OnSite® RSV Ag Rapid Test

REF R0186C CE

Instructions for Use

10108886

Barcode for RTR Use Only

INTENDED USE

The *OnSite* RSV Ag Rapid Test is a lateral flow immunoassay for the qualitative detection of Respiratory Syncytial Virus (RSV) antigens in nasal, throat, and aspirate specimens. It is intended to be used by healthcare professionals to aid in the diagnosis of RSV viral infections.

Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of health care providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

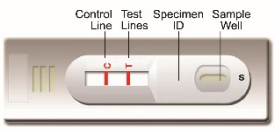
RSV is an RNA virus belonging to the paramyxoviridae family[1]. It is one of the most common and important pathogens causing lower respiratory tract infections in winter and spring. The rapid and accurate detection of respiratory syncytial virus is of great significance not only for monitoring and controlling the prevalence of RSV infection, but also by providing a reliable laboratory test for early clinical diagnosis, and is the basis for rational selection of treatment options.

The RSV genome is a single-stranded negative-strand RNA encoding 11 proteins, of which the fusion glycoprotein (F) and the adhesion glycoprotein (G) are the main neutralizing antigens[2]. As one of the most important surface structure proteins of RSV, F protein is 574 amino acid residues[3-4]. The gene of F protein is highly conserved in the A and B subtypes of RSV, and the F antibody produced is of A and B subtypes. It has a protective effect[5-6].

This product is capable of rapid and highly sensitive detection of RSV antigen in human epithelial cells of the nasopharyngeal region and is based on immunochromatography using monoclonal antibodies with high specificity for the RSV F protein.

The *OnSite* RSV Ag Rapid Test is an antigen detection test that provides a result in 15 minutes by minimally skilled personnel and without the use of laboratory equipment.

TEST PRINCIPLE



The *OnSite* RSV Ag Rapid Test is a lateral flow chromatographic immunoassay that uses highly sensitive monoclonal antibodies to detect the RSV F protein.

The test cassette consists of: 1) a colored conjugate pad containing monoclonal antibodies against RSV F protein conjugated with colloidal gold (antibody conjugate), and 2) a nitrocellulose membrane strip containing a test line (T line) and a control line (C line). The T line is pre-coated with another antibody for RSV, and the C line is pre-coated with a control line antibody.

The RSV antigen is first extracted from swab specimen with extraction buffer. The extracted sample is added to the sample window and migrates by capillary action across the test strip. RSV antigen, if present in the extract, binds to the antibody conjugate. The immunocomplex is then captured on the membrane by the pre-coated anti-RSV antibodies, forming a colored T line, indicating an RSV positive test result. Absence of the T line suggests a negative RSV test result.

The test contains an internal control (C line), which should exhibit a colored line regardless of color development on the test line. If the C line does not develop, the test result is invalid, and the specimen must be retested with a new device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Sample extraction tubes
3. Sample extraction tube rack
4. Sample extraction buffer
5. Nozzles with filter
6. Sterile swabs, each sealed in a plastic-paper pouch
7. Instructions for Use

MATERIALS MAY BE REQUIRED BUT NOT PROVIDED

1. Positive control
2. Negative control

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer

WARNINGS AND PRECAUTIONS

For in vitro Diagnostic Use

1. Read these instructions for use completely before performing the test. Failure to follow these instructions could lead to inaccurate test results.
2. Do not open the sealed pouch unless ready to conduct the assay.
3. Do not use expired devices.
4. Bring all reagents to room temperature (15-30°C) before use.
5. Do not use the components in any other type of test kit as a substitute for the components in this kit.
6. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
7. Follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other bloodborne pathogens.
8. Do not smoke, drink or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
10. Handle the negative and positive controls in the same manner as the patient specimens.
11. Read testing results 15 minutes after specimen is applied to the sample well. Any results interpreted outside of the 15-minute window should be considered invalid and must be repeated.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C**.** If stored at 2-8°C, ensure that the test device is brought to room temperature (15-30°C) before opening. The test device is stable through the expiration date printed on the pouch. Do not freeze or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them using standard bio-safety procedures.

1. Specimen collection


Nasal swab


Throat swab


Nasal aspirate

1.1 Nasal swab specimens
To collect a nasal swab specimen, insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation push the swab until resistance is met, which is at the level of the turbinate (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.

1.2 Throat swab specimens
To collect a throat swab specimen, rub the sterile swab on both tonsil surfaces and the posterior pharynx. Rotate the swab a few times to collect the specimen. Avoid contaminating the swab with saliva.

1.3 Nasal aspirate/wash specimens
Aspirate or wash volumes of 1-2 mL are recommended. Collect nasal aspirate fluids using the specific aspirator as instructed. Transfer the specimen into a clean, dry specimen container.

2. Specimen transport and storage:
Test specimens as soon as possible after collecting. If not tested immediately, store specimens extracted from swab at 2-8°C for up to 8 hours.

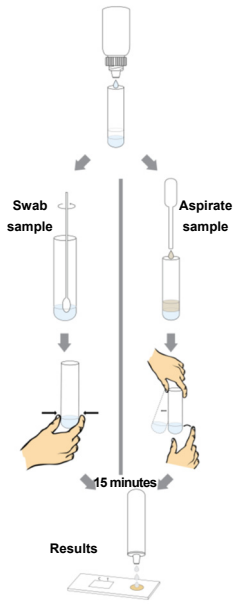
ASSAY PROCEDURE

Step 1: Bring the specimen and test components to room temperature (15-30°C) if needed. Mix the specimen well prior to performing the assay.

Step 2: **Specimen extraction**
Add **0.5 ml** of the sample extraction buffer into the extraction tube up to **the lower marked line,** then keep the tube upright using the provided sample extraction tube rack.

2.1 All swab samples
Insert swab into extraction tube containing 0.5 ml of the extraction buffer. Mix well and squeeze swab several times against the inside of the tube. Remove and discard the swab in a safe manner. The extracted specimen in the tube is now ready for testing.

2.2 Nasal aspirate/wash sample
Directly add 0.5 mL specimen into the sample extraction tube containing 0.5 ml of extraction buffer up to the upper marked line. Mix the specimen with extraction buffer well. The extracted specimen in the tube is now ready for testing.



Step 3: Remove test device from the sealed pouch just prior to testing. Lay the test device on a clean, flat surface.

Step 4: Insert filtered nozzle into sample extraction tube containing extracted specimen

Step 5: Invert tube and add 3 drops (~90 µl) of test sample into sample well by gently squeezing the tube.

Step 6: Set up timer.

Step 7: Read results at 15 minutes. Positive results can be visible in as soon as 3 minutes. Negative results must be confirmed at the end of 15 minutes. Any result interpreted after 15 minutes should be disregarded and must be repeated with a new device.

Discard used devices after interpreting the result following local laws governing the disposal of devices.

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QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. If the C line does not develop after sample application, the result is invalid. Review the entire procedure and repeat the test with a new device.
2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to ensure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing the testing of specimens.
   b. A new lot of test kits is used.
   c. A new shipment of test kits is used.
   d. The temperature during storage of the kits falls outside of 2-30°C.
   e. The temperature of the test area falls outside of 15-30°C.
   f. To verify a higher than expected frequency of positive or negative results.
   g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C line develops, the test indicates that no detectable RSV antigen is present in the specimen. The result is negative or non-reactive.

2. **POSITIVE RESULT:** In addition to the presence of the C line, if the T line develops, the test indicates the presence of RSV antigen in the specimen. The result is positive or reactive.

Specimens with positive or reactive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis is made.

3. **INVALID:** If no C line develops, the assay is invalid regardless of color development of the T line. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. **Clinical performance**

A total of 581 nasal aspirate specimens were collected from susceptible subjects and tested by the *OnSite* RSV Ag Rapid Test and by immunofluorescence assay (IFA).

	OnSite RSV Ag Rapid Test		
IFA	**Positive**	**Negative**	**Total**
Positive	232	9	241
Negative	7	333	340
Total	239	342	581

Relative Sensitivity: 96.3% (95% CI: 93.0-98.3%),
Relative Specificity 97.9% (95% CI: 95.8-99.2%),
Overall Agreement: 97.3% (95% CI: 95.6-98.4%)

A total of 248 nasal swab specimens were collected from susceptible subjects and tested by the *OnSite* RSV Ag Rapid Test and by immunofluorescence assay (IFA).

	OnSite RSV Ag Rapid Test		
IFA	**Positive**	**Negative**	**Total**
Positive	85	3	88
Negative	4	156	160
Total	89	159	248

Relative Sensitivity: 96.6% (95% CI: 90.4-99.3%),
Relative Specificity 97.5% (95% CI: 93.7-99.3%),
Overall Agreement: 97.2% (95% CI: 94.3-98.9%)

A total of 315 throat swab specimens were collected from susceptible subjects and tested by the *OnSite* RSV Ag Rapid Test and by immunofluorescence assay (IFA).

	OnSite RSV Ag Rapid Test		
IFA	**Positive**	**Negative**	**Total**
Positive	94	2	96
Negative	2	217	219
Total	96	219	315

Relative Sensitivity: 97.9% (95% CI: 92.7-99.8%),
Relative Specificity 99.1% (95% CI: 96.7-99.9%),
Overall Agreement: 98.7% (95% CI: 96.8-99.7%)

2. **Limit of Detection**

The minimum detection sensitivity of the *OnSite* RSV Ag Rapid Test is 1.07×10^4 $TCID_{50}$/mL for RSV subtype A and 1.2×10^4 $TCID_{50}$/mL for RSV subtype B.

3. **Analytical sensitivity**

It was confirmed that the test reagent reacted with respiratory syncytial virus type A (A2 strain, Long strain) and respiratory syncytial virus type B (9320 strain).

4. **Cross-Reactivity**

The cross-reactivity of the *OnSite* RSV Ag Rapid Test was determined from studies with the following pathogens. Specimens containing these pathogens were found not to cross-react with the *OnSite* RSV Ag Rapid Test:

Influenza type A & type B	Parainfluenza 1, 2, & 3
Grade 2 parainfluenza 1, 2, & 3	Adenovirus type 3, 6, & 7
Mumps	Grade 2 mumps
Rotavirus Antigen rotavirus	Measles
Grade 2 measles	*Chlamydia pneumoniae*
Chlamydia trachomatis	*Escherichia coli*
Pseudomonas aeruginosa	*Branhamella catarrhalis*
Enterococcus faecalis	*Citrobacter*
Staphylococcus aureus	*Klebsiella pneumoniae*
Yersinia enterocolitica	*Vibrio parahaemolyticus*
Fu Shigella	*Bacteroides fragilis*
Mycobacterium tuberculosis	*Mycobacterium avium*
Salmonella enteritidis	*Mycobacterium similis*
Mycobacterium marinum	*Campylobacter jejuni*

LIMITATIONS OF TEST

1. The Assay Procedure and the Interpretation of Assay Result must be followed closely when testing for the presence of RSV antigen in the swab specimen from individual subjects. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may lead to inaccurate results.
2. The *OnSite* RSV Ag Rapid Test is limited to the qualitative detection of RSV antigen. The intensity of the test line does not have linear correlation with virus titer in the specimen.
3. Sensitivity can differ with various strains of RSV due to differences of antigen expression. Specimens might contain a new or non-identified strain of RSV that expresses varying amounts of antigen.
4. A negative or non-reactive result for an individual subject indicates absence of detectable RSV antigen. However, a negative or non-reactive result does not preclude the possibility of RSV infection.
5. A negative or non-reactive result can occur if the quantity of the RSV antigen present in the specimen is below the detection limit of the assay, or if the virus that are detected are not present in the swab specimen sampled, or the viruses have undergone minor amino acid mutation in the epitope recognized by the antibody utilized in the test.
6. Infection may progress rapidly. If symptoms persist, while the result from the *OnSite* RSV Ag Rapid Test is negative or non-reactive, it is recommended to test with an alternative test device.
7. The results obtained with this test should only be interpreted in conjunction with other diagnostic procedures and clinical findings.
8. The *OnSite* RSV Ag Rapid Test detects both viable and non-viable RSV antigens. Test performance depends on antigen loaded in the 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.
9. Performance of the test has not been established for monitoring antiviral treatment of RSV infection.

REFERENCES

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Index of CE Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number	N	Tests per kit
2°C 30°C	Store between 2-30°C	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
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EC REP **MDSS GmbH**
Schiffgraben 41
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PI-R0186C Rev. A3.0
Date released: 2021-01-18
English Version

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