AMP Rapid Test INFLUENZA A+B

QUALITATIVE TEST

For professional *in vitro* diagnostic use only

Sample:	Swab, nasal aspirate
Reading:	Visual
Temperature:	Room temperature
Storage:	2°C - 30°C, well protected against moisture, light and heat

CE

IVD

REF	CONT
RT2801	10 Cassettes
RT2802	25 Cassettes
RT2805	50 Cassettes

METHOD

Rapid immunochromatographic test for the qualitative detection of Influenza A (incl. H1N1 subtype) and Influenza B nucleoprotein antigens in nasal swab, throat swab and nasal aspirate as an aid in the differential diagnosis of influenza A and B infection.

PRINCIPLE

The test is performed by applying the extracted sample to the sample well of the cassette and observing the formation of colored lines.
Influenza type A and type B antigens are detected by utilizing highly sensitive monoclonal antibodies.
The sample migrates by capillary effect along the membrane. If present in the sample, Influenza A and/or B react with monoclonal antibody coated colloid-gold particles and are captured by monoclonal antibodies immobilized in the test (A/B) region.
A colored line will form at the Test (A/B) region of the membrane. The presence of this colored line indicates a positive result, while its absence indicates a negative result.
As a procedure control a coloured line has to appear in the Control (C) region confirming that sufficient sample has been absorbed.

COMPOSITION

Individually packed test cassette, desiccant, extraction buffer
Sterile swab, extraction tube, dropper tip

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- For external use only. Do not swallow.
- Samples are potentially infectious and therefore have to be treated cautiously.
- Avoid cross-contamination of samples by using a new sample collection container for each sample obtained.
- Use gloves when performing the test.
- The test is designed for single use only. Discard after use according to the local regulations or laboratory rules for disposal of potentially infectious waste.
- Do not use test cassette beyond expiry date.
- Do not use test cassette in case that the pouch is punctured or not sealed correctly.
- Keep out of the reach of children.
- Humidity and temperature may affect the results.

STORAGE AND STABILITY

When stored in the sealed pouch at 2 - 30°C and protected from direct sunlight, moisture and heat the test cassette is stable until the indicated expiry date.
DO NOT FREEZE.
Care should be taken to protect components of the kit from contamination.

SAMPLE COLLECTION AND PREPARATION

Nasopharyngeal swab:
Insert sterile swab into a nasal cavity securely from a nostril and collect mucoepidermoid wiping turbinate several times.

Pharyngeal swab:
Insert sterile swab into pharynx and collect mucoepidermoid mainly wiping flare region of post-pharyngeal wall and palatine tonsil several times; avoid saliva getting attached to the swab.

Nasopharyngeal aspirate:

1. Connect an aspiration catheter to an aspiration trap attached to an aspiration device. Insert catheter into nasal cavity from a nostril, start aspiration device and collect nasal aspirate sample.
2. Dip sterile swab into the collected nasal aspirate sample and make sample cling to the swab.

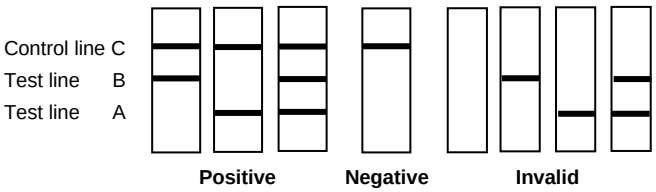
PROCEDURE

Test cassette, buffer and sample must be at room temperature (15 - 30°C) prior to testing.

1. Remove test cassette from the foil pouch and place it on a flat and clean surface.
   For best results, the assay should be performed immediately.
2. Hold **Buffer** bottle vertically and add 10 full drops (0.5 mL) to a new extraction tube without touching the extraction tube.
3. Immediately place the swab in the extraction tube and rotate the swab for app. **10 seconds** while pressing the head against the inside of the tube to release the antigen in the swab.
4. Remove swab while squeezing it against the inside of the extraction tube to expel as much liquid from the swab as possible. Discard swab in accordance with biohazard waste disposal protocol.
5. Fit a new dropper tip on the extraction tube.
   Apply **4 drops of extraction solution** (appr. 120 - 150 µL) to the sample well (S) of the cassette.
6. Wait for the colored lines to appear and read the test result after **10 minutes**.
   ***IMPORTANT:* Do not read the result after 15 minutes.**

INTERPRETATION OF RESULTS

Positive (+)
A: Two colored lines appear on the membrane. One line appears in the control (C) and another line in the test (A) region.
B: Two colored lines appear on the membrane. One line appears in the control (C) and another line in the test (B) region.
A & B: Three colored lines appear on the membrane. One line appears in the control (C) and two lines in the test (A & B) region.
Note: Color intensity of the lines appearing in the test (A & B) regions may vary depending on the concentration of Influenza A and/or B antigens in the sample. Therefore any shade of color in the test (T) region is to be considered as a positive result.
Negative (-)
Only one colored line appears in the control (C) region. No colored line appears in the test (T) region.
Invalid
If a color line is visible only in the test (A/B) region or no color line is visible at all the test is invalid and needs to be repeated with a new test cassette.
Note: Insufficient sample volume, incorrect procedure or expired test are most common reasons of invalid results.



QUALITY CONTROL

Although the test itself includes an internal procedural control use of external controls is highly recommended as part of Good Laboratory Practice to confirm and verify the test procedure and proper performance of the test. Controls are to be tested following the same procedure as applied for patient samples. Positive and negative controls shall give the expected results.

REF RD2800-E V4.2-CE

AMEDA Labordiagnostik GmbH

Prepared by: D. A. Popa
Approved by: G. Herfort, 2018-04-02

Krenngasse 12, 8010 Graz, Austria * Phone +43 316 69 80 69 * Fax +43 316 69 80 69 12 * e-mail: office.graz@amp-med.com

LIMITATIONS OF PROCEDURE

This test is for professional *in vitro* diagnostic use and is to be used for qualitative detection of Influenza A and/or B virus in nasal swab, throat swab or nasal aspirate samples only. No quantitative result or rate of increase in Influenza A and/or B virus concentration can be determined with this test.

This test indicates the presence of Influenza A and/or B virus both viable and non-viable strains in the sample only.

A negative result is to be confirmed by culture and may be obtained if the Influenza A and/or B virus in the sample is below the detection limit of the test.

Excess blood or mucus on the swab sample may interfere with the test performance yielding false positive result.

The accuracy of the test depends on the quality of the swab sample. False negative results may result from improper sample collection or storage.

Use of nasal sprays at high concentration may lead to invalid or incorrect test results.

A positive Influenza A+B test result does not preclude an underlying coinfection with another pathogen. Therefore, the possibility of an underlying bacterial infection is to be considered.

The performance of the test with human samples with H5N1 or other avian influenza viruses is unknown.

The performance of the test may vary when other viruses than A/H3 and A/H1 are in the sample.

False positive test results can be obtained during periods of low influenza activity when the prevalence is moderate to low.

As for all diagnostic tests the test must be interpreted by a physician only after all clinical and laboratory findings have been evaluated.

PERFORMANCE

Sensitivity and specificity:

AMP Rapid Test Influenza A+B has been tested versus cell culture. Sensitivity, specificity and correlation among the two methods has been found to be as following:

Nasal swab

		AMP Rapid Test Influenza A + B					
		A			B		
		+	-	Total	+	-	Total
Cell culture	+	25	3	28	27	4	87
	-	2	81	83	3	91	202
		27	84	111	30	95	289
Test sensitivity:		92.6%			90.0%		
Test specificity:		96.4%			95.8%		
Overall Agreement:		95.5%			94.4%		

Throat swab

		AMP Rapid Test Influenza A + B					
		A			B		
		+	-	Total	+	-	Total
Cell culture	+	20	3	23	19	6	25
	-	4	59	63	4	67	71
		24	62	86	23	73	96
Test sensitivity:		83.3%			82.6%		
Test specificity:		95.2%			91.8%		
Overall Agreement:		91.9%			89.6%		

Nasal aspirate

		AMP Rapid Test Influenza A + B					
		A			B		
		+	-	Total	+	-	Total
Cell culture	+	48	9	57	52	5	57
	-	6	125	131	5	98	103
		54	134	188	57	103	160
Test sensitivity:		88.9%			93.3%		
Test specificity:		93.3%			95.4%		
Overall Agreement:		92.0%			93.8%		

Precision:

Intra-assay:

Negative, Influenza A low positive, Influenza B low positive, Influen-za A high positive and Influenza B high positive samples have been tested in 10 replicates each. Results have been detected correctly for > 99% of the samples.

Inter-assay:

Negative, Influenza A low positive, Influenza B low positive, Influen-za A high positive and Influenza B high positive samples have been tested in 10 replicates each with AMP Rapid Test Influenza A+B from 3 different lots. Results have been detected correctly for >99% of the samples.

Reactivity with Human Influenza strains

AMP Rapid Test Influenza A+B is reactive to the following strains:

Influenza A:

A / Hubei / PR8 / 2001 (H1N1)
A / New Caledonia / 20 / 99 (H1N1)
A / Yamagata / 32 / 89 (H1N1)
A / Beijing / 262 / 95 (H1N1)
A / Singapore / 1 / 57 (H2N2)
A / Hubei / 3 / 2005 (H3N2)
A / Akita / 1 / 94 (H3N2)
A / Kita Kyusyu / 159 / 93 (H3N2)

Influenza B:

All influenza B strains

Interferences

Bacterial isolates at a concentration at 10^7 and 10^9 org/mL and viral isolates at a concentration of at least 10^4 – 10^8 TCID50/mL gave negative results when tested with AMP Rapid Test Influenza A+B:

Acinetobacter calcoacet.	*Neisseria meningitis*	*Strep. sanguinis*
Bacteroides fragilis	*Proteus vulgaris*	*Strep. sp. Group B*
Mycobacterium tubercul.	*Pseudom. aeruginosa*	*Strep. sp. Group C*
Mycoplasma orale	*Staphylococcus aureus*	*Strep. sp. Group G*
Neisseria gonorrhoeae	*Strep. pneumoniae*	
Human adenovirus B & C	*Coxsackievirus B5*	*Parainfluenza virus 3*
Adenovirus type 10	*Human Herpesvirus 2*	*Human Rhinovirus 2*
Adenovirus type 18	*Measles*	*Human Rhinovirus 14*
Human Coronavirus OC43	*Mumps*	*Human Rhinovirus 16*
Human Coxsackievirus A9	*Parainfluenza virus 2*	*Sendai virus*

BIBLIOGRAPHY

1. Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med. 19(3): 109-111.
2. Betts, R.F. 1995. Influenza virus, p. 1546-1567. In G.L. Mandell, R.G. Douglas, Jr. and J.E. Bennett (ed.), Principle and practice of infectious diseases, 4th ed. Churchill Livingstone, Inc., New York, N.Y.
3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.

EXPLANATION OF SYMBOLS USED ON LABEL AND PACKAGING

	Temperature limitation / Store at
REF	Code
IVD	For in vitro diagnostic use
CONT	Contents of kit
LOT	Lot number
	Use by (last day of the month)
	Manufacturer
	Consult instructions for use
	Do not reuse

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Krenngasse 12, 8010 Graz, Austria * Phone +43 316 69 80 69 * Fax +43 316 69 80 69 12 * e-mail: office.graz@amp-med.com