RSV Antigen Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

An in vitro diagnostic test for the qualitative detection of Respiratory Syncytial Virus antigens in nasal /pharyngeal swabs and nasal aspirate samples, using the rapid immunochromatographic method. For professional in vitro diagnostic use only.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

RSV Antigen Rapid Test Cassette (Colloidal Gold) is an in vitro diagnostic test for the qualitative detection of Respiratory Syncytial Virus antigens in nasal/pharyngeal swabs and nasal aspirate samples, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the F protein of the Respiratory Syncytial Virus. It will provide information for clinical doctors to prescribe correct medications. Negative results should be confirmed by other methods, such as cell culture.

PRINCIPLE

RSV Antigen Rapid Test Cassette (Colloidal Gold) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect the F protein antigen of Respiratory Syncytial Virus.

The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against Respiratory Syncytial Virus F protein; the reaction membrane contains the secondary antibodies for Respiratory Syncytial Virus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Respiratory Syncytial Virus is present in the sample, a complex formed between the anti-Respiratory Syncytial Virus conjugate and the virus will be caught by the specific anti- Respiratory Syncytial Virus monoclonal coated on the T region. Results appear in 15 minutes in the form of a red line that develops on the strip.

Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

MATERIALS PROVIDED

Test devices, each cassette is Individual sealed in a foil pouch with a package of desiccant.
Sterilized Swab
Extraction Tube
Tube Tip
Extraction Buffer
Package Insert

PRECAUTIONS

1) For in vitro diagnostic use only.
2) Do not use after the expiration date.
3) Ensure foil pouch containing test device is not damaged before opening for use.
4) Perform test at room temperature 15 to 30°C.
5) Wear gloves when handling the samples, avoid touching the reagent membrane and sample window.
6) All samples and used accessories should be treated as infectious and discarded according to local regulations.
7) Avoid using bloody samples.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The shelf-life of the kit under these storage conditions is 24 months.The kit is stable within the expiration date printed on the labeling. Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration. The LOT and the expiration date were printed on the labeling.

SAMPLE COLLECTION

It is applicable to the diagnosis of the respiratory syncytial virus from the specimens of nasal swabs or throat swabs. Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper specimen handling may yield a false-negative result.

1. Nasal Swabbing: Completely insert the sterilized swab supplied in this kit into the nasal basin, and swab several times to collect the epidermal cells of the mucus. It is recommended to collect specimen from nasal basin for more accurate results.
2. Throat Swabbing: Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. Caution must be paid to avoid the swab to be contaminated with saliva.
3. Specimen collected may be stored for 1 days at 2-8℃ if not tested within 1 hours. For long term storage, specimens should be kept below -20℃.

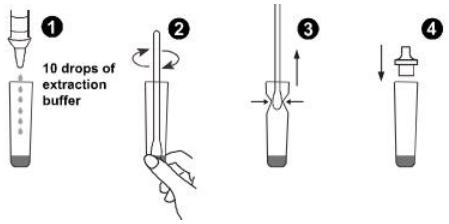
SAMPLE PREPARATION PROCEDURE

1) Nasal /pharyngeal Swabs

Insert swab with collected sample into extraction tube containing 10 drops (about 500μl) of sample extraction buffer. Squeeze the swab several times by compressing the outside walls of the tube end against the swab to mix well. Leave the swab in the Reagent Tube for one minute. Finally squeeze the swab to make most of the solution stays in the extraction tube and remove the swab. Use extraction solution as test sample.

2) Nasal Aspirate Fluids

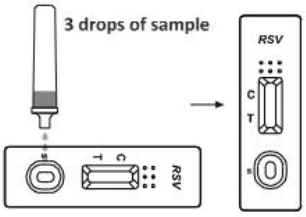
Add 10 drops of sample extraction buffer into extraction tube， then add about 500μl of the nasal aspirate fluids into extraction tube and mix well. Use extraction solution as test sample.



TEST PROCEDURE

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

1) Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2) Insert a tube tip into the sample extraction tube tightly.
3) Reverse the sample extraction tube, and add 3 drops (about 100μl) of test sample by squeezing the extracted solution tube into the sample window.
4) Read the result at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULT

POSITIVE: Two red lines appear. One red line appears in the control region(C), and one red 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 red line appears in the control region(C), and no line in the test region(T). The negative result indicates that there are no Respiratory Syncytial Virus particles in the sample or the number of viral particles is below the detectable range.
INVALID: No red 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.

LIMITATIONS OF TEST

1） RSV Antigen Rapid Test Cassette (Colloidal Gold) is an acute-phase screening test for qualitative detection.
2 ） Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with Respiratory Syncytial Virus
3 ）RSV Antigen Rapid Test Cassette (Colloidal Gold) detects both viable and non-viable Respiratory Syncytial Virus antigen. 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.
4 ）Performance of the test has not been established for monitoring antiviral treatment of Respiratory Syncytial Virus

PERFORMANCE

1）Detection Limit
The minimum detection limit of this reagent is as follows:

Subtype	Strain	TCID50/mL
A	RSV（long）	1.07×10^4
B	RSV（wild-type）	1.2×10^4

2）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）
3）Cross Reaction
No cross reaction has been confirmed of RSV Antigen Rapid Test Cassette (Colloidal Gold) with the following pathogens:
①Bacteria
Acinetobacter baumannii, Bordetella pertussis, Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis, Eikenella corrodens, Enterococcus faecalis, Enterococcus gallinarum. Escherichia coil ， Group C streptococcus, Group G streptococcus, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae, Neisseria gonorrhoeae Peptococcus asaccharolyticus, Peptostreptococcus anaerobius,
Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae (group B), Streptococcus mutants,
Streptococcus pneumoniae, Streptococcus pyogenes (group A), Villanelle parva.
②Virus
Influenza A，Influenza B，Adenovirus Type 1～8,11,19,37，Coxsackie virus Type A16, B1～5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, Mumps virus, Type I simple herpes virus Parainfluenza virus Type 1 ～ 3, Poliovirus Type 1 ～ 3, Respiratorysyncytial virus, Rhinovirus Type 1A,13,14
③Mycoplasma etc.
No cross reaction with Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis, Mycoplasma pneumoniae.
4) Clinical Study Data Summary
The RSV Antigen Rapid Test Cassette Performance vs Immuno-fluorescent test kit

Test Sensitivity			
Sample	+/+	-/+	%Sens
Nasal aspiration	379	15	96.2
Throat Swab	94	2	97.9
Nasal Swab	110	3	97.3
Overall	583	20	96.7
Test Specificity			
Sample	-/-	+/-	%Spec
Nasal aspiration	707	11	98.5
Throat Swab	217	2	99.1
Nasal Swab	212	4	98.1
Overall	1136	17	98.5

Code:GKPD022-1 Effective date: May 27, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

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