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fluorecare®

SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test(Kit (Colloidal Gold Chromatographic Immunoassay)

PRODUCT NAME

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

PRODUCT CODE: MP-71

PACKINGS: test/box

INTENDED USE

The SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test(Kit is applicable to the simultaneous qualitative detection and differentiation of novel Coronavirus (SARS-CoV-2) Antigen, Influenza A virus, Influenza B virus Antigen and RSV Antigen in Oropharyngeal swab/Nasal swab/Nasal secretion samples of individuals suspected of COVID-19 infection. For in vitro diagnostic use only.

INTRODUCTION

The novel coronaviruses belong to the β 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; Asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mainly 3 to 7 days, the main manifestations are fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, cough and other manifestations are found in a few cases. Influenza (flu) is a contagious respiratory illness caused by influenza viruses. Influenza viruses can cause mild to severe illness. Serious outcomes of the flu can result in hospitalization or even death. Influenza (flu) and COVID-19 are both respiratory illnesses that share many similarities. Rapid testing, which can be helpful in making treatment decisions, can be a significant factor in reducing the spread of influenza viruses. Types A and B are the influenza viruses regularly spread among people and cause seasonal epidemics. Influenza A viruses can be spread to others before and after a person shows signs and symptoms of COVID-19.

Respiratory syncytial virus (RSV) is a enveloped, single-stranded RNA virus with negative-sense genome. RSV is the most common cause of lower respiratory tract infections in infants and young children worldwide. RSV is the most common respiratory tract infection in children and adults with weakened immunity. Antigenic variation is known to exist in human respiratory syncytial virus (hRSV). Although hRSV is usually transmitted by droplet or direct contact, the population is generally susceptible. People of all ages are susceptible to hRSV, but symptoms vary. Infants (infants aged 2 to 6 months) are very sensitive to RSV, which often causes serious respiratory diseases such as bronchitis and pneumonia.

PRINCIPLE

The SARS-CoV-2 & Influenza A/B & RSV Antigen is qualitatively detected in population Oropharyngeal swab/ Nasal swab or Nasopharyngeal swab using the colloidal gold method. After sample added, the SARS-CoV-2 Antigen (or Influenza A/B & RSV) in the sample to be tested is combined with the SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody coupled with colloidal gold, and then moves forward by SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody-coloidal gold complex. Then, by chromatography, the SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody-coloidal gold compound is captured by the SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody coated on the test line, the antibodies-antigens complex is made to be perfectly connected with a blue/burgundy color band, thus showing a positive result. Colloidal gold-labelled SARS-CoV-2 Antigen (or influenza A/B & RSV) antibody diffuses to the quality control line (C) region and is expected to show another blue/burgundy color band. When the reaction is over, the results can be interpreted by visual interpretation.

MAJOR COMPONENTS

Components	Quantity	Major Components
Test Card (Including the desiccant)	25 Cassettes	Each test card is mainly composed of a plastic shell and strips. The test particles: test strip is coated with SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody-colloidal gold; Test strip: SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody coated with colloidal gold; Other components include pad+filter+ film and desiccant pouch
Sample treatment solution	1 tube	Optional (Normal saline solution 5 ml per tube)
Pregnant sample treatment solution	5 ml/tube	
Instruction for use	1 Copy	
Sterile swabs	25 Pieces	
Extraction tubes	25 Pieces	
Positive Control	1 tube	Optional: 1) SARS-CoV-2 Antigen, Influenza A and Influenza B & RSV Antigen Positive Control (inactivated) 2) Influenza A/H1N1 pdm09, Influenza B and Influenza B (yamata, RSV strain)
Negative Control	1 tube	

NOTE: All samples/specimens must be unprovoked.

- Timer
- Pharmaceutical-grade Water (Purified water), Saline, Sterile or Boiled Water (depending on available sample volume) may be used to dilute the extracted swabs. The volume of the diluent should be consistent with the volume of the extraction solution. Pharmaceutical-grade Water is recommended. Any other components that are not provided in this kit are required to be prepared by themselves.

STORAGE CONDITIONS AND EXPIRY DATE

Store kit at 4-30°C in a dry place. Avoid direct sunlight and heat. Do not freeze or expose to 2-4°C. Test kits valid for 24 months from date of manufacture. Discard test card pouch if opened, the test should be performed within 1 hour.

REQUIREMENTS OF SPECIMENS

1. Sample collection
1.1. Oropharyngeal swab collection method:
1.1.1 Tip the patient's head slightly.
1.1.2 Open the patient's mouth wide or ask the patient to extend the pharyngeal tonsils on either side. Swab the pharyngeal tonsils and posterior pharynx with swabs.
1.1.3 Slightly rub the pharyngeal tonsils back and forth on both sides at least 3 times.
1.1.4. Rub the posterior pharyngeal wall up and down at least 3 times.
1.1.5. Take the sample as soon as possible.
2. Nasopharyngeal swab collection method:
1.2.1. Tip the patient's head back and self-administer the sample. Gently insert the swab (head) into the nasal cavity (the proper specimen collection).
1.2.2. Insert the swab into the nasal cavity parallel to the palate (not upward) for a minimum of 2 cm or until resistance is encountered. Rotate the swab several times. Slowly remove the swab.
1.2.3. Place the swab into the provided tube containing the appropriate extraction reagent. Follow the manufacturer's instructions. Swab specimens should be tested as soon as possible after collection.
1.2.4. Do not freeze swabs.
1.2.5. Test the sample as soon as possible.
1.3. Nasal swab collection method:
1.3.1 Tip patient's head back 70 degrees.
1.3.2 Place the swab tip parallel to the palate. Insert it into the nostril perpendicular to the palate until resistance is encountered (approx. 1 cm).
1.3.3 Rotate the swab several times against nasal wall. Remove swab, insert it in to the other nostril and repeat the process.
2. Sample treatment
2.1 Add the Specimen Extraction Reagent to a tube.
2.2. Place the swab sample in the tube, clip the swab head to the tube and squeeze 3-5 times, then break the swab at the swab-tube, and leave the head left in the extraction tube. Place the tube in a rack.
2.3 Centrifuge the tube with sing. tube for 5minutes/3min, then wait for 1 minute of reaction.
2.4 Vial Transport Medium
2.5.1 Prepare a sterile breakpoint tube and open the breakpoint tube dropper.
2.5.2 Fill the tube with 300μL sample(VTM).
2.5.3 Place the sample tube back into the transport medium, then wait 1 minute for reaction.
2.5.4 Take Carefully out the VTM to conduct a test for the kit.

DETECTION METHOD

1.Before testing, read the operating instructions carefully, and remove the testing kit and sample to room temperature (15-30°C) for at least 30 minutes.
2. Take out the foil bag, remove the test card, and use it as soon as possible within 1 hour.
3. Wait 1 minute for results and 5 minutes and sample treatment solution.
4. Vertically drop 3 drops (100μL) of the treated sample solution into each of the three sample holes of the extract. Remove to add every 2 drops of the sample treatment. Maintain the interval of 10 seconds between each drop. Start timing after the first drop of the sample is added.
5. The test card is not to be moved during the test (avoid vibration or shaking). Observation results need after 20minutes. Results: Stop of the sample being added to the test card are not recommended.

NOTE: The non-interpretation of should be done at 20-30°C.

INTERPRETATION OF RESULTS

1. Result of COVID-19 Antigen

2. Result of Influenza A/B

3. Result of RSV

- Positive: Two red stripe, both the detection line (T) line and the quality control line (C line) display color.
- Negative: Just only quality control line (C line) display color.
- Invalid: Quality control line (C) no display color, the other observation window detected line(s) may or may not be displaying. Unreliable test result, we suggest retest and be carefully observed.

Note: Any positive (detected SARS-CoV-2 Antigen, Influenza A Antigen, Influenza B Antigen, Influenza A/B Antigen, Influenza A and Influenza B positive, RSV Antigen Detected) result provides prompt diagnosis of a sample (treatment solution).

INDEX OF CHARACTERISTICS

1. Performance evaluation: the positive reference evaluation rate of the enterprise should be 100%.
2. Sensitivity: reference/gold standard kit only rate; the negative reference product accordingly rate of the enterprise should be 100%.
3. Limit of detection (LoD):
① The LoD of the Beijinuo SARS-CoV-2 & Influenza A/B&RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) is first confirmed by using 20 samples with concentrations of the corresponding Antigen of the kit. The LoD of the Beijinuo SARS-CoV-2 & Influenza A/B&RSV Antigen Combo Test concentration resulting in positive detection of twenty (20) out of twenty (20) replicates. Based on this testing the LoD for each strain/ serotype is confirmed as 90 TCID50/mL.
② The LoD of the Influenza A/B:

Influenza subtype	Virus strains	LoD
A1	H1N1(PR)	1.96×10³TCID50/mL
A2	H3N2 (HongKong)	4×10²TCID50/mL
B1	Type A H1N2	4×10²TCID50/mL

③ The LoD for the group B virus

Influenza subtype	Virus strains	LoD
B1	B/Victoria	5×10³TCID50/mL
B2	B/Yamagata	2.42×10³TCID50/mL

Note: Type A or B: 1.19×10³ TCID50/mL, RSV type B is 1.48×10³ TCID50/mL.

4. Cross-reactivity: Cross-reactivity test of the kit has been cross-matched with SARS-CoV-2 & Influenza A/B & RSV Antigen Combo Test Kit, and no cross-reactivity with the following other samples: Adenovirus (ADV-31) (10⁷ TCID50/mL), Rotavirus (Rotavirus) (10⁶ CFU/mL), Candida albicans (C.albicans) (10⁶ CFU/mL), Streptococcus pneumoniae (S.pneumoniae) (10⁶ CFU/mL), Staphylococcus aureus (S.aureus) (10⁶ CFU/mL), Haemophilus influenzae (H.influenzae) (10⁶ CFU/mL), Mycobacterium tuberculosis (M.tuberculosis) (10⁶ CFU/mL), Mycoplasma pneumoniae (M.pneumoniae) (10⁶ CFU/mL), Human coronavirus (229E) (10⁶ TCID50/mL), Human coronavirus (OC43) (10⁶ TCID50/mL), Human coronavirus (NL63) (10⁶ TCID50/mL), Human coronavirus (HKU1) (10⁶ TCID50/mL), Legionella pneumophila (L.pneumophila) (10⁶ CFU/mL), Mycobacterium tuberculosis (M.tuberculosis) (10⁶ CFU/mL), Legionella pneumophila (1-6 of 10⁶CFU/mL), Legionella pneumophila (7-14 of 10⁶CFU/mL), Mycobacterium tuberculosis (10⁶ CFU/mL), Mycobacterium intracellulare (10⁶ CFU/mL), Mycobacterium avium (10⁶ CFU/mL), Mycobacterium kansasii (10⁶ CFU/mL), Mycobacterium chelonae (10⁶ CFU/mL), Mycobacterium fortuitum (10⁶ CFU/mL), Mycobacterium gordonae (10⁶ CFU/mL), Mycobacterium scrofulaceum (10⁶ CFU/mL), Mycobacterium marinum (10⁶ CFU/mL), Mycobacterium xenopi (10⁶ CFU/mL), Mycobacterium malmoense (10⁶ CFU/mL), Mycobacterium szulgai (10⁶ CFU/mL), Mycobacterium haemophilum (10⁶ CFU/mL), Nocardia asteroides (N.asteroides) (10⁶ CFU/mL), Streptococcus salivarius (S.salivarius) (10⁶ CFU/mL), Pneumocystis jirovecii (PCP) (pneumonia) (10⁶ CFU/mL), Staphylococcus epidermidis (S.epidermidis) (10⁶ CFU/mL), Staphylococcus salivarius (10⁶ CFU/mL), Streptococcus pneumoniae (10⁶ CFU/mL), Streptococcus salivarius (10⁶ CFU/mL), Streptococcus pyogenes (10⁶ CFU/mL), Streptococcus mitis (10⁶ CFU/mL), Streptococcus pneumoniae (10⁶ CFU/mL), Streptococcus pneumoniae (serotype14) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype6) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype23) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype1) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype7F) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype19A) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype5) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype9V) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype18C) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype19F) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype23F) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype4) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype9N) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype9L) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype18A) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype2) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype6B) (10⁶ CFU/mL), Streptococcus pneumoniae (serotype33F) (10⁶ CFU/mL), Salmonella typhimurium (S.typhimurium) (10⁶ CFU/mL), Salmonella enteritidis (S.enteritidis) (10⁶ CFU/mL), Escherichia coli (E.coli) (10⁶ CFU/mL), Escherichia coli (O157:H7) (10⁶ CFU/mL), Escherichia coli (O26:H11) (10⁶ CFU/mL), Escherichia coli (O111:B4) (10⁶ CFU/mL), Escherichia coli (O55:H7) (10⁶ CFU/mL), Escherichia coli (O44:H18) (10⁶ CFU/mL), Escherichia coli (O126:H27) (10⁶ CFU/mL), Escherichia coli (O86:H34) (10⁶ CFU/mL), Escherichia coli (O128:H2) (10⁶ CFU/mL), Escherichia coli (O111:H8) (10⁶ CFU/mL), Escherichia coli (O127:H6) (10⁶ CFU/mL), Escherichia coli (O26:H11) (10⁶ CFU/mL), Escherichia coli (O111:H8