Rapid Response™

RSV Test Cassette
(Nasopharyngeal Specimen)

REF RSV-19C, RSV-19C20, RSV-19C30

Product Insert

A rapid test for the qualitative detection of Respiratory Syncytial Virus in Nasopharyngeal specimens.

For laboratory *in vitro* diagnostic use only.

Intended Use

The Rapid Response™ RSV Test Cassette is an *in vitro* diagnostic test for the qualitative detection of Respiratory Syncytial Virus antigens (viral fusion protein) in nasopharyngeal swab, nasopharyngeal aspirate or nasopharyngeal wash specimens using the rapid immuno-chromatographic method. It is intended to aid in the rapid differential diagnosis of Respiratory Syncytial Virus viral infections.

Introduction

Human respiratory syncytial virus (HRSV) is a syncytial virus that causes respiratory tract infections. It is a major cause of lower respiratory tract infections and hospital visits during infancy and childhood. A prophylactic medication, palivizumab, can be employed to prevent HRSV in preterm (under 35 weeks gestation) infants, infants with certain congenital heart defects (CHD) or bronchopulmonary dysplasia (BPD), and infants with congenital malformations of the airway. Treatment is limited to supportive care (e.g. C-PAP), including oxygen therapy. In temperate climates there is an annual epidemic during the winter months. In tropical climates, infection is most common during the rainy season.

The Rapid Response™ RSV Test Cassette qualitatively detects the presence of Respiratory Syncytial Virus in nasopharyngeal swab, nasopharyngeal aspirate or nasopharyngeal wash specimens, providing results within 10 minutes. The test uses antibodies specific for Respiratory Syncytial Virus to selectively detect Respiratory Syncytial Virus antigen in nasopharyngeal swab, nasopharyngeal aspirate or nasopharyngeal wash specimens.

Principle

The Rapid Response™ RSV Test Cassette is an immuno-chromatographic membrane assay that uses antibodies specific to detect the RSV viral fusion protein in nasopharyngeal swab, nasopharyngeal aspirate or nasopharyngeal wash specimens.

The test is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The Rapid Response™ RSV Test Cassette contains the anti-RSV antibody conjugated with colloidal-gold the and the anti-RSV antibody coated on the test line regions. During testing, the extracted specimen reacts with the antibody to Respiratory Syncytial Virus that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Respiratory Syncytial Virus on the membrane and generate one colored line in the test regions. The presence of this colored line in the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

Reagents

The test contains anti-RSV antibody coated particles and anti-RSV antibody coated on the membrane.

Precautions

Please read all the information in this package insert before performing the test.

1. For laboratory *in vitro* diagnostic use.
2. Do not use after the expiration date.
3. The test should remain in the sealed pouch until ready to use.
4. Wash hands before and after the test.
5. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
6. The used test should be discarded according to the local regulations.
7. Avoid using bloody samples.
8. Wear disposable gloves when handling the samples, avoid touching the reagent membrane and sample well.
9. Wear a face covering when collecting swab from children or others.
10. Avoid touching the swab head when handling the swab.

Storage and Stability

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Materials

Materials provided

- Test cassettes
- Extraction tubes
- Extraction reagent
- Workstation
- Package insert
- Dropper tips
- Sterile swabs

Materials required but not provided

- Timer
- Aspiration device

Specimen Collection

It is applicable to the diagnosis of the Respiratory Syncytial Virus from the samples of nasopharyngeal swab, nasopharyngeal aspirate or nasopharyngeal wash. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

Nasopharyngeal swab Specimen:

Insert swab through the nostril parallel to the palate (not upwards) . The distance is equivalent to that from the ear to the nostril of the patient, indicating contact with the nasopharynx or until resistance is encountered. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Gently rub and roll the swab. Leave swab in place for several seconds to saturate tip with secretions. Slowly remove swab while rotating it. Specimens can be collected from both sides using the same swab, but it is not necessary to collect specimens from both sides if the swab is saturated with fluid from the first collection. If a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril.

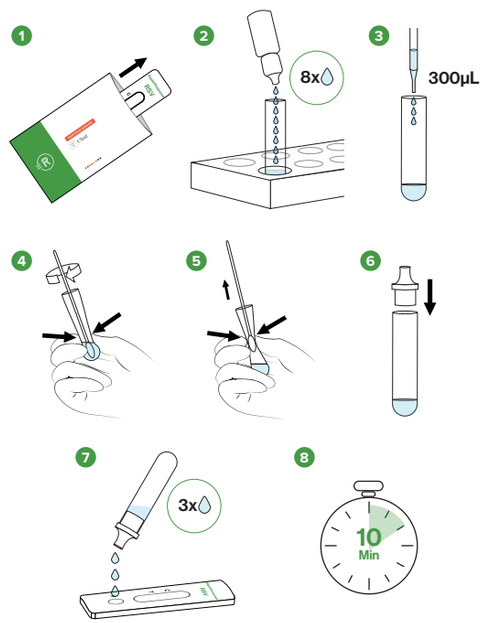
Nasopharyngeal aspirate specimen:

Connect an aspiration catheter to an aspiration trap that is attached to an aspiration device, insert the catheter to nasopharyngeal cavity from a nostril, start the aspiration device and then collect nasopharyngeal aspirate sample. Dip a sterilized swab into the collected nasopharyngeal aspirate sample and make the specimen cling to the swab

Nasopharyngeal wash specimen:

Fill a large syringe with the 5-10 mL sterile normal saline solution (NaCl 0.9%), stand over a sink, keep the head straight, put the nozzle of the syringe in one nostril, try to aim the nozzle towards the back of the head, squirt the whole solution and then repeat on the other nostril. Spit out any solution coming into their mouth and then blow nose gently.

Test Procedure



Allow the test device, test sample and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 8 drops of solution (Approx. 0.3mL) to the Extraction Tube.

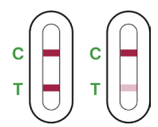
For nasopharyngeal wash specimen:

3. Add 300µL nasopharyngeal wash solution into the extraction tube then mix the solution.

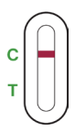
For nasopharyngeal swab and nasopharyngeal aspirate specimen:

4. Place the swab specimen in the extraction tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the extraction tube body to release the antigen in the swab.
5. 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.
6. Secure the nozzle dropper cap tightly onto the top of the extraction tube. Place the test cassette on a clean and flat surface.
7. Invert the tube and transfer 3 drops of the sample solution (approx. 80µL) to the sample well and then start the timer.
8. Read the result at 10 minutes. Do not interpret the result after 20 minutes.

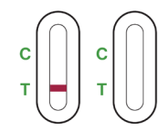
Results Interpretation



POSITIVE: Two lines appear. One colored line appears in the control region(C), and another apparent colored line in the test region (T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.



NEGATIVE: **Only one colored line appears in the control region (C). No line in the test region (T).** The negative result indicates that there are no Respiratory Syncytial Virus in the sample, or the virus is below the detectable range.



INVALID: No colored line appears in the control region (C). The test is invalid even if there is a line on test region (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and

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

Quality Control

Internal quality control:

An internal procedural control is included in the test. A colored line appearing in the control line region (C) is an internal positive procedural control. It confirms adequate membrane wicking

Limitations

1. The Rapid Response™ RSV Test Cassette is an acute-phase screening test for qualitative detection. A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Respiratory Syncytial Virus present in nasopharyngeal swab, nasopharyngeal aspirate or nasopharyngeal wash specimens is not adequate or is below the detectable level of the test.
2. The Rapid Response™ RSV Test Cassette will only indicate the presence of Respiratory Syncytial Virus in the specimen from both viable and non-viable Respiratory Syncytial Virus strains. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3. Performance of the test has not been established for monitoring antiviral treatment of Respiratory Syncytial Virus.
4. The Rapid Response™ RSV Test Cassette is for laboratory *in vitro* diagnostic use only. The test should be used for the detection of Respiratory Syncytial Virus in nasopharyngeal swab, nasopharyngeal aspirate or nasopharyngeal wash specimens. Neither the quantitative value nor the rate of increase in Respiratory Syncytial Virus concentration can be determined by this qualitative test.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for Respiratory Syncytial Virus does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

Performance Characteristics

Sensitivity, Specificity and Accuracy

The Rapid Response™ RSV Test Cassette has been evaluated with specimens obtained from the patients. RT-PCR is used as the reference method for the Rapid Response™ RSV Test Cassette.

Method		RT-PCR		Total Result
Rapid Response™ (RSV) Test Cassette	Results	Positive	Negative	
	Positive	65	2	67
	Negative	1	221	222
Total Result		66	223	289

Relative sensitivity: 98.5% (95%CI*: 91.8%~99.96%);
Relative specificity: 99.1% (95%CI*: 96.8%~99.9%);
Accuracy: 99.0% (95%CI*: 97.0%~99.8%).
*Confidence Intervals

Detection Limit

The minimum detection limit of this reagent is as follows:

ATCC ® Number	Strain	Detection Concentration
VR-1400™	B WV/14617/85	$1.12X10^2$ TCID50/mL
VR-1540 ™	A2	3.67×10^4 PFU/mL
VR-1580 ™	18537	32 PFU/mL

$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

Reaction with Various Serotype of Respiratory Syncytial Virus

The current test kit is able to detect the following serotype of the Respiratory Syncytial Virus: Subtype A（A2, long）, Subtype B（9320, wild type).

Cross Reaction

No cross reaction has been confirmed of the Respiratory Syncytial Virus Antigen Rapid Test Device with the following pathogens:

Bacteria

Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group C.

Virus

Adenovirus, Coxsackie virus, Cytomegalovirus, Parainfluenza Virus Type1,2,3,4a, Enterovirus, Mumps virus, Influenza A , Influenza B, Rhinovirus.

Bibliography

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2. Jadhao, S. J., & Anderson, L. J. (2016). Detection of RSV Antibodies in Human Plasma by Enzyme Immunoassays. Methods in Molecular Biology, 41–52.
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4. Yen, A. B., Demmler-Harrison, G. J. (2011). Rapid Antigen Testing to Detect Respiratory Syncytial Virus Performs Well in Neonates. The Pediatric Infectious Disease Journal, 30(3), 234–237.
5. Slinger, R., Milk, R., Gaboury, I., & Diaz-Mitoma, F. (2004). Evaluation of the QuickLab RSV Test, a New Rapid Lateral-Flow Immunoassay for Detection of Respiratory Syncytial Virus Antigen. Journal of Clinical Microbiology, 42(8), 3731–3733.

Glossary of Symbols

Consult instructions for use	Test per Kit	REF Catalogue #
Store between 2°C to 30°C	Use by	Do Not Reuse
LOT Lot Number	IVD For in vitro diagnostic use only	EC REP Authorized Representative

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover,
Germany

BTNX Inc.
722 Rosebank Road,
Pickering, ON, L3R 4G7
Canada

CE