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SensingSelf S4 Multiplex Covid-19 /MERS-CoV/ Influenza A/B Rapid Antigens Test Kit (Saliva/Sputum/Stool)

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Coronavirus Method De... SensingSelfMission 1 more workspace

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We use this protocol and it's working

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Disclaimer

Abstract

Summary:
The S4 Multiplex Covid-19 /MERS-CoV/ Influenza A/B Rapid Antigens Test Kit developed by Sensing Self Pte. Ltd. can quickly and qualitatively detect Novel Coronavirus / Influenza A/ Influenza B /MERS in human saliva/sputum/stool samples. It can be used as an aid for COVID-19 diagnosis. It provides an aid in the diagnosis of infection by the above viruses.

Objective:
According to the clinical trial plan, the S4 Multiplex Covid-19 /MERS-CoV/ Influenza A/B Rapid Antigen test kit or "test reagent", is to test saliva/sputum/stool samples from healthy subjects and confirmed patients with infections caused by these viruses. Test results are compared with another commercial Covid-19 /MERS-CoV/ Influenza A/B nucleic acid detection kit, which is defined as the "gold standard". The sensitivity, specificity, and total agreement rate are used to evaluate the feasibility of the test reagent in clinical applications.

Method:
A collection of clinical samples were examined by the S4 Multplex Covid-19 /MERS-CoV/ Influenza A/B Rapid Antigen test kit and the gold standard SARS-COV-2/MERS-CoV/ Influenza A/B nucleic acid detection kit in parallel, to calculate the clinical sensitivity, clinical specificity and total agreement rate of the test reagent.

Results:

For SARS-CoV-2, compared to the gold standard:
In **Saliva,** the clinical sensitivity of test reagent reached 88.3%, the clinical specificity reached 100.0%
In **Sputum,** the clinical sensitivity of test reagent reached 93.3%, the clinical specificity reached 100.0%
In **Stool,** the clinical sensitivity of test reagent reached 93.3%, the clinical specificity reached 100.0%

For MERS, compared to the gold standard:
In **Saliva,** the clinical sensitivity of test reagent reached 86%, the clinical specificity reached 100.0%
In **Sputum,** the clinical sensitivity of test reagent reached 90%, the clinical specificity reached 100.0%
In **Stool,** the clinical sensitivity of test reagent reached 90%, the clinical specificity reached 100.0%

For Influenza Virus A, compared to the gold standard:
In **Saliva,** the clinical sensitivity of test reagent reached 85.7%, the clinical specificity reached 98.3%
In **Sputum,** the clinical sensitivity of test reagent reached 91.4%, the clinical specificity reached 100.0%
In **Stool,** the clinical sensitivity of test reagent reached 90%, the clinical specificity reached 100.0%

For Influenza Virus B, compared to the gold standard:
In **Saliva,** the clinical sensitivity of test reagent reached 82.9%, the clinical specificity reached 100.0%
In **Sputum,** the clinical sensitivity of test reagent reached 87.1%, the clinical specificity reached 96.7%
In **Stool,** the clinical sensitivity of test reagent reached 85.7%, the clinical specificity reached 98.3%

Conclusions:

The performance of test reagent has a high agreement rate with the gold standard, proving its good feasibility in diagnosing suspected Covid-19 /MERS-CoV/ Influenza A/B cases.

Guidelines

This product is suitable for the qualitative detection of Novel Coronavirus / Influenza A/ Influenza B /MERS Virus in Saliva/Sputum/Stool samples. It provides an aid in the diagnosis of infection with the above viruses.

Materials

Materials needed for sample collection:

1. Disposable paper cup

Materials needed for sample preparation:

1. Disposable sample extraction tube
2. Cotton swab

Materials needed for performing the test procedure:

1. Disposable test card

Chemical Characterization: Substances List of ingredients:

1. PVC sheet

	Component	CAS #	% W/V
	PVC	9002-86-2	≤100 %
	Acrylic (Acrylate)	7910-7	<1%

2. Nitrocellulose membrane coated with a control line and a test line

	Component	CAS #	% W/V
	Nitrocellulose	9004-70-0	≤100 %
	Antibody	N/A	<3%
	Disodium hydrogen phosphate	10039-32-4	<0.5 %
	Sodium dihydrogen phosphate	13472-35-0	<0.1 %
	NaCl	7647-14-5	<1%

	Water	7732-18-5	> 95%

3. Absorbent Paper

	Component	CAS #	% W/V
	Cellulose microcrystalline	113669-95-7	≤100%

4. Fibreglass membrane

	Component	CAS #	% W/V
	Fiberglass	65997-17-3	≤100 %

5. Desiccant

	Component	CAS #	% W/V
	Silica gel	112945-52-5	≤100 %

6. Foil pouch and label

	Component	CAS #
	Poly(Ethylene Terephthalate)	25038-59-9
	Aluminium	7429-90-5
	Polypropylene	N/A

7. Reagent Solution / Buffer:

	Component	CAS #	Concentration
	NaCl	7647-14-5	136 mM
	Na2HPO4	7758-79-4	8m M
	KH2PO4	7778-77-0	2m M
	KCl	7447-40-7	2.6 mM
	Water	7732-18-5	> 95%

The test unit does not contain any human source material.

Troubleshooting

Safety warnings

1. S4 Multiplex Covid-19 / Influenza A/ Influenza B /MERS Rapid Antigen Test Kit (Latex Method) only suitable for testing saliva, sputum and stool samples. In whole blood, serum, plasma, urine and other samples or solutions, abnormal results may be detected.
2. Please ensure that the appropriate amount (3 drops) of the sample is used for testing. Too much or too little sample size may lead to deviations in the results.
3. 10-15 minutes after the completion of the sample is the effective reading time, more than 20 minutes will not be regarded as a valid reading.
4. This test reagent is a one-time item, please use it within the validity period. The used test reagents and samples and other wastes should be disposed of in accordance with relevant national regulations.
5. If the test strip in the reagent is partially out of the detection window, do not use it, otherwise the test result will be invalid and another reagent must be used
6. The test card is a disposable product. Please dispose of properly after use.
7. This test device is disposable, please use within the validity period. After use, the test reagent, sample and other waste should be treated in accordance with the relevant national regulations.

Before start

1. Store as packaged in the hermetic bag at the specified temperature (2 °C - 30 °C or 38 °F - 85 °F) and avoid direct sunshine. The kit is stable within the expiration date printed on the labelling.

2. Once the hermetic bag is opened, the test should be used within one hour. Prolonged exposure to a hot and humid environment will cause product deterioration.

3. Check the lot number and expiration date printed on the labelling.

While collecting sputum is significantly easier than swabs, sputum samples can be difficult to work with. It is important to follow the sample collection guidelines to ensure that sputum, not saliva, is being collected.

SALIVA SAMPLE COLLECTION

1 Saliva should be collected with the assistance of a healthcare worker or technician.

2 Before collection, clean hands using alcohol-based sanitizer or soap and water (no fragrances) and wear appropriate PPE (at minimum, gloves and a mask).

3 While preparing collection materials, direct the sample provider to begin pooling saliva in their mouth. Saliva production can be stimulated by thinking about food (favorite foods, upcoming meals, etc.) or about the saliva collection itself.

Note

This protocol is intended for the collection of the normal saliva that naturally pools into the mouth. No coughing or sniffing prior to sample collection is required.
Ideally, water should be avoided 10 minutes prior to collection. Other drinks, food, and nasal sprays should be avoided for half an hour before sample collection.

4 Once you have pooled saliva in your mouth, gently expel saliva into the disposable paper cup.

SPUTUM SAMPLE COLLECTION

5 Educate the patient about the difference between sputum and oral secretions (saliva).

6 Rinse the mouth with clean water. This is important to make sure there won't be mouth bacteria in the sputum collected.

7 Put one hand over the mouth with a tissue and put the other hand on your stomach.

8 Cough deeply, so that you can really feel it in your stomach. Do not take shallow coughs from the throat or chest.

Note

If you are having trouble-

1. Get a pat- ask somebody to pat you solidly up and down your back to help you release the sputum.

2. Stretch and try again- sometimes it helps to relax a bit. When you are ready, rinse and spit and try again.

9 Once the sputum (phlegm) is in your mouth, release it into the disposable paper cup.

STOOL SAMPLE COLLECTION

10 Use disposable gloves while handling a stool sample. Stools can contain material that spreads infection.

11 Do not collect the stool from the toilet. The stool must not have any contact with urine.

Note

1. To ensure the stool does not come in contact with urine, pass urine before collecting the stool specimen.

2. To ensure that the stool does not come in contact with the toilet bowl or water, loosely drape a long section of plastic wrap over the rim on both sides of the toilet bowl creating a “pocket” in the centre.

12 With the help of a disposable sample extraction tube collect the required quantity of stool sample for further steps.

TEST PROCEDURE

13 Allow the test device and specimens to equilibrate to temperature (15 °C - 30 °C or 59 °F - 86 °F) prior to testing.

14 Stool Sample: Unscrew the sampling bottle, use the sampling rod to pick up [M] 10 mg to [M] 50 mg of fresh stool samples (equivalent to the size of a match head) ; or swab the stool with a cotton swab.

Sputum Sample: Unscrew the sampling bottle, use the sampling rod or a cotton swab to pick up [M] 10 mg to [M] 50 mg of fresh sputum samples.

15 Put the sample collected into the tube and shake and mix completely.

16 Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add [M] 3 Drops of the sample into the sample hole vertically.

17 Wait for the appearance of the red stripe on T line, read the result in 00:15:00 minutes, and judge it invalid after 00:20:00 minutes.

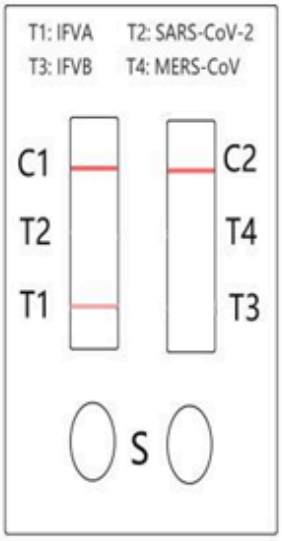
18 Take the test card from the packaging bag, place it on a table, cut off the protrusion of the collection tube, and add 150 µL (approximately 3 drops) of the sample into the sample hole vertically.

INTERPRETATION OF RESULTS

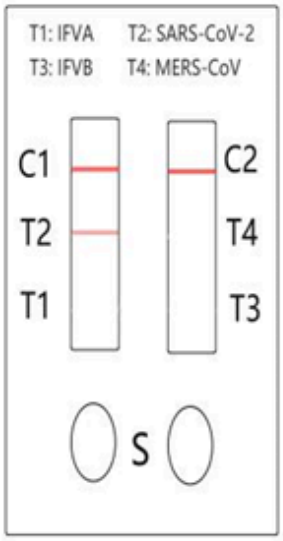
19 Positive (+): Both of T and C lines appear in 00:03:00 to 00:15:00 minutes.

Negative (-): C-line appears while no T line appears in 00:15:00 minutes after the sample added.

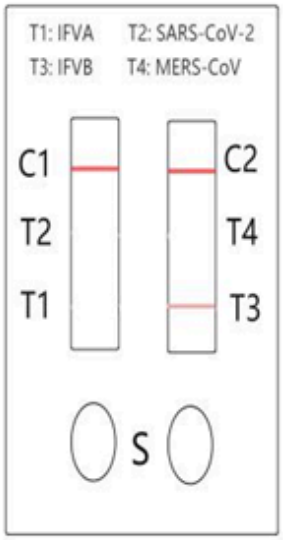
Invalid: As long as the C-line does not appear, it indicates that the test result is invalid, and should retest with another test card.



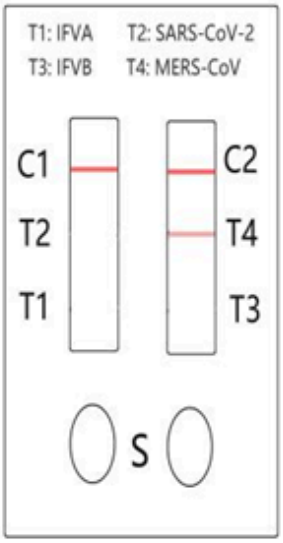
IFVA: Positive



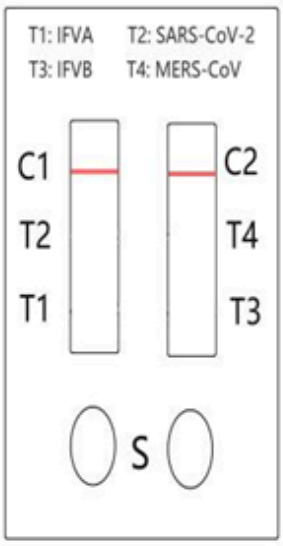
SARS-CoV-2: Positive



IFVB: Positive



MERS-CoV: Positive



All Negative

If C line is not appeared,

It is an invalid card