EN REF QRSV01G

STANDARD Q

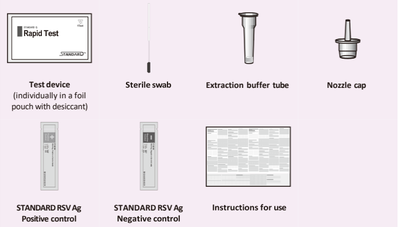
RSV Ag

STANDARD™ Q RSV Ag Test

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS



Test device (individually in a foil pouch with desiccant) | Sterile swab | Extraction buffer tube | Nozzle cap

STANDARD RSV Ag Positive control | STANDARD RSV Ag Negative control | Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

SPECIMEN COLLECTION AND PREPARATION

Nasopharyngeal Swab

1. To collect a nasopharyngeal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection.
2. Using gentle rotation, push the swab until resistance is met at the level of the turbinates.
3. Rotate the swab a few times against the surface of the nasopharyngeal.
4. Remove the swab carefully.
5. Specimen should be tested as soon as possible after collection.
6. If not use of transport media, specimens may be stored at room temperature for up to 24 hours or at 2 ~ 8°C / 36 ~ 46°F for up to 48 hours in a clean, dry, closed container prior to testing.

Nasopharyngeal swab in transport media

1. Transport fresh specimens to the laboratory as rapidly as possible in a suitable liquid transport system.
2. For nasopharyngeal swabs in transport media, a minimal volume of 1ml is recommended.

Minimal dilution of the specimen is recommended, as dilution may result in decreased test sensitivity.

Transport media

Viral Transport Medium(VTM)	Recommended Storage Condition	
	2°C to 8°C	25°C
Copan UTM™ Universal Transport Media	72 hours	12 hours
BD™ Universal Viral Transport	72 hours	12 hours
Copan eSwab	72 hours	12 hours
Hank's Balanced Salt Solution	72 hours	12 hours
M4	72 hours	12 hours
M4-RT	72 hours	12 hours
M5	72 hours	12 hours
Starplex Multitrans	72 hours	12 hours
Sigma Virocult Media	72 hours	12 hours
Normal saline	72 hours	12 hours
1x PBS	72 hours	12 hours
ASAN PHARM UTM	72 hours	12 hours
Noble Bio REST™ UTM	72 hours	12 hours
AMIES AGAR GEL - NO CHARCOAL	72 hours	12 hours

When using viral transport medium (VTM), it is important to ensure that the VTM containing the specimen is warmed to room temperature. Cold specimens will not flow correctly and can lead to erroneous or invalid results. Several minutes will be required to bring a cold specimen to room temperature.

PREPARATION AND TEST PROCEDURE

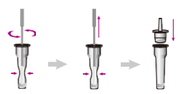
Preparation

1. Allow the test device and collected specimen to room temperature (15 ~ 30°C / 59 ~ 86°F) a minimum of 30 minutes prior to testing.
2. Carefully read the instructions for using the STANDARD Q RSV Ag Test.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.
4. Open the foil pouch, and check the test device and the desiccant pack inside the foil pouch.

Foil pouch | Test device | Desiccant

Test Procedure

1. Insert the nasopharyngeal swab specimen of patient into an extraction buffer tube. Swirl the swab at least 5 times.
2. Remove the swab while squeezing the side of the tube to extract the liquid from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
3. Tightly press the nozzle cap onto the tube.



Specimen and extraction buffer should be well mixed and then immediately applied the processed specimen mixture at the test device.

4. Apply 4 drops of mixed specimen to the specimen well of the test device.

5. Read the test result after 15 minutes. Test can be read up to 30 minutes.

Do not read test results after 30 minutes. It may give false results.

INTERPRETATION OF RESULT

Test result	Example	Description
Negative		Only band ("C" Control line) within the result window indicates negative result.
Positive		Two colored bands ("C" Control line and "T" Test line) within the result window, no matter which band appears first, indicate RSV antigen positive.
Invalid		If the control band ("C" Control line) is not visible within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. Re-test with a new patient specimen and a new test device.

- Positive results should be considered in conjunction with the clinical history and other data available.
- The presence of any line no matter how faint it is, should be considered as a line formed.
- This test is for screening purposes. Confirmatory testing according to national guidelines is recommended to confirm the infection status.

QUALITY CONTROL

1. Positive and negative controls are also supplied with each kit and these controls are provided as a means of additional quality control to demonstrate a positive or negative reaction.
2. SD BIOSENSOR recommends that positive and negative controls be run:
   - Once for each new lot.
   - Once for each untrained operator.
   - As required by instructions for use for STANDARD Q RSV Ag Test and in accordance with local, state and federal regulations or accreditation requirements.

EXPLANATION AND SUMMARY

Introduction

RSV (Respiratory syncytial virus) is an enveloped, negative-sense RNA virus belonging to the *Paramyxoviridae* family. It occurs throughout the world, and in each location it tends to occur in yearly winter outbreaks. The virus lives inside the cells lining the respiratory system, causing swelling of this lining coupled with the production of large amounts of excess mucus. In adults, this shows up as a bad, lingering cold with thick nasal congestion and a deep, productive cough. In infants, however, the excess mucus can be enough to plug their small airways or bronchioles, resulting in a severe illness called bronchiolitis that requires hospitalization. Children who first get it under 6 months of age or who have serious underlying illnesses are at the highest risk for severe disease. A serious RSV infection is a frightening experience for parents and their baby and one of the most severe public health problems worldwide. Therefore, rapid and accessible detection of RSV is important for efficient prevention and prompt treatment of it. STANDARD Q RSV Ag Test, containing a highly specific and sensitive antibody, provides significantly fast, easy and accurate system to identify the target antigen from nasopharyngeal swab specimens. The test may aid in the reliable clinical diagnosis of RSV and enables supportive treatment decisions.

Intended use

STANDARD Q RSV Ag Test is a rapid chromatographic immunoassay for the qualitative detection of RSV antigen present in nasopharyngeal swab from patients with symptoms of a viral respiratory infection. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of RSV infection. It provides only an initial screening test result. Specific alternative diagnosis method should be performed in order to obtain the confirmation of RSV infection.

Test principle

STANDARD Q RSV Ag Test has two pre-coated lines, "C" (Control line), "T" (Test line) on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Monoclonal anti-Chicken IgY is coated on the control line region and monoclonal anti-RSV is coated on the test line region. Monoclonal anti-RSV conjugated with colloidal gold particle is used as a detector for RSV antigen. During the test, RSV antigen in the specimens interacts with monoclonal anti-RSV conjugated with colloidal gold particle making antibody-antigen gold particle complex. This complex migrates on the membrane until the test line, where it will be captured by the monoclonal anti-RSV. A violet test line would be visible in the result window if RSV antigen is present in the specimens. The intensity of violet test line will vary depending upon the amount RSV antigen present in the specimens. If RSV antigen is not present in the specimens, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

KIT STORAGE AND STABILITY

Store the kit at 2 ~ 30°C / 36 ~ 86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use extraction buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
11. Improper specimen collection, handling or transport may yield inaccurate results.

LIMITATION OF THE TEST

1. The contents of this kit are to be used the qualitative detection of RSV antigen from nasopharyngeal swab of the symptomatic patients.
2. Failure to follow the test procedure and interpretation of test result may adversely affect test performance or invalidate the test result.
3. Positive test results cannot exclude co-infections with other pathogens.
4. Negative test results cannot exclude possible other non-RSV viral infections.
5. Negative test results can occur if the quantity of RSV antigens present in the specimen is below the detection limits of the assay, or the detected antigens are not present during the stage of disease in which a specimen is collected.
6. Positive and negative predictive values are highly dependent on prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods of low RSV activity when prevalence is moderate to low.
7. Monoclonal antibodies may fail to detect, or detect with less sensitivity, RSV viruses that have undergone minor amino acid changes in the target epitope region.

PERFORMANCE CHARACTERISTICS

Clinical performance

1. Clinical evaluation

Reference		STANDARD Q RSV Ag Test		Total Result
		Positive	Negative	
Anyplx RV 16	Positive	49	2	51
	Negative	4	126	130
Total Result		53	128	181
Sensitivity		49/53 x 100 = 92.45%		
Specificity		126/128 x 100 = 98.44%		

Analytical performance

1. Limit of Detection (LoD)

LoD is detemined as follows.

RSV antigen	Limit of Detection
RSV subgroup A	1.78 x 10^6
RSV subgroup B	1.35 x 10^7

2. Cross Reactivity

There was no cross-reaction with the potential cross-reacting microorganisms listed below.

Potential cross reacting substances	Concentration
Influenza A virus H1N1 (ATCC AR-1520)	1.0 x 10^5 $TCID_{50}$/mL
Influenza A virus H3N2 (ATCC AR-544)	1.0 x 10^5 $TCID_{50}$/mL
Influenza A virus H3N2 Brisbane (KBPV-VR-71)	1.0 x 10^5 $TCID_{50}$/mL
Influenza B virus (ATCC VR-101)	1.0 x 10^5 $TCID_{50}$/mL
Influenza B virus (ATCC VR-1535TM)	1.0 x 10^5 $TCID_{50}$/mL
Influenza B virus (KBPV-VR-34)	1.0 x 10^5 $TCID_{50}$/mL
Human Coronavirus OC43 (KBPV-VR-8)	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 1 (KBPV-VR-64)	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 2 (KBPV-VR-65)	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 3 (KBPV-VR-67)	1.0 x 10^5 $TCID_{50}$/mL
Parainfluenza virus 4 (KBPV-VR-69)	1.0 x 10^5 $TCID_{50}$/mL
Echovirus 6 (KBPV-VR-19)	1.0 x 10^5 $TCID_{50}$/mL
Enterovirus 70 (KBPV-VR-55)	1.0 x 10^5 $TCID_{50}$/mL
Enterovirus 71 (KBPV-VR-56)	1.0 x 10^5 $TCID_{50}$/mL
Rhinovirus 7(A) (KBPV-VR-82)	1.0 x 10^5 $TCID_{50}$/mL
Rhinovirus 42(B) (KBPV-VR-80)	1.0 x 10^5 $TCID_{50}$/mL
Human adenovirus 1(C), (KBPV-VR-1)	1.0 x 10^5 $TCID_{50}$/mL
Human adenovirus 40(F), (KBPV-VR-6)	1.0 x 10^5 $TCID_{50}$/mL
Human adenovirus 11(B), (KBPV-VR-63)	1.0 x 10^5 $TCID_{50}$/mL
Escherichia coli (ATCC 8739)	1.0 x 10^5 cells/mL
Haemophilus influenzae (ATCC 19418)	1.0 x 10^5 cells/mL
Klebsiella pneumoniae (ATCC 13883)	1.0 x 10^5 cells/mL
Legionella pneumophilla (ATCC BAA-74)	1.0 x 10^5 cells/mL
Neisseria meningitidis (ATCC 13100)	1.0 x 10^5 cells/mL
Pseudomonas aeruginosa (ATCC 9027)	1.0 x 10^5 cells/mL
Staphylococcus aureus (ATCC 6538)	1.0 x 10^5 cells/mL
Staphylococcus pneumoniae (ATCC BAA-2754)	1.0 x 10^5 cells/mL
Staphylococcus pyogenes (ATCC 19615)	1.0 x 10^5 cells/mL

3. Interference substances study:

There was no interference for potential interfering substances listed below.

Interfering substacnes	Test conc.
Ibuprofen	499.6μg/mL
Hemoglobin	20g/mL
Ciprofloxacin	10μg/mL
Acetaminophen	30μg/mL
Bilirubin	15mg/mL
Promethazine	1.2μg/mL

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2. Hall CB, and Douglas RG Jr. Modes of transmission of respiratory syncytial virus. J Pediatr. 1981; 99(1):100-103.
3. Macartney K.et al. Nosocomial Respiratory Syncytial Virus Infections: The Cost-Effectiveness and Cost-Benefit of Infection Control. Pediatrics. 2000; 106(3):520.
4. Falsey AR, Hennessey PA, Formica MA, Cox C, Walsh EE. Respiratory syncytial virus infection in elderly and high-risk adults. N Engl J Med. 2005; 352(17):1749-59.

SYMBOL

REF	Reference number		Caution		Use by	LOT	Batch code		Consult Instructions for Use		Do not re-use
IVD	*In vitro* Diagnostics		Note		Manufacturer		Date of manufacture		Contains Sufficient for <n> Tests		Keep away from sunlight
	Indicate that you should keep the product dry		To indicate the temperature limitations in which the transport package has to be kept and handled.		Do not use if packaging is damaged	EC REP	European Authorized Representative	CE	This product fulfills the requirements of the European Directive 98/79/EC

EC REP **Authorized Representative**
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