MEDIVEN®
MEDICAL INNOVATION VENTURES

PRODETECT®

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva)

IVD *In vitro* Diagnostic Use Only

PR-CVDCAgS1
REF PR-CVDCAgS5
PR-CVDCAgS20

Σ 1, 5 or 20

Please Read the Instruction Sheet Carefully Before Performing the Test.

INTENDED USE

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) is a rapid lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 nucleocapsid protein antigens in human saliva specimens. The test serves as an aid in the diagnosis of coronavirus infection disease (COVID-19) for individuals suspected of SARS-CoV-2 infection. ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) is used in conjunction with clinical presentation and the results of other laboratory tests. It is intended for home use only.

SUMMARY AND EXPLANATION OF THE TEST

Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) was identified as the causative agent for the outbreak of pneumonia cases in early January 2020. It is associated with common symptoms including fever, cough, fatigue, shortness of breath or breathing difficulties, and loss of smell and taste. While most people have mild symptoms, some people develop acute respiratory distress syndrome (ARDS). It starts with mild symptoms for about a week and then progresses to rapid deterioration and ARDS requiring advanced life support.

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) detects SARS-CoV-2 nucleocapsid protein antigens. During the acute phase of infection, an antigen is commonly detectable in the upper respiratory specimens.

PRINCIPLE OF THE TEST

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human saliva specimen. During the testing, the specimen reacts with SARS-CoV-2 nucleocapsid protein antibody-coated particles in the test line region of the test device. The mixture then migrates upward on the membrane chromatographically by capillary action and reacts with SARS-CoV-2 nucleocapsid protein antibody in test line region. A colored line will appear in test line region if specimen contains SARS-CoV-2 antigens. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedure control, a colored line will appear at the Control Region (C), indicating that the test has been performed properly.

REAGENTS AND MATERIALS SUPPLIED

Catalog Number	Item
PR-CVDCAgS1/ PR-CVDCAgS5/ PR-CVDCAgS20	One box consists of the following components: 1. 1/5/20 Individually sealed pouches, each containing: • One test device • One desiccant pouch 2. 1/5/20 collection device(s), each consisting of: • One funnel • One collection tube 3. 1/5/20 biosafety bag(s) 4. 1/5/20 single use buffer(s) 5. 1 leaflet with instruction for use

WARNINGS AND PRECAUTIONS

1. This test device is for *in vitro* diagnostic use only.
2. This instruction for use must be read completely before performing the test. Failure to follow directions in the instruction for use may yield inaccurate test results.
3. Do not eat, drink, or smoke in the area where the specimens or test devices are handled.
4. Clean up spills thoroughly with appropriate disinfectants.
5. Avoid splashing or aerosol formation while collecting the sample.
6. Discard after first use. The test device cannot be used more than once.
7. Do not use the test device beyond the expiry date.
8. Do not use the test device if the pouch is punctured or not well sealed.
9. Do not mix and interchange different specimens.
10. Keep out of reach of children.
11. Do not read after 20 minutes.
12. Do not swallow.
13. Discard of all specimens and used test device into biosafety bag.

STORAGE

1. The test device is stable until the indicated expiry date when stored in the sealed pouch at 2-30°C and protected from direct sunlight, moisture, and heat.
2. DO NOT FREEZE.
3. The test device must remain in the sealed pouch until use.

SAMPLE COLLECTION AND PREPARATION

Specimen Collection and Extraction

Saliva specimen should be collected using the collection device provided with the test device. Do not use other collection devices. Saliva collected at any time of the day may be used. Specimens should be tested immediately after collection if possible.

Prior to collection of saliva, you must not place anything into your mouth including food, drink, gum, or tobacco products for at least 10 minutes before collection.

Step 1:

- Attach the funnel to the collection tube prior to sample collection.
- Deeply cough 3-5 times and spit saliva into the collection device.
  Note: It is recommended to collect the first saliva after deep coughing in the morning.
- Repeat the steps above for sample collection until the saliva reaches the scale line indicated on the collection tube.

Step 2:

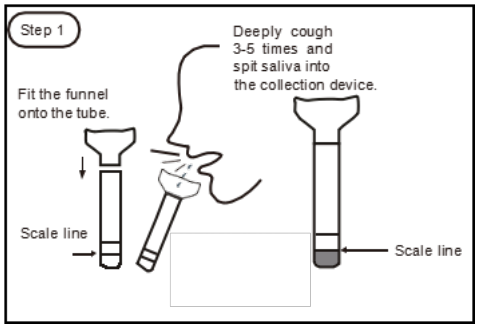
- Remove the funnel from collection tube.
- Empty the entire content of the disposable buffer into the collection tube.
- Place the cap securely on the collection tube. Gently squeeze the collection tube for 10-15 times to mix the sample with the buffer thoroughly.

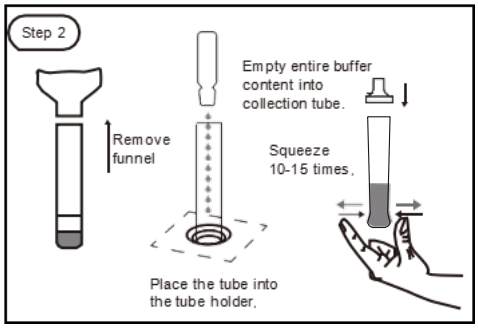
TEST PROCEDURE

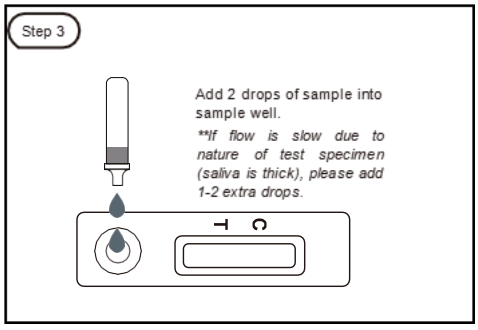
For video demonstration, please scan the QR code below:

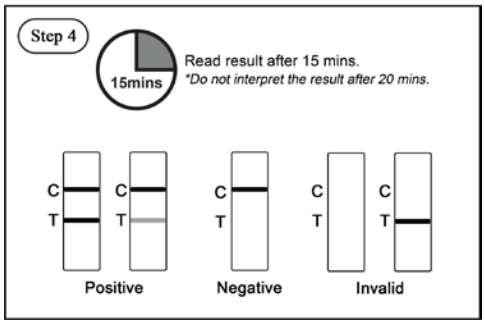
Bring the test device, buffer, and sample to room temperature (15-30°C) prior to testing. Best results will be obtained if the test is performed immediately after opening the foil pouch.

1. Remove device from the foil pouch (use within 1 hour) and place it on a flat and clean surface.
2. Transfer extracted sample to the test device.
3. Wait for the colored line(s) to appear. Read the results at 15 minutes.
4. Do not read results after 20 minutes.
5. Discard the used test device into the biosafety bag and dispose the biosafety bag.









INTERPRETATION AND REPORTING OF RESULTS

Positive (+)

Two colored lines appear at test line (T) and control line (C). It indicates a positive result for the SARS-CoV-2 antigens in the specimen.

Note: Color intensity of the line appearing in the test (T) region may vary depending on the SARS-CoV-2 antigen level in the specimen. Therefore, any shade of color in the test (T) region is to be considered as a positive result.

Procedure in reporting positive result via MySejahtera:

- If positive result is obtained, notify Ministry of Health by either using self-notification at *MySejahtera* mobile application or notify the District Health Office.
- Covid-19 positive individual should contact the nearest COVID-19 Assessment Center (CAC) (http://covid-19.moh.gov.my/hotline) to inform and get advice for further action to be taken.

1. Scan the QR code above to link you to MySejahtera Helpdesk page.
2. Select whether you are reporting for yourself or for your dependent.
3. Once select, you are required to update individual particulars (i.e name, mobile, identification number, and email address) as required.
4. Stay on the Helpdesk page and continue to update with your home address.
5. Stay on the Helpdesk page and select one of the options ("hospital/clinic"; "online"; "pharmacy"; "corporate", or "others") as to where you've obtained the self-test kits from.
6. Stay on the Helpdesk page and select one of the options ("saliva"; "nasal", or "others") as to what was tested with the self-test kits.
7. To submit the self-test results, on the following page, select one of the options ("positive"; "negative", or "invalid").

Negative (-)

The colored line appears at the control line (C) only. It indicates that the concentration of the SARS-CoV-2 antigen is zero or below the detection limit of the test.

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. If the problem persists, discontinue using the test device immediately and contact your local distributor.

LIMITATIONS OF THE TEST

1. The test procedure must be carefully followed when testing the presence of SARS-CoV-2 nucleocapsid protein antigens in human saliva specimen from suspected individuals. Failure to follow the instructions may cause incorrect results.
2. The performance of ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) was validated using the procedures provided in this instruction for use. Modification to these procedures may cause inaccurate performance.
3. ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) is for *in vitro* diagnostic use only. It is used for the detection of SARS-CoV-2 nucleocapsid protein antigens in human saliva specimens as an aid in the diagnosis of individuals suspected of SARS-CoV-2 infection in conjunction with clinical symptoms and the results of other laboratory tests. This qualitative test does not provide quantitative value and cannot determine the rate of increase in the concentration of SARS-Cov-2 nucleocapsid protein antigens.
4. This test will only indicate the presence of SARS-CoV-2 antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
5. If the test result is negative or non-reactive but clinical symptoms persist, it is recommended that you test again or test with a molecular diagnostic device to rule out infection.
6. Negative results may be obtained if the titre of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test. However, they do not rule out SARS-CoV-2 infection, particularly in individuals who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection.
7. Infection with non-SARS-CoV-2 coronavirus strains or other interference factors may show in positive results with ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva).

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity:

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) was compared with a leading commercial PCR test device. The results showed that the ProDetect® COVID-19 has high sensitivity and specificity.

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva)	Method	PCR		Total Results
	Results	Positive	Negative	
	Positive	91	2	93
	Negative	10	303	313
Total Result		101	305	406
Relative Sensitivity		90.1% (95%CI: 82.5% to 95.1%)		
Relative Specificity		99.3% (95%CI: 97.7% to 99.9%)		
Accuracy		97.0% (95%CI: 94.9% to 98.5.%)		

CI: Confidence Intervals

Specificity with other viral strains

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) has been tested with other viral strains. The results showed no discernible line at the test-line regions at the following concentrations:

Virus Type	Concentration ($TCID_{50}$/ml)
Adenovirus type 3	3.16×10^4
Adenovirus type 7	1.58×10^5
Human coronavirus OC43	1.00×10^6
Human coronavirus 229E	5.00×10^5
Human coronavirus HKU1	1.00×10^6
Human coronavirus NL63	1.00×10^6
Influenza A H1N1	3.16×10^5
Influenza A H3N2	1.00×10^5
Influenza B	3.16×10^6
Measles	1.58×10^4
Mumps	1.58×10^4
Parainfluenza virus 2	1.58×10^7
Parainfluenza virus 3	1.58×10^8
Respiratory syncytial virus	8.89×10^4

Precision (Intra-assay & Inter-assay)

Precision was determined by using three specimens of COVID-19 standard control. Three different lots of ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) have been tested using negative, weak SARS-CoV-2 antigen and strong SARS-CoV-2 antigen. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

CROSS REACTIVITY

The following organisms were tested at the concentration of 1.0×10^8 org/ml using the test device. All were found to be negative.

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus sub aureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pyogenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp.* Group F

Interfering Substances

The following substances were tested with ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) and no interference was observed:

Caffeine	1mg/ml
Dexamethasone	0.8mg/ml
Flunisolide	6.8ng/ml
Milk	11.2%
Mouthwash	2.0%
Mucin	50µg/ml
Mupirocin	12mg/ml
Orange Juice	100.0%
Oxymetazoline	0.6mg/ml
Phenylephrine	12.0 g/ml
Rebetol	4.5µg/ml
Relenza	282ng/ml
Tamiflu	1.1µg/ml
Tea	33.3mg/ml
Tobryamycin	2.43mg/ml

REFERENCES

1. Huang, C. et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 395, 497–506 (2020).
2. Steph H Tan, Orchid Allicock, Mari Armstrong-Hough, Anne L Wyllie. Saliva as a gold-standard sample for SARS-CoV-2 detection. The Lancet Respiratory Medicine, 562-564 (2021).
3. *Emerging respiratory viruses, including COVID-19: methods for detection, prevention, response and control.* (2020). World Health Organization. https://openwho.org/courses/introduction-to-ncov

INDEX OF SYMBOLS USED

Consult instructions for use	Do not re-use
Catalog number	No. of tests
Batch code	Temperature limitation
Date of manufacture	Use by
Manufacturer	

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PRCVDCAgS- Rev. 0 English Version
Effective: 2021- Nov Issued: 2021 Nov

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva)

IVD Untuk kegunaan *in vitro* diagnostik Σ 1,5,20

REF PR-CVDCAgS1
PR-CVDCAgS5
PR-CVDCAgS20

Sila baca arahan dengan teliti sebelum menjalankan ujian.

TUJUAN PENGGUNAAN

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) bertindak secara immunoesei untuk mengesan antigen protein nukleokapsid SARS-CoV-2 secara kualitatif dalam sampel bendalir mulut (saliva). Ujian ini berfungsi sebagai alat bantuan awal untuk mengenal pasti penyakit jangkitan koronavirus (COVID-19) bagi individu yang disyaki mendapat jangkitan SARS-CoV-2. Kit ujian ini mudah diguna, mempunyai kepekaan dan ketepatan yang tinggi. Kit ujian kendiri ini boleh digunakan oleh orang awam.

RUMUSAN DAN PENJELASAN PERIHAL UJIAN

Sindrom Pernafasan Akut Koronavirus 2 (SARS-CoV-2) dikenal pasti sebagai ejen penyebab wabak kes radang paru-paru pada awal Januari 2020. Wabak ni dikaitkan dengan gejala biasa seperti demam, batuk, kepenatan, sesak nafas atau kesukaran bernafas, dan kehilangan deria bau dan rasa. Walaupun bermula dengan gejala ringan tetapi potensi sindrom gangguan pernafasan akut (ARDS) boleh terjadi pada sesetengah orang. Gejala ringan ini akan mengambil masa selama seminggu dan kemudian mengalami kemerosotan yang membawa kepada sindrom gangguan pernafasan akut (ARDS) dan memerlukan alat sokongan bantuan pernafasan bagi mendapatkan oksigen yang mencukupi untuk terus hidup.

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) adalah untuk mengesan antigen protein nukleokapsid SARS-CoV-2. Semasa fasa akut jangkitan, antigen biasanya dikesan pada bahagian ruang atas saluran pernafasan.

TATACARA PENGENDALIAN UJIAN

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) merupakan immunoesei kromatografi aliran lateral yang cepat untuk pengesanan kualitatif antigen protein nukleokapsid SARS-CoV-2 dalam sampel cecair oral manusia. Semasa ujian dijalankan, sampel tersebut bertindak balas dengan partikel yang dikonjugasi dengan antibodi protein SARS-CoV-2 nukleokapsid di kawasan garis kit ujian. Konjugasi tersebut kemudian akan bergerak melintasi membran secara kromatografi melalui tindakan kapilari dan bertindak balas dengan antibodi protein nukleokapsid SARS-CoV-2 di kawasan garis ujian. Garis berwarna akan kelihatan di kawasan garis ujian sekiranya sampel mengandungi antigen SARS-CoV-2. Sekiranya sampel tidak mengandungi antigen terhadap SARS-CoV-2, tidak ada garis berwarna yang akan muncul di kawasan garis ujian, yang menunjukkan keputusan negatif. Garis berwarna akan kelihatan di garis kawalan (C) merupakan tanda pengawalan kualiti yang menunjukkan bahawa ujian telah dilaksanakan dengan betul.

BAHAN UJI YANG DIBEKALKAN

Nombor Katalog	Bahan
PRCVDCAgS1 PR-CVDCAgS5 PR-CVDCAgS20	Setiap kotak mengandungi komponen - komponen berikut : 1. 1/5/20 pek ujian individu, mengandungi: • 1 Kit ujian • 1 pek gel silika 2. 1/5/20 alat pengumpul sampel, masing-masing terdiri daripada: • 1 corong • 1 tiub pengumpulan 3. 1/5/20 beg biokeselamatan 4. 1/5/20 buffer 5. 1 risalah arahan pengguna

PERINGATAN DAN AMARAN

1. Kit ujian kendiri ini adalah untuk kegunaan *in vitro* diagnostik sahaja.
2. Arahan penggunaan ini mesti dibaca dengan teliti sebelum melaksanakan ujian. Kegagalan untuk mengikut arahan dalam risalah arahan penggunaan ini boleh menyebabkan keputusan ujian yang tidak tepat.
3. Jangan makan, minum, atau merokok semasa melakukan ujian.
4. Bersihkan tumpahan menggunakan pembasmi kuman yang sesuai.
5. Elakkan percikan atau pembentukan aerosol semasa mengumpulkan sampel.
6. Buang kit selepas mengendalikan ujian. Kit ujian tidak boleh digunakan lebih daripada satu kali.
7. Jangan menggunakan kit ujian ini jika sudah melebihi tarikh luput.
8. Jangan menggunakan kit ujian jika pek sudah terkoyak atau rosak.
9. Jangan mencampurkan dan menukar sampel yang berbeza.
10. Jauhkan daripada capaian kanak-kanak.
11. Jangan membaca keputusan selepas 20 minit.
12. Jangan menelan.
13. Buang semua sampel dan alatan terpakai ke dalam beg biokeselamatan yang disertakan.

PENYIMPANAN

1. Kit ujian ini stabil sehingga tarikh luput yang dinyatakan apabila disimpan di dalam pek tertutup pada suhu 2 - 30° C dan terlindung daripada cahaya matahari dan kelembapan.
2. JANGAN BEKUKAN.
3. Kit ujian mesti berada di dalam pek asal yang tertutup sehingga digunakan.

PERSEDIAAN DAN PENGUMPULAN SAMPEL

Pengumpulan Sampel dan Pengekstrakan
Sampel bendalir mulut (saliva) harus dikumpulkan menggunakan tiub pengumpul yang disediakan bersama kit. Jangan menggunakan tiub pengumpulan lain. Sampel harus diuji dengan segera.

Sebelum pengumpulan bendalir mulut (saliva), anda tidak boleh memasukkan apa-apa ke dalam mulut termasuk makanan, minuman, atau rokok sekurang-kurangnya 10 minit sebelum pengumpulan sampel.

Langkah 1:

- Pasang corong ke tiub pengumpulan sebelum pengambilan sampel.
- Batuk dengan kuat sebanyak 3-5 kali untuk mengeluarkan bendalir mulut (saliva) dan terus masuk ke corong alat pengumpul.
  Nota: Sebaiknya sampel diambil pada waktu pagi.
- Ulangi langkah di atas untuk pengambilan sampel sehingga bendalir mulut (saliva) mencapai garis skala yang ditunjukkan pada tiub pengumpulan.

Langkah 2:

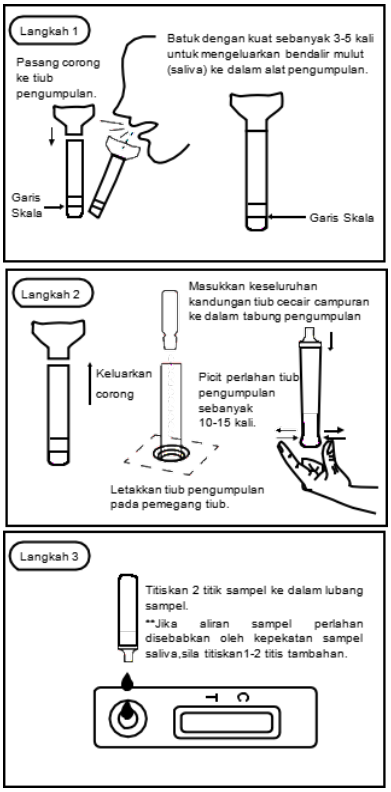
- Keluarkan corong dari tiub pengumpulan.
- Masukkan keseluruhan kandungan buffer ke dalam tiub pengumpulan.
- Pastikan tiub pengumpulan ditutup dengan ketat. Picit perlahan tiub pengumpulan sebanyak 10-15 kali untuk mencampurkan sampel dan buffer dengan baik.

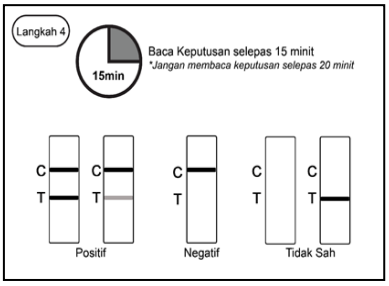
TATACARA PENGENDALIAN UJIAN

Untuk video demonstrasi, sila imbas QR kod dibawah:

Pastikan kit ujian, buffer, dan sampel berada pada suhu bilik (15-30°C) sebelum diuji. Keputusan terbaik akan diperoleh sekiranya ujian dilakukan sebaik sahaja membuka pek foil.

1. Keluarkan kit ujian dari pek foil (gunakan dalam 1 jam) dan letakkan di permukaan yang rata dan bersih.
2. Titiskan 2 titik sampel yang diekstrak ke dalam lubang sampel pada kit ujian.
3. Tunggu sehingga garis berwarna muncul. Baca keputusan dalam masa 15 minit.
4. Jangan membaca keputusan selepas 20 minit.
5. Buang kit ujian yang telah digunakan ke dalam beg biokeselamatan yang disertakan.





PENTERJEMAHAN DAN PEMAKLUMAN KEPUTUSAN UJIAN

Positif (+)

Dua garis berwarna kelihatan di garis ujian (T) dan garis kawalan (C). Ini menunjukkan keputusan positif untuk antigen SARS-CoV-2 dalam sampel.
Nota: Kejelasan warna garis yang kelihatan di garisan ujian (T) mungkin berbeza-beza bergantung pada tahap antigen SARS-CoV-2 dalam sampel. Oleh itu, sebarang warna di garis ujian (T) harus dianggap sebagai keputusan positif.

Cara pelaporan keputusan positif dalam sistem MySejahtera:

- Jika keputusan positif diperoleh, maklumkan kepada Kementerian Kesihatan sama ada melalui notifikasi kendiri dalam sistem MySejahtera atau hubungi Pejabat Kesihatan Daerah secara terus.
- Individu yang didapati positif Covid-19 perlu menghubungi Pusat Penilaian COVID-19 (http://covid-19.moh.gov.my/hotline) yang berhampiran untuk pemberitahuan dan mendapatkan nasihat untuk tindakan lanjut.

1.Imbas kod QR di atas untuk ke pautan halaman MySejahtera Helpdesk.
2.Pilih samaada anda ingin membuat laporan kendiri atau tanggungan anda.
3.Setelah memilih, anda dikehendaki mengemas kini butiran individu (iaitu nama,nombor telefon, nombor kad pengenalan dan alamat emel) seperti yang diperlukan.
4.Kekal di halaman Helpdesk dan terus mengemas kini dengan alamat rumah anda.
5.Kekal di halaman Helpdesk dan pilih salah satu daripada pilihan ("hospital/klinik"; "dalam talian"; "farmasi"; "korporat", atau "lain-lain") sebagai pilihan di mana kit ujian kendiri diperoleh.
6.Kekal di halaman Helpdesk dan pilih salah satu daripada pilihan ("air liur"; "hidung", atau "lain-lain") sebagai pilihan jenis sampel yang diuji.
7.Untuk menghantar keputusan ujian kendiri pada halaman berikut, pilih salah satu pilihan ("positif"; "negatif", atau "tidak sah").

Negatif (-)

Garis berwarna hanya kelihatan di garis kawalan (C). Ini menunjukkan bahawa kepekatan antigen SARS-CoV-2 adalah di bawah had pengesanan ujian.

Tidak Sah

Garis kawalan tidak kelihatan. Isipadu sampel yang tidak mencukupi atau teknik pengendalian yang salah berkemungkinan garis kawalan tidak muncul. Kaji semula prosedur tatacara pengendalian dan ulangi ujian dengan ujian baru. Sekiranya masalah berterusan, hentikan penggunaan kit ujian dengan segera dan sila hubungi pengedar tempatan yang berdekatan dengan anda.

HAD PENGESAN KIT UJIAN

1. Prosedur ujian mesti diikuti dengan teliti semasa menguji kehadiran antigen protein nukleokapsid SARS-CoV-2 dalam sampel cecair oral manusia dari individu yang disyaki. Kegagalan mengikuti arahan boleh menyebabkan keputusan yang salah.
2. Prestasi ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) disahkan menggunakan prosedur yang disediakan dalam manual arahan pengguna ini. Pengubahsuaian tatacara ini boleh menyebabkan prestasi yang tidak tepat.
3. ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) hanya untuk kegunaan diagnostik *in vitro*.
4. Ujian ini hanya akan menunjukkan wujudnya antigen SARS-CoV-2 dalam sampel dan tidak boleh dijadikan kriteria tunggal untuk diagnosis jangkitan SARS-CoV-2. Keputusan yang diperoleh dengan ujian harus dipertimbangkan dengan penemuan klinikal ujian yang lain dari makmal .
5. Sekiranya keputusan ujian negatif atau tidak reaktif tetapi gejala klinikal masih ada, anda disarankan untuk mengulangi ujian ini selepas beberapa hari atau melakukan ujian dengan alat diagnostik molekul untuk kepastian jangkitan pada anda.
6. Keputusan negatif dapat diperoleh jika tahap antigen koronavirus novel dalam sampel lebih rendah daripada had pengesanan minimum ujian. Namun, ini tidak bermakna tiada jangkitan SARS-CoV-2, terutamanya jika anda telah terdedah kepada virus. Ujian susulan dengan diagnostik molekul harus dipertimbangkan untuk mendapatkan kepastian terhadap status jangkitan SARS-CoV-2 anda
7. Jangkitan dengan strain koronavirus yang lain daripada SARS-CoV-2 atau faktor gangguan lain mungkin menunjukkan keputusan positif dengan ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva).

CIRI-CIRI PRESTASI

Kepekaan dan Kekhususan:

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) dibandingkan dengan kit ujian RT-PCR komersial. Keputusan menunjukkan ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) mempunyai kepekaan dan kekhususan yang tinggi.

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva)	Kaedah Keputusan	PCR		Jumlah
		Positif	Negatif	
	Positif	91	2	93
	Negatif	10	303	313
Jumlah		101	305	406
Kepekaan		90.1% (95%CI: 82.5% to 95.1%)		
Kekhususan		99.3% (95%CI: 97.7% to 99.9%)		
Ketepatan		97.0% (95%CI: 94.9% to 98.5.%)		

Ujian Kekhususan dengan Pelbagai Jenis Strain Virus

ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) diuji dengan strain virus berikut dan menunjukkan kekhususan yang baik.

Jenis Strain Virus	Tahap Ujian ($TCID_{50}$/ml)
Adenovirus type 3	3.16×10^4
Adenovirus type 7	1.58×10^5
Human coronavirus OC43	1.00×10^6
Human coronavirus 229E	5.00×10^5
Human coronavirus HKU1	1.00×10^6
Human coronavirus NL63	1.00×10^6
Influenza A H1N1	3.16×10^5
Influenza A H3N2	1.00×10^5
Influenza B	3.16×10^6
Measles	1.58×10^4
Mumps	1.58×10^4
Parainfluenza virus 2	1.58×10^7
Parainfluenza virus 3	1.58×10^8
Respiratory syncytial virus	8.89×10^4

Ketepatan (Intra-esei & Inter-esei)

Ketepatan ditentukan dengan menggunakan 3 sampel kawalan standard COVID-19. 3 lot ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva) yang berbeza telah diuji menggunakan antigen SARS-CoV-2 negatif, lemah dan kuat. Setiap peringkat ujian diulang 10 kali selama 3 hari berturut-turut. Sampel menunjukkan ketepatan >99% pada masa tersebut.

KEREAKTIFAN SILANG

Organisma berikut diuji pada tahap 1.0×10^8 org/ml mengunakan kit ujian. Keputusan menunjukkan semua negatif.

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus sub aureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pyogenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp.* Group F

BAHAN YANG MENGGANGGU

Tiada gangguan yang diperhatikan semasa menguji bahan-bahan berikut dengan ProDetect® COVID-19 Antigen Rapid Self-Test (Saliva).

Kafeine	1mg/ml
Dexamethasone	0.8mg/ml
Flunisolide	6.8ng/ml
Susu	11.2%
Ubat Kumur Mulut	2.0%
Mucin	50µg/ml
Mupirocin	12mg/ml
Jus Oren	100.0%
Oxymetazoline	0.6mg/ml
Phenylephrine	12.0 g/ml
Rebetol	4.5µg/ml
Relenza	282ng/ml
Tamiflu	1.1µg/ml
Teh	33.3mg/ml
Tobryamycin	2.43mg/ml

RUJUKAN

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INDEKS SIMBOL YANG DIGUNAKAN

 Rujuk risalah pengguna

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