SZABO SCANDIC

Part of Europa Biosite

Produktinformation

- Forschungsprodukte & Biochemikalien
- Zellkultur & Verbrauchsmaterial
- Diagnostik & molekulare Diagnostik
- Laborgeräte & Service

Weitere Information auf den folgenden Seiten!
See the following pages for more information!

Lieferung & Zahlungsart

siehe unsere Liefer- und Versandbedingungen

Zuschläge

- Mindermengenzuschlag
- Trockeneiszuschlag
- Gefahrgutzuschlag
- Expressversand

SZABO-SCANDIC HandelsgmbH

Quellenstraße 110, A-1100 Wien

T. +43(0)1 489 3961-0

F. +43(0)1 489 3961-7

mail@szabo-scandic.com

www.szabo-scandic.com

linkedin.com/company/szaboscandic

SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test

IVD

Cassette

Instructions For Use

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY

INTENDED USE

The SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 (COVID-19), influenza A (FLU A), influenza B (FLU B) and respiratory syncytial (RSV) virus antigen in nasopharyngeal swab specimens. This test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus infections in humans in conjunction with clinical and epidemiological risk factors.

Summary

The SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2, influenza A, influenza B and respiratory syncytial virus (RSV) antigen in nasopharyngeal swab specimens from individuals wit suspected SARS-CoV-2/influenz A+B/RSV infection in conjunction with clinical presentation and the results of other laboratory tests. Results are for the detection of SARS-CoV-2, influenza A+B and RSV antigen. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigen, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out other bacterial/viral infection. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary for patient management. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2, influenza A+B and RSV. The SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette is intended for use by trained clinical laboratory personnel.

TEST PRINCIPLE

The SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette is a qualitative membrane strip based immunoassay for the detection of SARS-CoV-2 virus, influenza A virus, and influenza B virus or respiratory syncytial virus antigen in nasopharyngeal swab specimens.
In this test procedure, SARS-CoV-2-N antibody, influenza A antibody, influenza B antibody or respiratory syncytial virus antibody is immobilized in the different test line regions of the device. After a nasopharyngeal swab specimen is placed in the specimen well, it reacts with SARS-CoV-2-N antibody, influenza A antibody, influenza B antibody and respiratory syncytial virus antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized SARS-CoV-2-N antibody, influenza A antibody, influenza B antibody or respiratory syncytial virus antibody. If the specimen contains SARS-CoV-2 virus antigen, influenza A virus antigen, influenza B virus antigen or respiratory syncytial virus antigen. A colored line will appear in the corresponding test line region indicating a positive result. If the specimen does not contain SARS-CoV-2 virus antigen, influenza A virus antigen, influenza B virus antigen or respiratory syncytial virus antigen, a colored line will not appear in these regions indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

Material Provided

- Test Cassette
- Disposable swab
- Workstation
- Instructions for use
- Extraction tube with buffer solution

Materials not provided:

Timer, specimen collection container, centrifuge, disposable latex gloves, sealed bag and disinfectant.

STORAGE AND STABILITY

- Stored at 2-30℃, the validity period of the product is 24 months. Do not freeze.
- The test cassette should be used within 1 hour after opening the sealed pouch. If the temperature is higher than 30℃ or in high humidity environment, it should be to use immediately.
- Kit contents are stable until the expiration date printed on the package.
- Keep away from sunlight, moisture and heat.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use only. Do not use after expiration date. Do not reuse the test cassette.
2. Do not eat, drink, or smoke in the area where the samples or kits are handled.
3. Handle all samples as if they contain infectious agents.
4. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
5. The test cassette should remain in a sealed foil pouch until use. Do not use the test cassette if the pouch is damaged or opened.
6. Allow the test device and specimens to equilibrate at room temperature (15-30℃) and humidity (<80%)prior to testing.
7. After use, the test cassette can be disposed of with household waste in a sealed bag.
8. Follow local standard biosafety guidelines for handling and disposal of potential infective materials.

SPECIMEN COLLECTION AND HANDLING

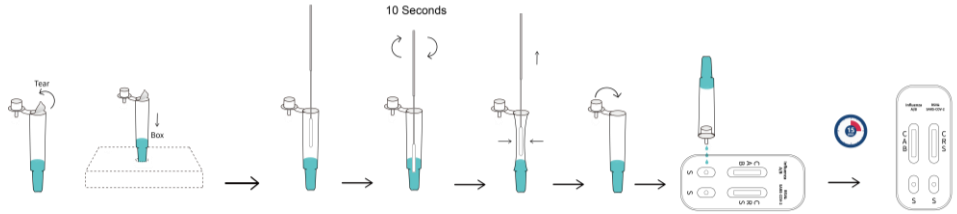
- Only the swab provided in the kit is to be used for nasopharyngeal swab collection.
- To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab 5 times or more against the nasopharyngeal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods.
- Bring specimens to room temperature prior to testing.
- If it is not possible to test immediately, it is strongly recommended that the swab is placed in a clean, unused plastic extraction tube labelled with patient information to maintain best performance and avoid possible contamination. The sample can be kept tightly sealed in this extraction tube at room temperature (15-30℃ or 59-86℉) for a maximum of one hour. Make sure that the swab is firmly seated in the extraction tube and that the cap is tightly closed. If a delay of more than one hour occurs , discard the sample. A new sample must be taken for the test.
- If specimens are to be transported, they should be packaged according to local regulations for the transport of atiological agents.

TEST PROCEDURE

Please read the instructions for use carefully before use.
Allow the test cassette, buffer to room temperature 15-30 ℃ (59-86 ℉) before testing.
1. Place the extraction tube in the workstation. Peel off aluminum foil seal from the top of the extraction tube containing the extraction buffer .
2. Place the swab into the extraction tube. Rotate the swab for 10-15 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
3. 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.
4. When ready to test, open the pouch at the notch and remove the test cassette. Place the test cassette on a clean, flat surface.
5. Fit the tube tip or close the cap onto the tube, then invert the extraction tube and add 3 drops of specimen (approximately 100μL) into the specimen well (S) and then start the timer.
6. Read the result at 15 minutes. If left unread for 20 minutes or more the results are invalid and a repeat test is recommended.

Notes:

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of specimen.



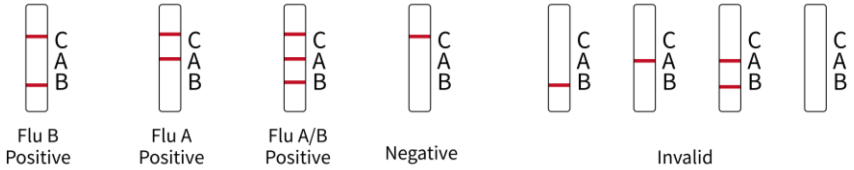
INTERPRETATION OF RESULTS

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking, and correct procedural technique.

1. **Interpretation of Flu A/B Results:**

Positive: Control line and at least one test line appear on the membrane. The appearance of A test line indicates the presence of Flu A antigen. The appearance of B test line indicates the presence of Flu B antigen. And if both A and B line appear, it indicates that the presence of both Flu A and Flu B antigen.
Negative: One colored line appears in the control region(C). No apparent colored line appear in the test line region.
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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Interpretation of Flu A/B Results:



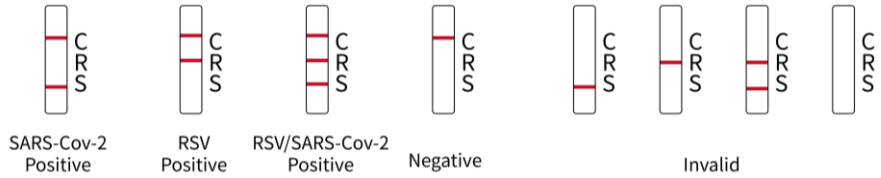
2. Interpretation of SARS-CoV-2/RSV Results

Positive: Two lines appear. One line should always appear in the control line region(C), and another one apparent colored line should appear in the test line region. Control line and at least one test line appear on the membrane. The appearance of S test line indicates the presence of SARS-CoV-2 antigen. The appearance of R test line indicates the presence of RSV antigen. And if both R and S line appear, it indicates that the presence of both RSV and SARS-CoV-2 antigen.

Negative: One colored line appears in the control region(C). No apparent colored line appear in the test line region.

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

Interpretaion of SARS-CoV-2/RSV Results



***NOTE:** The intensity of the color in the test line regions may vary depends on the concentration of virus antigen. Therefore, any shade of color in the test line region should be considered positive.

PROCEDURAL CONTROL

There are internal procedural controls in the test. A colored line displayed in the control area (C) is an internal procedural control. It confirms the presence of a sufficient amount of sample and correct procedure.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection

The limit of detection of SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette is showed on the follow tables.

Table1. Virus strains and LOD of the test

Item	Concentration
COVID-19 NP-protein	0.1ng/mL
COVID-19 inactivated virus culture	50 $TCID_{50}$/mL
Flu A NP-protein	2ng/ml
Flu A inactivated virus culture (Aichi/2/68)	1.25×10^3 $CEID_{50}$/mL
Flu B NP-protein	3ng/ml
Flu B inactivated virus culture(Hong Kong5/72)	$2.8\times10^3CEID_{50}$/mL
RSV inactivated virus culture (Subtype A (long))	$1.07\times 10^3TCID_{50}$/mL
RSV inactivated virus culture (Subtype B (wild-type))	$1.2\times 10^2TCID_{50}$/mL

2. Clinical performance

In a clinical study, the test was evaluated with confirmed positive samples and negative samples by RT-PCR test.

2.1 The evaluation assay results for Influenza A are as below:

Table 2. Influenza A: Comparison of evaluation assay and reference assay:

Reference		A leading Commercial FLU A test		Total Results
Method	Result	Positive	Negative	
SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette	Positive	108	0	108
	Negative	2	200	202
TOTAL RESULTS		110	200	310

The coincidence rate of sensitivity =108/110*100%=98.18% (95%CI: 93.61%-99.50%)

The coincidence rate of specificity =200/200*100%=100.00% (95%CI: 98.12%-100.00%)

Total coincidence rate =308/310*100%=99.35% (95%CI: 97.67%-99.82%)

2.2 The evaluation assay results for Influenza B are as below:

Table 3. Influenza B: Comparison of evaluation assay and reference assay

Reference		A leading Commercial FLU B test		Total Results
Method	Result	Positive	Negative	
SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette	Positive	97	0	97
	Negative	1	200	201
TOTAL RESULTS		98	200	298

The coincidence rate of sensitivity =97/98*100%=98.97% (95%CI: 94.44%-99.82%)

The coincidence rate of specificity=200/200*100%=100.00% (95%CI: 98.12%-100.00%)

Total coincidence rate =297/298*100%=99.66% (95%CI: 98.12%-99.94%)

2.3 The evaluation assay results for SARS-CoV-2 are as below:

Table 4. SARS-CoV-2: Comparison of evaluation assay and reference assay

Reference		A leading Commercial SARS-CoV-2 test		Total Results
Method	Result	Positive	Negative	
SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette	Positive	100	1	101
	Negative	2	106	108
TOTAL RESULTS		102	107	209

The coincidence rate of sensitivity = 100/102*100%=98%（95% CI:92.4%~99.7%）

The coincidence rate of specificity = 106/107*100%=99%（95% CI:94.2%~100.00%）

Total coincidence rate= 206/209*100%=98.6%（95% CI:91.8%~99.9%）

2.4 The evaluation assay results for RSV are as below:

Table 5. RSV: Comparison of evaluation assay and reference assay

Reference		A leading Commercial RSV test		Total Results
Method	Result	Positive	Negative	
SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette	Positive	101	0	101
	Negative	3	1201	1204
TOTAL RESULTS		104	1201	1305

The coincidence rate of sensitivity=101/104*100%=97.11% (95%Cl*:91.86%-99.01%)

The coincidence rate of specificity=1201/1201*100%=100.00% (95%Cl*:99.68%-100.00%)

Total coincidence rate =(101+1201)/1305*100%=99.77% (95%Cl*:99.33%-99.92%)

3. Interference

The following compounds had been tested using the SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette and no interference observed.

Table 6.The results of interference study

Analytes	Concentration	Analytes	Concentration
Whole Blood	20μl/mL	Naso Gel	5% (V/V)
Mucin	50μg/mL	Phenylephrine	12mg/mL
Budesonide Nasal Spray	200μL/mL	Relenza	282ng/mL

Dexamethasone	0.8mg/mL	Tamiflu	1.1μg/mL
Flunisolide	6.8ng/mL	Tobramycin	2.43mg/mL
Mupirocin	12mg/mL	CVS Nasal Spray(Cromolyn)	15% (V/V)
Oxymetazoline	0.6mg/mL	AZEP Nasal Spray(Azelastine)	10% (V/V)
Chloraseptic(Methol/Benzocaine)	1.5mg/mL	Mupirocin	10mg/mL
Sterimar Nasal Spray(Saline)	1:1 (V/V)		

4. Cross-reactivity

Cross-reactivity of Influenza A/B Antigen, COVID-19 Antigen, RSV Antigen Rapid Test was evaluated by testing commensal and pathogenic microorganisms listed in the following table that may be present in the clinical samples. Each of the bacterium and viruses were tested in triplicate with no false positive results of Influenza A, Influenza B, SARS-CoV-2 and RSV.

Table 7. The results of cross-reactivity study

Potential substances	Concentration Tested	Cross-reactivity (Yes/No)			
		Flu A	Flu B	SARS-CoV-2	RSV
Influenza A H3N2	1.0×10^5 $TCID_{50}$/mL	/	No	No	No
Influenza A H1N1	1.0×10^5 $TCID_{50}$/mL	/	No	No	No
Influenza A H5N1	1.0×10^5 $TCID_{50}$/mL	/	No	No	No
Influenza A H7N9	1.0×10^5 $TCID_{50}$/mL	/	No	No	No
Influenza B/Hong Kong5/72	1.0×10^5 $TCID_{50}$/mL	No	/	No	No
SARS-CoV-2 N Protein	10 μg/mL	No	No	/	No
SARS-CoV-2 S Protein	10 μg/mL	No	No	/	No
Respiratory syncytial virus	1.0×10^5 $TCID_{50}$/mL	No	No	No	/
Streptococcus pneumoniae	1.0×10^6 CFU/mL	No	No	No	No
Staphylococcus epidermidis	1.0×10^7 CFU/mL	No	No	No	No
Haemophilus influenzae	1.0×10^7 CFU/mL	No	No	No	No
Arcanobacterium haemolyticum	1.0×10^7 CFU/mL	No	No	No	No
Candida albicans	1.0×10^7 CFU/mL	No	No	No	No
Corynebacterium diphtheriae	1.0×10^7 CFU/mL	No	No	No	No
Moraxella catarrhalis	1.0×10^7 CFU/mL	No	No	No	No
Neisseria lactamica	1.0×10^7 CFU/mL	No	No	No	No
Pseudomonas aeruginosa	1.0×10^7 CFU/mL	No	No	No	No
Staphylococcus aureus subspaureus	1.0×10^7 CFU/mL	No	No	No	No
Streptococcus salivarius	1.0×10^7 CFU/mL	No	No	No	No
Streptococcus pyogenes (group A)	1.0×10^7 CFU/mL	No	No	No	No
Human Rhinovirus 2	2.81×10^4 $TCID_{50}$/mL	No	No	No	No
Human Rhinovirus 14	1.58×10^6 $TCID_{50}$/mL	No	No	No	No
Human Rhinovirus 16	8.89×10^6 $TCID_{50}$/mL	No	No	No	No
Measles virus	1.58×10^4 $TCID_{50}$/mL	No	No	No	No
Human coronaviruses 229E	2.35×10^6 $TCID_{50}$/mL	No	No	No	No
MERS-coronavirus	1.0×10^5 PFU/mL	No	No	No	No
Human Coronavirus OC43	2.45×10^6 $TCID_{50}$/mL	No	No	No	No
Coronavirus NL63	1.0×10^5 $TCID_{50}$/mL	No	No	No	No
Adenovirus	1.0×10^5 $TCID_{50}$/mL	No	No	No	No
Parainfluenza virus 1	1.0×10^5 $TCID_{50}$/mL	No	No	No	No
Parainfluenza virus 2	1.58×10^6 $TCID_{50}$/mL	No	No	No	No
Parainfluenza virus 3	1.58×10^7 $TCID_{50}$/mL	No	No	No	No
Parainfluenza virus 4	1.5×10^6 $TCID_{50}$/mL	No	No	No	No
Epstein-Barr virus	1.0×10^5 PFU/mL	No	No	No	No
human metapneumovirus (hMPV)	2.25×10^5 $TCID_{50}$/mL	No	No	No	No
Coronavirus HKU1	1.0×10^5 $TCID_{50}$/mL	No	No	No	No

5. Precision

Intra-assay

The intra-assay precision was determined by testing the same batches of products for 10 times with the same negative reference and positive reference. The color results of the same batch of products were consistent, and the coincidence rate was 100%.

Inter-assay

The inter-assay precision was determined by testing the three batches of products with the same negative solution and positive solution. The color results of the different batches of products were consistent, and the coincidence rate was 100%.

LIMITATIONS OF THE TEST METHOD

1. This test detects both viable (live) and non-viable, FLU A/B, SARS-CoV, SARS-CoV-2 and respiratory syncytial virus antigen. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. The performance of SARS-CoV-2 & FLU A&B & RSV Antigen Combo Test Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. False negative results may occur if a specimen is improperly collected, transported, or handled.
5. False results may occur if specimens are tested past 1 hour of collection. Specimen should be test as quickly as possible after specimen collection.
6. Positive test results do not rule out co-infections with other pathogens.
7. Positive test results do not differentiate between SARS-CoV and SARS-CoV-2 antigen.
8. Negative test results are not intended to rule in other viral or bacterial infections.
9. Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
10. If the differentiation of specific influenza A virus , influenza B virus, SARS-CoV-2 virus, respiratory syncytial virus antigen is needed, additional testing, in consultation with local public health departments, is required.
11. A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention and further testing if required.

REFERENCE

1. CDC, Biosafety in Microbiological and Biomedical Laboratories, 2nd Ed., HHS Publication No. 8808395, 4-6, 1988.
2. Lee D, Rosenfeld R, Adenoid bacteriology and sinonasal symptoms in children. Otolaryngology – Head and Neck Surgery. March 1997;116:301-307.
3. Lopez, Juan A., R. Bustos, C. Orvell, M. Berois, J. Arbiza, B. Garcia-Barreno, J.Melero. Antigenic Structure of Human Respiratory Syncytial Virus Fusion Glycoprotein. Jr. of Virology, vol. 72, no.8, August 1998, pp.6922-6928.
4. Cheung M, Lieberman JM. Influenza: update on strategies for management. Contemporary Pediatrics. October 2002;19:82.
5. Montalto N, Byrd R. An Office-Based Approach to Influenza: Clinical Diagnosis and Laboratory Testing. American Family Physician. January 2003;67:111-118.
6. Williams,KM, Jackon MA, Hamilton M. Rapid Diagnostic testing for URIs in children: impact on physician decision making and cost .Infect .med.19(3):109-111,2002.
7. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organization, July 2005.
8. Williams, KM, Jackon MA, Hamiliton M. Rapid Diagnostic Testing for URIs in Children: Impact on Physician Decision Making and Cost. Infect. Med. 19（3）: 109-111, 2002.
9. Rezaee,F.,Linfield,D.T.,Harford,T.J.,&Piedimonte,G.(2017).Ongoing developments in RSV prophylaxis: a clinician's analysis. Current Opinion in Virology,24, 70-78.

INDEX OF SYMBOLS

	Consult Instructions for Use		Contains sufficient for <n> tests		Temperature limit
IVD	In vitro diagnostic medical device		Use by date		Manufacturer
REF	Catalogue number	LOT	Batch code		Date of manufacture

CE	CE conformity marking	EC REP	Authorized representative in the European Community/ European Union		Do not re-use
	Do not use if package is damaged and consult instructions for use				

Jiangsu Mole Bioscience Co., Ltd.

G116 Building, No.805, Jiankang Avenue,Medical New&Hi-tech District, 225300 Taizhou, Jiangsu Province, P.R. China
info@molechina.com
www.molechina.com

MedUnion S.L.

Carrer de Tapioles,33, 2-1, Barcelona, 08004, Spain
Tel: +34-644173535
Email: rep@themedunion.com

REF **R223T020B0C0** **Reversion Date:2024.10.16**

Number: 301100077800 **EN version：0.0**