HA TECH
BioPharma & Diagnostics

SARS-COV-2 RAPID ANTIGEN TEST KIT RAT-01 (SELF-TEST) INSTRUCTIONS FOR USE

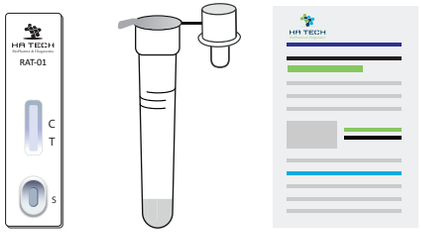
V1.4

MATERIALS PROVIDED

Components	1T/Kit	5T/Kit
Test Cartridge	1	5
Sample Extraction Tube with Extraction Solution	1	5
Sterile Swab Stick	1	5
Instruction For Use (IFU)	1	1

IN THE CASE

Sterile Swab

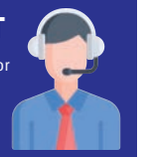


Test Cartridge | Sample Extraction Tube | Instructions For Use (IFU)

CUSTOMER SUPPORT

For assistance regarding the use of the kit or any other support please call our 24/7 HA TECH Customer Support Line on:

(+61) 431 581 133



SCAN FOR VIDEO GUIDE

Scan this QR code to access a video of these instructions. For further information please visit our website: https://ha-tech-ltd.com/covid-rapid-antigen-test/ or call us on: +61 (0)431 581 133

SCAN ME

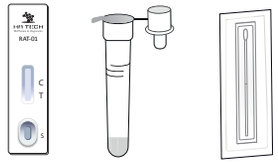
Please read the **"What you need to know before testing"** section before starting the test. You must carefully follow all instructions in the test procedure to achieve accurate results.

STEP 1 PREPARATION

1

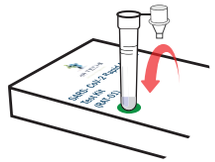
Wash your hands with soap and water for at least 20 seconds before the test.

2



Check the expiry date. Unpack the kit and check that you have all test components.

3



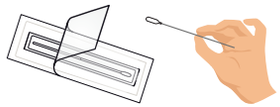
Take the extraction tube and place it in the tube holder marked on the box.

4

Gently peel off the foil covering the tube.

STEP 2 SAMPLE COLLECTION

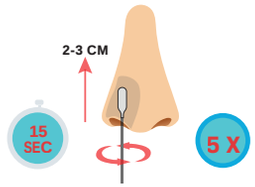
5



Remove the swab from its packaging

Caution: Be careful not to touch the swab tip.

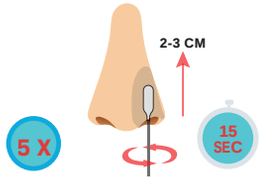
6



Gently insert the swab approximately **2-3 cm** into the **LEFT** nostril. Slowly rotate the swab at least **5 times** for around **15 seconds**

Caution: If your nose is blocked, blow it before swabbing.

7



Remove the swab from the **LEFT** nostril and insert into the **RIGHT** nostril. Again, rotate **5 times** for **15 seconds**.

STEP 3 TEST PROCEDURE

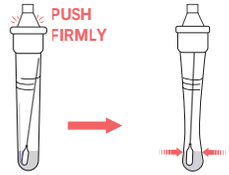
8

Place the swab in the extraction tube liquid. Rotate the swab tip against the walls of the tube vigorously at least 10 times.

9

Break the swab at the notched point and leave it in the tube.

10



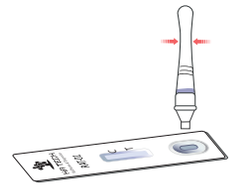
Close the nozzle firmly onto the tube. Squeeze the tube around the swab tip at least 5 times.

11

Take the cartridge out of its foil pouch and place it on a clean flat surface.

Caution: Do not use the cartridge if it has been out of the pouch for more than an hour

12



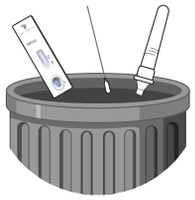
Hold the extraction tube above the sample well. Squeeze gently so that 2 drops fall into the well.

13

Set a timer for 10 minutes. Read the results after 10-15 minutes as weak positive take time to appear.

Caution: Results after 20 minutes may be inaccurate.

14



Carefully wrap the used test components and dispose of in general waste.

Please see the **"What to know after reading your result "** section on the next page for further information.

STEP 4 INTERPRETATION OF TEST RESULTS

Positive Result

(COVID-19 DETECTED)

Colored bands appear at both the test line (T) and control line (C). The result is considered positive even if the test line (T) is very faint.

Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance

Negative Result

(COVID-19 NOT DETECTED)

Colored band appears at control line (C) only. It indicates that SARS-COV-2 antigens were not detected in the sample.

Caution: You should re-test after 24-72 hours if you have symptoms. Negative result may not mean that the person is not infectious with Covid-19. If symptoms persist or if unwell please consult a medical practitioner for follow-up clinical care.

Invalid Result

No visible colored band appears at control line (C) after performing the test. The instructions may not have been followed correctly or the kit may have been defective and the test should be repeated with a new kit.

SARS-COV-2 RAPID ANTIGEN TEST KIT RAT-01(SELF-TEST)

Instructions for Use

HA TECH
BioPharma & Diagnostics

What you need to know before testing

Intended use:

The SARS-CoV-2 Rapid Antigen Test Kit (RAT-01) is intended to aid the diagnosis of COVID-19 in symptomatic patients through qualitative detection of SARS-CoV-2 nucleocapsid protein antigen. This test is intended for home use with nasal swab specimens from individuals who have experienced COVID-19-like symptoms within the last 7 days.
This test is a qualitative detection of SARS-CoV-2 antigen based on the principal of immuno-chromatography.

Warnings:

- Each test can only be used once, do not re-use any kit contents
- Test results should be read between 10 and 15 minutes:
  Interpretation of results before 10 minutes can cause weak positives to be missed. Interpretation of results after 20 minutes may be inaccurate
- Children must be tested or supervised by a parent or guardian
- Excess blood or mucus in the sample may interfere with test performance
- Keep foreign substances and household cleaning products away from kit components as contact can affect test results
- Do not use if the test device packaging is damaged or shows signs of being tampered with
- Do not use the test beyond the expiration date or if it has been stored incorrectly
- Avoid eye and skin contact with the extraction solution. Do not ingest the extraction solution

Storage and Stability:

- Store at 2-30°C
- Keep in a cool dry place away from sunlight, moisture and heat
- The test cartridge should be used within 1 hour of being taken out from the foil pouch
- The product batch number, production and expiry date are printed on the cartridge pouch. Under the correct storage conditions, the items in the kit are stable until the expiration date

Performance Characteristics:

Variants:
In-house evaluation using purified nucleocapsid proteins as well as inactivated virus at the limit of detection demonstrated that the performance of the SARS-CoV-2 Rapid Antigen Test Kit was not affected by Delta, and Omicron variants. Performance at the time of testing may differ depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

Clinical performance:
The SARS-CoV-2 Rapid Antigen Test Kit was compared to a TGA authorized RT-PCR molecular assay. The SARS-CoV-2 Rapid Antigen Test Kit correctly identified 96.5% (165 out of 171 people) of positive samples and 99.7% (302 out of 303 people) of negative samples.
A second study was conducted to evaluate clinical performance with self-testing. 105 lay persons were recruited, of which 32 were known positive and 73 were unknown. 96.97% (32 out of 33 people) of positive samples and 100% (72 out of 72 people) of negative samples were identified correctly compared to RT-PCR, demonstrating sensitivity and specificity was maintained in the hands of lay users. Sensitivty was 100% within the first 7 days of symptom onset.
In a third study the kit correctly identified 103/108 (95.6%) RT-PCR positive samples and 300/301 (99.7%) RT-PCR negative samples. All estimated Sensitivity and Specificity were within the 80% Sensitivity and 98% Specificity requirements set by TGA. When positive samples were stratified by days of symptoms onset, sensitivity was 100% for the first five days. Sensitivity decreased to 92.31% and 85.71% for 6 and 7 days of symptoms onset respectively.

Analytical specificity:
The potential cross-reactivity of the following pathogens was evaluated with SARS-CoV-2 negative and positive samples using The SARS-CoV-2 Rapid Antigen Test Kit, with no interference detected:
Human coronavirus 229E, Human coronavirus OC43, Human coronavirus HKU1, Human coronavirus NL63, MERS-coronavirus, Adenovirus, Human Metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A, Influenza B, Enterovirus D68, Respiratory syncytial virus, Rhinovirus, *Chlamydia pneumoniae, Haemophilus influenzae, Legionella pneumophila, Streptococcus pneumoniae, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Candida albicans.*

Analytical Sensitivity:
The Limit of Detection (LoD) was determined to be 1.3×10^2 $TCID_{50}$/mL.

Endogenous Interfering Substances:
The following substances were spiked into samples and tested with the SARS-CoV-2 Rapid Antigen Test Kit. No interference with results was observed.

Substance (Concentration): Purified Mucin, Human blood, Nasal spray, Afrin (Oxymetazoline), Tobramycin, Fluticasone , Budenoside and Dexamethasone.

What to know after reading your result

Limitations:

- False negative results are more likely to occur if the test is performed after 7 days of symptom onset.
- False negatives are more likely to occur in the later phase of infection and in asymptomatic individuals
- A negative result does not rule out infection with another type of respiratory virus.
- Negative results should be treated as presumptive only and may not mean you are not infectious. If you are experiencing any COVID-19 symptoms you should immediately seek further testing.
- Repeat testing is recommended (between 24-72 hours after your first test) if there is an ongoing suspicion of infection, been in a high risk setting or where there is an occupational risk or other requirement.
- A positive result cannot determine whether you are infectious.
- If your test result is positive, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- A red band at the 'T' line indicates detection of COVID-19. The test also contains a quality control zone indicated by the 'C'. A red band should always appear at the 'C' line. If the quality control line does not appear, the test result is invalid, and the sample needs to be tested again.

COVID-19 Safety Information:

- Wear a safety mask or other face-covering when collecting the sample from another individual
- Handle all specimens as though they are potentially infectious
- Carefully wrap the used test kit components and swab samples and dispose in normal household waste

To help slow the spread of COVID and protect yourself and others:

- practice good hygiene (e.g., washing your hands, covering your coughs)
- practice physical distancing
- 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

Contact Information:

For assistance regarding the use of the kit or any other related questions, please call the HA TECH Customer Support Line available 24/7 on (+61) 431 581 133

You can also 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.

Support Services:

For further information regarding available support services, contact your local state and territory health department at:

ACT: 02 5124 9213
www.health.act.gov.au

NT: 08 8922 8044
www.health.nt.gov.au

NSW: 1300 066 055
www.health.act.gov.au

QLD: 13 432 584
www.health.qld.gov.au

SA: 1300 232 272
www.sahealth.sa.gov.au

VIC: 1300 650 172
www.dhhs.vic.gov.au

TAS: 1300 135 513
www.health.tas.gov.au

WA: 08 9222 4222
www.healthywa.wa.gov.au

Index of Symbols

IVD — In Vitro Diagnostic Use	Store between 2~30°C
Tests per Kit	Keep Dry
LOT — Batch Number	Keep away from sunlight
See Instruction for Use	This Side Up
Manufacturer	Expiry Date
Manufacturing Date	EC REP — Authorized Representative
Do Not Reuse	REF — Catalog #

General Information

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