



SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit

PRODUCT NAME

Common Name: SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay)

WHAT DOES THE KIT TEST?

The fluororapid SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit is applicable to the detection of SARS-CoV-2 e Influenza A/B e RSV Antigen (SARS-CoV-2 antigen, Influenza A virus antigen, Influenza B virus antigen, and RSV antigen) in nasal swab samples.

USER AGREEEMENT

This kit is suitable for people over 2 years of age. People ages 2-14 should not use the kit by themselves. Sample collection and testing with this kit should be performed by adults or parents (aged 18-60 years old).

BACKGROUND

The novel coronavirus belongs to the beta genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection.

PRINCIPLE

The SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit is a qualitative test to detect SARS-CoV-2 Antigen, Influenza A/B Antigen, and RSV Antigen in nasal swab samples by chromatographic immunoassay method.

SPECIFICATIONS

Table with 3 columns: Components, 1 Test/box, 2 Tests/box, 5 Tests/box. Rows include Components, Test Card, Sterile nasal swabs, Prefilled Sample treatment tube, and Instructions for Use.

MATERIALS REQUIRED BUT NOT PROVIDED

STORAGE CONDITIONS AND EXPIRATION DATE

1. Store test kit at 2-30°C in a dry place, protected from light. Test kit is valid for 24 months. 2. The Test Card must remain in the sealed pouch until use.

at room temperature (20-25°C) for 5 minutes before testing. 1. Twist off the cap of the Sample treatment tube and remove the inner blue stopper.

3. Nasal swab collection method

2. Turn open the fall bag, take out the test card, and use it as soon as possible within 1 hour.

1. Carefully remove sterile nasal swab from the packaging (Avoid touching the end with the cotton swab)

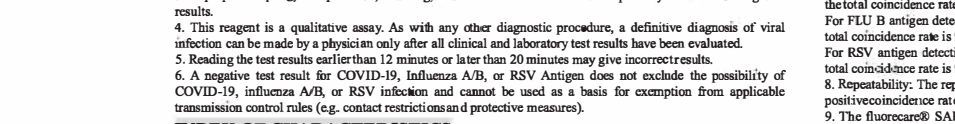
Insert the nasal swab into the left nostril to a depth of 2.5 cm (1 inch) from the entrance of the nostril.

2. Rotate the nasal swab on the nostril wall (Mucous membrane) 5 times to ensure adequate sampling.

If there is a mixed infection of COVID-19 virus, Influenza virus, and RSV virus, the disease may be more infectious. You will need to be hospitalized or admitted to personal protection to prevent infecting others and go to the hospital for diagnosis as soon as possible.

3. Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap tightly.

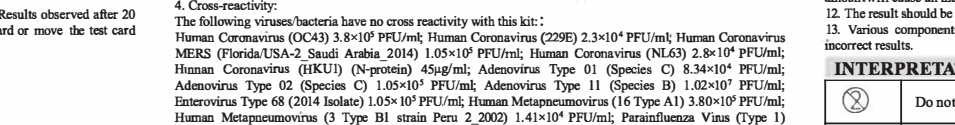


5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Uncover the tip cover at the top of the cap. If the tip cover is not uncovered, and the blue stopper inside the cap is not uncovered, the test is INVALID.

Each sample well of the test card requires 2 drops (about 60 µl) of the treated sample solution. The oval wells marked with "S" at the bottom of the test card are the sample wells. You can squeeze sample solution into 3 sample wells at the same time to detect 3 different types of antigens or squeeze into only one sample well to detect one type of antigen.

INDEX OF CHARACTERISTICS

Table with 2 columns: Virus strains, LoD. Rows include 2009H1N1, Seasonal H1N1, Type A H2N2, and The LoD for Influenza A/B.



TAKE THE FOLLOWING MEASURES TO PREVENT THE SPREAD OF INFECTION

1. After the completion of testing and observation, put all the used components into a plastic bag, close and put the bag into another plastic bag and dispose of it. 2. Place someone the above test procedures alone in an isolated room.

INTERPRETATION OF RESULTS

1. COVID-19 or RSV Positive: Two purple lines, both the detection line (T) and the quality control line (C) can be observed. 2. Influenza A/B Positive: Two or three purple lines. The presence of Line A and Line B indicates a positive result for influenza A/B.

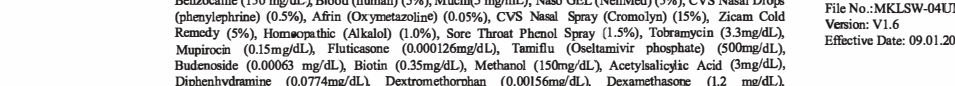
INSTRUCTIONS FOR USE

1. Store the test kit at 2-30°C in a dry place, protected from light. 2. The test kit is valid for 24 months.

3. Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap tightly.

5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Uncover the tip cover at the top of the cap.



6. Hook: When the Virus strains in the sample do not exceed the concentration in the following table, the high concentration of Virus strains in the sample has no effect on the detection results of the fluororapid SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit.

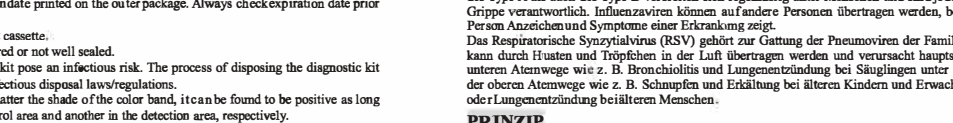
Table with 2 columns: Virus strains, Limit value. Rows include SARS-CoV-2, 2009H1N1, Seasonal H1N1, Type A H2N2, B/Victoria, B/Yamagata, RSV type A, RSV type B.

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis. 2. Negative test results may occur if the level of antigen in the sample is below the limit of detection of the test or due to improper sample collection.

INDEX OF CHARACTERISTICS

Table with 2 columns: Virus strains, LoD. Rows include 2009H1N1, Seasonal H1N1, Type A H2N2, and The LoD for Influenza A/B.



6. The test card is kept at room temperature for 12 minutes to observe the test results.

1. After the completion of testing and observation, put all the used components into a plastic bag, close and put the bag into another plastic bag and dispose of it. 2. Place someone the above test procedures alone in an isolated room.

INTERPRETATION OF RESULTS

1. COVID-19 or RSV Positive: Two purple lines, both the detection line (T) and the quality control line (C) can be observed. 2. Influenza A/B Positive: Two or three purple lines. The presence of Line A and Line B indicates a positive result for influenza A/B.

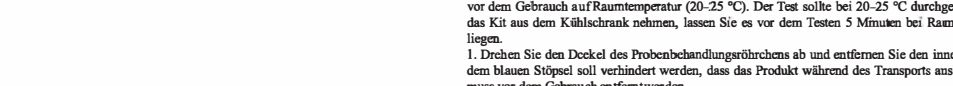
INSTRUCTIONS FOR USE

1. Store the test kit at 2-30°C in a dry place, protected from light. 2. The test kit is valid for 24 months.

3. Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap tightly.

5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Uncover the tip cover at the top of the cap.



6. Hook: When the Virus strains in the sample do not exceed the concentration in the following table, the high concentration of Virus strains in the sample has no effect on the detection results of the fluororapid SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit.

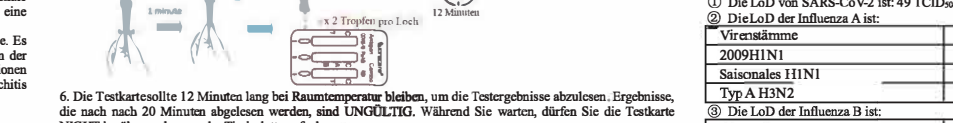
Table with 2 columns: Virus strains, Limit value. Rows include SARS-CoV-2, 2009H1N1, Seasonal H1N1, Type A H2N2, B/Victoria, B/Yamagata, RSV type A, RSV type B.

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis. 2. Negative test results may occur if the level of antigen in the sample is below the limit of detection of the test or due to improper sample collection.

INDEX OF CHARACTERISTICS

Table with 2 columns: Virus strains, LoD. Rows include 2009H1N1, Seasonal H1N1, Type A H2N2, and The LoD for Influenza A/B.



6. The test card is kept at room temperature for 12 minutes to observe the test results.

1. After the completion of testing and observation, put all the used components into a plastic bag, close and put the bag into another plastic bag and dispose of it. 2. Place someone the above test procedures alone in an isolated room.

INTERPRETATION OF RESULTS

1. COVID-19 or RSV Positive: Two purple lines, both the detection line (T) and the quality control line (C) can be observed. 2. Influenza A/B Positive: Two or three purple lines. The presence of Line A and Line B indicates a positive result for influenza A/B.

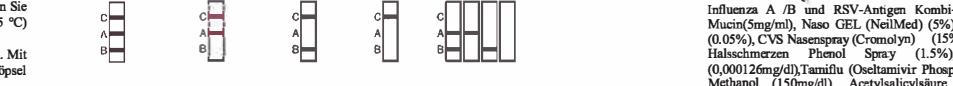
INSTRUCTIONS FOR USE

1. Store the test kit at 2-30°C in a dry place, protected from light. 2. The test kit is valid for 24 months.

3. Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap tightly.

5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Uncover the tip cover at the top of the cap.



6. Hook: When the Virus strains in the sample do not exceed the concentration in the following table, the high concentration of Virus strains in the sample has no effect on the detection results of the fluororapid SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit.

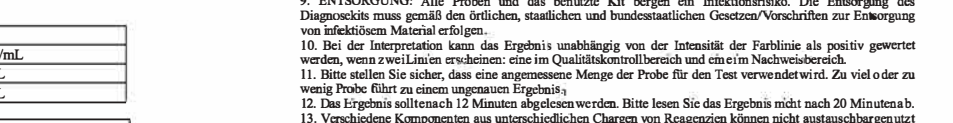
Table with 2 columns: Virus strains, Limit value. Rows include SARS-CoV-2, 2009H1N1, Seasonal H1N1, Type A H2N2, B/Victoria, B/Yamagata, RSV type A, RSV type B.

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis. 2. Negative test results may occur if the level of antigen in the sample is below the limit of detection of the test or due to improper sample collection.

INDEX OF CHARACTERISTICS

Table with 2 columns: Virus strains, LoD. Rows include 2009H1N1, Seasonal H1N1, Type A H2N2, and The LoD for Influenza A/B.



6. The test card is kept at room temperature for 12 minutes to observe the test results.

1. After the completion of testing and observation, put all the used components into a plastic bag, close and put the bag into another plastic bag and dispose of it. 2. Place someone the above test procedures alone in an isolated room.

INTERPRETATION OF RESULTS

1. COVID-19 or RSV Positive: Two purple lines, both the detection line (T) and the quality control line (C) can be observed. 2. Influenza A/B Positive: Two or three purple lines. The presence of Line A and Line B indicates a positive result for influenza A/B.

INSTRUCTIONS FOR USE

1. Store the test kit at 2-30°C in a dry place, protected from light. 2. The test kit is valid for 24 months.

3. Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap tightly.

5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Uncover the tip cover at the top of the cap.



6. Hook: When the Virus strains in the sample do not exceed the concentration in the following table, the high concentration of Virus strains in the sample has no effect on the detection results of the fluororapid SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit.

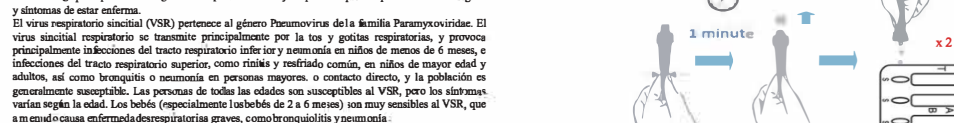
Table with 2 columns: Virus strains, Limit value. Rows include SARS-CoV-2, 2009H1N1, Seasonal H1N1, Type A H2N2, B/Victoria, B/Yamagata, RSV type A, RSV type B.

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis. 2. Negative test results may occur if the level of antigen in the sample is below the limit of detection of the test or due to improper sample collection.

INDEX OF CHARACTERISTICS

Table with 2 columns: Virus strains, LoD. Rows include 2009H1N1, Seasonal H1N1, Type A H2N2, and The LoD for Influenza A/B.



6. The test card is kept at room temperature for 12 minutes to observe the test results.

1. After the completion of testing and observation, put all the used components into a plastic bag, close and put the bag into another plastic bag and dispose of it. 2. Place someone the above test procedures alone in an isolated room.

INTERPRETATION OF RESULTS

1. COVID-19 or RSV Positive: Two purple lines, both the detection line (T) and the quality control line (C) can be observed. 2. Influenza A/B Positive: Two or three purple lines. The presence of Line A and Line B indicates a positive result for influenza A/B.

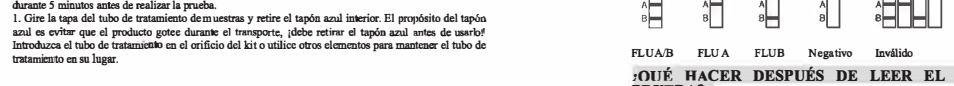
INSTRUCTIONS FOR USE

1. Store the test kit at 2-30°C in a dry place, protected from light. 2. The test kit is valid for 24 months.

3. Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap tightly.

5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Uncover the tip cover at the top of the cap.



6. Hook: When the Virus strains in the sample do not exceed the concentration in the following table, the high concentration of Virus strains in the sample has no effect on the detection results of the fluororapid SARS-CoV-2 e Influenza A/B e RSV Antigen Combo Test Kit.

Table with 2 columns: Virus strains, Limit value. Rows include SARS-CoV-2, 2009H1N1, Seasonal H1N1, Type A H2N2, B/Victoria, B/Yamagata, RSV type A, RSV type B.

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis. 2. Negative test results may occur if the level of antigen in the sample is below the limit of detection of the test or due to improper sample collection.

INDEX OF CHARACTERISTICS

Table with 2 columns: Virus strains, LoD. Rows include 2009H1N1, Seasonal H1N1, Type A H2N2, and The LoD for Influenza A/B.



6. The test card is kept at room temperature for 12 minutes to observe the test results.

1. After the completion of testing and observation, put all the used components into a plastic bag, close and put the bag into another plastic bag and dispose of it. 2. Place someone the above test procedures alone in an isolated room.

INTERPRETATION OF RESULTS

1. COVID-19 or RSV Positive: Two purple lines, both the detection line (T) and the quality control line (C) can be observed. 2. Influenza A/B Positive: Two or three purple lines. The presence of Line A and Line B indicates a positive result for influenza A/B.

INSTRUCTIONS FOR USE

1. Store the test kit at 2-30°C in a dry place, protected from light. 2. The test kit is valid for 24 months.

3. Repeat the process in the right nostril with the same nasal swab, collecting from both nasal passages to ensure an adequate sample.

4. Place the swab sample into the tube, then break the swab at the break line and leave the lower half in the treatment tube. Secure the cap tightly.

5. Squeeze the swab 10 times in the test tube then wait for 1 minute of sample reaction time. Uncover the tip cover at the top of the cap.



