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fluorecare®

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

PRODUCT NAME

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

PRODUCT CODE: MF-71
PACKING:25 tests/ box

INTENDED USE

The fluorecare® SARS-CoV-2 & Influenza A/B & RSV Antigen Combined 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/or RSV Antigen in population Oropharyngeal swabs, Nasal swabs and Nasopharyngeal swabs samples in vitro. FOR PROFESSIONAL USE ONLY.For prescription use only.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, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea 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 death. Some people, such as older people, young children, and people with certain underlying health conditions, are at higher risk for serious flu complications. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread among people, and are responsible for seasonal flu each year. Influenza viruses can be spread to others before and after a person shows signs and symptoms of being sick.

Respiratory syncytial virus (RSV) is a nonpolar, single-stranded RNA virus with negative strand envelope. RSV is prevalent in all parts of the world, and the peak season is from November to April in temperate regions. RSV is the most common virus that causes lower respiratory tract infection in infants and young children worldwide. Respiratory syncytial virus is mainly transmitted by droplet or direct contact, and the population is generally susceptible. People of all ages are susceptible to RSV, but symptoms vary. Infants (especially infants aged 2 to 6 months) are very sensitive to RSV, which often causes serious respiratory diseases, such as bronchiolitis and pneumonia.

PRINCIPLE

The SARS-CoV-2 & Influenza A/B & RSV Antigen is qualitatively detected in population Oropharyngeal swabs，Nasal swabs or Nasopharyngeal swabs samples by 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 labelled with colloidal gold on the binding pad to form the SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody-colloidal gold complex. Due to chromatography, the SARS-CoV-2 Antigen (or Influenza A/B & RSV)-antibody-colloidal gold complex diffuses along the nitrocellulose's membrane. Within the detection line area, the SARS-CoV-2 Antigen (or Influenza A/B & RSV)-antibody complex binds to the antibody enclosed within the detection line area, showing a purple-red band. Colloidal gold labelled SARS-CoV-2 Antigen (or Influenza A/B & RSV) antibody diffuses to the quality control line (C) region and is captured by sheep anti-mouse IgG to form red bands. When the reaction is over, the results can be interpreted by visual observation.

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 main part of the test strip is coated with SARS-CoV-2 Antigen (or Influenza A/B) antibody, combined with SARS-CoV-2 Antigen (or Influenza A/B) antibody coated with colloidal gold. Other components include polyester film and absorbent paper.
Sample treatment solution	1 tube	Optional (Normal saline solution 9mL per tube)
Prepack sample treatment solution	25 tubes	0.5mL/tube
Instruction of use	1 Copy	/
Sterile swabs	25 Pieces	/
Extraction tubes	25 Pieces	/
Positive Control	1 tube	Optional (a SARS-CoV-2 Antigen, Influenza A and Influenza B,RSV,positive freeze-dried powder, prepared from synthetic SARS-CoV-2 protein, Influenza A protein and Influenza B , RSV protein)
Negative Control	1 tube	Optional(a negative freeze-dried powder,prepared from a sample treatment solution)
Droppers lid	25 Pieces	/

NOTE: Accessories required but not provided:

- Timer
- For samples sent in Viral Transport Media, there is a need for a plastic transfer pipette (Or a reusable sample collector) to collect the sample and transfer the measured volume to the extraction tube.

The components in each batch can only be used in the kit of the same batch, and the components in the kit of different batches can not be mixed.

STORAGE CONDITIONS AND EXPIRY DATE

Test kit store at 2-30℃ in dry place and protect from light and the controls store at 2-8℃. Test kit is valid for 24 months from date of manufacture. Once the test card pouch is opened, the test should be performed within 1 hour.

EQUIREMENTS OF SPECIMENS

1. Sample collection

1.1 Oropharyngeal swab collection method:

1.1.1 Tip the patient's head slightly.

1.1.2 Instruct the patient to open mouth as wide as possibly to reveal the pharyngeal tonsils on either side.

1.1.3 Wipe the base of patient's tongue with swab.

1.1.4 Slightly rub the pharyngeal tonsils back and forth on both sides of the collected position at least 3 times.

1.1.5 Rub the posterior pharyngeal wall up and down at least 3 times.

1.1.6 Test the sample as soon as possible

1.2 Nasopharyngeal swab collection method:

1.2.1 Tip the patient's head back and collect sample from the nostril that has more mucus (head should be inclined from vertical for proper specimen collection).

1.2.2 Insert the swab through the nostril entry and then slowly move along the bottom of the nasal cavity (Move gently to avoid traumatic bleeding).

1.2.3 When the tip of the swab reaches the posterior wall of the nasopharyngeal cavity, gently rotate it several times. (Collect as much secretion as possible)

1.2.4 To prevent reflex coughing, stop for one minute.

1.2.5 Slowly remove the swab.

1.2.6 Test the sample as soon as possible

1.3 Nasal swab collection method:

1.3.1 Tilt patient's head back 70 degrees.

1.3.2 While gently rotating the swab, insert it less than one inch (about 2 cm) into nostril parallel to the palate until

resistance is met at turbi-nates.

1.3.3 Rotate the swab several times against nasal wall. Remove swab, insert it into the other nostril and repeat the process.

2. Sample treatment

2.1 Swab samples/Positive Control/Negative Control:

2.1.1 Place the swab sample in the tube, dip the swab in the solution and rotate it 10 times, then break the swab at the swab node, and leave the lower half in the treatment tube.

2.1.2 Cover treatment tube cap, shake the tube upside down, then wait for 1 minute of reaction.

2.2 Viral Transport Media:

2.2.1 Prepare a sample treatment tube and open the treatment tube dropper.

2.2.2 Take 200μL sample(VTM)to the tube.

2.2.3 Load the dropper lid, shake the tube upside down, then wait for 1 minute of reaction.

Note: Confirm whether VTM is suitable for the kit

DETECTION METHOD

1. Before testing, read the operating instructions carefully, and restore the testing kit and samples to room temperature (20- 25℃) before using.

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

3. Wait for 1 minute reaction of sample and sample treatment solution.

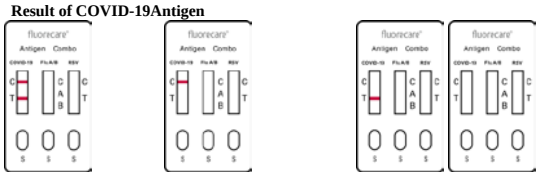
4. Vertically drop 2 drops (about 60μL) of the treated sample solution into each of the two sample holes of the test card.Only 2 drops of the treated sample solution can be added！ Adding too much or too little of the treated sample solution may result in invalid test results.

5. The test card is kept at room temperature for 15 minutes prior to observing the test results. Observation results read after 20 minutes from the time of the sample being added to the test card are considered invalid

NOTE: The test use/experiment should be done at 20~25℃.

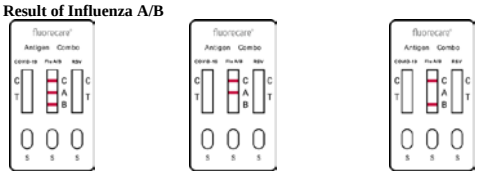
INTERPRETATION OF RESULTS

1. Result of COVID-19Antigen

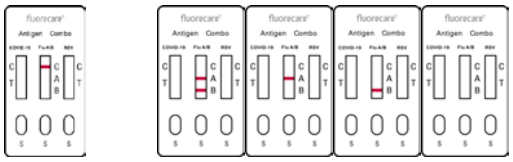


Positive Negative Invalid

2. Result of Influenza A/B

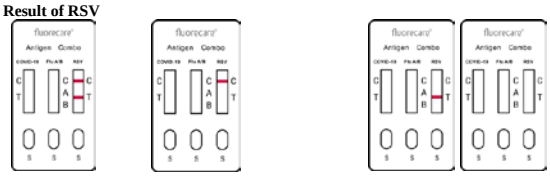


FLU A/B Positive FLU A Positive FLU B Positive



Negative Invalid

3. Result of RSV



Positive NegativeInvalid

- Positive: Two red strips, both the detection line (T line) and the quality control line (C line) display color.
- Negative: a red strip, quality control line (C line) color;
- Invalid: The position of the quality control line (Line C) in the observation window does not show any color rendering, indicating that the test is invalid, so the sample should be re-sampled for testing.
- Positive control showed SARS-CoV-2 /Influenza A/ Influenza B RSV positive results, negative control showed SARS-CoV-2 /Influenza A/ Influenza B RSV negative results.

Target 1 SARS-CoV-2 Antigen	Target 2 Influenza A	Target 3 Influenza B	Target 4 RSV	Interpretation
Negative	Negative	Negative	Negative	No target Antigen detected
Positive	Positive	Positive	Positive	SARS-CoV-2 Antigen, Influenza A Antigen, Influenza B Antigen, RSV Antigen Detected

LIMITATION OF METHODOLOGY

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis.
2. With the limit from the method of Antigen detection reagent, the minimum detection limit (sensitivity analysis) is generally lower than the nucleic acid reagent. So, the researcher should pay attention to the possible cases of false negatives. The researcher should also look at symptoms of patients. Further tests, including nucleic acid tests are recommended for suspected negative results to assist in judgement.
3. Unreasonable sampling, transportation, handling, and low virus content in samples may lead to false negatives.
4. The test results of this reagent are for clinical reference only and should not be used as the sole basis

for clinical diagnosis and treatment. The final diagnosis of the disease should be based on a comprehensive assessment of all clinical situations and laboratory results after making.

INDEX OF CHARACTERISTICS

1. Positive reference coincidence rate: the positive reference coincidence rate of the enterprise should be 100%.
2. Negative reference product conformity rate: the negative reference product conformity rate of the enterprise should be 100%.
3. Limit of detection (LoD)：

① The LoD of the fluorecare SARS-CoV-2 & Influenza A/B&RSV Antigen Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) is then confirmed by testing 20 replicates with concentrations at the tentative Limit of Detection. The final LoD of the fluorecare SARS-CoV-2 Ag Test is determined to be the lowest concentration resulting in positive detection of twenty(20) out of twenty (20) replicates. Based on this testing the LoD for nasal swab specimens is confirmed as:49 $TCID_{50}$/mL..

② The LoD of the Influenza A is:

Reference code	Virus strains	LoD
S1	2009H1N1	1.96×10^4TCID50/mL
S2	Seasonal H1N1	2×10^4TCID50/mL
S5	Type A H3N2	S4 4×10^4TCID50/mL

③ The LoD the Influenza B is:

Reference code	Virus strains	LoD
S3	B/Victoria	5×10^3TCID50/mL
S4	B/Yamagata	2.625×10^3TCID50/mL

④RSV type A is 1.15×10^4 TC ID_{50}/mL,RSV type B is 1.6×10^4 TC ID_{50}/mL.

4. Cross-reactivity: Virus/bacteria listed below are confirmed not to have cross-reactivity with SARS-CoV-2 & Influenza A/B & RSV Antigen Combined Test Kit.

Adenovirus (AdV-1)($1.0\times10^5$$TCID_{50}$/mL), Bordetella pertussis(1.0×10^6CFU/mL) , Candida albicans(1.0×10^6 CFU/mL) , Chlamydia pneumoniae(7.9×10^4 $TCID_{50}$/mL) , Corynebacterium diphtheriae(1.0×10^6 CFU/mL) , Cytomegalovirus(1.0×10^5 IU/mL) , Enterovirus (EV68)(1.0×10^5 $TCID_{50}$/mL) , Epstein Barr Virus(1.0×10^5cp/mL) , Escherichia coli(1.0×10^6 CFU/mL) , Haemophilus influenzae(1.0×10^6 CFU/mL) ,Human coronavirus 229E(1.0×10^5 $TCID_{50}$/mL) , Human coronavirus HKU1(1.0×10^5 genome cp/mL) , Human coronavirus NL63(2.5×10^4 TCID50/mL) , Human coronavirus OC43(1.0×10^5 $TCID_{50}$/mL) , Human Metapneumovirus(1.0×10^5 $TCID_{50}$/mL) , Lactobacillus acidophilus(1.0×10^6 CFU/mL) , Legionella pneumophila(1.0×10^6 CFU/mL) , Legionella longbeachae(1.0×10^6 CFU/mL) , Measles virus (1.0×10^5 $TCID_{50}$/mL) , MERS-coronavirus(1.0×10^5 cp/mL) , Moraxella catarrhalis(1.0×10^6 CFU/mL) , Mumps Virus(1.0×10^5 $TCID_{50}$/mL) , Mycobacterium tuberculosis(1.0×10^6 CFU/mL) , Mycoplasma pneumoniae(1.0×10^6 CCU/mL) , Neisseria elongata(1.0×10^6 CFU/mL) , Neisseria meningitidis(1.0×10^6 CFU/mL) , Parainfluenza virus 1(1.0×10^5 $TCID_{50}$/mL) , Parainfluenza virus 2(1.0×10^5 $TCID_{50}$/mL) , Parainfluenza virus 3(1.0×10^5 $TCID_{50}$/mL) , Parainfluenza virus 4(1.0×10^5 $TCID_{50}$/mL) , Parechovirus(1.0×10^5 $TCID_{50}$/mL) , Pseudomonas aeruginosa(1.0×10^6 CFU/mL) , Pneumocystis jirovecii(5.0×10^3 organisms/mL) , Respiratory Syncytial Virus(1.0×10^5 PFU/mL) , Human Rhinovirus(1.0×10^5 PFU/mL) , SARS-coronavirus (SARS-CoV-1)(1.0×10^5 PFU/mL) ,Staphylococcus aureus(1.0×10^6 CFU/mL) , Staphylococcus epidermidis(1.0×10^6 CFU/mL) , Streptococcus salivarius (1.0×10^6 CFU/mL) , Streptococcus pneumoniae(1.0×10^6 CFU/mL) , Streptococcus pyogenes(1.0×10^6 CFU/mL) , Human coronavirus HKU1 (1 x 10^5PFU/mL).

5. Interference

Substances listed below are confirmed not to have interference response with SARS-CoV-2 & Influenza A/B & RSV Antigen Combined Test Kit. Benzocaine (150 mg/dL), Blood (human) (5%), Mucin(5 mg/mL), Naso GEL (NeilMed) (5%), CVS Nasal Drops (phenylephrine) (0.5%), Afrin (Oxymetazoline) (0.05%), CVS Nasal Spray (Cromolyn) (15%) ,Zicam Cold Remedy (5%), Homeopathic (Alkalol) (1.0%), Sore Throat Phenol Spray (1.5%), Tobramycin(3.3mg/dL), Mupirocin(0.15mg/dL), Fluticasone (0.000126mg/dL),Tamiflu (Oseltamivir phosphate) (500mg/dL), Budenoside (0.00063 mg/dL), Biotin (0.35mg/dL), Methanol (150mg/dL), Acetylsalicylic Acid (3mg/dL), Diphenhydramine (0.0774mg/dL), Dextromethorphan (0.00156mg/dL), Dexamethasone (1.2 mg/dL), Mucinex(5%).

6. Co-infection (Competitive interference)

To assess potential competitive interference between Influenza A, Influenza B, and SARS-CoV-2 & RSV Antigen, samples were tested in replicates of 5 where low (approximately 3 x LoD) concentrations of any two targets were mixed with very high (1.0x 10^5 TCID50/mL) concentrations of the third target. None of the targets present at very high concentration interfered with the detection of low levels of the other two targets.

7. Clinical accuracy

The clinical performance of the SARS-CoV-2 & Influenza A/B Antigen Combined Test Kit (Colloidal Gold Chromatographic Immunoassay) was evaluated compared to RT-PCR positive cases. Positive percent agreement is 92.9% and negative percent agreement is 100% in the SARS-CoV-2 Antigen test. Positive percent agreement is 91.8 % and negative percent agreement is 99.6% in the Influenza A test. Positive percent agreement is 92.7 % and negative percent agreement is 100.0% in the Influenza B test, Positive percent agreement is 96.97 % and negative percent agreement is 100.0% in the RSV test.

7.1 Results and Analysis of SARS-CoV-2

Sample type	Number of Samples	Test Results				Agreement Statistics		
		Concordant Positive (N)	Discordant Positive (N)	Concordant Negative (N)	Discordant Negative (N)	Agreement Parameter	Percent Agreement (%)	95% CI (LCL, UCL)
Total	668	342	0	300	26	PPA	92.93%	(89.82%, 95.33%)
						NPA	100.0%	(98.78%, 100%)
Nasopharyngeal swabs	268	158	0	100	10	PPA	94.05%	(89.33%, 97.11%)
						NPA	100.00%	(96.38%, 100%)
Nasal swabs	200	93	0	100	7	PPA	93.00%	(86.11%, 97.14%)
						NPA	100.00%	(96.38%, 100.0%)
Oropharyngeal swabs	200	91	0	100	9	PPA	91.00%	(83.60%,95.80%)
						NPA	100.00%	(96.38%,100%)

7.2 Results and Analysis of Influenza A

Sample type	Number of Samples	Test Results				Agreement Statistics		
		Concordant Positive (N)	Discordant Positive (N)	Concordant Negative (N)	Discordant Negative (N)	Agreement Parameter	Percent Agreement (%)	95% CI (LCL, UCL)
Total	315	56	1	253	5	PPA	91.80%	(81.90%, 97.28%)
						NPA	99.61%	(97.83%, 99.99%)
Nasopharyngeal swabs	86	20	0	65	1	PPA	95.24%	(74.13%, 99.75%)
						NPA	100.00%	(93.05%, 99.86%)
Nasal swabs	159	17	1	138	3	PPA	85.00%	(62.11%,96.79%)
						NPA	99.28%	(96.06%,99.98%)
Oropharyngeal swabs	70	19	0	50	1	PPA	95.00%	(73.06%,99.74%)
						NPA	100.00%	(91.11%,99.82%)

7.3 Results and Analysis of Influenza B

Sample type	Number of Samples	Test Results				Agreement Statistics		
		Concordant Positive (N)	Discordant Positive (N)	Concordant Negative (N)	Discordant Negative (N)	Agreement Parameter	Percent Agreement (%)	95% CI (LCL, UCL)
Total	316	51	0	261	4	PPA	92.73%	(82.41%, 97.98%)
						NPA	100.0%	(98.60%,100.00%)
Nasopharyngeal swabs	86	21	0	65	0	PPA	100.00%	/
						NPA	100.00%	/
Nasal swabs	159	19	0	139	1	PPA	95.00%	(73.06%, 99.74%)
						NPA	100.00%	(96.65%, 99.93%)
Oropharyngeal swabs	71	17	0	51	3	PPA	85.00%	(61.14%,96.04%)
						NPA	100.00%	(91.27%,99.82%)

7.4 Results and Analysis of RSV

Sample type	Number of Samples	Test Results				Agreement Statistics		
		Concordant Positive (N)	Discordant Positive (N)	Concordant Negative (N)	Discordant Negative (N)	Agreement Parameter	Percent Agreement (%)	95% CI (LCL, UCL)
Total	323	64	0	257	2	PPA	96.97%	(89.48%,99.63%)
						NPA	100.0%	(98.58%, 100.0%)
Nasopharyngeal swabs	120	20	0	100	0	PPA	100.00%	/
						NPA	100.00%	/
Nasal swabs	128	24	0	102	2	PPA	92.31%	(74.87%, 99.05%)
						NPA	100.00%	(96.45%,100.00%)
Oropharyngeal swabs	75	20	0	55	0	PPA	100.00%	/
						NPA	100.00%	/

8. Repeatability: The repeatability reference products of the enterprise were tested, repeated for 10 times, and the SARS-CoV-2 Antigen/Influenza A/Influenza B/RSV positive coincidence rate is 100%.

9.SARS-CoV-2 & Influenza A/B Antigen & RSV Combo Test Kit (Colloidal Gold Chromatographic Immunoassay) is test for SARS-CoV-2 nucleocapsid protein.
The kit can detect Alpha, Beta, Gamma, Delta and Omicron mutant strains.

ATTENTION

1. The kit is only used for in vitro diagnosis; it cannot be used repeatedly and is single-use. Kits should be treated as infectious materials.
2. During the time of interpretation, no matter the shade of the color band, it can be found to be positive as long as two lines appear on the quality control area and the detection area, respectively.
3. Please ensure that an appropriate amount of sample is used for testing, too much or too little of the sample volume may cause a deviation in the result
4. The final result should be read in 15 minutes. Please do not read the result after 20 minutes.
5. Only 2 drops of the treated sample solution can be added！Adding too much or too little of the treated sample solution may result in invalid test results.

INTERPRETATION OF ICONS

	Do not re-use		Temperature limit
IVD	*In vitro* diagnostic medical device		Consult instructions for use
Σ n	Contains sufficient for <*n*> tests		Keep dry
	Keep away from sunlight	EC REP	Authorized representative in the European Community
	Manufacturer		Caution
	Biological risks	CE	CE marking
REF	Catalogue number	LOT	Batch code
	Date of manufacture		Use-by date

GENERAL INFORMATION

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EC REP **CMC MEDICAL DEVICES & DRUGS, S.L.**
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