AG- RESPIRATORY PANEL 1 Ag RAPID TEST KIT

INSTRUCTION FOR USE

AstraGene – Respiratory Panel 1 Ag Rapid Test Kit is used for the qualitative detection of SARS-CoV-2, influenza A&B antigens, respiratory syncytial virus, adenovirus and mycoplasma pneumoniae in nasal swab and nasopharyngeal swab samples and can be used for the differential diagnosis ofSARS-CoV-2 infection, respiratory syncytial virus infection, adenovirus infection, mycoplasma pneumoniae infection and influenza A or B virus infection. The test results are for clinical reference only and cannot be used as the sole basis for diagnosis and treatment.

PRINCIPLE

AstraGene – Respiratory Panel 1 Ag Rapid Test Kit uses immunochromatography technology and double-antibody sandwich method to detect the antigens of SARS-CoV-2, influenza A&B, respiratory syncytial virus, adenovirus, and mycoplasma pneumoniae. The test strip contains specific antibodies to form respective test lines. During test, the processed sample to be tested is added to the sampling well of the test strip. When the sample to be tested contains the target pathogen and the concentration is higher than the LoD, the target antigen and the corresponding target labeled antibody form a reaction complex. Under the action of chromatography, the reaction complex moves forward along the nitrocellulose membrane, agglutinates at the test line and finally forms a red band, indicating that the corresponding test item is positive; On the contrary, if the sample does not contain the target pathogen or the antigen concentration is lower than the LoD, no red band will appear at the test line, indicating that the corresponding test item is negative. Regardless of whether there is a target pathogen in the sample, a red band should appear at quality control line C, which serves as an internal control todetermine whether the chromatography process is normal and whether the kit has failed.

PACKAGE CONTENTS

Description	10 tests	1 test
Test Cassettes with desiccant	10	1
Disposable specimen droppers	10	1
Sample Extraction Buffer	1×5.0mL	1×0.50mL
Sterile Swab	10	1
IFU	1	1

Catalogue Number	10 tests	1 test
Cassette Model	AG/RTK/REP1Ag/24/01	AG/RTK/REP1Ag/24/02

MATERIALS REQUIRED (BUT NOT PROVIDED)

- Clock or Timer
- Disposable Gloves
- Lancets
- Centrifuge

STORAGE &STABILITY

- Test device should be stored at 2-30ºC in the original sealed pouch.
- Do not freeze the test device.
- The test device should be kept away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION & PREPARATION

- Requirements for sampling swabs and sample preservation solutions: It is recommended that the sterile swabs used to collect samples be nylon fluff-tipped swabs with ABS resin rods, and the sample extraction solution provided by this kit be used as the sample preservation solution.
- **Nasopharyngeal swab:** The sampler gently holds the head of the subject with one hand, holds the swab against the nostril with the other hand, and slowly goes deep back along the bottom of the inferior nasal passage. Because the nasal passage is curved, do not use excessive force to avoid traumatic bleeding. When the tip of the swab reaches the back wall of the nasopharyngeal cavity, gently rotate it for a round (if you encounter a reflex cough, stay for a while), and then slowly take out the swab (Figure 1).

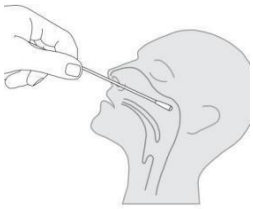

Figure 1. Schematic Diagram of Nasopharyngeal Swab Sampling

- **Nasal swab:** When collecting samples, first blow your nose with tissue, head with your hands. Then tilt your head slightly, hold the tail of the swab in one hand against one nostril, then slowly go along the bottom of the inferior nasal passage and penetrate 1-1.5 cm (for subjects aged 2-14 years old, 1 cm deep), and then rotate it against the nasal cavity for 4 rounds (stay for no less than 15 seconds) and then repeat the same operation on the other nasal cavity using the same swab. Dip the swab head into the sample extraction solution provided in the kit.
- Sample processing and storage: Samples should be processed with the sample extraction solution provided by this kit as soon as possible after collection. The processed samples can be stored for 24 hours at 2 8°C and for 12 months below 70°C. The number of freezing and thawing cycles should not exceed 4 cycles (Figure 2).

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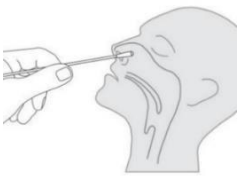

Figure 2. Schematic Diagram of Nasal Swab Sampling

PROCEDURE

Please read the instruction for use carefully before testing. Before testing, please take out the required reagents and samples to be tested from storage conditions and return them to room temperature. The test should be performed at room temperature.

1) Sample Processing:

Nasopharyngeal swab collection:

- Tear off the sealing film of the sample extraction solution and open the sample extraction solution.
- Immediately insert the collected nasopharyngeal swab into the sample extraction solution, rotate it close to the inner wall of the tube about 10 times, and keep the swab head rotating and mixing in the preservation solution for at least 30 seconds to ensur e that the sample is fully eluted.
- Then squeeze the head of the swab against the inner wall of the bottle at least 5 times to keep the liquid in the bottle as much as possible. Take out and discard the swab to prepare the processed sample extract.
- Cover the dropper tip.

		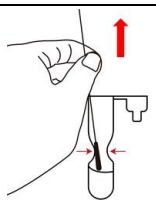	
1)Tear off the sealing film of the sample extraction solution and open the sample extraction solution.	2) Rotate it close to the inner wall of the tube about 10 times, and keep the swab head rotating and mixing in the preservation solution for at least 30 seconds .	3)Then squeeze the head of the swab against the inner wall of the bottle at least 5 times. Take out and discard the swab.	4) Cover the dropper tip.

Figure 3. Schematic Diagram of Nasopharyngeal Swab Processing Nasal swab collection:

Nasal swab collection:

- Tear off the sealing film of the sample extraction solution and open the sample extraction solution.
- Immediately insert the collected nasal swab into the sample extraction solution, rotate it close to the inner wall of the tube about 10 times, and keep the swab head rotating and mixing in the preservation solution for at least 30 seconds to ensure that the sample is fully eluted.
- 3)Then squeeze the head of the swab against the inner wall of the bottle at least 5 times. Break the swab along the breaking point, discard the swab rod, and prepare the processed sample extract.
- Cover the dropper tip.

			
1)Tear off the sealing film of the sample extraction solution and open the sample extraction solution.	2)Rotate it close to the inner wall of the tube about 10 times, and keep the swab head rotating and mixing in the preservation solution for at least 30 seconds.	3)Squeeze the head of the swab against the inner wall of the bottle at least 5 times. Break the swab along the breaking point, discard the swab rod.	4)Cover the dropper tip.

Figure 4. Schematic Diagram of Nasal Swab Processing

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5) Sample Testing

- Open the aluminum foil bag of the test cassette, place the test cassette on a clean and flat surface, place it horizontally and mark it.
- Add 80 µL (approximately 3 drops) of the processed sample extract into the sampling well on the test cassette.
- Read the results in the test cassette window within 15-20 minutes. Results displayed after 20 minutes are invalid.

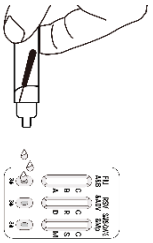
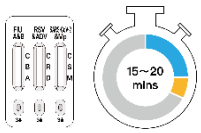
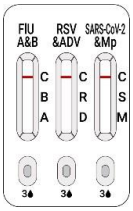
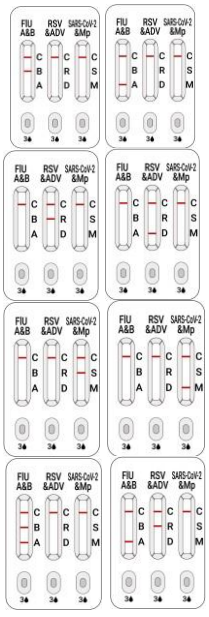
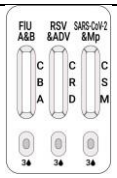
		
1)Open the aluminum foil bag of the test cassette, place the test cassette on a clean and flat surface, place it horizontally and mark it.	2)Add 3 drops of the processed sample extract vertically into the sampling well on the test cassette.	3)Place the test cassette stand at room temperature for 15-20 minutes before reading the result.

Figure5. Schematic Diagram of Nasopharyngeal Swaband Nasal Swab Sample Testing

RESULT INTERPRETATIONS

Figure	Result	Result Interpretation
	Negative	A negative result indicates that the sample does not contain SARS-CoV-2, respiratory syncytial virus(RSV), influenza A virus (FluA), influenza B virus (FluB), adenovirus or mycoplasma pneumoniae or the virus content is lower than the LoD of this kit.
	Positive	If the three quality control lines (C) show color, and one or more of the test lines B, A, R, D, S and M show color, then the result of the virus corresponding to the colored test line is positive, and the result of the virus corresponding to non-colored test line is negative. Test Line Corresponding Virus B Influenza B A Influenza A R Respiratory syncytial virus D Adenovirus S SARS-CoV-2 M Mycoplasmapneumoniae A positive result indicates that the sample contains one or more of the SARS-CoV-2, respiratory syncytial virus(RSV), influenza A virus (FluA), influenza B virus (FluB), adenovirus and mycoplasma pneumoniae.
		

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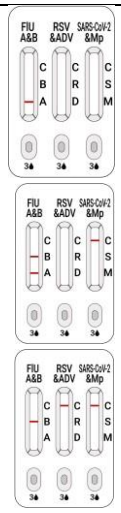	Invalid	If one or two or three of the quality control lines (C) do not show color, regardless of whether one or more of the test lines B, A, R, D, S or M show color, it is an invalid result, indicating an incorrect operation process or the kit has deteriorated and expired. In this case, re-test is needed. If the problem persists, contact the manufacturer or local supplier immediately.

Note: The color depth of the test line is related to the content of the tested substance contained in the extracted sample. Regardless of the color intensity, the result should be judged according to whether the test line is colored. The figures are for reference only and do not represent all possible results.

LIMITATION OF THE PROCEDURE

1) This kit is only used to detect SARS-CoV-2, respiratory syncytial virus, influenza A virus, influenza B virus, adenovirus and mycoplasma pneumoniae antigens in human nasopharyngeal swab and nasal swab samples.
2) Due to technical and operational errors, as well as the influence of other interfering substances in the sample, erroneous results may occur. If there is any doubt about the test results, it can be re-tested.
3) The kit only provides qualitative detection of the SARS-CoV-2, respiratory syncytial virus, influenza A virus, influenza B virus, adenovirus and mycoplasma pneumoniae antigens in the sample, and cannot determine the content of the pathogens in the sample.
4) The test results of this kit are for clinical reference only and should not be used as the sole basis for clinical diagnosis. The clinical management of patients should be comprehensively considered in conjunction with their symptoms/signs, medical history, other laboratory tests, and treatment response.
5) This product has limitations inherent in immunochromatographic methodology. For suspicious negative/positive test results, it is recommended to use nucleic acid testing or virus culture identification methods for further confirmation.
6) For positive results of influenza A virus, it is recommended to conduct further experiments to confirm the subtype of influenza A virus and consult with the local public health prevention agency.

Analysis on the possibility of false negative results:

1) Unreasonable sample collection, transportation and processing, low virus titers in samples, stale samples or repeated freezing and thawing of samples may lead to false negative results.
2) Viral genetic mutations may lead to changes in antigenic determinants, resulting in false negative results. This situation is more likely to occur with reagents using monoclonal antibody.
3) For emergencies of SARS-CoV-2, respiratory syncytial virus and influenza A virus, influenza B virus, adenovirus and mycoplasma pneumoniae, the optimal sample type for detection and the optimal sampling time after infection (peak virus titer) have not been verified. Collecting samples from multiple sites in the same patient separately may reduce the possibility of false negative results.

WARNING AND PRECAUTION

1) This product is only used for in vitro diagnosis. The test kit is for one-time use. Please read the instruction for use carefully before testing.
2) Under room temperature conditions, the test cassette should be used as soon as possible within 1 hour after being taken out of the aluminum foil bag to avoid being exposed to the air for too long and damped to affect the test results.
3) During testing, the test cassette should be placed on a horizontal surface to prevent the tilt of the test cassette from causing the sample chromatography to be too fast or too slow, affecting the test results.
4) After the specified reading time is exceeded, the results will be invalid. To ensure the accuracy of the interpretation results, please do not interpret the results in dimly lit areas.
5) It is recommended to use fresh samples.
6) Please use the sample extraction solution provided in this kit for sampling. Do not mix test cassettes and sample extraction solutions from different batches.
7) Improper sample collection or handling may result in false negative results.
8) Children are more likely to spread the virus over larger areas and for longer periods of time than adults, so testing in children may be more sensitive than in adults.
9) For the detection of influenza viruses or subtypes, small changes in antigenic epitopes due to small-scale mutations in nucleic acid sequences may lead to negative results or reduced analytical sensitivity of the kits.
10) The aluminum foil bag contains desiccant, please do not take it internally.
11) Used test cassettes and various wastes should be treated as pollutants, and the disinfection and isolation system should be strictly implemented.

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12) Operators should wear disposable gloves and work clothes, and the place should be disinfected after the test is completed.

SYMBOLS

Do not use if package is damaged | Manufacturer | Batch Code

CE mark of Conformity | Refer to the instructions | ISO | GMP

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