

# RSV Respi-Strip



www.corisbio.com

IFU-5706/TB/05

Manufacturer:

**Coris BioConcept**  
Science Park CREALYS  
B – 5032 GEMBLoux  
BELGIUM  
Tel.: +32(0)81.719.917  
Fax: +32(0)81.719.919  
info@corisbio.com

Produced in BELGIUM

## ***In vitro rapid diagnostic test for the detection of Respiratory Syncytial Virus in nasopharyngeal secretions***

**FOR IN VITRO USE**

**FOR PROFESSIONAL USE ONLY**

Reference: C-1006, 25 tests per kit.

EN

(EN) For Instructions For Use in your language : (FR) Pour obtenir les notices dans la langue de votre choix : (ES) Para las instrucciones de uso en su idioma : (PT) Para Instruções de Uso na sua língua : (IT) Per le Istruzioni di Uso nella sua lingua : (DE) Für Gebrauchsanleitungen in Ihrer Sprache : (NL) Voor Gebruiksaanwijzing in uw eigen taal :	
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### I. INTRODUCTION

RSV, Respiratory Syncytial Virus, is the major cause of respiratory illness in all ages. It represents the most frequent cause of serious respiratory tract infections in infants and children younger than 4 years of age but is also responsible for severe problems in elderly and immunocompromised patients giving rise to high death rates. Pneumonia and bronchiolitis are the two most frequent severe infections prevalent in infants aged 2 to 6 months. Infection of older children and adult may be mild, usually self-limiting, causing nasal stuffiness and discharge not distinguishable from a common cold.

Every year, up to 50% of infants are infected. RSV disease causes about 70% of bronchiolitis and results in 80,000 to 125,000 hospitalisations in the US. Those children who require hospitalisation are newborns and children suffering from asthma, lung disorders or heart problems. Moreover, RSV bronchiolitis in the first year of life is one of the most important risk factors for the subsequent development of asthma.

It is a highly contagious disease through contact with respiratory secretions. It is also a common cause of nosocomial infections whose prevalence increases during community outbreaks through casual contacts. RSV affects both the upper and lower respiratory tracts, but pneumonia and bronchiolitis are the most prevalent lower respiratory illnesses. Bronchiolitis is diagnosed by coughing, wheezing, and the onset of dyspnoea, increase of respiratory rate up to 40 breaths per minute and bluish discoloration of the skin around the mouth. Rattling in the chest and respiratory distress are common symptoms of pneumonia.

### II. PRINCIPLE OF THE TEST

This test is ready to use and is based on a membrane technology with colloidal gold nanoparticles. A nitrocellulose membrane is sensitized with a monoclonal antibody directed against one epitope of the F protein of the Respiratory Syncytial Virus. Another monoclonal antibody directed against a second epitope of the F protein is conjugated to colloidal gold particles. This conjugate is dried on a membrane.

This test is aimed to the detection of RSV either in nasopharyngeal secretions or in supernatant after several days of culture in order to reach a better sensitivity.

When the extraction solution of NPS (nasopharyngeal secretions) or culture extracted solution comes into contact with the strip, the solubilised conjugate migrates with the sample by passive diffusion and both the conjugate and sample material come into contact with the anti-RSV antibody that it is adsorbed onto the nitrocellulose strip. If the sample contains RSV, the conjugate-RSV complex will remain bound to the anti-RSV antibody adsorbed onto the nitrocellulose. The result is visible within 15 minutes in the form of a red line that develops on the strip. The solution continues to migrate to encounter a control reagent that binds a control conjugate, thereby producing a second red line.

### III. REAGENTS AND MATERIALS

#### 1. RSV Respi-Strip (25)

These strips come in a bottle with a desiccant.

#### 2. Extraction buffer (15 mL)

Saline solution buffered to pH 7.5 containing Borate, NaN<sub>3</sub> (<0,1%) and a detergent.

#### 3. Instruction for use (1)

#### 4. Required materials

- 3 or 5 mL test tubes,
- Micropipettes.

Materials to be ordered separately:

- RSV positive control (Ref.:C-1086)
- Negative control (Ref.: CTR-1000)

### IV. SPECIAL PRECAUTIONS

- All operations linked to the use of the test must be performed in accordance with Good Laboratory Practices (GLP).
- All reagents are for *in vitro* diagnostic use only.
- Avoid touching nitrocellulose with your fingers.
- Wear gloves when handling samples.
- Never use reagents from another kit.
- If strips are stored in a container, the container must be resealed as soon as the necessary number of strips for the operation has been removed as the strips are sensitive to humidity. Make sure that the desiccant bag is present.
- Green lines indicate immunoreagents adsorption sites. Green colour disappears during the test.
- Reagents' quality cannot be guaranteed beyond their shelf-life dates or if reagents are not stored under required conditions as indicated in the insert.

**To avoid diluting the colloidal gold conjugate in the solution, take care not to immerse the strip above the line indicated under the arrows printed on the sticker.**

### V. WASTE DISPOSAL

- Dispose of gloves, swabs, test tubes and used devices in accordance with GLP.
- Each user is responsible for the management of any waste produced, and must ensure that it is disposed of in accordance with the applicable legislation.

### VI. STORAGE

- An unopened kit may be kept at between 4 and 30°C and used until the shelf-life date indicated on the packaging.
- The strips remain stable for 15 weeks (in the closed container) after bottle opening if they are kept at between 4 and 30°C and in a dry environment.
- Avoid freezing strips and buffer.

### VII. SPECIMEN HANDLING AND COLLECTION

Specimens to be tested should be obtained and handled by standard methods for the collection of nasopharyngeal aspirates, nasopharyngeal washes or nasal/nasopharyngeal swabs<sup>1</sup>

Specimens must be tested as soon as possible after collection. If they are not immediately used, they must be stored at 2-8°C or frozen at -20°C for long periods of time, depending on the transport medium used. Copan Flock swabs with Copan UTM may be stored at 2-8°C for up to 72 hours prior to testing.

The following transport media have been tested and found to be compatible with Coris BioConcept respiratory kits: M4 and M5 from Remel (Oxoid), Virocult medium (MWE), Hank's BSS used in Viricell medium and RPMI. Stuart transport medium and Amies medium are not compatible with this device.

Coris BioConcept recommends using the Flocked Swabs of Copan Flock Technologies in order to guarantee the same performances as when nasopharyngeal washes or aspirates are used. The efficiency of other brands of swabs has not been established with our respiratory kits. It is strongly recommended to avoid the use of sputum or saliva as it may lead to invalid results.

Make sure that the specimens are not treated with solutions containing formaldehyde or its derivatives.

### VIII. PROCEDURE

#### PREPARATIONS OF THE TEST:

Allow kit components, in unopened packaging, and specimens to reach room temperature (15-30°C) before performing a test.

Once opened, run the test immediately. Indicate the patient's name or specimen number on the tube. Place the marked test tubes in a rack.

#### SPECIMEN PREPARATION PROCEDURE:

Performance claims with regard to samples types other than Nasopharyngeal Secretions have not been established. We recommend the use of fresh NPS for optimal test performance.

1. Liquid nasopharyngeal washings and/or aspirates or culture supernatant. If the sample to be tested is liquid, mix 250 µL with 250 µL or 8 droplets of the extraction buffer to reach a sample dilution ratio of 1/2.
2. Swabs. Swabs can be stored either in a tube containing a transport medium either in a device with a gel or a sponge matrix. Alternatively, Copan Flock dry swabs can be used.
  - a- If the swab is stored in a liquid transport medium, it should be wiped out in the medium by pressing its matrix on the tube's wall and the resulting solution should be processed according to point 1.
  - b- Dry swab procedure: When there is no dilution medium available, dry swab must be dipped in 15 droplets or 500 µL of extraction buffer, twisted and wiped out by pressing swab on the tube wall. Take care not to press the swab against any surface before expressing the sample, as this could lead to virus loss and reduced sensitivity.
3. Stir thoroughly to homogenize the solution
4. Immerse the sensitized strip in the direction indicated by the arrows.
5. Leave to react for 15 minutes. Positive results may be reported sooner the moment the test and control lines become visible.

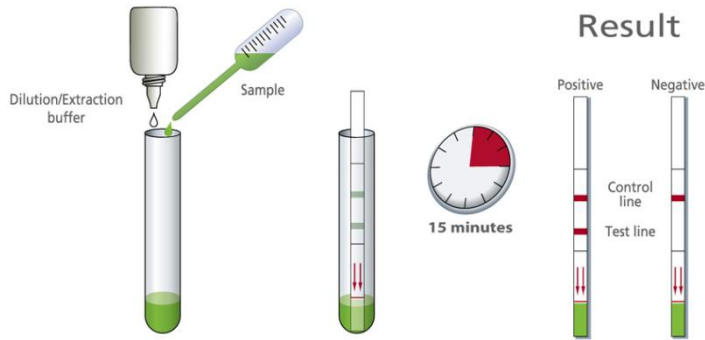
**Do not take the appearance of new lines into account after the reaction time is passed.**

**The result must be read on still wet strip.**

<sup>1</sup> Hall, C.B., Douglass, R.G., Jr., and Geiman, M. 1975. Clinically useful method for the isolation of Respiratory Syncytial Virus. *J. Infect. Dis* 131: 1-5.

## IX. INTERPRETING RESULTS

The results are to be interpreted as follows:



**Negative test result:** a reddish-purple line appears at the Control line (C) position (upper line). No other band is present.

**Positive test result:** in addition to a reddish-purple band at the Control line (C), a visible reddish-purple band appears at the Test line position (T). Intensity of the test line may vary according to the quantity of antigens found in the sample. Any reddish-purple line (T), even weak, should be considered as a positive result.

**Invalid test result:** The absence of a Control line indicates a failure in the test procedure. Repeat invalid tests with a new strip.

Note: during the drying process, a very faint shadow may appear at the Test line position. It should not be regarded as a positive result.

## X. QUALITY CONTROL

In accordance with Good Laboratory Practices, we recommend checking the test's performance regularly according to the laboratory's requirements. Dip the strip in 500 µL of prepared control (see CTR-1000 or C-1086 instructions for use).

### XI. PERFORMANCE

#### A. Detection Limit

The detection limit has been realised with a quantified virus (RS Virus Strain A-2) and has been evaluated at  $3.7 \times 10^5$  vp/mL.

#### B. Sensitivity - Specificity (Correlation):

1<sup>o</sup>) The kit was validated by comparison with a cell culture method in a routine laboratory lab (Belgium).

Coris BioConcept	Culture	Positive	Negative	Total
Positive		153	22	175
Negative		17	308	325
Total		170	330	500

95 % Confidence Interval<sup>2</sup>

Sensitivity:	90 %	(84.2 to 93.9 %)
Specificity:	93.3 %	(89.9 to 95.7 %)
Positive Predictive value:	87.4 %	(81.4 to 91.8 %)
Negative predictive value:	94.8 %	(91.6 to 96.8 %)
Accuracy:	92.2 %	(461/500)

2<sup>o</sup>) The kit was validated by comparison with an Enzymatic kit

Coris BioConcept	Enzymatic quick test	Positive	Negative	Total
Positive		40	0	40
Negative		8	34	42
Total		48	34	82

95 % Confidence Interval

Sensitivity:	83.3 %	(69.2 to 92 %)
Specificity:	100 %	(87.3 to 100 %)
Positive Predictive value:	100 %	(89.1 to 100 %)
Negative predictive value:	81 %	(65.4 to 90.9 %)
Accuracy:	90.2 %	(74/82)

3<sup>o</sup>) The kit was validated by an independent research center (Canada) by comparison with DFA, with nasopharyngeal washes.

Coris BioConcept	DFA	Positive	Negative	Total
Positive		106	2	108
Negative		9	119	128
Total		115	121	236

95 % Confidence Interval

Sensitivity:	92.2 %	(85.2 to 96.1 %)
Specificity:	98.3 %	(93.6 to 99.7 %)
Positive Predictive value:	98.1 %	(92.8 to 99.7 %)
Negative predictive value:	93 %	(92.9 to 96.5 %)
Accuracy:	95.3 %	(225/236)

4<sup>o</sup>) The kit was validated (by a third party) in comparison with IF on nasal aspirates of childrens under 3 years. Discordands have been confirmed by RT-PCR (France).

Coris BioConcept	IF	Positive	Negative	Total
Positive		48	0	48
Negative		2	50	52
Total		50	50	100

95 % Confidence Interval

Sensitivity:	96 %	(85.1 to 99.3 %)
Specificity:	100 %	(91.1 to 100 %)
Positive Predictive value:	100 %	(90.8 to 100 %)
Negative predictive value:	96.2 %	(85.7 to 99.3 %)
Accuracy:	98 %	(98/100)

#### C. Accuracy

To check intra-batch accuracy, the same positive samples and a buffer solution were processed 15 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.

To check inter-lot accuracy, some samples (positive and buffer) were processed on kits from three different production batches. All results were confirmed as expected.

#### D. Interference

Cross-reactivity to samples positive for the following pathogens was tested and found to be negative: Adenovirus, HSV, Parainfluenza, Enterovirus, Influenza A, Influenza B, Rhinovirus, *Nocardia asteroides*, *Streptococcus pneumoniae*, *Moraxella catarrhalis*, *Streptococcus pyogenes*, *Aspergillus niger*, *Legionella pneumophila*, *Candida albicans*, *Haemophilus influenzae*.

Tests for cross-reactivity has been tested on *Staphylococcus aureus* and found positive at a high bacteria concentration ( $10^9$  cfu/mL).

## XII. LIMITS OF THE KIT

The test is qualitative and cannot predict the quantity of antigens present in the sample. Clinical presentation and other test results must be taken into consideration to establish diagnosis.

A positive test does not rule out the possibility that other pathogens may be present.

Kit test is an acute-phase screening test. Specimens that are collected after this phase may contain antigen titres below the reagent's sensitivity threshold. If a sample is given a negative result despite the observed symptoms, any other relevant test should be run to check the sample.

## XIII. TECHNICAL PROBLEMS / COMPLAINTS

If you encounter a technical problem or if performances do not correspond with those indicated in this package insert:

- Record batch number of incriminated kit
- If possible, keep the problematic sample in the freezer for the time lapse of complaint management
- Contact Coris BioConcept (client.care@corisbio.com) or your local distributor

## XIV. BIBLIOGRAPHIC REFERENCES

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REF	Catalogue number		Manufactured by
IVD	In vitro diagnostic medical device		Temperature limitation
	Contains sufficient for <n> tests	DIL SPE	Diluent specimen
	Consult instructions for use		Do not reuse
	Keep dry		Use by
DIL AS	Diluent assay	CONT NaN <sub>3</sub>	Contains Sodium azide

<sup>2</sup> Newcombe, Robert G. "Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods," *Statistics in Medicine*, 17, 857-872 (1998).