INTENDED USE

This kit is intended for the qualitative detection of SARS-CoV-2 nucleoprotein antigen and influenza A/B nucleoprotein antigen using the rapid immunochromatographic method in human anterior nasal swab specimens from individuals within 7 days of onset of symptoms as an aid for diagnosis of COVID-19 and within 4 days of onset of symptoms as an aid for diagnosis of Influenza A/B.

This kit is intended for layperson' s home use in a non-laboratory environment (e.g. in a person's residence or certain non-traditional places such as offices, sporting events, airports, schools, etc.).

PRINCIPLE

The Novel Coronavirus (SARS-Cov-2) Antigen Rapid Test is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to Novel coronavirus. The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal gold conjugated with the monoclonal antibodies against Novel coronavirus; the reaction membrane contains the secondary antibodies for Novel coronavirus, and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane. When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Novel coronavirus is present in the sample, a complex formed between the anti- Novel coronavirus conjugate and the virus will be caught by the specific anti- Novel coronavirus monoclonal coated on the T region. Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

The Influenza A/B Rapid Test is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test device. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate 1 or 2 colored lines in the test regions. The presence of this colored line in either or both test regions indicate a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

PRECAUTIONS

- For in vitro diagnostic use only.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform the test at room temperature 15 to 30℃.
- Do not substitute the swab and sample extraction buffer provided in this kit with components from other kits.
- Place the soft tip of the swab into the nostril.
- Strictly follow the operating instructions.
- The samples should be tested immediately after collection.
- Children aged 2 to 15 years old should have their samples collected and tested by an adult. Do not use the test for anyone under 2 years of age.
- The test can only be used once.

STORAGE AND STABILITY

•The test can be stored at 2℃-30℃and all reagents are stable until the expiration dates marked on their outer packaging.

•Do not use after expiry.

LIMITATIONS

•False positive results may occur, particularly in individuals without SARS-Cov-2 symptoms and/or individuals who live in areas with low numbers of SARS-Cov-2 infections and without known exposure to COVID-19.

•The test is less reliable in the later phase of infection and in asymptomatic individuals.

•Repeat testing within 1 - 3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection.

•Negative results may not mean that a person is not infectious and if symptoms are present the person must seek professional medical advice.

•A negative result does not rule out infection with another type of respiratory virus.

•If you have a SARS-Cov-2 POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

•If you have a Influenza POSITIVE result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.

•In the early stages of infection or before symptoms appear, low antigen expression may lead to negative results.

•The test results are related to the quality of the specimen collection, processing, transportation and storage. Any faults can lead to imprecise results. If the cross-contamination is not controlled during specimen processing, false-positive results may occur.

•A positive result cannot necessarily determine if a person is infectious.

SAFETY INFORMATION

- Please dispose of the test materials in a closed plastic bag with the household refuse.
- •Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.
- Follow the directions of your local state or territory government health department to protect yourself.
- Test kit buffer should only be used as directed; do not ingest.
- Do not dip the swab into provided solution or other liquid before inserting the swab into the nose.
- The buffer should avoid contact with skin and eyes.
- The buffer should keep out of the reach of children and pets before taking samples and after use.
- If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation

Using SARS-Cov-2&Influenza A/B Combo Rapid Test Cassette (swab) by professional was compared to the RT-PCR kit. The sensitivity is 95.28% (101/106 known confirmed positive) for SARS-Cov-2 and 96% (72/75 known confirmed positive) for influenza A and 93.33% (28/30 known confirmed positive) for influenza B, the specificity is ＞ 99.9% (463/463 known confirmed negatives) for SARS-Cov-2 and 99.8% (493/494 known confirmed negatives) for influenza A and ＞99.9% (539/539 known confirmed negatives) for influenza B.

Usability Study

Using SARS-Cov-2&Influenza A/B Combo Rapid Test Cassette (swab) by layperson was compared to the RT-PCR kit. The sensitivity is 94.44% (34/36 known confirmed positive) for SARS-Cov-2 and 93.33% (28/30 known confirmed positive) for influenza A/B, the specificity is＞99.9% (74/74 known confirmed negative) for SARS-Cov-2 and ＞99.9% (80/80 known confirmed negative) for influenza A/B.

Variants Information

The following SARS-CoV-2 variants can be detected with SARS-Cov-2&Influenza A/B Combo Rapid Test Cassette (swab) : Alpha, Beta, Gamma ,Epsilon, Delta and Omicron.

The following Influenza strains can be detected with SARS-Cov-2&Influenza A/B Combo Rapid Test Cassette (swab) :A/Darwin/6/2021, A/Darwin/9/2021, A/Victoria/2570/2019, Hong Kong/2671/2019, A/Guangdong-Maonan/SWL1536/2019, A/Brisbane/02/2018, A/Michigan/45/2015, A/Victoria/361/2011, A/Texas/50/2012,A/California/7/2009,A/South Australia/34/2019, A/Switzerland/8060/2017, A/Singapore/INFIMH-16-0019/2016,A/Sydney/5/2021,B/Phuket/3073/2013,B/Austria/1359417/2021,B/ Washington/02/2019, B/Colorado/06/2017, B/Massachusetts/2/2012.

Limit of Detection (LOD)

The Limit of Detection (LoD) of the SARS-Cov-2&Influenza A/B Combo Rapid Test Cassette (swab) is 625 $TCID_{50}$/mL for SARS-Cov-2, 1.0×10^2 $TCID_{50}$/mL for Influenza A（H1N1）, 2.0×10^2 $TCID_{50}$/mL for Influenza A（H3N2) and 1.0×10^3 $TCID_{50}$/mL for Influenza B.

Cross Reaction

The Cross reactive study results show that the pathogens below do not affect the test results of SARS-Cov-2&Influenza A/B Combo Rapid Test Cassette (swab).

MERS-coronavirus; Adenovirus Type 1, Type 3, Type 5, Type 7, Type 8,Type 11, Type 18, Type 23, Type 55; Respiratory syncytial virus; Legionella pneumophila Bloomington-2, Los Angeles-1, 82A3105; Rhinovirus A16; candida albicans CICC 1965; pseudomonas aeruginosa ATCC9027; Enteroviruse EV68, EV71; chaamydia pneumoniae VR2282; Mycobacterium tuberculosis K, Erdman, HN878, CDC1551, H37Rv; Streptococcus pneumonia 4752-98 [Maryland (D1)6B-17], 178 [Poland 23F-16], 262 [CIP 104340], Slovakia 14-10 [29055]; Streptococcus pyrogens; Mycoplasma pneumoniae Mutant 22, FH strain of Eaton Agent [NCTC10119], 36M129-B7; Coronavirus 229E, OC43, NL63, HKU1; Human etapneumovirus(hMPV) 3 Type B1; Human Metapneumovirus (hMPV) 16 Type A1; Parainfluenza virus Type 1, Type 2, Type 3, Type 4A; staphylococcus epidermis; staphylococcus salivarius; haemophilus influenzae; bordetella pertussis.

The Cross-reactive study results show that the SARS-coronavirus affect the test results for SARS-Cov-2 and not affect the test results for Influenza A/B. The SARS-CoV-2 is not affecting the test results for Influenza A/B. The influenza A is not affecting the test results for SARS-CoV-2 and Influenza B. The influenza B is not affecting the test results for SARS-CoV-2 and Influenza A.

The kit can detect SARS-CoV-2, Influenza A and Influenza B in presence of co-infection.

Interfering Substances

When tested using the SARS-Cov-2&Influenza A/B Combo Rapid Test Cassette (swab), there was no interference between the device reagents and the Potential interference substances listed in below that would create false positive or negative results.:

Mucin; Whole Blood; Biotin; Neo-Synephrine (Phenylephrine); Afrin Nasal Spray (Oxymetazoline); Saline Nasal Spray; Homeopathic; Sodium Cromoglycate; Olopatadine Hydrochloride; Zanamivir; Oseltamivir; Artemether-lumefantrine; Doxycycline hyclate; Quinine; Lamivudine; Ribavirin; Daclatasvir; Acetaminophen; Staphylococcus aureus; Acetylsalicylic acid; Ibuprofen; Mupirocin; Tobramycin; Erythromycin; Ciprofloxacin; Ceftriaxone; Meropenem; Tobramycin; Histamine Hydrochloride;Peramivir; Flunisolide; Budesonide; Fluticasone; Lopinavir; Ritonavir; Abidor; Pooled human nasal wash; HAMA.

STATE AND TERRITORY CONTACT NUMBERS

Medical Device Incident Report

You can contact the Therapeutic Goods Administration (TGA) to report performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361.

Local state and territory health departments

Contact details and websites of the local state and territory health departments

•Australian Capital Territory Coronavirus Helpline

Business hours：02 5124 9213

Coronavirus helpline (8am to 8pm daily)：02 6207 7244

Website：https://health.act.gov.au/

•New South Wales Department of Health

General enquiries：1300 066 055

Coronavirus hotline (Service NSW, 24/7)：137 788

Website：https://www.health.nsw.gov.au/

•Northern Territory Department of Health

General enquiries：08 8922 8044

Coronavirus hotline (National helpline)：1800 020 080

Website：https://health.nt.gov.au/

•Queensland Department of Health

General enquiries：13HEALTH or 13 432 584

Coronavirus hotline：134COVID or 134 268

Website：https://www.health.qld.gov.au/

•South Australian Department of Health

General enquiries：1300 232 272

Coronavirus hotline (9am to 5pm daily)：1800 253 787

Website：https://www.sahealth.sa.gov.au/

•Tasmanian Department of Health

General enquiries：1300 135 513

Public Health Hotline (coronavirus)：1800 671 738

Website：https://www.health.tas.gov.au/

•Victorian Department of Health

Department of Health and Human Services：1300 650 172

Victorian coronavirus hotline (24/7)：1800 675 398

Website：https://www.dhhs.vic.gov.au/

•Western Australian Department of Health

General enquiries：08 9222 4222

Coronavirus hotline：13COVID (8am to 6pm, Mon - Fri) or 1800 595 206

Website：https://www.healthywa.wa.gov.au/

SYMBOL

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number	Σ	Contains sufficient for <n> tests

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