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Dearsens Covid Self Test Kit DS0125
2019-nCoV Antigen Rapid Test Cassette

Saliva

For self-testing use only

NOTES BEFORE TESTING

1.The 2019-nCoV Antigen Rapid Test Cassette is used for the qualitative in vitro detection of SARS-CoV-2 antigen in human saliva. The test can be used as screening assay, also for individuals who are suspected of COVID-19 and symptomatic individuals.

2. This test is suitable for people of all ages. The recommended operators are aging from 14 to 90. Children under 14 years of age and illiterate persons should be tested by an adult supervisor. Infection with the SARS-CoV-2 may lead to death and serious complications

3. If the test result is positive:
- There is currently a suspicion of a COVID-19 infection.
- Contact your doctor / general practitioner or the local health department immediately. You need to self-report your result to MySejahtera through the link below: https://mysejahtera.malaysia.gov.my/help_en/selfReport/
- Please follow local guidelines for self-isolation.
- Follow-up diagnostic procedure in accordance with local requirements will be required to confirm infection.

4. If the test result is negative:
- Continue to comply with all applicable rules regarding contact with others and protective measures.
- There may be an infection even if the test is negative.
-If you have symptoms similar to COVID-19 infection, repeat the test after 1 - 2 days, as the SARS-CoV-2 cannot be precisely detected in all phases of an infection.

5. If the test result is invalid:
- Possibly caused by incorrect test execution.
- Repeat the test.
- If the test results remain invalid, contact your doctor or COVID-19 test center.

6. Suggest conducting the test in separate area to avoid potential infection spreading. Please read the instructions carefully and follow the testing steps, otherwise may cause the incorrect results. Please wash your hands with soap for minimum 20 seconds before open the test cassette.

7. Please do not use any nasal spray prior the testing.If you have a nosebleed during or immediately after the test, or if you feel pain due to sample collection, please contact your doctor.

8. The test kit can be disposed of with normal household waste in compliance with the applicable local regulations.

Content of The Test Kit:

Specification / Components	1 Test / Kit
Test Cassette	1
Biohazard disposal bag	1
Manual	1

Notes:

Material required but not provided: Timer.

Do not use the components from different kits

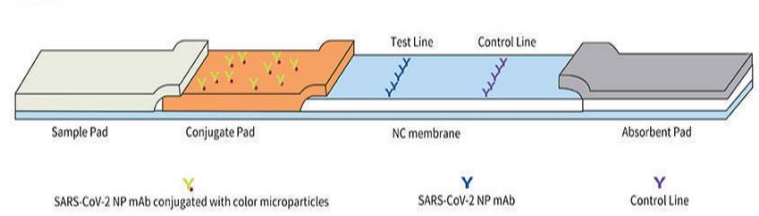
GENERAL INFORMATION

COVID-19 is an acute respiratory infection. SARS-CoV-2 belongs to the β genus of coronaviruses. People diagnosed with COVID-19 are the main source of infection. According to current epidemiological studies, the incubation period is 1 to 14 days, usually 3 to 7 days. The main symptoms are fever, fatigue and dry cough. In some cases, nasal congestion, runny nose, sore throat, muscle pain, and diarrhea may occur. During the acutely detectable stage of infection, antigens are usually present in upper respiratory tract samples. Infection with SARS-CoV-2 can lead to hospitalization, serious complications and even death.

TEST PRINCIPLE:

2019-nCoV Antigen Rapid Test Cassette is based on the specific antibody-antigen reaction and immunoanalytical technology to detect SARS-CoV2 antigen from saliva specimens. During testing, a specimen migrates upward by capillary action. The SARS-CoV-2 antigens if present in the specimen will bind to the antibody conjugates. The immune complex is then captured on the

membrane by the pre-coated SARS-CoV-2 nucleocapsid protein monoclonal antibody, and a visible colored line will show up in the test line region indicating a positive result. In the absence of SARS-CoV-2 antigens, a colored line will not form in the test line region indicating a negative result.



The COVID-19 Antigen Rapid Test (Saliva) is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. A colored test line (T) would be visible in the result window, if SARS-CoV-2 antigens are present in the specimen. Absence of the T line suggests a negative result.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane siphoning has occurred. The SARS-CoV-2 N protein is frequently used in vaccine development and serological assays. The N protein is the most abundant viral structural protein in the process of SARS-COV-2 infection. After the virus infects human cells, it will be expressed in large quantities and cause a strong immune response. The gene sequence of the N protein is relatively conservative and stable, and has about 90% homology with the SARS-CoV N protein, which is the closest in the lineage.

Compared with the S protein, the N protein has fewer mutations over time. Because of its good immunogenicity and stability, N protein is often used as a detection target for SARS-COV-2. If the epitope region of the virus recognized by the SARS-CoV-2 monoclonal antibody has amino acid mutations, false negative results may occur.

STORAGE CONDITIONS AND SHELF LIFE:

Storage conditions and expiration date: The kit should be stored at 2-30℃, and is valid for 12 months. Once open the pouch, the test should be used within 30min. Don't freeze the Test Cassette, Unopened Test Cassette are stable until the expiration date printed on the product label when stored at 2–30°C.

TEST PROCEDURE

This test is suitable for people of all ages. The recommended operators are aging from 14 to 90. Children under 14 years of age and illiterate persons should be tested by an adult supervisor.

1. Applicable samples: Do not put anything in your mouth, including food, drink, gum or tobacco products, etc. at least 30 minutes before collection. Remove the blue cover led from the cassette.

Reference 1.1

2. Put the absorbent tip of the cassette into the mouth.

All the absorbent tip is pressed under the tongue for 2 minutes.

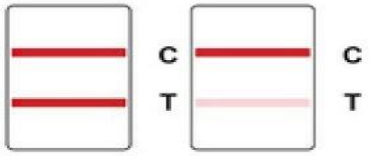
Reference 2.1

3. Take out the absorbent tip from the mouth and close by blue cover led.

Reference 3.1

4. Wait for colored lines to appear. Interpret the test results at 15 minutes.

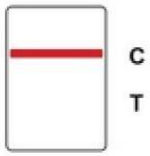
Reference 4.1



Positive

Positive (+): Red bands appear at both of T and C line in 15 to 20 minutes. A white band at the T line should be considered as a negative result.

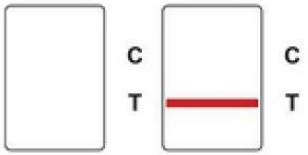
There is currently a suspicion of a COVID-19 infection. You are therefore encouraged to:
To contact a doctor/general practitioner or the local health department immediately. You need to self-report your result to MySejahtera https://mysejahtera.malaysia.gov.my/help_en/selfReport/
• Comply with local guidelines for self-isolation.
• Have a PCR confirmatory test performed.



Negative (-): A red band appears at C line while no red band appears at T line in 15 to 20 minutes after sample loading.

Negative

A negative result cannot completely exclude the possibility of viral infection. You are therefore encouraged to:
• Continue to comply with all applicable rules regarding contact with others and protective measures.
• An infection may also be present if the test is negative.
• In case of suspicion, repeat the test after 1 - 2 days because the coronavirus is not present in all phases of an infection can be precisely detected.



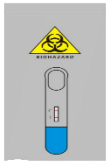
Invalid: If no red band appears at C line, it indicates that the test result is invalid. Retest with another test card.

Invalid

If the test result is invalid:
• Possibly caused by incorrect test execution.
• Repeat the test.
• If the test results are still invalid, contact a doctor or a COVID-19 test center.

5. Use a household bleach spray, or a 70% - 75% alcohol spray to disinfect used product components.

6. Put used product components in the plastic bag provided with the kit. Close the bag and put it in another plastic bag. Dispose of the bag with household garbage.



Reference 6.1

7. Wash the hands thoroughly.

Reference 7.1

Audio visual presentation link： https://youtu.be/0amB10bI4ok

LIMITATIONS：

1. The SARS-CoV-2 Antigen Rapid Test Cassette is limited to provide a qualitative detection and used to aid diagnosis.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. This test does not determine the etiology of the respiratory infection caused by micro-organisms other than the SARS-CoV-2.
4. This test can detect both the viable and the non-viable SARS-CoV-2. The accuracy of the test depends on the quality of the saliva sample-false negative results may be given following poor sampling.
5. Any failure to respect the test procedure may negatively impact the performance of the test and/or invalidate the test result.
6. If the result of the test is negative, yet clinical symptoms persist, it is advised that you carry out additional tests using other clinical methods. A negative result at no time rules out the presence of antigens of the SARS-CoV-2 in the sample, as they may be present but at a level inferior to the minimum detection level of the test, or if the sample has been collected incorrectly.
7. A negative result does not rule out infection by the SARS-CoV-2, particularly in people who have infect the virus. Follow-up tests according to local regulations should be scheduled to rule out infection in these people. Persons who show symptoms of the disease but have a negative result until infection is ruled out should follow country-specific restrictions.
8. This test is not a substitute for a medical consultation, or for the result of a biological analysis carried out in a medical analysis laboratory.
9. Positive test results do not exclude the possibility of co-infections of other pathogens.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity (Limit of Detection)：

Note：Limit of detection is the lowest amount of SARS-CoV-2 antigen which can be detected by the test.

The limit of detection was determined with a quantified SARS-CoV-2 virus and has been evaluated at 2 × 102 TCID50/mL (the concentration of SARS-CoV-2 in the saliva sample).

The limit of detection was also determined with recombinant SARS-CoV-2 nucleoprotein and has been evaluated at 50 pg/mL(concentration of synthetic antigen).

2. Analytical specificity

a) Cross-reactivity

There is no cross-reaction with other pathogens including bacteria and viruses which can cause similar symptoms and be present in respiratory tract or natural physiological microbiological flora etc. Such as endemic human coronavirus (HKU1, OC43, NL63 and 229E); H1N1 (new H1N1 influenza virus (2009), seasonal H1N1 influenza virus), H3N2, influenza B (Yamagata, Victoria), Respiratory syncytial virus A and B, Parainfluenza virus (type 1, 2, 3), Rhinovirus, Adenovirus (Type 3, 7), Enterovirus, hMPV, EBV, Measles virus, CMV, Mumps virus, Varicella zoster virus; Mycoplasma pneumoniae, Chlamydia pneumoniae; Legionella, Pertussis, Hemophilus influenzae, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes, Klebsiella pneumoniae; Aspergillus fumigatus, Candida albicans, Candida glabrata, Cryptococcus neoformans, etc.

b）Interfering substances:

There is no significant effect on the test results for verification of 7.5% blood, mucin (≤1.35mg/mL), and external or internal use of common drugs for patients with colds and other respiratory symptoms such as phenserine, oxymetazoline, sodium chloride (with preservatives), beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, fluticasone, histamine hydrochloride, alpha -Interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, arborol, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin were verified, there was no significant impact on the results.

3. Clinical Evaluation:

The clinical performance of the 2019-nCoV Antigen Rapid Test Cassette was determined by testing 120 positive and 400 negative samples for SARS-CoV-2 antigen with a sensitivity of 90.54% and a specificity of 100% determined by saliva clinical specimens were determined to be positive or negative using an RTPCR reference method.

Note:

a) Sensitivity：95.83%（115/120）,95%CI（90.54%，98.63%）;

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b) Specificity：98.50%（394/400）,95%CI（96.76%，99.45%）;

c) Total coincidence rate: 97.88%（509/520）,95%CI（96.25%，98.94%）

4. Minimum detection limit: When the virus content is greater than 600TCID50/ml, the positive detection rate is greater than 95%. When the virus content is less than 300TCID50/ml, the positive detection rate is less than 95%, so the minimum detection limit of this product is 600TCID50/ml.

5. HOOK effect: When the virus content in the sample to be tested reaches 4.0*10 5TCID50/ml, the test result still does does not show the HOOK effect.

PRECAUTIONS：

1. For in vitro diagnostic use only, please read this instruction for use carefully before testing. Please use the kit within the expiration date.
2. This kit does not contain active human derived substances.
3. This is a single-use in vitro diagnostic reagent, do not reuse.
4. Operators should operate in strict accordance with the instructions.
5. Do not use the product if the pouch is damaged or the seal is broken. Please open the sealed aluminum foil bag before use, and use it as soon as possible after opening the aluminum foil bag.
6. Operate at room temperature. Test cards kept at low temperature should be restored to room temperature before opening to avoid moisture absorption.
7. The aluminum foil bag contains desiccant and must not be taken orally.
8. If the initial test is a positive sample, contact your local public health agency.
9. Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.
10. When using the extraction reagent, prevent it from entering the eyes or swallowing.
11. If you get a positive result, please contact your family doctor, or seek help from a professional medical facility as soon as possible. You need a nucleic acid test to confirm viral infection.
12. A negative result cannot completely exclude the possibility of viral infection. Incorrect sampling or low viral load may also cause a false negative result.
13. If your nose is injured by sampling, please seek medical attention.
14. When the test is completed, please disinfect the test cards, and other used components with a household bleach spray or a 70%-75% alcohol spray.
15. Wrap the disinfected items and discard them in accordance with local regulations.
16. Wash the hands thoroughly after the test.

INSTRUCTION OF SYMBOLS

【Interpretation of the Logo】

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

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