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

OnSite CE

REF R0187S IVD In vitro Diagnostic

INTENDED USE

The Influenza A/B Rapid Test is a lateral flow immunoassay for the qualitative detection and differentiation of Influenza A virus, including H5N1 and H1N1, and Influenza B virus in nasal/throat/nasopharyngeal swab or nasopharyngeal aspirate/wash specimens. It is intended to be used by professionals as a screening test and provides a preliminary test result to aid in the diagnosis of Influenza A and B viral infections.

Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

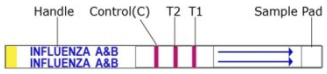
SUMMARY AND EXPLANATION OF THE TEST

Influenza A and B are contagious infections attributed to a filterable virus[1-3]. The viral infection affects mainly the nose, throat, bronchi and occasionally the lungs causing fever, cough, sore throat, headache and 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 are mainly diagnosed by clinical symptoms. Collection of clinical specimens for viral culture remains critical to provide information regarding circulating influenza subtypes and strains[4]. Since there is a trend of more global outbreaks of Influenza A, the laboratory rapid test has become an urgent need for screening patients[4-8].

The Influenza A/B Rapid Test is an immunological antigen test that provides an instant test result in 15 minutes by minimally skilled personnel without the use of laboratory equipment.

TEST PRINCIPLE



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

The Influenza antigen is firstly 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 presents 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 line, indicating an Influenza A positive test result. Absence of the T1 line suggests a negative Influenza A 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 line, indicating Influenza B positive test result. Absence of the T2 line suggests a negative Influenza B result.

The test contains an internal control (C line) which should exhibit a burgundy colored line of the of the control antibodies regardless of color development on any of the test lines. If the C line does not develop, the test result is invalid and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One strip device
   b. One desiccant
2. Sample extraction tubes, each containing 0.3 mL of extraction buffer (REF SB-R0187)
3. 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°C) 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. Users of this test should follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11. The testing results should be read 15 minutes after a specimen is applied to the sample well. Any results interpreted outside of the 15 minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

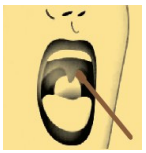
All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable until the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety 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:
Test specimens as soon as possible after collecting. If not tested immediately, store specimens extracted from swab at 1-8°C for up to 8 hours. For longer storage, specimens should be kept frozen at -20°C.

ASSAY PROCEDURE

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

Raise the swab head above the buffer level and swirl against the inside of the test tube at least 3 times to extraction buffer and sample before removing it.

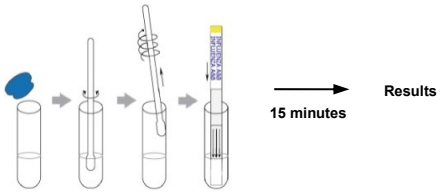
Discard the swab in a safe manner. The extracted specimen is now ready for testing.

Nasal/Nasopharyngeal wash sample

Directly add 0.3 mL specimen into the test tube. Mix the specimen with extraction buffer well.

Step 3: Open a pouch at the notch and remove the test strip.

Step 4: Insert the test strip into the test tube with direction arrows on the test strip pointing down ward. The test strip should be submerged in the extracted sample to the level indicated on the test strip.



Step 5: Incubate the test strip in test tube and set up a timer. Don't remove the strip from the test tube.

Step 6: Read the test results at 15 minutes. Strip may be removed out from the test tube for result reading. Positive result can be visible as soon as 3 minute. Negative result must be confirmed at the end of 15 minutes only. Any result interpreted outside of the 15 minute window should be considered invalid and must be repeated. Discard used devices after interpreting the result following local requirements governing the disposal of devices.

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. If the C line does not develop, review the whole procedure and repeat test with a new device.

2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of kits is used.
   d. The temperature during storage of the kit falls outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

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

2. POSITIVE RESULT:

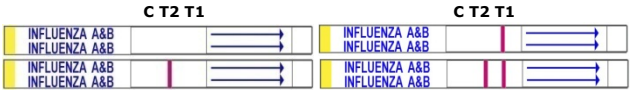
2.1 In addition to the presence of the C line, if the T1 line develops, the test indicates the presence of Influenza A virus. The result is Influenza A positive or reactive.

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

2.3 In addition to the presence of the C line, if both the T1 and T2 lines develop, the test indicates 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 diagnosis is made.

3. INVALID: If the C line does not develop, the assay is invalid regardless of color development of the T line as indicated below. Repeat the assay with a new device.



PERFORMANCE CHARACTERISTICS

1. Clinical Performance for the Influenza A Line

A total of 359 patient specimens were tested by the Influenza A/B Rapid Test and by cell culture. Comparison for all subjects is shown in the following table:

	Influenza A/B Rapid Test		
Cell Culture	**Positive**	**Negative**	**Total**
Positive	79	12	91
Negative	16	252	268
Total	95	264	359

Relative Sensitivity: 86.8%, Relative Specificity: 94.0%, Overall Agreement: 92.2%

2. Clinical Performance for the Influenza B Line

A total of 359 patient specimens were tested by the Influenza A/B Rapid Test and by cell culture. Comparison for all subjects is shown in the following table:

	Influenza A/B Rapid Test		
Cell Culture	**Positive**	**Negative**	**Total**
Positive	77	7	84
Negative	7	268	275
Total	84	275	359

Relative Sensitivity: 91.7%, Relative Specificity: 97.5%, Overall Agreement: 96.1%

3. Limit of Detection

The limit of detection (LOD) of the Influenza A/B Rapid Test is 3.0 x 10^4 $TCID_{50}$/Test as determined on Influenza A virus and 1.5 x 10^5 $TCID_{50}$/Test on Influenza B virus.

4. Analytical Sensitivity

A study to demonstrate the analytical sensitivity of the Influenza A/B Rapid Test was performed using 15 Influenza A virus strains, including 5 strains of H1N1, 3 strains of H2N2, and 7 strains of H3N2, and 9 Influenza B virus strains. The results showed that all 24 virus strains can be detected by the Influenza A/B Rapid Test.

5. Cross-reactivity

The cross-reactivity of the Influenza A/B Rapid Test was determined from studies with the following pathogens. Specimens containing these pathogens were found not to cross-react with the Influenza A/B Rapid Test.

Adenovirus type1-8,11,19,37	Coxsackie virus type A16, B1-5	Cytomegalovirus
Echovirus type 3,6,9,11,14,18,30	Enterovirus type 71	HSV-1
Mumps virus	Parainfluenza virus, type 1-3	Poliovirus type 1-3
Respiratory yncytial virus	Rhinovirus type 1A, 13, 14	*Chlamydia pneumaniae*
Chlamydia psittaci	*Chlamydia trachomatis*	*Mycoplasma pnemoniae*
Acinetobacer baumannii	*Bacteroides fragilis*	*Bordetella pertussis*
Candida albicans	*Candida glabrata*	*Cardiobacterium hominis*
Eikenella corrodens	*Enterococcus gallinarum*	*Escherichia coil*
Haemophilus phrophlus	*Haemophilus influenzae*	*Haemophilus parainfluenzae*
Haemophilus paraphrophilus	*Kingella kingae*	*Klebsiella pneumoniae*
Listeria monocytogenes	*Moraxella catarrhalis*	*Neisseria gonorrhoeae*
Proteus mirabilis	*roteus vulgaris*	*Pseudomonas aeruginosa*
Serratia marcescens	*Staphylococcus aureus*	*Staphylococcus epidermidis*
Streptococcus pneumoniae	*Streptococcus*	

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result 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 lead to inaccurate results.
2. The Influenza A/B Rapid Test is limited to the qualitative detection of Influenza A and B virus. The intensity of the test line 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 non-identified 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[5-7,9].
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. Infection may progress rapidly. If symptoms persist, while the result from the Influenza A/B Rapid Test is negative or non-reactive, it is recommended to 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

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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°C	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

Mfd. By: M/s. CTK Biotech, Inc.
13855 Stowe Drive, Poway, California 92064, USA (United States) having factory premises at M/s Beijing Genesee Biotech Inc., #36, Yanqi Donger Road, Huairou Yanqi Industrial Development Zone, Beijing, China

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

PI-R0187S-ATH Rev. FP
Date Released: 2018-11-28
English Version

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