AESKU.*RAPID* SARS-CoV-2 Antigen Test

INSTRUCTIONS FOR USE

REF 840001E (20 pcs) REF 840003E (5 pcs) REF 840005E (2 pcs) REF 840007E (1 pcs) *For home use.* CE IVD

INTENDED USE

The ***AESKU**.RAPID* SARS-CoV-2 rapid test is an immunochromatographic sandwich method with two specific antibodies for the qualitative detection of the N-protein antigen in human nasal swab samples from individuals aged 12 years or older. Persons younger than 12 must be assisted in the application.

The test is designed to detect SARS-CoV-2 N-protein antigens during the acute phase of infection within the first 7 days of onset of symptoms. ***AESKU**.RAPID* is for the aid for diagnosis of COVID-19.

***AESKU**.RAPID* is for non-prescription home use. The test kit is intended for single use only.

DIAGNOSTIC RELEVANCE

COVID-19 is an acute infectious disease of the respiratory tract caused by the novel coronavirus SARS-CoV-2. The primary sources of infection are symptomatic and asymptomatic infected persons. The incubation period is up to 14 days but usually lies between 5 and 6 days. The main manifestations are loss of smell and taste, fever, malaise and fatigue, and dry cough. In some cases, stuffy nose, shortness of breath, sore throat, and myalgia may occur.

Positive test results confirm the presence of viral antigens, but a clinical history is still necessary to determine the infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses.

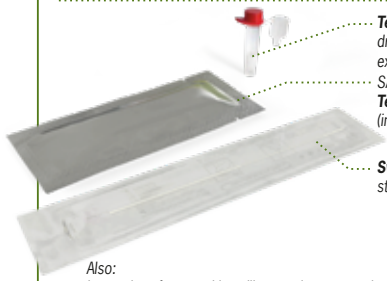
Negative test results do not entirely rule out COVID-19 and should be considered in conjunction with recent exposure, medical history, and the presence of clinical signs and symptoms.

TEST PRINCIPLE

The ***AESKU**.RAPID* SARS-CoV-2 rapid test is based on immunochromatographic polymer technology combined with the sandwich principle for the qualitative detection of the nucleocapsid protein antigen in human nasal swab samples. The sample is mixed with coloured polymer-labelled SARS-CoV-2 monoclonal antibody 1 in the test device's sample well and chromatographed along the nitrocellulose membrane. If SARS-CoV-2 antigens are present in the sample, they will bind to SARS-CoV-2 antibody 1, and the mixture will bind to immobilized SARS-CoV-2 antibody 2 on the nitrocellulose membrane.

The resulting complex of antibody 1, antigen and antibody 2 forms the coloured test line. The test device's control line is coated with secondary antibodies, resulting in a coloured result during a standard test procedure.

CONTENTS TEST KIT



***Test tube** with dropper filled with extraction buffer SARS-CoV-2 Antigen **Test Cassette** (incl. desiccant)*

***Swab** sterile, CE0197*

Also:
Instructions for use with an illustrated test procedure Holder for test tubes (kit of 5) – alternatively: Tab with pre-punched holes (kit of 1 or 2)

NOTES ON THE TEST

Please take about 30 minutes when reading the instructions for the first time and performing the test!

Before starting the test, please read these instructions for use entirely and carefully. Allow the reagents to warm up to **room temperature** before use. Store the test at 4°C-30°C away from light and in a dry place. Never freeze the test. Make sure that the test has not expired and that the foil pouch is not damaged.

Expiration date: See the label placed on the packaging. Do not use after the expiry date.

After removing the test cassette from the aluminium packaging, the test should be performed **immediately**.

Be sure to follow the steps listed in the IFU.

Make sure that a clock with a second display is available for the test.

Only nasal swabs from the anterior nasal region can be used for this test.

PRECAUTIONS AND WARNINGS

The package contains ingredients classified according to EC Regulation 1272/2008. The following warnings, prevention, and reaction statements refer to the pure substances (including citric acid) used to prepare the extraction buffer.

The buffer itself is a mixture of low-concentration substances with different biochemical properties, all of which are below their respective GHS limit value:

Warning: H317: May cause allergic skin reaction.

Prevention: P280: Wear protective gloves/protective clothing/face shield.

Reaction: P333+P313: If skin irritation occurs: seek medical advice/attention. P362+P364: Remove contaminated clothing and wash before reuse. Wash before reuse.

Do not allow to enter the environment, drains, or waterways.

Do not use any of the test components other than the included test stick in the body.

This product is authorized only to detect proteins of SARS-CoV-2, not for any other viruses and pathogens.

For in vitro diagnostic use only. Do not use it after the expiration date.

Samples should be considered as potentially infectious.

Follow the Instructions For Use carefully. The accuracy of the assay results cannot be guaranteed if there is any deviation from the *Instructions For Use*.

PREPARATION OF THE TEST

Before you start, please blow your nose and wash your hands!

First, please open the aluminium packaging of the test cassette. Place the test cassette in front of you.

Take the test tube in your hand and carefully remove the lid.

Have the enclosed holder for the sample tube ready – alternatively fold up the flap with the pre-punched holes. Insert this into the opening provided for this purpose.

Take out the packaging of the test stick (swab) and open it at the position "OPEN" or "PEEL". *Please open only there, as you will insert the other sterile end into the nose later.*

Then take out the test stick. Grasp the test stick according to the illustration in the IFU (*step 1*).

PERFORMANCE OF THE TEST

You can find complete and illustrated instructions in the IFU.

Limitations:

- If the test is not performed within the first 7 days of symptom onset, the risk of false-negative results may occur.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.
- Repeat testing within 1-3 days is recommended if there is an ongoing suspicion of infection, high-risk setting or occupational.
- A negative result does not rule out infection with another type of respiratory virus.
- Negative results may not mean that a person is not infectious, and if symptoms are present, the person must seek immediate further testing by PCR.
- Positive test results do not rule out co-infections with other pathogens.
- Positive results cannot determine whether a person is infectious.
- Reading the results earlier than 15 minutes or later than 20 minutes may give incorrect results.
- This IVD has been evaluated for use with human specimen material only.

Test for self-testing

Version 005. C.I.AIE: 2022-09-28 EN AUSTRALIA

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INTEGRATED SCIENCES NUMBER: 1800 252204 HOURS: 9AM TO 7PM (AEST) AND 7DAYS

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CLINICAL PERFORMANCE OF THE TEST

The clinical performance was evaluated in a study with 140 positive ($C_t \leq 32$) and 301 negative samples confirmed by PCR testing.

The diagnostic specifity of ***AESKU**.RAPID* is 99.3 % (95% CI: 97.6-99.8 %) and the sensitivity was determined in relation to the Ct-Value as follows:

***AESKU**.RAPID* SARS-CoV-2	RT-PCR		
	Positiv	Negativ	Total
Positiv	138	2	140
Negativ	2	299	301
Total	140	301	441

C_t-Value	Number of Samples	Number of *true-positive* Rapid Test Samples	Number of *false-negative* Rapid Test Samples	Sensitivity of *AESKU.RAPID* SARS-CoV-2 Rapid Test (CI)
≤ 30	119	119	0	100 % (96.9-100)
≤ 32	140	138	2	98.6 % (94.9-99.6)

ANALYTICAL PERFORMANCE OF THE TEST

Detection limit: The detection limit was determined using positive samples diluted with the sample matrix of the nasal swabs – the detection limit of ***AESKU**.RAPID* SARS-CoV-2 is 50 $TCID_{50}$/mL.

Cross-Reactivity and Microbial Interference: The following cross-reactants and microorganisms have no impact on the performance of ***AESKU**.RAPID*:

Coronavirus (229E), Coronavirus (NL63), Coronavirus (OC43), MERS-CoV (Florida/USA-2_Saudi Arabia_2014), Coronavirus (HKU1), Adenovirus Type 01 (Species C), Adenovirus Type 02 (Species C), Adenovirus Type 118 (Species B), Enterovirus Type 68 (2014 Isolate), Human Metapneumovirus (hMPV) 16 Type A1, Parainfluenza Virus Type 1, Parainfluenza Virus Type 2, Parainfluenza Virus Type 2, Parainfluenza Virus Type 3, Parainfluenza Virus Type 4B, Respiratory Syncytial Virus Type A (Isolate: 2006), Influenza A H_3N_2 (HK/8/68), Influenza A H_1N_1 (Brisbane/59/07), Influenza A H_1N_1pdm (Canada/6294/09), Influenza B Virus (Washington/02/19), Influenza B (Texas/6/11), Influenza B (Alabama/2/17), Staphylococcus epidermidis, Bordetella pertussis, Legionalle pneumophila, Streptococcus pyogenes, Haemophilus influenzae, Mycobacterium tuberculosis, Streptococcus pneumoniae, Mycoplasma pneumoniae, Candida albicans, Pseudomonas aeruginosa, Streptococcus salivarius, Staphylococcus aureus (DSM 346), Staphylococcus aureus (DSM 683).

Cross-reactivity with SARS-CoV-1 cannot be excluded.

Hook Effect: Even in samples with high virus doses (3.6×10^5 $TCID_{50}$/mL), no hook effect was detectable.

Based on the detection of the nucleocapsid protein, it can be assumed that ***AESKU**.RAPID* SARS-CoV-2 detects all known mutations. This is applicable to the spike protein and therefore has no impact on the test. This is proven for the Alpha, Beta, Delta, Gamma, and Omicron variant.

WHAT'S NEXT?

The ***AESKU**.RAPID* SARS-CoV-2 is a presumptive test, and positive results require confirmation by a PCR laboratory. Contact your State or Territory Coronavirus testing services to get a laboratory PCR test. You can never exclude the possibility of a false positive and a false negative result. Suppose you receive a negative result but still experience symptoms such as cough, fever, or cold. In that case, contact your State or Territory Coronavirus testing services to get a laboratory PCR test. *Even without symptoms and in case of a negative result, please continue to adhere to the applicable distance rules, contact restrictions, and hygiene measures.*

	Observe instructions for use	STERILE EO	Ethylene oxide sterilization		Do not reuse		Attention
IVD	In Vitro Diagnostic		Best before		Protect from light	CE	European Conformity
	Storage at room temperature	LOT	Lot designation	REF	Order number		
	Number of determinations		Manufactured by		Store in a dry place		

IMPORTANT CONTACTS

TGA Medical Device Incident Report
To report poor performance or usability issues.
Phone: 1800 809 361 Email: iris@tga.gov.au
You can find testing locations by calling the numbers below or visitingthese websites.

Australian Capital Territory Department of Health
General Enquiries: 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)
Website: https://www.healthywa.wa.gov.au/

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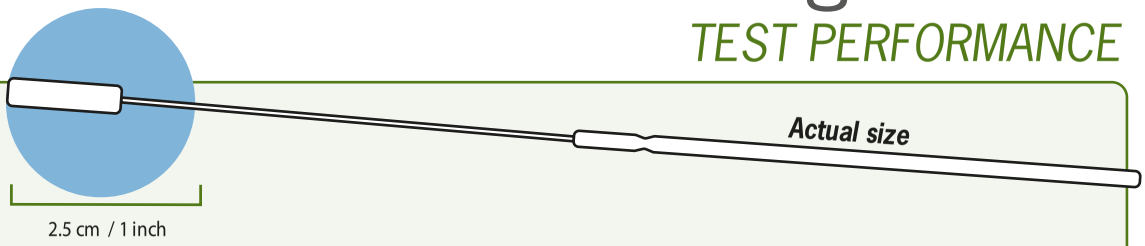
TEST PERFORMANCE

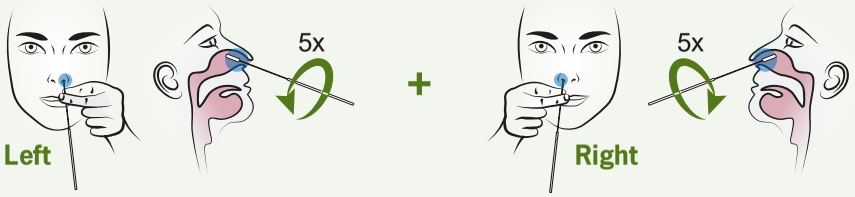


1 Swab

Prepare for test

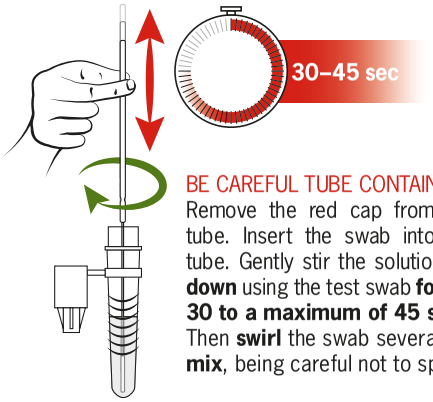
1. Blow your nose.
2. Wash your hands.
3. Read all instructions before test.
4. Check kit contents.
5. Have timer ready.

Watch tutorial video

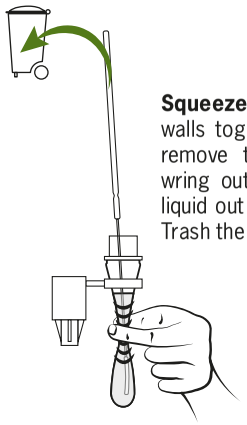


Carefully insert the swab **no more than 1 - 1.5 cm (1/2 - 3/4 inch) deep into one nostril** – for children/adolescents only until a slight resistance is felt. **Roll** the swab **five times** along the nasal mucosa. **Repeat** this process in the **other nostril** with the same swab.

2 Prepare the Solution

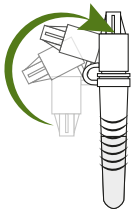


BE CAREFUL TUBE CONTAINS LIQUID!
Remove the red cap from the test tube. Insert the swab into the test tube. Gently stir the solution **up and down** using the test swab **for at least 30 to a maximum of 45 seconds**. Then **swirl** the swab several times to **mix**, being careful not to spill.

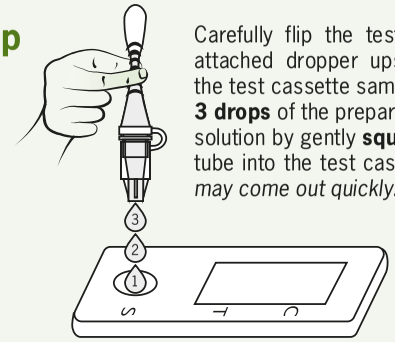


Squeeze the test tube walls together as you remove the swab to wring out any excess liquid out of the swab. Trash the swab.

Take the attached dropper top and press it onto the tube. Make sure it is secured.



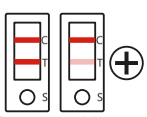
3 Drop



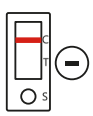
Carefully flip the test tube with the attached dropper upside down over the test cassette sample well (S). Add **3 drops** of the prepared sample liquid solution by gently **squeezing** the test tube into the test cassette (S). *Liquid may come out quickly.*

Start timer and **wait 15 minutes** after sample application for the result. *Please leave the test cassette still and on a flat surface during this time.*

4 Read & Interpret



Corona positive



Corona negative

invalid

invalid

Result interpretation must be **read within 15 - 20 minutes** after sample has been added to sample well. *Test results should not be read after more than 20 minutes as it may falsify the result. Control line (C) may develop sooner.*

If your test result is positive
If your result is positive, you must immediately isolate, contact the authorities in your state or territory and arrange to have a laboratory PCR test.

If your test result is negative
Negative results may not mean that a person is not infectious and if symptoms are present you should arrange to have a laboratory PCR test.

If your test result is invalid
If you receive an invalid test result, please repeat the test with a new test kit!

5 Disposal

Dipose of used test cassette in the trash. Ensure you wash your hands thoroughly.

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