CE IVD

SARS-CoV-2 Antigen Rapid Test Cassette

Instruction for Use For Private Use

(Self-testing)

Package Information

REF CP01750011

Components	1 T
Test Cassette	×1
Sample extraction solution	×1
Disposable sampling swab CE 0197 93/42/EEC	×1
Biohazard Specimen Bag	×1

REF CP01760011

Components	20 T
Test Cassette	×20
Sample extraction solution	×20
Disposable sampling swab CE 0197 93/42/EEC	×20
Biohazard Specimen Bag	×20

REF CP01770011

Components	50 T
Test Cassette	×50
Sample extraction solution	×50
Disposable sampling swab CE 0197 93/42/EEC	×50
Biohazard Specimen Bag	×50

REF CP01800011

Components	1 T
Test Cassette	×1
Sample extraction solution	×1
Specimen Collection Swab Model N150 CE REGULATION (EU) 2017/745	×1
Biohazard Specimen Bag	×1

REF CP01810011

Components	20 T
Test Cassette	×20
Sample extraction solution	×20
Specimen Collection Swab Model N150 CE REGULATION (EU) 2017/745	×20
Biohazard Specimen Bag	×20

REF CP01820011

Components	50 T
Test Cassette	×50
Sample extraction solution	×50
Specimen Collection Swab Model N150 CE REGULATION (EU) 2017/745	×50
Biohazard Specimen Bag	×50

Specification

1 Test Cassette/Kit, 20 Test Cassettes/Kit, 50 Test Cassettes/Kit.

Test Cassette

Rapid Test for Detection of SARS-CoV-2's Nucleocapsid protein in white plastic cassette packed in aluminum foil bag. For single use only.

Sample extraction solution

300 μL per test.

Others

-Instructions for use

Materials required but not provided

Clock

Intended Use

The cassette is used for qualitative detection of antigen of SARS-CoV-2 in human nasal swabs.

The cassette is intended for screening of patients suspected for infection with SARS-CoV-2, and as an aid in the diagnosis of the coronavirus disease (COVID-19).

For single use only.The test cassette can be used from the age of 18 years. Children and adolescents under the age of 18 may only use the test cassette under adult supervision.

Our test detected the nucleocapsid protein of SARS-CoV-2 and not the surface protein ("spike"). Therefore, the test also recognizes the British variant.

For self-testing.

Summary

COVID-19 is a respiratory disease caused by infection with SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breathing difficulties. In severe cases, infection can cause pneumonia, server acute respiratory syndrome (SARS), kidney failure and death.

Method

Gold Immunochromatographic Assay (GICA).

Principle

→ The Cassette is a one-step lateral flow chromatographic immunoassay. The test strip in the device includes: 1) a conjugate pad containing anti-SARS-CoV-2's Nucleocapsid protein antibody, Chicken IgY antibody, all of which are conjugated to colloidal gold, and 2) nitrocellulose membrane containing a test line (T line) and a control line (C line).

→ The T line is coated with anti-SARS-CoV-2's Nucleocapsid protein antibody, when the specimen is added, it migrates by capillary diffusion rehydrating the gold conjugate, if present in specimen, SARS-CoV-2's Nucleocapsid protein and its antibody labeled with colloidal gold formed antigen-antibody complexes. These complexes will continue to migrate along the strip until the T line, where they are captured by the anti-SARS-CoV-2's Nucleocapsid protein antibody generating a visible red violet line in T line. If the specimen does not contain SARS-CoV-2 or the SARS-CoV-2 level is below the lower level, the T line will not appear.

→ The C line is coated with Goat anti-chicken antibodies, which should bind to the gold-chicken IgY antibodies conjugate and form a red violet line regardless of the presence of SARS-CoV-2's Nucleocapsid protein.

Storage and validity

1. Sealed in aluminum foil bag at 2-30 ℃ .Valid for 24 months.
2. Protect from light and don't freeze.

Specimen transport and storage

Type: Nasal Swabs

1. The samples should be used as soon as possible after collected within 1 hour at room temperature (15-30°C).
2. After processing the swab in the extraction solution, the sample should be analyzed within 30 minutes.

Test procedure

Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.

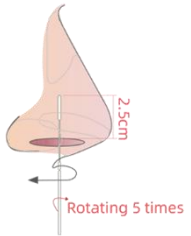
Preparation

1. Allow all cassette components and specimens to reach room temperature between 15°C~30°C prior to testing.
2. Remove the test cassette from the foil pouch and place on a clean dry surface.

Operation

1. Specimen collection: Carefully insert the swab into one nostril, the swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and

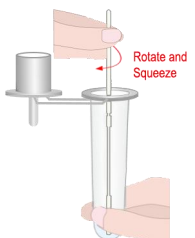
cells are collected. Using the same swab, repeat this process for the other nostril.



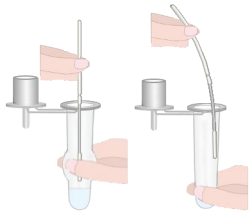
2.Carefully tear off the sealing paper on the mouth of the sample extraction liquid tube, being careful not to spill the liquid.

3. Withdraw the swab from the nasal cavity, completely immerse the swab head in the sample extraction buffer in the tube.

4. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) for about 1 minute



5. Squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the sample extraction solution.（Tips: Squeeze the swab head along the inner wall of the extraction tube）



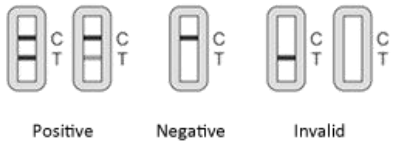
6.Cover the drip head to mix the liquid thoroughly

7. Dispense 3 drops（80μL）of the specimen into the circular sample well on the cassette. Interpret the test results at 15~20 minutes. （Tips: Do not interpret the results after 20 minutes.）

8.After the test is completed, place the test cassette / swab / solution in the Biohazard Specimen Bag and dispose all test kit materials via biohazard waste disposal protocol. Lastly wipe down all surfaces the kit came in contact with and wash your hands or use hand sanitizer

Interpretation of results

1. Positive: Both of T line and C line appear, as shown in the figure.
2. Negative: T line do not appear, while C line appear, as shown in the figure.
3. Invalid: If C line does not appear, the result is invalid whether the T line appear or not, as shown in the figure. Prepare another cassette and specimen to test again. Tips: please analysis the volume of sample addition.



What to do with a positive result?

- There is currently a suspicion of COVID-19 infection
- Immediately contact a doctor/family doctor or the local health authority
- Comply with local self-insulation guidelines
- to have a PCR confirmation test carried out

What should I do if the result is negative?

The rules that apply locally to contain the pandemic with regard to contact with other people and other protective measures continue to apply.
A COVID-19 infection can also be present if the rapid test result is negative.
In case of suspicion, a rapid test should be repeated after 1 to 2 days, as an infection cannot be reliably detected in all phases of the infection using the rapid test.

What should I do if the result is invalid?

An invalid test result can be caused by an incorrect test execution.
You should repeat the test.
If invalid test results continue to occur despite strict adherence to the instructions for use, you should contact a doctor or a COVID-19 test center and discuss how to proceed.

Benefit of the testing process

Rapid antigen tests (also referred to as point-of-care tests, POCT) can be carried out outside of the laboratory near the patient and faster than the PCR (polymerase chain reaction) in 15-30 minutes. Suitable SARS-CoV-2 POC antigen tests can therefore play a role in situations in which a quick result is important and in which the contagiousness (infectiousness) of people should be assessed promptly and on site. The use of rapid antigen tests is so intended to interrupt the contribute to transmission through targeted isolation of the infected and their close contacts.

Limitation of Test Methods

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only.

Judgement should be made along with RT-PCR results, clinical symptoms, epidemiological information and further clinical data.

2. The contents of this cassette are to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab.
3. Sensitivity of the test after the first seven days of the onset of symptoms has been demonstrated to decrease as compared to a RT-PCR SARS-CoV-2 assay.
4. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.
5. The Sample buffer and test cassette must be equilibrated to room temperature (15℃~30℃) before used, otherwise the results may be incorrect.
6. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly.
7. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
8. React less than 15 minutes may lead a false negative result; React more than 20 minutes may lead a false positive result.
9. Positive test results do not rule out co-infections with other pathogens.
10. Clinical performance was evaluated with frozen samples, and performance may be different with fresh samples.
11. Users should test specimens as quickly as possible after specimen collection.
12. After processing the swab in the extraction solution, the sample should be analyzed within 30 minutes.

Performance Data

1. Clinical validation

Sample type: nasal swab

The results have been summarized in the following tables:

Method		PCR		Total Results
SARS-Cov-2 Antigen Rapid Test	Results	Positive	Negative	
	Positive	125	1	126
	Negative	7	128	135
Total Results		132	129	261

Positive coincidence rate =94.70%, (95% CI: 89.46%-97.41%);
Negative coincidence rate =99.22%, (95% CI: 95.74%-99.86%);
Total coincidence rate =96.93%, (95% CI: 94.07%-98.44%)

2. Sensitivity

The sensitivity was tested with three reference materials. These reference materials differed in their concentration of inactivated SARS-CoV-2 virus culture. The concentrations of the reference material used were:

S1 = 0.8 × 10^2 $TCID_{50}$ / mL
S2 = 1.6 × 10^2 $TCID_{50}$ / mL
S3 = 3.2 × 10^2 $TCID_{50}$ / mL

The S1 reference material gave a negative test result.

The S2 and S3 reference material each produced a positive test result.

As a result, the minimum detection limit of the test cassette is 1.6 × 10^2 $TCID_{50}$ / mL

3. Precision

1 precise reference material from the manufacturer, consisting of inactivated SARS-CoV-2 virus culture and a defined concentration, was tested 10 times individually. The depth of color development of the test line (T) should be uniform and consistent, and the results should all be positive. A uniform, consistent color and a positive test result were achieved in each of the 10 tests.

The concentration of the reference material used was 4.8 × 10^2 $TCID_{50}$ / mL.

4. Cross-reactivity

Cross-reactivity of the cassette was evaluated. The results showed no cross reactivity with the following microorganism.

No.	Microorganism	Conc.	Cross reactivity (YES NO)
1	Human Coronavirus OC43	1×10^5 pfu/mL	NO
2	Human Coronavirus 229E	1×10^5 pfu/mL	NO
3	Human Coronavirus NL63	1×10^5 pfu/mL	NO
4	Influenza A H1N1 (2009)	1×10^5 pfu/mL	NO
5	MERS-coronavirus	1×10^5 pfu/mL	NO
6	SARS-coronavirus	1×10^5 pfu/mL	NO
7	Influenza A H3N2	1×10^5 pfu/mL	NO
8	Influenza B Yamagata	1×10^5 pfu/mL	NO
9	Influenza B Victoria	1×10^5 pfu/mL	NO
10	Respiratory syncytial virus A	1×10^5 pfu/mL	NO
11	Respiratory syncytial virus B	1×10^5 pfu/mL	NO
12	Adenoviridae 1	1×10^5 pfu/mL	NO
13	Adenoviridae 2	1×10^5 pfu/mL	NO
14	Adenoviridae 3	1×10^5 pfu/mL	NO
15	Adenoviridae 4	1×10^5 pfu/mL	NO
16	Adenoviridae 5	1×10^5 pfu/mL	NO
17	Adenoviridae 7	1×10^5 pfu/mL	NO
18	Adenoviridae 55	1×10^5 pfu/mL	NO
19	Enterovirus EV71	1×10^5 pfu/mL	NO
20	Enterovirus CA16	1×10^5 pfu/mL	NO
21	Enterovirus CA10	1×10^5 pfu/mL	NO
22	Enterovirus CB5	1×10^5 pfu/mL	NO
23	Enterovirus CA24	1×10^5 pfu/mL	NO
24	Enterovirus CB4	1×10^5 pfu/mL	NO
25	Enterovirus CB3	1×10^5 pfu/mL	NO
26	Enterovirus CB2	1×10^5 pfu/mL	NO
27	Enterovirus CB1	1×10^5 pfu/mL	NO
28	Enterovirus CA6	1×10^5 pfu/mL	NO
29	EB virus	1×10^5 pfu/mL	NO
30	Human cytomegalovirus	1×10^5 pfu/mL	NO
31	Human Rhinovirus A30	1×10^5 pfu/mL	NO
32	Human Rhinovirus A31	1×10^5 pfu/mL	NO
33	Human Rhinovirus A2	1×10^5 pfu/mL	NO
34	Human Rhinovirus A81	1×10^5 pfu/mL	NO
35	Human Rhinovirus B52	1×10^5 pfu/mL	NO
36	Human Rhinovirus B70	1×10^5 pfu/mL	NO
37	Human Rhinovirus B72	1×10^5 pfu/mL	NO
38	Metapneumovirus A2	1×10^5 pfu/mL	NO
39	Metapneumovirus Type B1	1×10^5 pfu/mL	NO
40	Metapneumovirus Type B2	1×10^5 pfu/mL	NO
41	Measles virus	1×10^5 pfu/mL	NO
42	Rubella virus	1×10^5 pfu/mL	NO
43	Mumps virus	1×10^5 pfu/mL	NO
44	Boca virus	1×10^5 pfu/mL	NO
45	Parainfluenza Virus 1	1×10^5 pfu/mL	NO
46	Parainfluenza Virus 2	1×10^5 pfu/mL	NO
47	Parainfluenza Virus 3	1×10^5 pfu/mL	NO
48	Parainfluenza Virus 4	1×10^5 pfu/mL	NO
49	Bordetella pertussis	1×10^6 cfu/mL	NO
50	Candida albicans	1×10^6 cfu/mL	NO
51	Legionella pneumophila	1×10^6 cfu/mL	NO
52	Haemophilus influenzae	1×10^6 cfu/mL	NO
53	Human Metapneumovirus	1×10^6 cfu/mL	NO
54	Streptococcus pneumoniae	1×10^6 cfu/mL	NO
55	Streptococcus pyogenes	1×10^6 cfu/mL	NO
56	Mycobacterium tuberculosis	1×10^6 cfu/mL	NO
57	Pneumocystis jirovecii (PJP)	1×10^6 cfu/mL	NO
58	Staphylococcus aureus	1×10^6 cfu/mL	NO
59	Staphylococcus epidermidis	1×10^6 cfu/mL	NO
60	Mycoplasma pneumoniae	1×10^6 cfu/mL	NO
61	Chlamydia pneumoniae	1×10^6 cfu/mL	NO

5. Interference Substances

The test results do not be interfered with the substance at the following concentration:

No.	Substances	Conc.
1	Ibuprofen	1mg/mL
2	Tetracycline	3μg/mL
3	Chloramphenicol	3μg/mL
4	Erythromycin	3μg/mL
5	Tobramycin	5%
6	Throat spray (Menthol)	15%
7	Mupirocin	10mg/mL
8	Throat lozenge (Menthol)	1.5mg/mL
9	Oseltamivir	5mg/mL
10	Naphthoxoline hydrochloride nasal	15%

	drops	
11	Mucin	0.50%
12	Fisherman's Friend	1.5mg/mL
13	Compound Benzocain Gel	1.5mg/mL
14	Cromoglycate	15%
15	Phenylephrine Hydrochloride	15%
16	Afrin (Oxymetazoline)	15%
17	Fluticasone propionate spray	15%
18	Whole Blood	4%

Precautions

→For in vitro diagnostic use only.
→ Do not use package when damaged, unclear label or even expired.
→The test shall be operated in strict accordance with the instructions.
→The results must be interpreted within 15 minutes.
→ The disposable cassette is referred to biological waste when used.(e.g. in a tear-resistant, sealed plastic bag in the residual waste)
→Dispose the cassette and components according to local guidelines.
→Ensure that the test is performed hygienically so as not to contaminate the swab, reagents or test cassette. This might lead to incorrect test results.
→Make sure that the test cassette or other components do not get wet. Otherwise, this may lead to incorrect results.
→ Avoid splashing specimen material. This can lead to contamination and, in the case of positive samples, to the risk of infection.
→Avoid splashing, ingestion, skin and mucous membrane and eye contact of/with buffer. This could lead to irritation. Wash your hands after using the extraction solution or rinse the affected parts of the body thoroughly with water if it comes into contact with the extraction solution. If symptoms persist, you should seek medical advice / assistance.
→ Do not touch the test window or sample window of the test cassette to avoid contamination and false results.
→ Do not mix buffer solutions or other components of different batches. This might lead to incorrect results.
→Do not mix patient samples. This might lead to incorrect results.

References

1.Chen Wei, Zhang Chunyang, Zhu Ying, Zhang Yanhua, You Libin, Wu Bingshan, Huang Zhimiao, Zheng Kuicheng, Weng Yuwei. Comparison of nucleic acid detection in pharyngeal swabs and sputum specimens in 4 cases of new coronavirus infection. Chinese Journal of Zoonoses 2020; 1-7 (in Chinese)
2.Guo Yuanyuan, Wang Kun, Zhang Yu, Zhang Wenjia, Wang Liying, Liao Yi. Comparison and analysis of detection performance of six domestic new coronavirus nucleic acid detection reagents. Chongqing Yixue 2020; 1-10 (in Chinese).

Merlin Biomedical (Xiamen) Co., Ltd.
Add: 4th Floor, Building B3,
2054 West Wengjiao Rd.,
Haicang, Xiamen, 361028, China
Tel: 86-592-5210772; 86-592-5210773
Fax: 86-592-5210772
Email: info@merlinbio.com.cn
Website: http://www.merlinbio.com.cn

EC REP **Qarad EC-REP BV**
Pas 257, 2440 Geel, Belgium

Distributor &Importer: **Arterial Global Sdn. Bhd. (894261-H)**
3-2, Jalan Ara SD 7/3B,
Bandar Sri Damansara,
52200 Kuala Lumpur, Malaysia
Tel/Fax: 03-6263-1491
Email: sales@arterialglobal.com.my

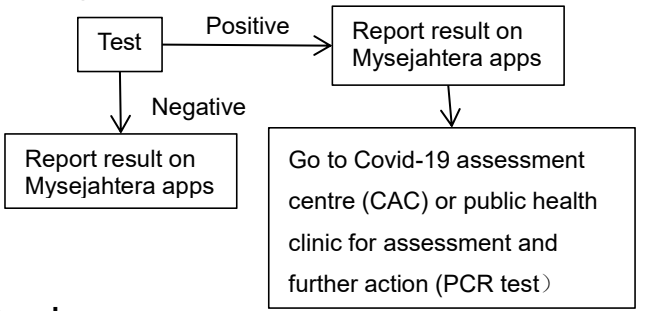
Instruction Approval and Revision Date

Approval Date: 12 Aug 2020 en-Self-testing
Revision Date: 02 Mar 2022 en-Self-testing
Date of Issue: 02 Mar 2022 en-Self-testing

Symbols

REF	Catalogue number
	Consult instructions for use
IVD	*In vitro* diagnostic medical device
	Manufacturer
	Temperature limit
LOT	Batch code
	Use-by date
	Keep dry
EC REP	Authorized representative in the European Community
	Don't use the product when the package is damaged
	Do not re-use
	Warning
	Contains sufficient for <n> tests
	Date of manufacture
STERILE EO	Sterilized using ethylene oxide
	Do not resterilize
	Avoid overexposure to the sun
Test Cassette	Test Cassette
Sample extraction solution	Sample extraction solution
Disposable sampling swab	Disposable sampling swab
Specimen Collection Swab	Specimen Collection Swab
Biohazard Specimen Bag	Biohazard Specimen Bag

Reporting COVID-19 Result Method



QR code

Please scan the QR code on the box for more details

Disposal Procedure

Throw all Test Cassette, Sample extraction solution, Tube, Dropper, swab into Biohazard Specimen Bag. Throw the Biohazard Specimen Bag and others general waste into general waste bin.

Note: All components of the kit: Discard as per the Guidelines for handling, Treatment and Disposal of waste Generated during Treatment/Diagnosis/Quarantine of COVID-19 patients issued by Local Regulatory Requirements or Regulatory Authorities.

EN

CE IVD

SARS-CoV-2 Antigen Rapid Test Cassette

Arahan untuk Kegunaan Persendirian

(Ujian-Kendiri)

Maklumat Pakej

REF CP01750011

Komponen	1 T
Kaset ujian	×1
Larutan Ekstraksi Sampel	×1
Swab sampel pakai-buang CE 0197 93/42/EEC	×1
Beg Spesimen Biohazard	×1

REF CP01760011

Komponen	20 T
Kaset ujian	×20
Larutan Ekstraksi Sampel	×20
Swab sampel pakai-buang CE 0197 93/42/EEC	×20
Beg Spesimen Biohazard	×20

REF CP01770011

Komponen	50 T
Kaset Ujian	×50
Larutan Ekstraksi Sampel	×50
Swab sampel pakai-buang CE 0197 93/42/EEC	×50
Beg Spesimen Biohazard	×50

REF CP01800011

Komponen	1 T
Kaset Ujian	×1
Larutan Ekstraksi Sampel	×1
Swab Pengambilan Spesimen Model N150 CE REGULATION (EU) 2017/745	×1
Beg Spesimen Biohazard	×1

REF CP01810011

Komponen	20 T
Kaset Ujian	×20
Larutan Ekstraksi Sampel	×20
Swab Pengumpulan Spesimen Model N150 CE REGULATION (EU) 2017/745	×20
Beg Spesimen Biohazard	×20

REF CP01820011

Komponen	50 T
Kaset Ujian	×50
Larutan Ekstraksi Sampel	×50
Swab Pengumpulan Spesimen Model N150 CE REGULATION (EU) 2017/745	×50
Beg Spesimen Biohazard	×50

Specifikasi

1 Kaset Ujian/Kit, 20 Kaset Ujian/Kit, 50 Kaset Ujian/Kit

Kaset Ujian

Rapid Test untuk mengesan protein nukleokapsid SARS-CoV-2's di dalam kaset plastik putih dibungkus di dalam beg aluminium. Untuk 1 kali guna sahaja.

Sampel Larutan Extraksi

300μL per test.

Lain-lain

Arahan Penggunaan

Bahan diperlukan tetapi tidak disediakan

Jam

Kegunaan

Kaset ini digunakan untuk mengesan secara kualitatif antigen SARS-CoV-2 di dalam swab hidung manusia.

Kaset ini digunakan untuk menyaring pesakit yang disyaki dijangkiti SARS-CoV-2, dan sebagai bantuan di dalam diagnosis penyakit coronavirus (COVID-19).

Untuk 1 kali guna sahaja. Kaset ujian boleh digunakan untuk pesakit berumur 18 tahun ke atas. Kanak-kanak dan remaja di bawah umur 18 tahun hanya boleh menggunakan kaset ujian ini di bawah pengawasan orang dewasa.

Ujian kami mengesan protein nukleokapsid SARS-CoV-2 dan bukan protein permukaan ("spike"). Maka, ujian ini dapat mengesan varian British. Untuk ujian kendiri.

Ringkasan

COVID-19 ialah sejenis penyakit respiratori yang disebabkan oleh jangkitan virus SARS-CoV-2. Tanda-tanda biasa jangkitan termasuk gejala pernafasan, demam, batuk, sesak nafas. Dalam kes-kes teruk, jangkitan boleh menyebabkan pneumonia, sindrom kesukaran pernafasan akut (SARS), kegagalan buah pinggang dan kematian.

Kaedah

Gold Immunochromatographic Assay (GICA).

Prinsip

-Kaset ini ialah satu imunoasai kromatografi aliran lateral selangkah. Jalur ujian di dalam alat ini termasuk: 1) satu pad konjugat mengandungi antibodi protein nukleokapsid anti-SARS-CoV-2's, antibodi Chicken IgY, yang semuanya dikonjugasikan ke koloid emas , dan 2) membran nitroselulosa mengandungi garis ujian (garis T) dan garis kawalan (Garis C).

-Garis T disaluti dengan antibodi protein anti-SARS-CoV-2's apabila spesimen ditambah, ia berpindah melalui difusi kapilari menghidrasi konjugat emas, sekiranya ada dalam spesimen, protein nukleokapsid anti-SARS-CoV-2's dan antibodinya dilabel dengan kompleks antibodi-antigen dalam bentuk koloid emas. Kompleks ini akan terus berpindah menerusi jalur sehingga garis T, di mana akan ditangkap oleh antibodi protein nukleokapsid anti-SARS-CoV-2's menghasilkan satu garisan merah ungu yang kelihatan di garis T. Sekiranya spesimen tidak mengandungi SARS-CoV-2 atau tahap SARS-CoV-2 di bawah tahap rendah, garis T tidak akan kelihatan.

-Garis C disaluti antibodi Goat anti-chicken yang bergabung dengan konjugat antibodi gold Chicken IgY dan membentuk garisan merah ungu, tidak kira samada protein SARS-CoV-2's Nucleocapsid ada atau tidak.

Penyimpanan dan tempoh sah

1. Di dalam beg aluminium bertutup ketat dan disimpan pada suhu 2-30 ºC. Sah sehingga 24 bulan.
2. Lindungi dari cahaya dan jangan dibekukan.

Pengendalian Spesimen dan Penyimpanan

Jenis: *Swabs* Hidung

1. Sampel harus digunakan secepat mungkin selepas diambil dalam masa 1 jam pada suhu bilik (15-30°C).
2. Selepas memproses swap dalam larutan ekstraksi, larutan mesti di analisa dalam masa 30 minit.

Prosedur Ujian

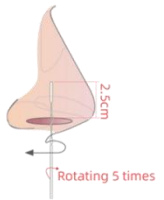
Jangan buka bungkusan sehingga anda bersedia untuk melakukan ujian, dan ujian sekali-guna ini harus digunakan di persekitaran lembab (RH≤70%) dalam masa 1 jam.

Persediaan

1. Tunggu sehingga semua komponen kaset dan spesimen berada pada suhu bilik antara 15°C~30°C sebelum melakukan ujian.
2. Keluarkan kaset ujian dari bungkusan dan letakkan di atas permukaan yang kering.

Operasi

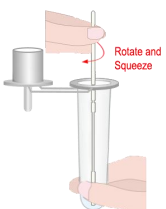
1. Pengumpulan spesimen: Berhati-hati masukkan swab ke dalam satu lubang hidung, hujung swab hendaklah dimasukkan sehingga 2.5 cm (1 inci) dari tepi lubang hidung. Gulungkan sapu 5 kali sepanjang mukosa di dalam lubang hidung untuk memastikan kedua-dua lendir dan sel terkumpul. Menggunakan swab yang sama, ulangi proses ini untuk lubang hidung yang satu lagi.



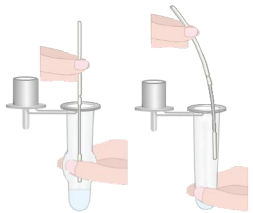
2. Berhati-hati mengoyakkan kertas pengedap pada mulut tiub cecair pengekstrakan sampel, berhati-hati agar tidak menumpahkan cecair.

3. Keluarkan swab dari rongga hidung, rendam sepenuhnya kepala swab dalam penimbal pengekstrakan sampel di dalam tiub.

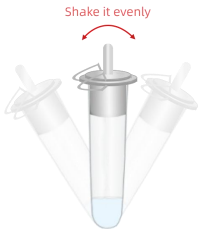
4. Campurkan larutan dengan kuat dengan memutarkan swab dengan kuat pada sisi tiub sekurang-kurangnya 10 kali (semasa terendam) selama kira-kira 1 minit.



5. Picit tiub 5 kali dengan tangan untuk memastikan sampel pada swab pensampelan dicairkan sepenuhnya ke dalam larutan pengekstrakan sampel.（Petua: Picit kepala swab di sepanjang dinding dalam tiub pengekstrakan）



6.Tutup kepala titisan untuk mencampurkan cecair dengan teliti



7.Tuangkan 3 titis（80μL）spesimen ke dalam telaga sampel bulat pada kaset. Tafsirkan keputusan ujian pada 15~20 minit. （Petua: Jangan tafsir keputusan selepas 20 minit.）

8. Selepas ujian selesai, letakkan kaset ujian / swab / larutan dalam Beg Spesimen Biohazard dan buang semua bahan kit ujian melalui protokol pelupusan sisa biohazard. Akhir sekali, lap semua permukaan yang terkena kit dan basuh tangan anda atau gunakan pembersih tangan

Interpretasi Keputusan

1. Positif: Kedua-dua garis T and C ada seperti tertera.
2. Negatif: Garis T tiada, Garis C ada , seperti tertera
3. Tidak Sah: Sekiranya garis C tiada, keputusan adalah tidak sah, tidak kira sama ada Garis T ada atau tidak, seperti tertera. Sediakan kaset lain dan lakukan ujian sekali lagi. Tip: Sila analisa isipadu sampel.

Positif **Negatif** **Tidak Sah**

Apa perlu dilakukan sekiranya keputusan positif?

Disyaki ada jangkitan COVID-19
Segera hubungi doktor atau pihak berkuasa kesihatan tempatan
-Sila patuhi kuarantin kendiri yang digariskan kerajaan
- Perlu melakukan ujian PCR untuk pengesahan

Apa yang perlu anda lakukan sekiranya keputusan negatif?

Patuhi Prosedur Operasi Standard (SOP) yang ditetapkan kerajaan dengan mengambil langkah-langkah keselamatan untuk mengekang pandemik
Jangkitan COVID-19 masih boleh berlaku walaupun keputusan *rapid test* negatif.
Sekiranya anda curiga, *rapid test* perlu diulangi selepas 1-2 hari, kerana jangkitan tidak dapat dikesan dengan mudah pada semua tahap jangkitan menggunakan *rapid test.*

Apa yang perlu anda lakukan sekiranya keputusan tidak sah?

Keputusan tidak sah boleh disebabkan oleh kesalahan ketika melaksanakan ujian
Anda perlu ulangi ujian.
Sekiranya anda terus mendapat keputusan tidak sah walaupun telah mengikuti arahan dengan ketat, anda perlu menghubungi doktor atau pusat ujian COVID-19 dan bincangkan apa langkah seterusnya.

Faedah Proses Ujian

Rapid antigen tests (yang juga di panggil sebagai point-of-care tests, POCT) boleh dilakukan di luar makmal berdekatan pesakit dan lebih cepat dari PCR (polymerase chain reaction) dalam masa 15-30 minit. Ujian antigen SARS-CoV-2 POC boleh memainkan peranan dalam situasi di mana keputusan pantas diperlukan segera dan penting untuk menilai kebolehjangkitan orang di tempat kejadian. Penggunaan rapid test boleh memutuskan jangkitan dengan mengasingkan orang-orang yang dijangkiti dan kontak rapat.

Limitasi Kaedah Ujian

1. Keputusan ujian tidak boleh diambil sebagai diagnosis yang sah, untuk rujukan klinikal sahaja. Perlu pertimbangan seiring dengan keputussan RT-PCR, gejala klinikal, maklumat epidemiologi dan data klinikal lanjut.
2. Kandungan dalam kaset ini sebagai pengesanan kualitatif

antigen SARS-CoV-2 dari *swab* hidung.
3. Sensitiviti ujian selepas tujuh hari pertama gejala telah menunjukkan penurunan dibandingkan asai RT-PCR SARS-CoV-2 .
4. Prestasi ujian ini belum dinilai untuk kegunaan pesakit tanpa tanda dan gejala jangkitan respiratori dan prestasi mungkin berlainan untuk individu tanpa gejala. (asimtomatik)
5. Sampel *buffer* dan kaset ujian perlu diimbang kepada suhu bilik (15 -30 ºC) sebelum digunakan, sebaliknya, keputusan mungkin tidak betul.
6. Keputusan ujian boleh jadi negatif sekiranya tahap antigen di dalam sampel di bawah had pengesanan ujian atau sampel tidak diambil dengan betul.
7. Kegagalan mengikuti prosedur ujian mungkin memberi kesan buruk kepada prestasi ujian dan/atau menyebabkan keputusan ujian tidak sah.
8. Bertindak kurang dari 15 minit mungkin membawa kepada keputusan ujian negatif palsu; Bertindak lebih dari 20 minit mungkin membawa kepada keputusan ujian positif palsu.
9. Keputusan ujian positif tidak menolak kemungkinan ada jangkitan dengan patogen lain.
10. Prestasi klinikal telah dievaluasi dengan sampel beku, dan prestasi mungkin berlainan dengan sampel segar.
11. Pengguna mesti melakukan ujian secepat mungkin selepas spesimen diambil.
12. Selepas memproses swab di dalam larutan ekstrasi, sampel mesti dianalisa dalam masa 30 minit.

Prestasi Data

1. Validasi Klinikal

Jenis sampel: *swab* hidung

Keputusan diringkaskan di dalam jadual berikut:

Kaedah		PCR		Jumlah Keputusan
SARS-Cov-2 Antigen Rapid Test	Keputusan	Positif	Negatif	
	Positif	125	1	126
	Negatif	7	128	135
Jumlah Keputusan		132	129	261

Kadar Kebetulan Positif =94.70%, (95% CI: 89.46%-97.41%);
Kadar Kebetulan Negatif=99.22%, (95% CI: 95.74%-99.86%);
Jumlah Kadar Kebetulan =96.93%, (95% CI: 94.07%-98.44%)

2. Sensitiviti

Sensitiviti telah diuji dengan tiga bahan rujukan. Bahan rujukan ini berlainan kepekatan kultur virus SARS-CoV-2 tidak aktif. Kepekatan bahan rujukan yang digunakan adalah:

S1 = 0.8 × 10^2 $TCID_{50}$ / mL
S2 = 1.6 × 10^2 $TCID_{50}$ / mL
S3 = 3.2 × 10^2 $TCID_{50}$ / mL

Bahan rujukan S1 memberi keputusan negatif.
Bahan rujukan S2 dan S3 memberi keputusan positif.

Keputusannya, had pengesanan minimum kaset ujian adalah 1.6 × 10^2 $TCID_{50}$ / mL.

3. Kejituan

1 bahan rujukan jitu dari pengilang, mengandungi kultur virus SARS-CoV-2 tidak aktif dan satu kepekatan yang ditakrif telah diuji 10 kali secara individu. Kepekatan warna pada garis T semestinya seragam dan konsisten, dan keputusan semestinya semua positif. Warna yang seragam dan konsisten diperolehi di dalam setiap 10 ujian. Kepekatan bahan rujukan yang digunakan adalah 4.8 × 10^2 $TCID_{50}$ / mL.

4. Tindakbalas Silang

Tindakbalas Silang kaset telah dinilai. Keputusan menunjukkan tiada tindakbalas silang dengan mikroorganisma berikut:

Bil.	Mikroorganisma	Kepekatan.	Tindakbalas Silang (YA TIDAK)
1	Human Coronavirus OC43	1×10^5 pfu/mL	TIDAK
2	Human Coronavirus 229E	1×10^5 pfu/mL	TIDAK
3	Human Coronavirus NL63	1×10^5 pfu/mL	TIDAK
4	Influenza A H1N1 (2009)	1×10^5 pfu/mL	TIDAK
5	MERS-coronavirus	1×10^5 pfu/mL	TIDAK
6	SARS-coronavirus	1×10^5 pfu/mL	TIDAK
7	Influenza A H3N2	1×10^5 pfu/mL	TIDAK
8	Influenza B Yamagata	1×10^5 pfu/mL	TIDAK
9	Influenza B Victoria	1×10^5 pfu/mL	TIDAK
10	Respiratory syncytial virus A	1×10^5 pfu/mL	TIDAK
11	Respiratory syncytial virus B	1×10^5 pfu/mL	TIDAK
12	Adenoviridae 1	1×10^5 pfu/mL	TIDAK
13	Adenoviridae 2	1×10^5 pfu/mL	TIDAK
14	Adenoviridae 3	1×10^5 pfu/mL	TIDAK
15	Adenoviridae 4	1×10^5 pfu/mL	TIDAK
16	Adenoviridae 5	1×10^5 pfu/mL	TIDAK
17	Adenoviridae 7	1×10^5 pfu/mL	TIDAK
18	Adenoviridae 55	1×10^5 pfu/mL	TIDAK
19	Enterovirus EV71	1×10^5 pfu/mL	TIDAK
20	Enterovirus CA16	1×10^5 pfu/mL	TIDAK
21	Enterovirus CA10	1×10^5 pfu/mL	TIDAK
22	Enterovirus CB5	1×10^5 pfu/mL	TIDAK
23	Enterovirus CA24	1×10^5 pfu/mL	TIDAK
24	Enterovirus CB4	1×10^5 pfu/mL	TIDAK
25	Enterovirus CB3	1×10^5 pfu/mL	TIDAK
26	Enterovirus CB2	1×10^5 pfu/mL	TIDAK
27	Enterovirus CB1	1×10^5 pfu/mL	TIDAK
28	Enterovirus CA6	1×10^5 pfu/mL	TIDAK
29	EB virus	1×10^5 pfu/mL	TIDAK
30	Human cytomegalovirus	1×10^5 pfu/mL	TIDAK
31	Human Rhinovirus A30	1×10^5 pfu/mL	TIDAK
32	Human Rhinovirus A31	1×10^5 pfu/mL	TIDAK
33	Human Rhinovirus A2	1×10^5 pfu/mL	TIDAK
34	Human Rhinovirus A81	1×10^5 pfu/mL	TIDAK
35	Human Rhinovirus B52	1×10^5 pfu/mL	TIDAK
36	Human Rhinovirus B70	1×10^5 pfu/mL	TIDAK
37	Human Rhinovirus B72	1×10^5 pfu/mL	TIDAK
38	Metapneumovirus A2	1×10^5 pfu/mL	TIDAK
39	Metapneumovirus Type B1	1×10^5 pfu/mL	TIDAK
40	Metapneumovirus Type B2	1×10^5 pfu/mL	TIDAK
41	Measles virus	1×10^5 pfu/mL	TIDAK
42	Rubella virus	1×10^5 pfu/mL	TIDAK
43	Mumps virus	1×10^5 pfu/mL	TIDAK
44	Boca virus	1×10^5 pfu/mL	TIDAK
45	Parainfluenza Virus 1	1×10^5 pfu/mL	TIDAK
46	Parainfluenza Virus 2	1×10^5 pfu/mL	TIDAK
47	Parainfluenza Virus 3	1×10^5 pfu/mL	TIDAK
48	Parainfluenza Virus 4	1×10^5 pfu/mL	TIDAK
49	Bordetella pertussis	1×10^6 cfu/mL	TIDAK
50	Candida albicans	1×10^6 cfu/mL	TIDAK
51	Legionella pneumophila	1×10^6 cfu/mL	TIDAK
52	Haemophilus influenzae	1×10^6 cfu/mL	TIDAK
53	Human Metapneumovirus	1×10^6 cfu/mL	TIDAK
54	Streptococcus pneumoniae	1×10^6 cfu/mL	TIDAK
55	Streptococcus pyogenes	1×10^6 cfu/mL	TIDAK
56	Mycobacterium tuberculosis	1×10^6 cfu/mL	TIDAK
57	Pneumocystis jirovecii (PJP)	1×10^6 cfu/mL	TIDAK
58	Staphylococcus aureus	1×10^6 cfu/mL	TIDAK
59	Staphylococcus epidermidis	1×10^6 cfu/mL	TIDAK
60	Mycoplasma pneumoniae	1×10^6 cfu/mL	TIDAK
61	Chlamydia pneumoniae	1×10^6 cfu/mL	TIDAK

5. Interferens Bahan

Keputusan ujian tidak terganggu oleh bahan dengan kepekatan berikut:

Bil.	Bahan	Kepekatan
1	Ibuprofen	1mg/mL
2	Tetracycline	3µg/mL
3	Chloramphenicol	3µg/mL
4	Erythromycin	3µg/mL
5	Tobramycin	5%
6	Throat spray (Menthol)	15%
7	Mupirocin	10mg/mL
8	Throat lozenge (Menthol)	1.5mg/mL
9	Oseltamivir	5mg/mL
10	Naphthoxoline hydrochloride nasal drops	15%

11	Mucin	0.50%
12	Fisherman's Friend	1.5mg/mL
13	Compound Benzocain Gel	1.5mg/mL
14	Cromoglycate	15%
15	Phenylephrine Hydrochloride	15%
16	Afrin (Oxymetazoline)	15%
17	Fluticasone propionate spray	15%
18	Whole Blood	4%

Langkah Berjaga-jaga

→ Untuk kegunaan *in vitro diagnostic* sahaja.
→Jangan guna sekiranya bungkusan rosak, label tidak jelas atau luput taikh.
→Ujian mesti dilakukan dengan mengikut ketat arahan.
→Keputusan mesti ditafsirkan dalam masa 15 minit.
→Kaset pakai-buang ini dirujuk sebagai sisa biologi apabila digunakan (e.g.di dalam bungkusan plastik tahan koyak dalam sisa residual).
→ Buang kaset dan komponen menurut garis panduan kerajaan tempatan.
→ Pastikan ujian dilaksanakan secara hygenic untuk mengelakkan kontaminasi *swab, reagents* atau kaset test. Ini mungkin akan memberi keputusan ujian yang tidak betul.
→ Pastikan kaset ujian atau komponen lain tidak basah. Sebaliknya, ini mungkin akan memberi keputusan ujian yang tidak betul.
→ Elakkan dari bahan spesimen terpercik. Ini boleh menyebabkan kontaminasi, dan dalam kes sampel positif, menyebabkan risiko jangkitan.
→ Elakkan dari *buffer* terkena atau terpercik ke kulit, mata dan membran mukus atau tertelan. Ini boleh menyebabkan iritasi.
→Basuh tangan selepas menggunakan larutan ekstraksi atau bilas dengan air bahagian yang terkena. Sekiranya gejala berterusan, anda perlu dapatkan nasihat/bantuan perubatan.
→Jangan sentuh tetingkap ujian atau tetingkap sampel kaset ujian untuk mengelakkan kontaminasi dan keputusan palsu.
→Jangan campurkan larutan *buffer* atau komponen lain dari kelompok yang berlainan. Ini boleh memberi keputusan ujian yang tidak betul.
→ Jangan campurkan sampel pesakit yang lain. Ini boleh memberi keputusan ujian yang tidak betul.

Rujukan

1.Chen Wei, Zhang Chunyang, Zhu Ying, Zhang Yanhua, You Libin, Wu Bingshan, Huang Zhimiao, Zheng Kuicheng, Weng Yuwei. Comparison of nucleic acid detection in pharyngeal swabs and sputum specimens in 4 cases of new coronavirus infection. Chinese Journal of Zoonoses 2020; 1-7 (in Chinese)
2.Guo Yuanyuan, Wang Kun, Zhang Yu, Zhang Wenjia, Wang Liying, Liao Yi. Comparison and analysis of detection performance of six domestic new coronavirus nucleic acid detection reagents. Chongqing Yixue 2020; 1-10 (in Chinese).

Merlin Biomedical (Xiamen) Co., Ltd.
Add: 4th Floor, Building B3,
2054 West Wengjiao Rd.,
Haicang, Xiamen, 361028, China
Tel: 86-592-5210772; 86-592-5210773
Fax: 86-592-5210772
Email: info@merlinbio.com.cn
Website: http://www.merlinbio.com.cn

EC REP **Qarad EC-REP BV**
Pas 257, 2440 Geel, Belgium

Pengedar & Pengimport: **Arterial Global Sdn. Bhd. (894261-H)**
3-2, Jalan Ara SD 7/3B,
Bandar Sri Damansara,
52200 Kuala Lumpur, Malaysia
Tel/Fax: 03-6263-1491
Email: sales@arterialglobal.com.my

Kelulusan Arahan dan Tarikh Ulang Kaji

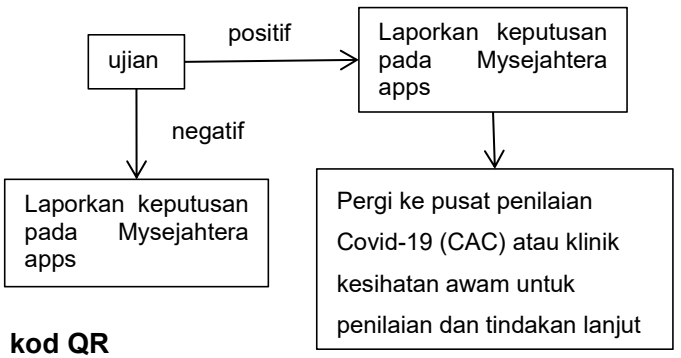
Tarikh Kelulusan: 22 Jun 2021 *en-Self-testing*
Tarikh Ulang kaji: 02 Mar 2022 *ms-Self-testing*
Tarikh dikeluarkan: 02 Mar 2022 *ms-Self-testing*

Simbol

REF	Nombor Katalog
	Rujuk Arahan untuk Menggunakan
IVD	*Alat Perubatan diagnosis In vitro*
	Pengilang
	Had Suhu
LOT	Kod Kelompok
	Tarikh Guna-sehingga
	Pastikan Kering
EC REP	Wakil Sah di *European Community*
	Jangan guna Produk apabila pakej rosak.
	Jangan guna berulang kali
	Amaran
	Mengandungi cukup untuk n> tests
	Tarikh Pembuatan
STERILE EO	Disterilkan dengan ethylene oxide
	Jangan Steril
	Elakkan terdedah berlebihan kepada matahari

Test Cassette	Kaset ujian
Sample extraction solution	Larutan Ekstraksi Sampel
Disposable sampling swab	*Swab* Sampel Pakai-buang
Specimen Collection Swab	*Swab* Pengambilan Spesimen
Biohazard Specimen Bag	Beg Spesimen Biohazard

Melaporkan Kaedah Keputusan COVID-19



kod QR

Sila imbas kod QR pada kotak untuk mendapatkan butiran lanjut

Prosedur Pelupusan

Buang semua Kaset Ujian, Larutan Ekstraksi Sampel, Tiub, Penitis, Swab, masukkan ke dalam Beg Spesimen Biohazard. Buangkan Beg Spesimen Biohazard dan sampah yang lain ke dalam tong sampah
am.

Catatan: Semua komponen kit: Buang mengikut Garis Panduan pengendalian, Rawatan dan Pembuangan sisa yang dihasilkan semasa Rawatan / Diagnosis / Kuarantin pesakit COVID-19 yang dikeluarkan oleh Keperluan Peraturan Tempatan atau Pihak Berkuasa Peraturan.

MS