ANICE COVID-19 Antigen Saliva Lollipop (Ujian kendiri)

Arahan Penggunaan

REF ISP-CA2

【Tujuan Pengunaan】

Lollipop air liur ini digunakan untuk pengesanan kualitatif in vitro bagi antigen protein N novel coronavirus (COVID-19) dalam sampel air liur manusia. Untuk Kegunaan Ujian Kendiri.Ujian antigen biasanya digunakan dalam tempoh jangkitan akut, apabila sampel diuji dalamtujuh hari bermulanya gejala dalam populasi yang disyaki.Keputusan positif ujian antigen boleh digunakan untuk triage awal dan pengurusan pantasdisyaki orang yang dijangkiti, tetapi keputusan positif hanya menunjukkan kehadiran novel ituantigen coronavirus N dalam sampel, dan tidak boleh digunakan sebagai asas untuk diagnosis danpengecualian radang paru-paru yang disebabkan oleh novel coronavirus. Ia harus digabungkan dengan asid nukleikujian, pengimejan dan maklumat diagnostik lain, sejarah perubatan dan sejarah hubungan kemenentukan status jangkitan.Keputusan negatif tidak boleh menolak jangkitan coronavirus novel, dan ia tidak boleh digunakan secara bersendirian sebagai aasas untuk rawatan dan keputusan pengurusan penyakit. Orang yang disyaki dijangkiti dengan antigenkeputusan ujian positif dan negatif perlu ujian asid nukleik selanjutnya.Coronavirus tergolong dalam ordo Nidoviridae, dan keluarga Coronavirus dibahagikan kepada tigagenera α, β, dan γ. α dan β hanya patogenik kepada mamalia, dan γ terutamanya menyebabkan jangkitan burung.CoV terutamanya dihantar melalui sentuhan langsung dengan rembesan atau melalui aerosol dan titisan.Terdapat juga bukti bahawa ia boleh disebarkan melalui laluan najis atau mulut.Sehingga kini, terdapat 7 jenis coronavirus manusia (HCoV) yang menyebabkan pernafasan manusiapenyakit: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV dan COVID-19 , Merupakan patogen penting jangkitan pernafasan manusia. Antaranya, klinikalManifestasi virus SARS-CoV-2 adalah gejala sistemik seperti demam dan keletihan,disertai dengan batuk kering, sesak nafas, dsb., yang boleh berkembang dengan cepat menjadi radang paru-paru yang teruk,kegagalan pernafasan, sindrom gangguan pernafasan akut, kejutan septik, dan kegagalan organ berbilang,Gangguan metabolisme asid-bes yang teruk, dsb., malah mengancam nyawa.

【Prinsip ujian】

Lollipop air liur ini menggunakan kaedah sandwic antibodi berganda. Pad pengikat jalur ujian ini masing-masingditutup dengan antibodi monoklonal Coronavirus anti-novel tikus 1 dengan emas koloid danAntibodi IgY ayam sebagai penanda warna. Garis pengesanan (T) pada nitroselulosamembran ditutup dengan antibodi monoklonal Coronavirus anti-novel tikus 2, dantalian kawalan kualiti (C) ditutup dengan antibodi poliklon IgY anti-ayam Kambing. Apabila ujian,apabila sampel yang akan diuji mengandungi novel coronavirus, ia bergabung dengan koloidantibodi monoklonal coronavirus novel berlabel emas untuk membentuk kompleks imun, iaituditangkap dan diperkaya pada garis pengesanan (T) oleh reagen yang ditetapkan pada membran. Theantibodi berlabel emas koloid meresap ke kawasan garis kawalan kualiti (C) dan ditangkap oleh antibodi sekunder untuk membentuk jalur ungu-merah di kawasan kawalan **kualiti.**

【Spesifikasi dan Komponen Utama】

- 1 Lollipop Air Liur Antigen COVID-19
- 1 Beg Pelupusan Bioharzard dengan 1 Lap Disinfektan
- 1 Arahan penggunaan

Bahan berikut yang diperlukan tetapi tidak disediakan dalam kit:

- Pemasa (jam tangan)
- Sebarang peralatan perlindungan diri yang diperlukan (sarung tangan, cermin mata dan lain.)

【Storan dan Jangka hayat】

Simpan pada 4℃~30℃, Lihat label untuk tarikh pengeluaran dan tarikh luput. Selepas kad reagen dibuka, ia tidak akan menjejaskan prestasi kit dalam masa 60 minit apabilaterdedah kepada suhu 25°C dan kelembapan 40-65%.

【Koleksi Contoh】

1. Dalam masa 30 minit sebelum pensampelan, jangan makan, merokok, minum wain dan minum air. Basuhtangan dengan hand sanitizer.
2. Apabila mengambil sampel, orang itu hendaklah duduk atau berdiri teguh dengan paras kepala dan sedikitke bawah, perlahan-lahan masukkan hujung penyerap kad ujian ke dalam mulut dan letakkan di bawahlidah, supaya air liur diserap secara semula jadi oleh hujung penyerap.
3. Semasa proses pensampelan, kad ujian (tetingkap pemerhatian mesti ke atas), tahapkad ujian hendaklah disimpan sedikit ke bawah, dan sudut kecondongan kad ujian tidak sepatutnyaterlalu tinggi atau terlalu rendah (seperti kepala ke bawah, kepala ke atas).
4. Langkah berjaga-berjaga:Sampel air liur sesuai untuk menguji produk ini, tetapi disyorkan untuk mengumpul sampel air liurpada waktu pagi sebelum dibilas, makan atau minum.
5. Sampel yang sangat tercemar oleh sisa makanan oral tidak boleh digunakan untuk ujian produk ini.
6. Selepas sejumlah besar darah tercemar, tidak disyorkan untuk menggunakan produk ini untuk mengujisampel air liur.
7. Jika sampel air liur terlalu likat, keputusan ujian mungkin berbeza-beza.

【Prosedur Ujian】

Baca arahan dengan teliti sebelum menggunakan kit, dan kendalikan dengan ketat mengikut peraturanarahan:

1. Keluarkan kad reagen ujian, selepas diseimbangkan kepada suhu bilik (15-30 ℃), buka bungkusan beg aluminium foil kad reagen ujian dan letakkannya rata.

2. Tanggalkan penutup kad ujian, masukkan kepala penjerapan kad ujian ke dalam mulut, tekan hujung penjerapan di bawah lidah, supaya air liur secara semula jadi diserap oleh hujung penjerapanpetua, keluarkan kad ujian selepas 2 minit, dan tutup penutup kad ujian.

3. Letakkan kad ujian secara mendatar, baca keputusan yang dipaparkan dalam masa 15-30 minit, dan hasilnyadibaca selepas 30 minit adalah tidak sah

【Pembuangan sisa selepas Prosedur Ujian】

1. Selepas ujian, letakkan kad ujian dalam beg sisa biohazard dan tutup beg itu.

2. Buang baki item kit sampel.

3. Pakai semula hand sanitizer

【TAFSIRAN KEPUTUSAN UJIAN】

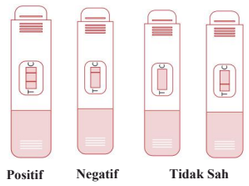
1. **Positif:** Terdapat dua jalur merah, dan kedua-dua garis pengesanan (garisan T) dan kawalan kualitigarisan (garisan C) diwarnakan.

Berhati-hati: Pada masa ini terdapat syak wasangka jangkitan COVID-19. Oleh itu, anda digalakkan untuk:

Untuk menghubungi doktor/pengamal am atau jabatan kesihatan tempatan dengan segera. Anda perlu melaporkan sendiri keputusan anda kepada My Sejahteraihttps://mysejahtera.malaysia.gov.my/help_en/selfReport/

- **Mematuhi garis panduan tempatan untuk pengasingan diri.**
- **Lakukan ujian pengesahan PCR.**

2. **Negatif:** Hanya jalur merah, garis kawalan kualiti (garisan C) berwarna;
3. **Tidak sah:** Tiada jalur warna muncul pada garis kawalan kualiti (C), dan ia dinilai sebagai tidak sahkeputusan tanpa mengira sama ada garis pengesanan (T) menunjukkan jalur warna atau tidak, dan ujian itu sepatutnyasampel semula.



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

【Had Ujian】

1. Kit ini adalah ujian kualitatif dan hanya digunakan untuk diagnosis tambahan in vitro.
2. Kit ini digunakan untuk pengesanan kualitatif in vitro bagi novel coronavirus (COVID-19) protein Nantigen dalam sampel air liur manusia.
3. Ujian positif hanya boleh menunjukkan bahawa mungkin terdapat novel coronavirus (COVID-19) Nantigen protein, dan tidak boleh digunakan sebagai satu-satunya kriteria untuk mentafsir coronavirus novel(Jangkitan Covid19. Ia harus digabungkan dengan maklumat diagnostik lain seperti nukleikujian asid dan pengimejan Menilai status jangkitan dengan sejarah perubatan dan sejarah hubungan.
4. Jika jumlah antigen N-protein dalam sampel adalah di bawah had pengesanan, negatif palsukeputusan ujian mungkin berlaku.
5. Samplig yang cacat, pengangkutan, pengendalian dan kandungan virus yang tidak mencukupi dalam sampel boleh menyebabkankeputusan negatif palsu.
6. Sila pastikan saiz sampel yang sesuai untuk ujian. Terlalu banyak atau terlalu sedikit saiz sampel bolehmembawa kepada keputusan yang tidak tepat.

Ciri-ciri prestasi

1.**Kadar kebetulan produk rujukan negatif.**Ambil produk rujukan negatif perusahaan (N1-N10) sebagai sampel untuk ujian, dan kebetulankadar sepatutnya 10/10.

2. **Kadar pematuhan produk rujukan positif.**Ambil produk rujukan positif perusahaan (P1-P5) sebagai sampel untuk ujian, dan kebetulankadar sepatutnya 5/5.

3. **Had Rujukan Pengesanan**S1~S4 semuanya positif, S5 boleh positif atau negatif.

4. **Rujukan Kebolehulangan**Ambil produk rujukan kebolehulangan korporat (J) sebagai sampel untuk ujian selari, dankeputusan ujian hendaklah positif.

5. **Kereaktifan silang**: Mikroorganisma patogen berikut telah diuji untuk kereaktifan silangdengan Kit Ujian Antigen COVID-19 . Bagi tiada mikroorganisma yang diuji, kereaktifan silang adalah diperhatikan.

Nama virus	Tahap Ujian
Endemic human coronavirusNL63	≤9.87x10²PFU/mL
MERS Coronavirus	≤793PFU/mL
Influenza A virus（H3N2）	≤8.82x10⁴ PFU/mL
Influenza B virus（Malaysia）	≤2.92x10⁴PFU/mL
Rhinovirus	≤4.17x10²PFU/mL
Endemic human coronavirus OC43	≤ 1.0x10²PFU/mL
Endemic human coronavirus 229E	≤ 1.0x10²PFU/mL
Adenovirus	≤ 1.0x10²PFU/mL
Metapneumovirus	≤ 1.0x10²PFU/mL
Parainfluenza virus type 1	≤ 1.0x10²PFU/mL
Parainfluenza virus type 2	≤ 1.0x10²PFU/mL
Parainfluenza virus type 3	≤ 1.0x10²PFU/mL
Parainfluenza virus type 4	≤ 1.0x10²PFU/mL
Influenza A virus (H1N1)	≤ 1.0x10²PFU/mL
Enterovirus	≤ 1.0x10²PFU/mL
Respiratory syncytial virus respectively	≤ 1.0x10²PFU/mL
Haemophilus influenzae	≤1.0x10⁶CFU/mL
Streptococcus pneumoniae	≤1.0x10⁶CFU/mL
Streptococcus pyogenes	≤1.0x10⁶CFU/mL
Candida albicans	≤1.0x10⁶CFU/mL
Bordetella parapertussis	≤1.0x10⁶CFU/mL
Mycoplasma pneumoniae	≤1.0x10⁶CFU/mL
Chlamydia pneumoniae	≤1.0x10⁶CFU/mL
Legionella pneumophila	≤1.0x10⁶CFU/mL
Mycobacterium tuberculosis	≤1.0x10⁶CFU/mL
Pneumocystis yersinensis	≤1.0x10⁶CFU/mL
Pseudomonas aeruginosa	≤1.0x10⁶CFU/mL
Staphylococcus aureus	≤1.0x10⁶CFU/mL
Streptococcus salivarius	≤1.0x10⁶CFU/mL
Endemic human coronavirus HKU1	≤1 x 10³ PFU/mL
SARS coronavirus	≤1 x 10³ PFU/mL
Staphylococcus salivarius	≤1 x 10⁶ CFU/mL
Human nasal rinse	≤14%

6. **Gangguan** : Komponen berikut telah diuji dengan Kit Ujian Antigen COVID-19 untukmenentukan potensi pengaruh mereka terhadap hasil ujian. Semua keputusan ujian adalah negatif, menunjukkanb ahawa tiada komponen yang mengganggu ujian.

Kepepatan	Bahan
Purified mucin	≤10mg/mL
α-interferon	≤3million U
Ribavirin	≤2.0mg/mL
Oseltamivir	≤375ug/L
Peramivir	≤20ug/mL
Levofloxacin	≤5ug/mL
Azithromycin	≤0.15g/L
Ceftriaxone	≤100mg/mL
Meropenem	≤1ug/mL
Tobramycin	≤0.125mg/mL
Oxymetazoline	≤0.126ug/dL
Sodiumchloride	≤0.9%
Flutimethasone	≤200ug/mL
Budesonide	≤0.64nmol/L
Benzocaine	≤150mg/dL
Mupirocin	≤0.15mg/dL
Biotin	≤0.354mg/dL
Diphenhydramine	≤0.0774mg/dL
Dextromethorphan	≤0.00156mg//dL
Dexamethasone	≤1.2mg/dL
Normal nasopharyngeal mucus	≤5%
Whole blood	≤5%

7. Had Pengesanan: Gunakan sampel air liur manusia biasa sebagai pelarut matriks negatif untuk dikesanpenyelesaian virus yang tidak aktif coronavirus novel selepas pencairan bersiri. Had pengesanan terendah ialah600 TCID 50 /mL.

8. Kesan cangkuk: Sampel dalam ujian bahawa tahap kepekatan novel coronaviruspenyelesaian virus tidak aktif ialah 2.0x10 5 TCID 50 /mL tidak menunjukkan kesan Cangkuk

【Prestasi Klinikal】

Keputusan produk ini dan asid nukleik coronavirus novelreagen pengesanan (RT-PCR) dibandingkan dan dikaji. 821 sampel air liur telah diuji. Thekeputusan ditunjukkan di bawah.

Ujian		RT-PCR		Jumlah
ANICE COVID-19 Antigen Saliva Lollipop (Ujian Kendiri)	Keputusan	Positif	Negatif	
	Positif	390	3	393
	Negatif	15	413	428
Jumlah		405	416	821

Kadar kebetulan positif (Sensitiviti): 96.30% (95% CI: 93.96%~97.91%)
Kadar kebetulan negatif (Kekhususan): 99.28%(95%CI: 97.91%~99.85%)
Jumlah kadar kebetulan: 97.81% (95%CI: 96.56%~98.70%)

[Langkah Berjaga-Berjaga]

1. Kit ini hanya digunakan untuk ujian in vitro. Sila baca manual ini dengan teliti sebelum mencubadan ikuti prosedur pengendalian dalam manual dengan ketat.
2. Pengumpulan, penyimpanan dan ujian sampel hendaklah dijalankan mengikut ketatgaris panduan yang berkaitan.
3. Selepas pemeriksaan, sampel yang tinggal diawet dan pelbagai rawatan sisa. Thesisa atau baki sampel yang dijana semasa proses pemeriksaan disyorkan untuk dirujukgaris panduan di atas. Pertama, dietil eter, etanol 75%, pembasmi kuman yang mengandungi klorin, peraceticasid, kloroform dan pelarut lipid lain digunakan untuk merendam virus untuk menyahaktifkan, dan kemudiannyaagen berjangkit dirawat mengikut garis panduan di atas.

【Soalan Lazim (Soalan Lazim)】

- **Bilakah saya boleh/harus menguji diri saya sendiri?**
- Anda boleh membuat ujian ke atas diri anda sama ada anda mempunyai simptom atau tidak. Sila ambil perhatian bahawa keputusan ujian ialah petikan yang sah untuk masa ini. Oleh itu, ujian harus diulang mengikut peraturan tempatan.
- **Saya telah mengambil ujian, tetapi garis kawalan (C) tidak muncul. Apa patut saya buat?**
  Mengikut arahan penggunaan, keputusan ujian ini tidak sah. Sila uji semula dengan menggunakan kad ujian baharu.
- **Saya tidak pasti tentang membaca keputusan ujian. Apa patut saya buat?**
- Baca arahan penggunaan sekali lagi, dan jika ini tidak membantu, sila hubungi kemudahan kesihatan terdekat yang disyorkan oleh pihak berkuasa tempatan anda untuk mendapatkan bantuan.
- **Jika keputusan ujian saya positif, apakah yang perlu saya lakukan?**
- Terdapat kemungkinan kemasukan ke hospital, komplikasi dan juga kematian selepas jangkitan COVID-19. Anda hendaklah segera menghubungi kemudahan kesihatan terdekat yang disyorkan oleh pihak berkuasa tempatan anda.
- **Jika keputusan ujian saya negatif, apakah yang perlu saya lakukan?**
- Jika keputusan ujian anda negatif dengan ujian, anda juga perlu mematuhi peraturan tempatan. Jika anda mengalami simptom seperti demam, sakit kepala, migrain, hilang deria bau dan rasa, hubungi fasiliti kesihatan terdekat yang disyorkan oleh pihak berkuasa tempatan anda.

【Simbol】

Simbol	Penerangan	Simbol	Penerangan
IVD	Diagnostik in vitro peranti pembuatan	LOT	Nombor Lot
Σ	Mengandungi mencukupi untuk <n>ujian		Tarikh pembuatan
	Pengilang		Tarikh luput
EC REP	Wakil yang diberi kuasa di Eropah	4°C 30°C	Simpan pada suhu bilik 4~30℃
CE	Tanda CE		Arah ini ke atas
	Berhati-hati		Simpan kering
	Rujuk arahan untuk digunakan		Rapuh: mengendalikan dengan jaga
	Risiko Biologi		Jauhkan daripada cahaya matahari
REF	Nombor katalog		Jangan guna semula

ISP WELLNESS SDN BHD (1433750-M)
No 47, Jalan Chung Ah Ming, 31650 Ipoh, Perak, Malaysia.
Tel：+(60)5-321 7673

Terima kasih membeli ANICE COVID-19 Antigen Saliva Lollipop ini(Ujian Kendiri). Sila baca manual ini dengan telitisebelum beroperasi untuk memastikan penggunaan yang betul

VIDEO TUTOURIAL

ANICE COVID-19 Antigen Saliva Lollipop (For Self-Test Only)

REF ISP-CA2 **Instruction for Use**

[Intended use]

Used for the in vitro qualitative detection of the novel coronavirus (COVID-19) N protein antigen in human saliva samples. For Self-testing only.Antigen testing is generally used in the acute infection period, when samples are tested within seven days of the onset of symptoms in a suspected population.The positive result of the antigen test can be used for early triage and rapid management of suspected infected people, but the positive result only indicates the presence of the novel coronavirus N antigen in the sample, and cannot be used as the basis for the diagnosis and exclusion of pneumonia caused by the novel coronavirus. It should be combined with nucleic acid testing, imaging and other diagnostic information, medical history, and contact history to determine the status of infection. The negative result cannot rule out novel coronavirus infection, and it can not be used alone as a basis for treatment and disease management decisions.Suspected infected people with the antigen test results of positive and negative should be further nucleic acid testing.Coronavirus belongs to the order Nidoviridae, and the Coronavirus family is divided into three genera of α, β, and γ. α and β are only pathogenic to mammals, and γ mainly causes bird infections.

CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence that it can be transmitted through fecal or oral routes.Until now, there are 7 kinds of human coronaviruses (HCoV) that cause human respiratory

diseases: HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, MERS-CoV and COVID-19 , Is an important pathogen of human respiratory infections. Among them, the clinical manifestations of SARS-CoV-2 virus are systemic symptoms such as fever and fatigue, accompanied by dry cough, dyspnea, etc., which can rapidly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, and multiple organ failure , Severe acid-base metabolism disorder, etc., even life-threatening.

[Test principle]

Using double antibody sandwich method. The binding pad of this test strip was respectively covered with mouse anti-novel Coronavirus monoclonal antibody 1 with colloidal gold and Chicken IgY antibody as the color marker. The detection line (T) on the nitrocellulocellulose membrane was covered with mouse anti-novel Coronavirus monoclonal antibody 2, and the quality control line (C) was covered with Goat anti-chicken IgY polyclonal antibody.When testing,when the sample to be tested contains the novel coronavirus, it combines with the colloidal gold-labeled novel coronavirus monoclonal antibody to form an immune complex, which is captured and enriched at the detection line (T) by the reagents fixed on the membrane. Thecolloidal gold-labeled antibody diffuses to the quality control line (C) area and is captured by the secondary antibody to form a purple-red band in the quality control area.

【Specifications and Main Components】

- 1 ANICE Covid-19 Antigen Saliva Lollipop
- 1 disposal biohazard bag and 1 disinfectant wipes
- 1 Instruction For Use

Following materials required but not provided in the kit:

- Timer (watch)
- Any necessary personal protective equipment (gloves, glasses etc.)

【Storage and Shelf life】

The kit should be stored at 4~30°C. See the label for the production date and expiration date. Afterthe reagent card is opened, it will not affect the performance of the kit within 60 minutes when exposed to temperature of 25°C and humidity of 40-65%.

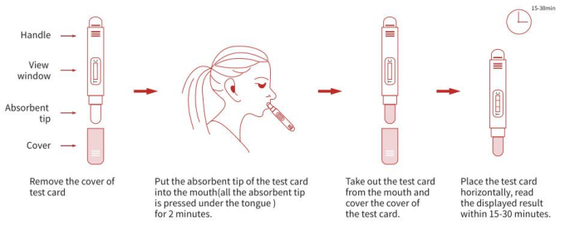
·【Sample Collection】

1. Within 30 minutes before sampling,do not eating, smoking, drink wine and drink water. Wash the hands with hand sanitizer.
2. When taking a sample, the person should sit or stand firmly with the head level and slightly downward, gently put the absorbent tip of the test card into the mouth and place it under the tongue, so that the saliva is naturally absorbed by the absorbent tip.
3. During the sampling process, the test card (observation window must be upward), the level of the test card should be kept slightly downward, and the inclination angle of the test card should not be too high or too low (such as head down, head up).
4. Precautions:Saliva samples are suitable for testing this product, but it is recommended to collect saliva samples in the morning before rinsing, eating or drinking.
5. Samples heavily contaminated by oral food residues cannot be used for testing of this product. After a large amount of blood is contaminated, it is not recommended to use this product to test saliva samples.If the saliva sample is too viscous, the test results may vary greatly.

【Test Method】

Read the instructions carefully before using the kit, and operate in strict accordance with the instructions:

1. Take out the test reagent card, after equilibrating to room temperature(15-30℃), unpack the aluminum foil bag of the test reagent card and place it flat.
2. Remove the cover of the test card, put the adsorption head of the test card into the mouth, press the adsorption tip under the tongue, so that saliva is naturally absorbed by the tip of the adsorption tip, take out the test card after 2 minutes, and close the cover of the test card.
3. Place the test card horizontally, read the displayed result within 15-30 minutes, and the results read after 30 minutes is invalid



【Waste Disposal after Test Procedures】

1. After testing, place the used devices in the biohazard waste bag and seal the bag.
2. Throw away the remaining sample kit items.
3. Re-apply hand sanitizer.

【INTERPRETATION OF TEST RESULTS】

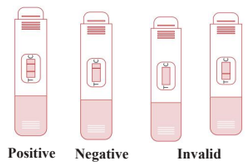
1. **Positive**: There are two red bands, and both the detection line (T line) and the quality control line (C line) are colored.

Caution: There is currently a suspicion of a COVID-19 infection. You are therefore encouraged to:

To contact a doctor/general practitioner or the local health department immediately. You need to self-report your result to My Sejahtera https://mysejahtera.malaysia.gov.my/help_en/selfReport/

- Comply with local guidelines for self-isolation.
- Have a PCR confirmatory test performed.

2. **Negative**: Only a red band, the quality control line (C line) is colored;
3. **Invalid**: No color band appears on the quality control line (C), and it is judged as an invalid result regardless of whether the detection line (T) shows color band or not, and the test should be re-sampled.



Positive Negative Invalid

【Limitations】

1. This kit is a qualitative test and is only used for in vitro auxiliary diagnosis.
2. This kit is used for in vitro qualitative detection of novel coronavirus (COVID-19) N protein antigen in human saliva samples.
3. The positive test can only indicate that there may be a novel coronavirus (COVID-19) N protein antigen, and cannot be used as the only criterion for interpreting a novel coronavirus (COVID-19) infection. It should be combined with other diagnostic information such as nucleic acid testing and imaging Judging the infection status with medical history and contact history.
4. If the amount on N-protein antigen in a sample is below the limit of detection, a false-negative test result may occur.
5. Flawed samplig, transport, handling and insufficient virus content in a sample may lead to false-negative results.
6. Please ensure an appropriate sample size for testing. Too much or too little sample size may lead to inaccurate results.

【Perfomance Characteristics】

1. **Negative reference product coincidence rate**
   Take enterprise negative reference products (N1-N10) as samples for testing, and the coincidence rate should be 10/10.
2. **Positive reference product compliance rate**
   Take enterprise positive reference products (P1-P5) as samples for testing, and the coincidence rate should be 5/5.
3. **Reference Limit of Detection**
   S1~S4 are all positive, S5 can be positive or negative.
4. **Repeatbility Reference**
   Take the corporate repeatability reference product (J) as the sample for parallel testing, and the test result should be positive.
5. **Cross reactivity**:
   The following pathogenic microorganisms were tested for cross reactivity with the COVID-19 Antigen Test Kit . For none of the tested microorganisms, cross reactivity was observed.

Analytes	Test concentration
Endemic human coronavirusNL63	≤9.87x10²PFU/mL
MERS Coronavirus	≤793PFU/mL
Influenza A virus（H3N2）	≤8.82x10²PFU/mL
Influenza B virus（Malaysia）	≤2.92x10²PFU/mL
Rhinovirus	≤4.17x10²PFU/mL
Endemic human coronavirus OC43	≤1.0x10²PFU/mL
Endemic human coronavirus 229E	≤1.0x10²PFU/mL
Adenovirus	≤1.0x10²PFU/mL
Metapneumovirus	≤1.0x10²PFU/mL
Parainfluenza virus type 1	≤1.0x10²PFU/mL
Parainfluenza virus type 2	≤1.0x10²PFU/mL
Parainfluenza virus type 3	≤1.0x10²PFU/mL
Parainfluenza virus type 4	≤1.0x10²PFU/mL
Influenza A virus (H1N1)	≤1.0x10²PFU/mL
Enterovirus	≤1.0x10²PFU/mL
Respiratory syncytial virus respectively	≤1.0x10²PFU/mL
Haemophilus influenzae	≤1.0x10⁶CFU/mL
Streptococcus pneumoniae	≤1.0x10⁶CFU/mL
Streptococcus pyogenes	≤1.0x10⁶CFU/mL
Candida albicans	≤1.0x10⁶CFU/mL
Bordetella parapertussis	≤1.0x10⁶CFU/mL
Mycoplasma pneumoniae	≤1.0x10⁶CFU/mL
Chlamydia pneumoniae	≤1.0x10⁶CFU/mL
Legionella pneumophila	≤1.0x10⁶CFU/mL
Mycobacterium tuberculosis	≤1.0x10⁶CFU/mL
Pneumocystis yersinensis	≤1.0x10⁶CFU/mL
Pseudomonas aeruginosa	≤1.0x10⁶CFU/mL
Staphylococcus aureus	≤1.0x10⁶CFU/mL
Streptococcus salivarius	≤1.0x10⁶CFU/mL
Endemic human coronavirus HKU1	≤1 x 10²PFU/mL
SARS coronavirus	≤1 x 10²PFU/mL
Staphylococcus salivarius	≤1 x 10⁶CFU/mL
Human nasal rinse	≤14%

6. Interference： The following components were tested with COVID-19 Antigen Test Kit to determine their potential influence on the test outcome. All test results were neg ative, indicating that none of the components interfered with the test.

Analytes	Concentration
Purified mucin	≤10mg/mL
α-interferon	≤3million U
Ribavirin	≤2.0mg/mL
Oseltamivir	≤375ug/L
Peramivir	≤20ug/mL
Levofloxacin	≤5ug/mL
Azithromycin	≤0.15g/L
Ceftriaxone	≤100mg/mL
Meropenem	≤1ug/mL
Tobramycin	≤0.125mg/mL
Oxymetazoline	≤0.126ug/dL
Sodiumchloride	≤0.9%
Flutimethasone	≤200ug/mL
Budesonide	≤0.64nmol/L
Benzocaine	≤150mg/dL
Mupirocin	≤0.15mg/dL
Biotin	≤0.354mg/dL
Diphenhydramine	≤0.0774mg/dL
Dextromethorphan	≤0.00156mg//dL
Dexametnasone	≤1.2mg/dL
Normal nasopharyngeal mucus	≤5%
Whole blood	≤5%

7. Limit of Detection: Use normal human saliva samples as the negative matrix diluent to detect the novel coronavirus inactivated virus solution after serial dilution. The lowest detection limit is 600 TCID50/mL.
8. Hook effect: The samples in the test that the concentration level of the novel coronavirus inactivated virus solution is 2.0x105TCID50/mL did not show the Hook effect.

【Clinical Performance】

The results of this product and the novel coronavirus nucleic acid detection reagent (RT-PCR) were compared and studied. 821 saliva samples were tested. The results are shown below.

Test		RT-PCR		Total
ANICE COVID-19 Antigen Saliva Lollipop (For Self-Test Only)	Result	Positive	Negative	
	Positive	390	3	393
	Negative	15	413	428
Total		405	416	821

Positive coincidence rate (Sensitivity):96.30% (95% CI: 93.96%~97.91%)
Negative coincidence rate (Specificity): 99.28%(95%CI: 97.91%~99.85%)
Total coincidence rate: 97.81% (95%CI: 96.56%~98.70%)

【Precautions】

1.This kit is only used for in vitro testing. Please read this manual carefully before experimenting and strictly follow the operating procedures in the manual.
2.The collection, storage and testing of samples should be carried out in strict accordance with relevant guidelines.
3.After the inspection, the remaining samples are preserved and various waste treatments. The waste or remaining samples generated during the inspection process are recommended to refer to the above guidelines. First, diethyl ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid, chloroform and other lipid solvents are used to soak the virus for inactivating, and then the infectious agents are treated according to the above guidelines.

【Frequently Asked Questions (FAQ)】

- **When can/should I test myself?**
- You can have a test on yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to local regulations.
- **I have taken the test, but the control line (C) doesn't appear. What should I do?**
- According to the instructions for use, this test result is invalid. Please retest by using a new test card.
- **I am not sure about reading test result. What should I do?**
- Read the instructions for use again, and if this doesn't help, please contact the nearest health facility recommended by your local authorities for help.
- **If my test result is positive, what should I do?**
- There is possibility of hospitalization, complications and even death after infection with COVID-19. You should immediately contact the nearest health facility recommended by your local authorities.
- **If my test result is negative, what should I do?**
- If you test result is negative by the test, you also need to obey the local regulations. If you experience symptoms such as fever, headaches, migraines, loss of sense of smell and taste, contact the nearest health facility recommended by your local authorities.

【Symbol】

Symbol	Explanation	Symbol	Explanation
IVD	In vitro diagnostic medical device	LOT	Lot number
Σ	Contains sufficient for <n>tests		Date of manufacture
	Manufacturer		Expirate Date
EC REP	Authorized representative in the European Community	30℃ 4℃	Temperature limit: 4~30℃
CE	CE Marking		This way up
	Caution		Keep dry
	Consult instructions for use		Fragile: handle with care
	Biological risks		Keep away from sunlight
REF	Catalogue number		Do not re-use

ISP WELLNESS SDN BHD (1433750-M)

No 47, Jalan Chung Ah Ming, 31650 Ipoh, Perak, Malaysia.

Tel：+(60)5-321 7673

Thank you for purchasing ANICE COVID-19 Antigen Saliva Lollipop (for self-test only).Please read this manual carefully before operating to ensure proper use.

VIDEO TUTOURIAL