab a few times against the nasal wall.

1.2 Throat swab specimens
To collect a throat swab specimen, rub the sterile swab on both tonsil surfaces and the posterior pharynx.

1.3 Nasopharyngeal swab specimens
To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril parallel to the palate and leave in place for a few seconds to absorb secretions.

1.4 Nasal/Nasopharyngeal aspirate or wash specimens
Aspirate or wash volumes of 2-2.5 ml are recommended. Transfer the specimen into a clean, dry specimen container.

2. Specimen transport and storage:
Testing should be performed immediately after the specimens have been collected. Specimens extracted from swab may be stored and tested at 1-8℃ for up to one day. For long term storage, specimens should be kept below -20℃.

ASSAY PROCEDURE

Step 1: Bring all specimens and test components to room temperature (15℃-30℃) if refrigerated or frozen. Once thawed, mix the specimen well prior to assay.

Step 2: Specimen extraction

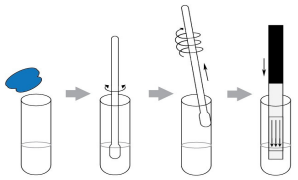
All swab samples
Remove the cap to the extraction solution tube and insert the patient swab sample. Swirl the swab at least 3 times while pressing the head against the bottom and side of test tube.

Swirl the swab head against the inside of the test tube at least 3 times to extract solution and sample before removing it.

Discard the swab in a safe manner. The diluent specimen is now ready for assay.

Nasal/Nasopharyngeal wash sample
Directly add 100µl of extracted specimen into the test tube.
Mix specimen well.

Step 3: Open a pouch at the notch and remove devise. Place the test strip on a clean, flat surface.



Step 4. Dip the strip into the test tube with the direction arrows on the test strip pointing down. Meanwhile, set up a timer.

Step 5: Results can be read in10-15 minutes.

Don't read result after 15 minutes. To avoid confusion, discard the test device after interpreting the result

Recommendation: take a digital photograph for record keeping.

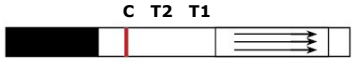
QUALITY CONTROL

Using individual *OnSite* Influenza A/B Rapid Test cassettes as described in the Assay Procedure above, run 1 Positive Control and 1 Negative Control under the following circumstances to monitor test performance:

1. A new operator uses the kit, prior to performing testing of specimens.
2. A new test kit is used.
3. A new shipment of kits is used.
4. The temperature used during storage of the kit falls outside of 2℃ -30℃.
5. The temperature of the test area falls outside of 15℃ -30℃.

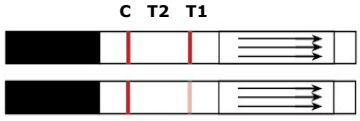
INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT**: If only the C band is developed, the test indicates that no detectable Influenza virus is present in the specimen. The result is negative or non-reactive.



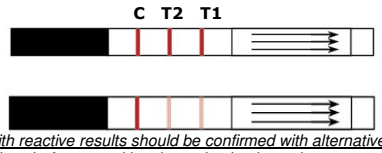
2. **POSITIVE RESULT**:

2.1 In addition to the presence of the C band, if only the T1 band is developed, the test indicates for the presence of Influenza A virus. The result is Influenza A positive or reactive.



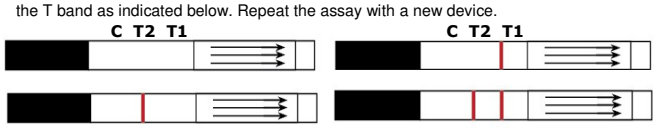
2.2 In addition to the presence of C band, if only the T2 band is developed, the test indicates for the presence of Influenza B virus. The result is Influenza B positive or reactive.

2.3 In addition to the presence of C band, if both the T1 and T2 bands are developed, the test indicates for the presence of both Influenza A virus and Influenza B virus. The result is Influenza A and B positive or reactive.



Samples with reactive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.

3. **INVALID:** If no C band is developed, the assay is invalid regardless of color development of the T band as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. **Sensitivity and Specificity**

A study was performed using 229 positive and negative specimens. Each specimen was assayed with the *OnSite* Influenza A/B Rapid Test and a commercially available DFA after cell culture according to the respective instructions for use. The result is shown in the following table:

	OnSite Influenza A/B Rapid Test		
DFA	**Positive**	**Negative**	**Total**
Positive	75	4	79
Negative	0	150	150
Total	75	154	229

Relative Sensitivity: 94.9%, Relative Specificity: 100%, Overall Agreement:

2. **Cross-reactivity:**

The Cross-reactivity of the *OnSite* Influenza A/B Rapid Test was determined from studies with the following pathogens: respiratory syncytial virus, parainfluenza virus I, parainfluenza virus III, adenovirus III, mumps virus, respiratory chlamydia, mycoplasma. Specimens containing above pathogens were found not to cross-react with the *OnSite* Influenza A/B Rapid Test

LIMITATIONS OF TEST

1. The Assay Procedure and the Test Result Interpretation must be followed closely when testing for the presence of Influenza A virus in the swab specimen from individual subjects. **For optimal test performance, proper sample collection is critical.** Failure to follow the procedure may give inaccurate results.
2. The *OnSite* Influenza A/B Rapid Test is limited to the qualitative detection of Influenza A and B virus. The intensity of the test band does not have linear correlation with virus titer in the specimen.
3. Sensitivity can differ with various strains of Influenza due to differences of antigen expression. Specimens might contain a new or nonidentified strain of Influenza that expresses varying amounts of antigen.
4. Individuals who have received nasally administered Influenza vaccine might have positive test results for up to three days after vaccination.
5. A negative or non-reactive result for an individual subject indicates absence of detectable Influenza A or B virus. However, a negative or non-reactive result does not preclude the possibility of Influenza A and B virus infection.
6. A negative or non-reactive result can occur if the quantity of the Influenza A and B virus present in the specimen is below the detection limits of the assay, or if the virus that are detected are not present in the swab specimen sampled, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.
7. If symptoms persist, while the result from the *OnSite* Influenza A/B Rapid Test is negative or non-reactive, it is recommended to re-sample the patient a few days later or test with an alternative test device.
8. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.

REFERENCES

1. Drescher, J., Verhagen, W. Method for determining the equilibrium constant and the concentration of Influenza virus IgG antihaemagglutinin antibody molecules by use of EIA titres determined with and without guanidine hydrochloride. J. Virol. Methods, 47(3): 307-19 (1994).
2. Drescher, J., Verhagen, W. Determination of the concentration of Influenza virus antihaemagglutinin antibody molecules of the IgG class and of the equilibrium constant by use of enzyme immunoassay titres determined for graded epitope concentrations. J. Virol. Methods, 55(2): 257-70 (1995).
3. Lupulescu, E. et al. ELISA in the rapid diagnosis of Influenza using as the detecting antibodies polyclonal antinucleoprotein sera. Bacteriol. Virusol. Parazitol. Epidemiol., 41(1-2): 63-7 (1996).
4. Marcante, R. et al. Rapid diagnosis of Influenza type A infection: comparison of shell-vial culture, directigen flu-A and enzyme-linked immunosorbent assay. New Microbiol., 19(2): 141-7 (1996).
5. Marinich, IG. et al. The immunoprophylaxis of Influenza among elderly persons. Zh. Mikrobiol. Epidemiol. Immunobiol. (1997/3): 60-4.
6. Moldoveanu, Z. et al. Human immune responses to Influenza virus vaccines administered by systemic or mucosal routes. Vaccine 13(11): 1006-12 (1995).
7. Naikhin, AN. et al. Immuno-enzyme analysis of post-vaccination secretory immunity to Influenza A and B viruses using a manufactured monoclonal immunoenzyme test system. Vopr. Virusol. 42(6): 271-5 (1997).
8. Naikhin, AN. et al. Monoclonal immuno-enzyme test-system for evaluating secretory immunity to Influenza A and B viruses. Vopr. Virusol. 42(5): 212-6 (1997).
9. Powers, DC. et al. Neuraminidase-specific antibody responses to inactivated Influenza virus vaccine in young and elderly adults. Clin. Diagn. Lab. Immunol. 3(5): 511-6 (1996).

Index of CE Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	Σ N	Tests per kit
2°C 30°C	Store between 2-30℃	EC REP	Authorized Representative	2	Do not reuse
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
10110 Mesa Rim Road
San Diego, CA 92121, USA
Tel: 858-457-8698
Fax: 858-535-1739,
E-mail: info@ctkbiotech.com

EC REP **CEpartner4U**
Esdoornlaan 13, 3951DB Maarn. The Netherlands
Tel.: +31 (0)6.516.536.26

PI-R0187S Rev. A
Effective date: 06-22-2011
English Version