MEDIVEN
MEDICAL INNOVATION VENTURES

PRODETECT

ProDetect® COVID-19 Antigen Rapid Self-Test

IVD *In vitro* Diagnostic Use Only

REF PR-CVDCAgN1S
PR-CVDCAgN5S
PR-CVDCAgN20S

Σ 1,5 or 20

Please Read the Instruction Sheet Carefully Before Performing the Test.

INTENDED USE

ProDetect® COVID-19 Antigen Rapid Self-Test is a lateral flow chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasal swab samples. The test serves as an aid in the diagnosis of coronavirus infection disease (COVID-19) in persons with clinical symptoms and the results of other laboratory tests. It is intended for home use.

SUMMARY AND EXPLANATION OF THE TEST

The coronavirus disease 19 (COVID-19) is a highly transmittable and pathogenic viral infection caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). This 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.

PRINCIPLE OF THE TEST

ProDetect® COVID-19 Antigen Rapid Self-Test is a qualitative membrane-based lateral flow chromatographic immunoassay for the detection of SARS-CoV-2 antigens in nasal swab samples. The test line region is coated with SARS-CoV-2 antibody. The sample will react with SARS-CoV-2 antibody-coated particles in the test. The mixture then will migrate upward on the membrane by capillary action to react with SARS-CoV-2 antibody in test line region.

A colored line will appear in test line region if the sample contains SARS-CoV-2 antigens. No colored line will appear in the test line region if the sample does not contain antigens to SARS-CoV-2, thus indicating a negative result.

A colored line will always appear in the control line region, to serve as a procedural control. This serves as an indication that the proper volume of sample has been added and membrane wicking has occurred.

REAGENTS AND MATERIALS SUPPLIED

1. 1/5/20 Individual sealed, pouches, each containing:
   - One test device
   - One desiccant pouch
2. 1/5/20 Prefilled extraction buffer(s)
3. 1/5/20 Sterile nasal swab(s)
4. 1/5/20 Biosafety bag(s)
5. 1 leaflet with instruction for use

MATERIALS NEEDED BUT NOT SUPPLIED

- Timer

WARNINGS AND PRECAUTIONS

1. For home use *in vitro* diagnostic use only.
2. Do not use the kit beyond the expiration date.
3. Do not swallow.
4. Wash hands thoroughly after performing the test.
5. Do not eat, drink or smoke in the area where the samples or kits are handled.
6. Clean up spills thoroughly with appropriate disinfectants.
7. Discard after first use. The test kit cannot be used more than once.
8. Do not use the test kit if the pouch is punctured or not well sealed.
9. Do not mix and interchange different samples.
10. Keep out of reach of children.
11. Do not interpret the results after 20 minutes.
12. Dispose all samples and used devices in a proper biosafety bag.
13. Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.

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.

PROCEDURE

For video demonstration, please scan the QR code below:

SCAN ME

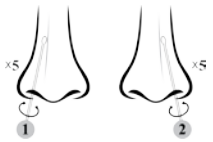
Wash hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

Nasal Swab Sample Collection

1. Take out the sterile swab from the pouch.
2. Insert the swab into your nostril until you feel slight resistance (about 2 cm up the nose).
3. Rotate the swab 5-10 times against the nasal wall. Using the same swab, repeat the collection procedure with the second nostril.
   Note: This may feel uncomfortable. Do not insert the swab any deeper if strong resistance or pain is felt.
4. Gently remove the sterile swab from the nasal cavity, avoid excess volume and high-viscous nasal discharge.

Caution:

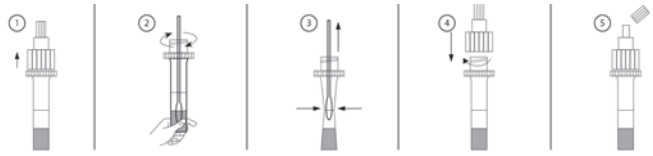
If you are swabbing others, please wear a face mask. If swabbing children, you may not need to insert the swab as far into the nostril. You may need another person to hold steady the child's head while swabbing very young children.



Sample Preparation

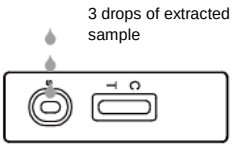
Use only the provided extraction buffer and tubes in the kit for swab sample preparation.

1. Place the swab sample in the extraction tube and ensuring it touches the bottom. Rotate the swab for approximately 10-15 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
2. Remove the swab while squeezing the swab head against the inside of the extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab into the biosafety bag.
3. Cap the extraction tube tightly.



Testing

1. Remove the test device from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Please place the test device on a flat and clean surface.
3. Open the small cap and invert the sample extraction tube to add 3 drops of extracted sample (approx.100µl) to the sample well(S) and then start the timer.
   Note: Do not move the test device about at this step.
4. Wait for the colored line(s) to appear. Read the result at 15 minutes. Do not interpret the result 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 antigen in the sample.

Note: Color intensity of the line appearing in the test (T) region may vary depending on the SARS-CoV-2 antigen level in the sample. 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:

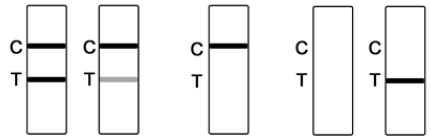
- If positive result is obtained, notify Ministry of Health by either using self-notification at *MySejahtera* mobile application or notify the District Health Office.
- Covid-19 positive individual should contact the nearest COVID-19 Assessment Center (CAC) (http://covid-19.moh.gov.my/hotline) to inform 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 sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat with a new test. If the problem persists, discontinue the use of the test kit immediately and contact the local distributor.



Positive **Negative** **Invalid**

LIMITATIONS OF THE TEST

1. The test procedure must be carefully followed when testing the presence of SARS-CoV-2 antigens. Failure to follow the instructions may cause incorrect results.
2. This test is to be used for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab sample from suspected individuals. For the optimal test performance, proper sample collection is crucial. Failure to follow the procedure may be erroneous results.
3. ProDetect® COVID-19 Antigen Rapid Self-Test will only indicate the presence of SARS-CoV-2 antigen in the sample and should not be used as the sole criteria for diagnosing COVID-19 infections. The test should be used as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical symptoms and the results of other laboratory tests. This qualitative test cannot give a quantitative value or the rate of increase in the concentration of SARS-CoV-2 antigens.
4. It is recommended to re-test with new kit or test with a molecular diagnostic device to rule of infection in individuals with negative or non-reactive test results but with persistent clinical symptoms.
5. The test will show negative results if the concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
6. Excess blood or mucin on the swab sample may interfere with test performance and may yield a false positive result.
7. The accuracy of the tests depends on the quality of the swab samples. It may result in false negatives from improper sample collection or storage.
8. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity
ProDetect® COVID-19 Antigen Rapid Self-Test was compared with a commercial RT-PCR kit. The results showed that the ProDetect® COVID-19 Antigen Rapid Test has high sensitivity and specificity.

Note:
1. 97.69% Sensitivity: Out of 130 PCR confirmed positive samples,127 PCR confirmed positive samples were correctly detected by ProDetect® COVID-19 Antigen Rapid Self-Test. There are 3 false negative cases.
2. 99.70% Specificity: Out of 330 PCR confirmed negative samples, 329 PCR confirmed negative samples were correctly detected by ProDetect® COVID-19 Antigen Rapid Self-Test. There is 1 false positive case.
3. 99.13% Accuracy: Out of 460 PCR confirmed samples, 456 PCR confirmed samples were correctly detected by ProDetect® COVID-19 Antigen Rapid Self-Test.

The observed accuracy may vary depending on the virus prevalence in the population.

	PCR confirmed sample number	Correctly identified sample number	Rate
Positive sample	127	1	97.69% (Sensitivity)
Negative sample	3	329	99,70% (Specificity)
Total	130	330	99.13% (Total Accuracy)

Specificity Testing with Various Viral Strains
ProDetect® COVID-19 Antigen Rapid Self-Test was tested with the following viral strains. No discernible line at the test-line region was observed at these concentrations:

Description	Test Level
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human coronavirus OC43	2.45 x 10^6 LD50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Respiratory syncytial virus	8.89 x 10^4 TCID50/ml

CROSS REACTIVITY

ProDetect® COVID-19 Antigen Rapid Self-Test was tested for cross-reactivity with *Arcanobacterium, Pseudomonas aeruginosa, Candida albicans, Staphylococcus aureus subsp. aureus, Corynebacterium, Staphylococcus epidermidis, Escherichia coli, Streptococcus pneumoniae, Moraxella catarrhalis, Streptococcus pyogenes, Neisseria lactamica, Streptococcus salivarius, Neisseria subflava, Group F streptococci.* The results showed no cross-reactivity.

INTERFERING SUBSTANCES

No interference was observed when tested the following compounds with ProDetect® COVID-19 Antigen Rapid Self-Test.

1. Whole Blood 20µl/ml; Mucin 50µg/ml; Budesonide Nasal Spray 200µl/ml; Dexamethasone 0.8mg/ml; Flunisolide 6.8ng/ml; Mupirocin 12mg/ml; Oxymetazoline 0.6mg/ml; Phenylephrine 12mg/ml; Rebetol 4.5µg/ml; Relenza 282ng/ml; Tamiflu 1.1µg/ml; Tobramycin 2.43mg/ml
2.

REFERENCES

1. Adnan, S.H. et al. COVID-19 infection: Origin, transmission, and characteristics of human coronavirus. Journal of Advanced Research, 91-98 (2020).
2. *Angela, M. C & Kimberlly, E.H. Coronavirus disease 2019 (COVID-19): Diagnosis* (2020). https://www.uptodate.com/contents/coronavirus-disease-2019-covid-19-diagnosis
3. Westgard JO, Barry PL,Hunt MR, Groth T. A multi-rule Shewhart for quality control in clinical chemistry, Clinical Chemistry 1981;27:493-501

INDEX OF SYMBOLS USED

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

Medical Innovation Ventures Sdn. Bhd. (Co. No. 988633-U),
1st Floor, Plot 88f, Lintang Bayan Lepas 10,
Bayan Lepas Industrial Park, Phase 4,
11900 Bayan Lepas, Penang, Malaysia.
Phone: +604-3052730 Fax: +604-3052730
Email: sales@mediven.com.co

PR-CVDCAgNS Rev. 0 English Version
Effective: 2021- Nov Issued: 2021-Nov

ProDetect® COVID-19 Antigen Rapid Self-Test

IVD Untuk kegunaan *in vitro* diagnostik

REF PR-CVDCAgN1S
PR-CVDCAgN5S
PR-CVDCAgN20S

Σ 1,5 atau 20

Sila baca arahan dengan teliti sebelum menjalankan ujian.

TUJUAN PENGGUNAAN

ProDetect® COVID-19 Antigen Rapid Self-Test bertindak secara immunoesei untuk mengesan antigen SARS-CoV-2 secara kualitatif dalam sampel swab lubang hidung. Ujian ini berfungsi sebagai alat bantuan awal untuk mengenal pasti penyakit jangkitan koronavirus (COVID-19) bagi individu yang mempunyai simptom klinikal. Kit ujian kendiri ini adalah untuk kegunaan orang awam.

RUMUSAN DAN PENJELASAN PERIHAL UJIAN

Penyakit koronavirus (COVID-19) adalah jangkitan virus patogen yang sangat mudah merebak yang dibawa oleh sindrom pernafasan akut koronavirus 2 (SARS-CoV-2). Ini dikaitkan dengan gejala tipikal seperti demam, batuk, keletihan, sesak nafas atau kesukaran bernafas, dan kehilangan deria bau dan rasa. Sebilangan besar individu mungkin mengalami gejala ringan namun akan ada sebilangan kecil individu yang berpotensi mengalami sindrom gangguan pernafasan akut (ARDS). Biasanya gejala ringan ini akan mengambil masa selama seminggu dan kemudian akan menjadi serius sehingga alat sokongan bantuan pernafasan diperlukan bagi mendapatkan oksigen yang mencukupi untuk terus hidup.

TATACARA PENGENDALIAN UJIAN

ProDetect® COVID-19 Antigen Rapid Self-Test bertindak secara immunoesei untuk mengesan antigen SARS-CoV-2 secara kualitatif dalam sampel swab lubang hidung. Kawasan garis ujian disaluti dengan antibodi SARS-CoV-2. Sampel akan bertindak balas dengan partikel yang disaluti dengan antibodi SARS-CoV-2 di kawasan garis kit ujian. Konjugasi tersebut kemudian akan bergerak melintasi membran melalui tindakan kapilari untuk bertindak balas dengan antibodi 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

1. 1/5/20 pek ujian individu, mengandungi:
   - 1 kit ujian
   - 1 pek gel silika
2. 1/5/20 buffer
3. 1/5/20 swab hidung yang disteril
4. 1/5/20 beg biokeselamatan
5. 1 risalah arahan pengguna

BAHAN UJI YANG TIDAK DIBEKALKAN

- Pemasa

• PERINGATAN DAN AMARAN

1. Kit ujian kendiri ini adalah untuk kegunaan *in vitro* diagnostik sahaja.
2. Jangan menggunakan kit ujian ini jika sudah melebihi tarikh luput.
3. Jangan menelan.
4. Basuh tangan dengan bersih selepas melakukan ujian.
5. Jangan makan, minum, atau merokok semasa melakukan ujian.
6. Bersihkan tumpahan menggunakan pembasmi kuman yang bersesuaian.
7. Buang kit selepas mengendalikan ujian. Kit ujian tidak boleh digunakan lebih daripada satu kali.
8. Jangan menggunakan kit ujian jika pek sudah terkoyak atau rosak.
9. Jangan mencampur dan menukar sampel yang berbeza.
10. Jauhkan daripada capaian kanak-kanak.
11. Jangan membaca keputusan selepas 20 minit.
12. 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.

LANGKAH-LANGKAH

Untuk video demonstrasi, sila imbas kod QR dibawah:

SCAN ME

Basuh tangan dengan sabun dan air sekurang-kurangnya untuk 20 saat sebelum dan selepas melakukan ujian. Sekiranya sabun dan air tidak tersedia, gunakan cecair pembasmi kuman yang mengandungi alkohol sekurang-kurangnya 60%.

Kaedah Pengambilan Sampel Swab Hidung

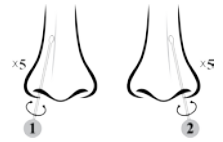
1. Keluarkan swab hidung steril dari pek ujian.
2. Masukkan swab ke dalam lubang hidung mengikut keselesaan anda (kira-kira 2 cm ke dalam hidung).
3. Putarkan swab 5-10 kali di sekeliling lubang hidung anda. Gunakan swab yang sama, ulangi langkah pengambilan sampel pada sebelah lubang hidung kedua.

Nota:Ini boleh menyebabkan ketidakselesaan. Jangan masukkan swab terlalu dalam jika berasa tidak selesa atau berasa sakit.

4. Keluarkan swab dari lubang hidung secara perlahan dan elakkan pengambilan mukus yang pekat dan berlebihan.

Peringatan:

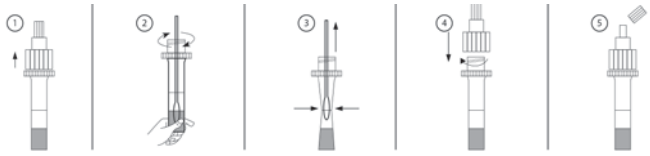
Jika anda melakukan ujian ke atas individu lain, sila pakai pelitup muka. Jika anda melakukan ujian ke atas kanak-kanak,anda tidak perlu memasukkan swab hidung terlalu dalam. Anda mungkin perlukan bantuan individu lain untuk memegang kepala kanak-kanak semasa melakukan swab hidung.



Persediaan Sampel

Sila guna tiub buffer yang disertakan dengan kit ujian untuk persediaan sampel swab.

1. Letakkan sampel swab ke dalam tiub buffer dan pastikan ia menyentuh bahagian bawah tiub. Putarkan swab untuk 10-15 saat sambil menekan kepala swab ke bahagian dalam tiub untuk mencampurkan antigen yang berada di sampel swab.
2. Tarik keluar sampel swab sambil memicit kepala swab ke bahagian dalam tiub buffer dan keluarkan cecair sebanyak mungkin daripada swab. Buangkan sampel swab ke dalam beg biokeselamatan.
3. Tutup tiub buffer pengumpulan dengan ketat.



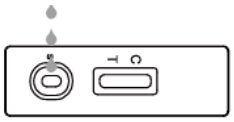
Ujian

1. Keluarkan kit ujian dari pek foil dan gunakan dalam masa 1 jam. Keputusan terbaik akan diperoleh sekiranya ujian dilakukan sebaik sahaja membuka pek foil.
2. Sila letakkan kit ujian di permukaan rata dan bersih.
3. Buka penutup kecil dan terbalikkan tiub buffer dan titiskan sampel (3 titik) ke dalam lubang sampel pada kit ujian.

Nota: Jangan gerakkan kit ujian pada langkah ini.

4. Tunggu sehingga garis berwarna muncul, Baca keputusan dalam masa 15 minit. Jangan membaca keputusan selepas 20 minit.
5. Buang kit ujian yang telah digunakan ke dalam beg biokeselamatan yang disertakan.

Titiskan 3 titik sampel buffer



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 garis berwarna 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.

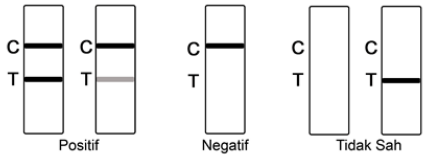
Cara pelaporan keputusan positif dalam sistem MySejahtera:

•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 tahap antigen SARS-CoV-2 adalah kosong atau berada di bawah had pengesanan ujian.

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



HAD KIT UJIAN

1. Prosedur ujian mesti diikuti dengan teliti semasa menguji kehadiran antigen protein SARS-CoV-2. Kegagalan mengikuti arahan boleh menyebabkan keputusan yang salah.
2. ProDetect® COVID-19 Antigen Rapid Self-Test 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 ini harus dipertimbangkan dengan penemuan ujian klinikal makmal yang lain. Ujian kualitatif ini tidak dapat memberikan nilai kuantitatif atau memberi nilai kepekatan antigen SARS-CoV-2.
3. Anda disarankan mengulangi ujian dengan kit ujian baru atau kit ujian molekul diagnostik untuk mengesahkan jangkitan pada individu yang diuji negatif tetapi masih mempunyai gejala klinikal.
4. Keputusan negatif dapat diperoleh jika tahap antigen koronavirus novel dalam sampel lebih rendah daripada had pengesanan minimum ujian.
5. Lebihan darah atau mukus pada sampel swab boleh menganggu keputusan dan menyebabkan keputusan positif palsu.
6. Ketepatan keputusan ujian bergantung kepada kualiti sampel swab. Ia boleh menyebabkan keputusan negatif jika pengambilan dan penyimpanan sampel tidak betul.
7. Keputusan positif COVID-19 juga mungkin disebabkan oleh jangkitan strain koronavirus selain daripada SARS-CoV-2 atau faktor gangguan lain.

CIRI-CIRI PRESTASI

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

	Nombor sampel yang disahkan PCR	Nombor sampel yang dikenalpasti dengan betul	Kadar
Sampel positif	127	1	97.69% (Kepekaan)
Sampel negatif	3	329	99.70% (Kekhususan)
Jumlah	130	330	99.13% (Jumlah ketepatan)

Nota:
1. Kepekaan 97.69%: Daripada jumlah 130 sampel positif PCR yang disahkan, didapati 127 PCR sampel positif dikesan dengan betul oleh ProDetect® COVID-19 Antigen Rapid Self-Test. Terdapat 3 kes negatif palsu.
2. Kekhususan 99.70%: Daripada jumlah 330 sampel negatif PCR, didapati 329 PCR sampel negatif dikesan dengan betul oleh ProDetect® COVID-19 Antigen Rapid Self-Test. Terdapat 1 kes positif palsu.
3. Ketepatan 99.13%: Daripada jumlah 460 sampel PCR yang disahkan, 456 sampel PCR dikesan dengan betul oleh ProDetect® COVID-19 Antigen Rapid Self-Test.

Pemerhatian menunjukkan ketepatan mungkin berbeza-beza bergantung pada penularan virus dalam populasi.

Ujian Kekhususan dengan Pelbagai Jenis Strain Virus
ProDetect® COVID-19 Antigen Rapid Self-Test diuji dengan strain virus berikut dan menunjukkan kekhususan yang baik.

Jenis Strain Virus	Tahap Ujian
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human coronavirus OC43	2.45 x 10^6 LD50/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Respiratory syncytial virus	8.89 x 10^4 TCID50/ml

KEREAKTIFAN SILANG

ProDetect® COVID-19 Antigen Rapid Self-Test telah diuji kereaktifan silang dengan *Arcanobacterium, Pseudomonas aeruginosa, Candida albicans, Staphylococcus aureus subsp. aureus, Corynebacterium, Staphylococcus epidermidis, Escherichia coli, Streptococcus pneumoniae, Moraxella catarrhalis, Streptococcus pyogenes, Neisseria lactamica, Streptococcus salivarius, Neisseria subflava, Group F streptococci*. Keputusan menunjukkan tiada kereaktifan silang.

BAHAN YANG MENGGANGGU

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

Darah 20µl/ml; Mucin 50µg/ml; Budesonide Nasal Spray 200µl/ml; Dexamethasone 0.8mg/ml; Flunisolide 6.8ng/ml; Mupirocin 12mg/ml; Oxymetazoline 0.6mg/ml; Phenylephrine 12mg/ml; Rebetol 4.5µg/ml; Relenza 282ng/ml; Tamiflu 1.1µg/ml; Tobramycin 2.43mg/ml.

RUJUKAN

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INDEKS SIMBOL YANG DIGUNAKAN

Rujuk risalah pengguna
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Nombor Siri
Tarikh dikilangkan
Pengilang
Jangan guna semula
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