SALIXIUM

IVD

For use with saliva and anterior nasal swab specimen
For *in vitro* Diagnostic Use
For home self-testing

Salixium COVID-19 Rapid Antigen Test

(Saliva/Nasal Swab Samples)

Convenient, fast and cost-effective.

REF **SLXHB1-0621001**
SLXHB1-0621005
SLXHB1-0621020

ARTG Identifier 418208

Intended Use

The Salixium COVID-19 Rapid Antigen Test (Saliva/Nasal Swab Samples) is a lateral flow immunoassay intended as an aid in diagnosis of SARS-CoV-2 virus that causes COVID-19 in human saliva and anterior nasal swab specimen. This test is intended to detect SARS-CoV-2 nucleocapsid antigen. This test is for non-prescription home use with self-collected saliva and anterior nasal swab samples from individuals with symptoms of COVID- 19 within the first 7 days of symptom onset.

Principles of the Test

The Salixium COVID-19 Rapid Antigen Test utilises lateral flow immunoassay technology to detect SARS-CoV-2 nucleocapsid antigen in human saliva and anterior nasal swab specimen. The test strip in the test device comprises of a series of components: sample pad, conjugate pad, nitrocellulose membrane and the absorbent pad. When the sample containing SARS-CoV-2 antigen is added into the sample pad, it will react to the conjugate (COVID-19 antibody-gold conjugate) to form a complex, moved along the nitrocellulose membrane by capillary principle and bind to the COVID-19 antibody immobilized in the test line region, a pink-purplish line will appear. If the sample does not contain the SARS-CoV-2 antigen, it does not make a complex that can bind to the test region; no colour band will appear at the test region, indicating a negative result. To serve as a procedural control, a colour band will appear in the control region of the product regardless of the presence/ absence of the SARS-CoV-2 antigen in the sample.

Reagents and Materials Supplied

	1 Test SLXHB1-0621001	5 Tests SLXHB1-0621005	20 Tests SLXHB1-06210020
COVID-19 Rapid Antigen Test device individually sealed in foil pouch with desiccant	1 pc	5 pcs	20 pcs
Extraction buffer tube and dripper	1 set	5 sets	20 sets
Disposable swab	2 pcs	10 pcs	40 pcs
Biohazard waste bag	1 pc	5 pcs	20 pcs
Tube holder	-	-	4 pcs
Instruction for use (product insert)	1 pc	2 pcs	5 pcs

Materials Required but Not Supplied

1. Clock or timer
2. Hand soap and water or hand sanitizer for cleaning your hands

Storage and Stability

Stable until expiration date printed on outer packaging. Store at 4-30ºC, do not freeze. Keep the test device sealed until used. Keep away from direct sunlight, moisture and heat.

This home self-testing kit is suitable for the following people:

Adults aged 18+:
Self-collect and report (unless unable to do so).

Teenagers aged 12-17:
Self-collect and report with adult (18+) supervision. Do not conduct this test if you do not feel confident testing a child. Do not continue the test if the child feels any pain.

Children aged 2-11:
Adult (18+) to collect and report.

Do not use on anyone under 2 years of age.

Internal Quality Control

An internal procedural quality control is embedded in the test strip to ensure that the test device is functioning properly. The control line (C) on the test device will appear as a red-colored line and should appear regardless of the test result. If the control line does not develop within 15 minutes, the test result is considered invalid. Retesting should be performed with a new patient sample and test device.

Warning and Precautions

1. For home self-testing.
2. Do not use on anyone under 2 years of age.
3. This product insert must be strictly followed in order to produce accurate test results.
4. Keep the test device sealed until use. Once the device pouch has been opened, the test device must be used immediately.
5. All test devices, reagents and specimens must be atroom temperature (15-30°C) before running the assay.
6. Do not use device if the sealed pouch is visibly damaged.
7. Do not use the kit contents beyond the expiration date.
8. Avoid cross-contamination by using a new specimen extraction tube and dripper for each specimen preparation.
9. Place all used test kit components into the biohazard waste bag provided, then seal bag and dispose with normal household waste.
10. Wipe any spills of samples specimen promptly with disinfectant.
11. Do not reuse test device.
12. Do not drink the buffer in the tube. Rinse immediately with water in case of contact with skin or eyes.
13. Store test kit out of reach of pets and children.

Limitation of the Test

1. This product is designed for use with saliva and anterior nasal swab specimens only.
2. The test is for *in vitro* diagnostics use only. It is only suitable for qualitative and auxiliary diagnosis.
3. This test detects the presence of specific SARS-CoV-2 antigen in the specimen and should not be used as the sole criterion for the diagnosis of a SARS- CoV-2 viral infection.
4. Negative result does not rule out infection with another type of respiratory virus.
5. The test is a qualitative assay and it is not for quantitative determination of antigen concentration level. The intensity of the band does not have linear correlation with the antigen titer of the specimen.
6. The performance of the test depends on antigen load in the specimen and may not correlate with PCR performed on the same specimen.
7. Inadequate or inappropriate specimen collection,may cause false negative results.
8. A positive result can not necessarily determine whether a person is infectious.
9. Repeat testing (e.g., within 1 – 3 days) is recommended if there is an ongoing suspicion of infection, high risk setting, or occupational or other requirement.
10. A negative result at any time does not exclude the possibility of an early infection of SARS-CoV-2 virus. A negative result can occur if the quantity of SARS-CoV-2 virus antigen present in the specimen is below the detection limits of the assay.
11. False negative results are more likely to occur if the test is performed in the later phase of infection and in asymptomatic individuals. It is recommended to use the test within the first 7 days of symptom onset.

Warranty and Limited Liability

The performance characteristics stated were obtained by using the assay procedure in this insert. Failure to follow the assay procedure may derive inaccurate results. In such event, the manufacturer disclaims all warranties expressed, implied or statutory, including the implied warranty of merchantability and the fitness for use.

The manufacturer will not be liable for any damage caused by misuse, improper handling and storage, non-compliance with warnings and procedures, damage caused by events occurring after the product is released, failure to ensure the product is in proper condition before use, or any warranty given by independent distributor.

References

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020. [Accessed 26 Jan 2020]. https://www.who.int/china/news/detail/09-01- 2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan- china
2. To KKW, Chan KH, Ho J, Pang PKP, Ho DTY, Chang ACH Respiratory virus infection among hospitalized adult patients with or without clinically apparent respiratory infection: a prospective cohort study Clinical Microbiology and Infection 25 (2019) 1539e1545.
3. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Advances in Virus Research (2011), 81:85-164.
4. Su S, Wong G, Shi W et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology (2016), 24:490-502.
5. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nature Reviews Microbiology (2019), 17:181-192.

Performance Characteristics

Clinical Performance

A clinical study was conducted by healthcare professionals to compare the results obtained with Salixium COVID-19 Rapid Antigen Test (Saliva/Nasal Swab Samples) and FDA Emergency Use Authorized real-time RT-PCR assay. The Salixium COVID-19 Rapid Antigen Test (Saliva/Nasal Swab Samples) produced 97.24% sensitivity and 100% specificity out of 534 participants.

Usability study

A usability study was conducted with the enrolment of 540 users who were instructed to self-collect their saliva swab and nasal swab samples. The sensitivity and specificity of Salixium COVID-19 Rapid Antigen Test (Saliva/Nasal Swab Samples) were 96.92% and 100% respectively. The overall feedback from lay users was that they agreed that the test was user-friendly and easy to use.

Variants

In-house evaluation test indicated that Salixium COVID-19 Rapid Antigen Test (Saliva/Nasal Swab Samples) was able to detect SARS-CoV-2 variants: Alpha (B.1.1.7), Beta (B.1.351) and Omicron (B.1.1529) at specific concentrations.

Analytical Performance

Limit of Detection (LoD)

The LoD of Salixium COVID-19 Rapid Antigen Test (Saliva/Nasal Swab Samples) is 2.8 x 10^2 $TCID_{50}$/ml.

Cross-reactivity

No cross-reactivity was observed for the following organisms.

Bacteria *Acinetobacter calcoaceticus, Bacteroides fragilis, Neisseria gonorrhoeae Neisseria meningitidis, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus sanguis, Proteus vulgaris, Streptococcus sp. Gp. B, Streptococcus sp. Gp. C, Streptococcus sp. Gp. G, Mycobacterium tuberculosis, Mycoplasma orale, Bordetella pertussis, Chlamydia pneumoniae, Haemophilus influenza, Legionella pneumophila, Staphylococcus epidermidis, Staphylococcus salivarius, Streptococcus pyogenes, Mycoplasma pneumoniae*

Virus Adenovirus B, Adenovirus C, Adenovirus type 10, Adenovirus type 18, Human Coronavirus OC43, Human Coronavirus 229E, Human Coronavirus NL63, Human Coxsackievirus A9, Coxsackievirus B5, Human herpesvirus2, Human Rhinovirus 2, Human Rhinovirus 14, Human Rhinovirus 16, Measles, Mumps, Sendai virus, Respiratory syncytial virus, Human Coronavirus HKU1, SARS-coronavirus, MERS-coronavirus, Human Metapneumovirus (hMPV), Enterovirus (EV68), Parainfluenza virus 2, Parainfluenza virus 3

Influenza virus Taiwan/1/86 Type A, Beijing/262/95 Type A, H1N1 Strain A/ New Caledonia/20/99 IVR 116 Type A, H1N1 Solomon Islands/03/06 Type A, H3N2 Strain A/ Shangdong/9/93, Type A H3N2 Strain A/ Panama/2007/99 Type A, H3N2 Strain A/ Kiev/301/94 Type A, Wisconsin/67/05 Type A, Brisbane/10/06 Type A Type A, Panama Type B, Lee Type B, Hong Kong Type B, Maryland Type B, Stockholm Type B,

Yeast *Candida albicans*

Fungus *Pneumocystis jirovecii* (PJP)

Interfering Substances

No interference was observed for the following substances.

Whole blood, mucin, three types of OTC mouthwashes, toothpaste, lozenges, chloroseptic sore throat spray, nasal gel, tobramycin, mupirocin, 4-Acetamidophenol, chlorpheniramine, dextromethorphan, diphenhydramine, oxymetazoline, phenylephrine, hand sanitizer, nasal corticosteroid (Rhinocort Aqua), anti-viral drug (Tamiflu), chewing gum, coffee, tea, soft drink, nicotine, HAMA and biotin.

Frequently Asked Questions (FAQ)

How does Salixium COVID-19 Rapid Antigen Test (Saliva/Nasal Swab Samples) work?

This test is an immunochromatographic assay designed for the qualitative detection of specific SARS-CoV-2 nucleocapsid antigen in human saliva swab and nasal swab specimen. It is intended to be used for the detection of SARS-CoV- 2 virus infection.

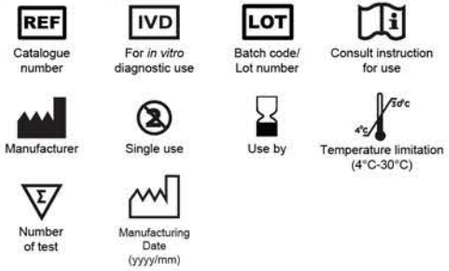
When should I use this test?

Nucleocapsid antigen is generally detectable during the acute phase of infection (within 7 days from symptom onset). However, the performance of the test depends on antigen load in the specimen and may not correlate with PCR performed on the same specimen. Inadequate or inappropriate specimen collection, may cause false negative results.

Will this test hurt?

Anterior nasal swab and saliva swab are required for this kit. Saliva swab sample collection should not hurt the user. During anterior nasal swab collection, a slight irritation might occur but it should not be painful.

Explanation of Symbols



State and Territory Contact Numbers

National Coronavirus Helpline (24/7)	**1800 020 080** www.health.gov.au/contacts/national-coronavirus-helpline
Australian Capital Territory Department of Health	**02 6207 7244** https://health.act.gov.au/
New South Wales Department of Health	**137 788** https://www.health.nsw.gov.au/
Northern Territory Department of Health	**1800 490 484- NT** https://health.nt.gov.au/
Queensland Department of Health	**134 268** https://www.health.qld.gov.au/
South Australian Department of Health	**1800 253 787** https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	**1800 671 738** https://www.health.tas.gov.au/
Victorian Department of Health	**1800 675 398** https://www.health.vic.gov.au/
Western Australian Department of Health	**1800 595 206** https://www.health.wa.gov.au/

TGA Contact Information

Contact the TGA to report poor performance or usability issues in the self-test environment via the Users Medical Device Incident Report, email iris@tga.gov.au or call **1800 809 361**

Customer Support Helpline:
Call 1300 418 188
For information on the correct use of this test and for interpretation of the test results.

Customer Service Hours:
(24/7)

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IFU No: SLXHB1-0621-EN-AU
Version: 4:01
Effective Date: 2024.04.29

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