SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit Package Insert

REF **ISIRAH-9655** **Sample:** Nasopharyngeal/Oropharyngeal/Nasal swabs
Version: A **Effective Date: 2025.04.21**
For professional in vitro diagnostic use only

INTENDED USE

The Sejoy® SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit is applicable to the simultaneous qualitative detection and differentiation of novel Coronavirus (SARS-CoV-2 Antigen), Influenza A virus Antigen, Influenza B virus Antigen, RSV Antigen, ADV Antigen and HMPV Antigen in population Nasopharyngeal swab, Oropharyngeal swab and Nasal swab samples in vitro.
FOR PROFESSIONAL USE ONLY. For in vitro diagnostic use only.

PACKAGE SPECIFICATIONS

1 test/kit, 25 tests/ kit

INTRODUCTION

The novel coronaviruses belong to the β genus. COV1D-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.
Adenoviruses are also one of the important causes of respiratory diseases, however, depending on serum classification, they may also lead to various other diseases such as gastroenteritis, conjunctivitis, cystitis, and rash diseases. The symptoms of respiratory diseases caused by adenovirus are like common cold symptoms in the early stages of pneumonia, laryngitis, and bronchitis. Patients with immune dysfunction are particularly susceptible to severe complications of adenovirus infection. Adenovirus is transmitted through direct contact, fecal oral route, and occasional water transmission. Some types can lead to long-term asymptomatic tonsils, tonsil hypertrophy, and intestinal infections, which can last for several months or years.
Human metapneumovirus (HMPV) can cause upper and lower respiratory disease in people of all ages, especially among young children, older adults, and people with weakened immune systems. Discovered in 2001, HMPV is in the Pneumoviridae family. Symptoms commonly associated with HMPV include cough, fever, nasal congestion, and shortness of breath. Clinical symptoms of HMPV infection may progress to bronchitis or pneumonia and are similar to other viruses that cause upper and lower respiratory infections. The estimated incubation period is 3 to 6 days, and the median duration of illness can vary depending upon severity but is similar to other respiratory infections caused by viruses.

PRINCIPLE

The SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit is qualitatively detected in population Nasopharyngeal swab, Oropharyngeal swab and Nasal swab samples by the colloidal gold method. After sample added, the SARS-CoV-2 Antigen (or Influenza A/B & RSV & ADV & HMPV) in the sample to be tested is combined with the SARS-CoV-2 (or Influenza A/B & RSV & ADV & HMPV) antibody labelled with colloidal gold on the binding pad to form the SARS-CoV-2 Antigen (or Influenza A/B & RSV & ADV & HMPV) antibody-colloidal gold complex. Due to chromatography, the SARS-CoV-2 Antigen (or Influenza A/B & RSV & ADV & HMPV)-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 & ADV & HMPV)-antibody complex binds to the antibody enclosed within the detection line area, showing a purple-red band. Colloidal gold labelled chicken IgY diffuses to the quality control line (C) region and is captured by sheep anti-chicken IgY antibody to form red bands. When the reaction is over, the results can be interpreted by visual observation.

KIT COMPONENTS

Components	Major Components
Test Card (including the desiccant)	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 (or Influenza A/B, RSV, ADV, HMPV) antibody, combined with SARS-CoV-2 (or Influenza A/B, RSV, ADV, HMPV) antibody coated with colloidal gold. Other components include polyester film and absorbent paper.
Extraction Buffer with Integrated Extraction Tube	0.6mL/tube.
Sterile swab	/
Package Insert	/
Tube holder	The tube holder of 1 test is on the color box.
Positive Control (optional)	SARS-CoV-2 (or Influenza A/B, RSV, ADV, HMPV) antigen positive control solution prepared from synthetic SARS-CoV-2 (or Influenza A/B, RSV, ADV, HMPV) protein.
Negative Control (optional)	Negative control solution, prepared from sample treatment solution.

NOTE: Accessories required but not provided: **Timer.**

PRECAUTIONS

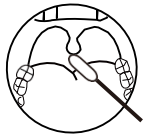
Please read all the information in this package insert before performing the test.
1) For professional in vitro diagnostic use only. Do not use after the expiration date.
2) The test should remain in the sealed pouch until ready to use.
3) Once the test card pouch is opened, the test should be performed within 1 hour.
4) 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 cannot be mixed.
5) All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
6) The used test should be discarded according to local regulations.
7) Avoid using bloody samples.
8) Wear gloves when handling the samples, avoid touching the reagent membrane and sample well.

STORAGE AND STABILITY

Store in 2-30℃ environment, the validity period sees aluminum foil bag. The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.

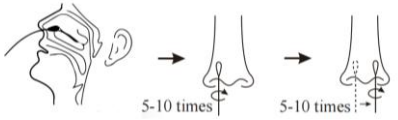
SAMPLE COLLECTION

1. Oropharyngeal swab collection method:
1) Tip the patient's head slightly.
2) Instruct the patient to open mouth as wide as possibly to reveal the pharyngeal tonsils on either side.
3) Wipe the base of patient's tongue with swab.
4) Slightly rub the pharyngeal tonsils back and forth on both sides of the collected position at least 3 times.
5) Rub the posterior pharyngeal wall up and down at least 3 times.
6) Test the sample as soon as possible.



2 Nasopharyngeal swab collection method:
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).
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).
3) When the tip of the swab reaches the posterior wall of the nasopharyngeal cavity, gently rotate it several times. (at least 5 times, collect as much secretion as possible).
4) To prevent reflex coughing, stop for one minute.
5) Slowly withdraw the swab.
6) Test the sample as soon as possible.

3. Nasal swab collection method:
1) Tilt patient's head back at a 70-degree angle.
2) Insert a sterile swab into one nostril until slight resistance is met (Approx. 2cm up the nose). Slowly rotate the swab, rubbing it along the inside of the nostril for 5-10 times against the nasal wall.
3) Gently withdraw the swab. Using the same swab, repeat step 2 with the other nostril. Then, gently withdraw the swab.

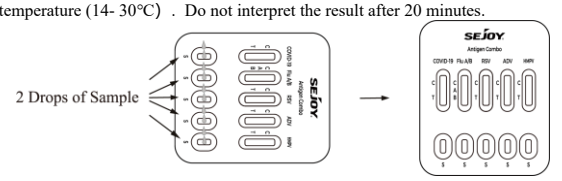


SAMPLE TREATMENT

Swab samples/Positive Control/Negative Control:
1. Place the swab sample in the tube, dip the swab in the solution and rotate it 10 times, then leave the swab in the tube for 1 minute.
2. Press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.

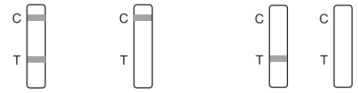
DIRECTIONS FOR USE

1. Before testing, read the operating instructions carefully, and restore the testing kit and samples to room temperature (14- 30℃) 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 65μL) of the treated sample solution into each of the five 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. Start the timer. Wait for the colored line(s) to appear. Read the result at 10 minutes in room temperature (14- 30℃) . Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

1. Result of SARS-CoV-2 Antigen



2. Result of Influenza A/B

3. Result of RSV

Positive Negative Invalid

4. Result of ADV

Positive Negative Invalid

5. Result of HMPV

Positive Negative Invalid

POSITIVE SARS-CoV-2/RSV/ADV/HMPV:*Two distinct colored lines appear in the window. One colored line should be in the control region (C) and another colored line should be in the test region (T). Positive result in the test region indicates detection of SARS-CoV-2/RSV/ADV/HMPV antigens in the sample.

POSITIVE Influenza A:*Two distinct colored lines appear in the window. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B: *Two distinct colored lines appear in the window. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B: *Three distinct colored lines appear in the window. One colored line should be in the control region (C) and two-colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

***NOTE:** The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen, Flu A and/or B antigen, RSV antigen, ADV antigen, HMPV antigen present in the sample. So any shade of color in the test region (T/A/B) should be considered positive.

NEGATIVE:One colored line appears in the control region (C). No apparent colored line appears in the test line region (T/A/B).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test Cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Positive control showed SARS-CoV-2 /Influenza A/ Influenza B /RSV/ADV/HMPV positive results, negative control showed SARS-CoV-2/Influenza A/Influenza B /RSV/ADV/HMPV negative results.

Target 1 SARS-CoV-2	Target 2 Influenza A	Target 3 Influenza B	Target 4 RSV	Target 5 ADV	Target 6 HMPV	Interpretation
Negative	Negative	Negative	Negative	Negative	Negative	No target Antigen detected
Positive	Positive	Positive	Positive	Positive	Positive	SARS-CoV-2 Antigen, Influenza A Antigen, Influenza B Antigen, RSV Antigen, ADV Antigen, HMPV 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. Thus, 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.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

The SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit has been evaluated with Nasopharyngeal swab, Oropharyngeal swab and Nasal swab samples obtained from the patients. PCR is used as the reference method for the SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit. Specimens were considered positive if PCR indicated a positive result. The comparative PCR tests were performed with Nasopharyngeal samples.

1. COVID-19 clinical study compare with RT-PCR

Product		PCR		Total Results
		Positive	Negative	
COVID-19	Positive	371	0	371
	Negative	11	300	311
Total Results		382	300	682

Relative Sensitivity :97.12%(95%CI*:94.92%-98.38%)
Relative Specificity:100.00%(95%CI*:98.74%-100.00%)
Accuracy:671/682*100%=98.39%(95%CI*:97.14%-99.10%)
*Confidence Intervals

2. Influenza A clinical study compare with RT-PCR

Product		PCR		Total Results
		Positive	Negative	
Influenza A	Positive	142	0	142
	Negative	5	282	287
Total Results		147	282	429

Relative Sensitivity :96.60%(95%CI*:92.29%-98.54%)
Relative Specificity:100.00%(95%CI*:98.66%-100.00%)
Accuracy:424/429*100%=98.83%(95%CI*:97.30%-99.50%)

3. Influenza B clinical study compare with RT-PCR

Product		PCR		Total Results
		Positive	Negative	
Influenza B	Positive	105	0	105
	Negative	3	321	324
Total Results		108	321	429

Relative Sensitivity :97.22%(95%CI*:92.15%-99.05%)
Relative Specificity:100.00%(95%CI*:98.82%-100.00%)
Accuracy:426/429*100%=99.30%(95%CI*:97.96%-99.76%)

4. RSV clinical study compare with RT-PCR

Product		PCR		Total Results
		Positive	Negative	
RSV	Positive	132	0	132
	Negative	3	299	302
Total Results		135	299	434

Relative Sensitivity :97.78%(95%CI*:93.67%-99.24%)
Relative Specificity:100.00%(95%CI*:98.73%-100.00%)
Accuracy:431/434*100%=99.31%(95%CI*:97.99%-99.76%)

5. ADV clinical study compare with RT-PCR

Product		PCR		Total Results
		Positive	Negative	
ADV	Positive	75	2	77
	Negative	0	228	228
Total Results		75	230	305

Relative Sensitivity :100.00%(95%CI*:95.13%-100.00%)
Relative Specificity:99.13%(95%CI*:96.89%-99.76%)
Accuracy:303/305*100%=99.34%(95%CI*:97.64%-99.82%)

6. HMPV clinical study compare with RT-PCR

Product		PCR		Total Results
		Positive	Negative	
HMPV	Positive	358	2	360
	Negative	11	928	939
Total Results		369	930	1299

Relative Sensitivity:97.02%(95%CI*:94.74%-98.33%)
Relative Specificity:99.78%(95%CI*:99.22%-99.94%)
Accuracy:1286/1299*100%=99.00%(95%CI*:98.30%-99.41%)

Limit of detection (LoD)

The LoD of the SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit is then confirmed by testing 20 replicates with concentrations at the tentative Limit of Detection. Based on this testing the LoD of the Sejoy SARS-CoV-2 Ag Test in nasal swab specimens is confirmed as:45 $TCID_{50}$/mL.

The LoD of the Influenza A is:

Reference code	Virus strains	LoD
S1	2009H1N1	$1.22\times10^4TCID_{50}$/mL
S2	Seasonal H1N1	$3.25\times10^4TCID_{50}$/mL
S5	Type A H3N2	$1.25\times10^3TCID_{50}$/mL

The LoD of the Influenza B is:

Reference code	Virus strains	LoD
S3	B/Victoria	$5.25\times10^3TCID_{50}$/mL
S4	B/Yamagata	$1.0\times10^4TCID_{50}$/mL

The LoD of the RSV is:

RSV type A is 1.1×10^4 $TCID_{50}$/mL, RSV type B is 1.5×10^4 $TCID_{50}$/mL.

The LoD of the ADV is:

Adeno virus 3 is 2.0×10^3PFU/mL, Adeno virus 7 is 2.5×10^2PFU/mL.

The LoD of the HMPV is:

Genotype A: 450$TCID_{50}$/mL
Genotype B: 300 $TCID_{50}$/mL

Precision:

Three consecutive batches of reagents were tested for precision. Different batches of reagents were used to test the same negative sample 10 times in succession, and the results were all negative, the negative coincidence rate is 100%. Different batches of reagents were used to test the same positive sample 10 times in succession, and the results were all positive, the positive coincidence rate is 100%.

Cross-reactivity:

Virus/bacteria listed below are confirmed not to have cross-reactivity with the SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit.

Name	Concentration
Epstein-Barr virus	10^5TCID_{50}/mL
Measles virus	10^5TCID_{50}/mL
Mumps virus	10^5TCID_{50}/mL
Mycoplasma pneumonia	10^6TCID_{50}/mL
Paraimfluenzavirus, type2	10^5TCID_{50}/mL
Influenza B Victoria STRAIN	10^5TCID_{50}/mL
Influenza B YSTRAIN	10^5TCID_{50}/mL
Influenza A H1N1 2009	10^5TCID_{50}/mL
Influenza A H3N2	10^5TCID_{50}/mL
H7N9	10^5TCID_{50}/mL
H5N1	10^5TCID_{50}/mL
Respiratory syncytial virus	10^5TCID_{50}/mL
Enterovirus CA16	10^5TCID_{50}/mL
SARS-Cov-1	10^5TCID_{50}/mL
MERS coronavirus	10^5TCID_{50}/mL
Human coronavirus NL63	10^5TCID_{50}/mL
Human coronavirus OC43	10^5TCID_{50}/mL
Human coronavirus 229E	10^5TCID_{50}/mL
CoV-NP HKU1	10^5TCID_{50}/mL
mycoplasma pneumoniae	10^9 CFU/mL
staphylococcus aureus	10^9 CFU/mL

Interference:

Substances listed below are confirmed not to have interference response with the SARS-CoV-2 & Influenza A/B & Respiratory Syncytial Virus & Adeno Virus & Human Metapneumovirus Antigen Combo Test Kit.

Name	Concentration
Whole Blood	4%
Ibuprofen	1mg/mL
tetracycline	3ug/mL
chloramphenicol	3ug/mL
Erythromycin	3ug/mL
Tobramycin	5%
menthol	15%
Mupirocin	10mg/mL

Oseltamivir	5mg/mL
Naphazoline Hydrochloride Nasal Drops	15%
Mucin	0.5%
Compound Benzoin Gel	1.5mg/mL
Cromolyn glycate	15%
Deoxyepinephrine hydrochloride	15%
Afrin	15%
Fluticasone propionate spray	15%

INDEX OF SYMBOLS

	Consult Instruction for use		Tests per kit		Caution
IVD	For in vitro diagnostic use only		Use by date		Do not reuse
2°C 30°C	Store between 2-30℃	LOT	Lot Number	REF	Catalogue number
	Manufacturer		keep dry		Keep away from sunlight
	Do not use if package is damaged		Date of manufacturer	EU REP	European Union Authorized representative

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Tel: +34951214054
Fax: +34952330100
Email: info@cmcmedicaldevices.com

Swab information

Accessory	Manufacturer	EC Representative	CE-Mark
Swab A	Hangzhou Yiguoren Biotechnology Co., Ltd Room 402, Building 2, No.2628, Yuhangtang Road, Cangqian Street, Yuhang District, Hangzhou City, Zhejiang, People' s Republic of China	Zoustech S.L. Paseo de la Castellana, 141 28049 Madrid	CE 0197
Swab B	Jiangsu Changfeng Medical Industry Co., Ltd. Tougiao Town, Guangling District, Yangzhou, 225109 Jiangsu, P.R. China	LIins Service & Consulting GmbH Obere Seegasse 34/2, 69124 Heidelberg, Germany	CE 0197
Swab C	Jiangsu Rongye Technology Co., Ltd. Tougiao Town, Yangzhou City, 225109, Jiangsu, P.R. China	Riomavix S.L. Calle de Almansa 55, 1D, Madrid 28039 Spain	CE 0197