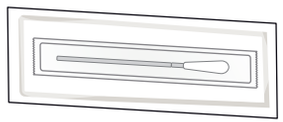
HA TECH
BioPharma & Diagnostics

SARS-CoV-2 & Influenza A/B Combo Rapid Antigen Test Kit RAT-03 (Self-Test) Instructions for Use

MATERIALS PROVIDED

Components	1T/Kit	5T/Kit	20T/Kit
Test Cartridge	1	5	20
Sample Extraction Tube with Extraction Solution	1	5	20
Sterile Swab Stick	1	5	20
Instructions For Use (IFU)	1	1	4

IN THE BOX



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 (0)431 581 133

SCAN ME

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/sars-cov-2-flua-flub-combo-rapid-test/ or call us on: +61 (0)431 581 133 This service is available 24/7.

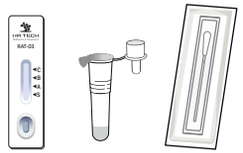
Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

STEP 1 PREPARATION

1

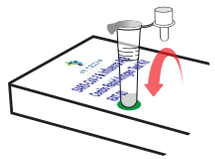
Wash your hands with soap and water for at least 20 seconds before the test.

2



Check the expiry date. Check all kit components are present and have not been opened.

3



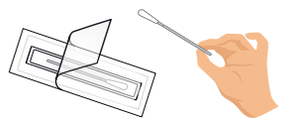
Take the extraction tube and place it in the tube holder marked on the box.

4

Peel the foil seal off the extraction tube. Take care to avoid spilling the liquid.

STEP 2 SAMPLE COLLECTION

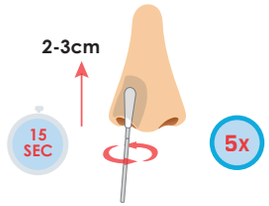
5



Remove the swab from its packaging.

Caution: Be careful not to touch the swab tip.

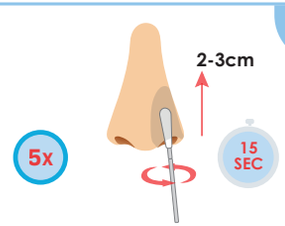
6



Gently insert the swab **2-3cm** into the **LEFT** nostril or until resistance is felt. Slowly rotate the swab at least **5 times** for around **15 seconds.**

Note: With children, the swab may not reach 3cm deep and a second person may be needed to hold the child's head steady.

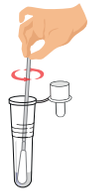
7



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

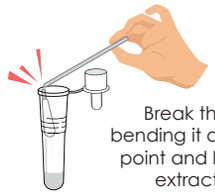
STEP 3 TEST PROCEDURE

8



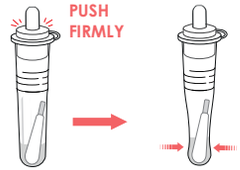
Place the swab in the extraction tube liquid. Rotate the swab tip against the walls of the tube vigorously at least 10 times.

9



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

10



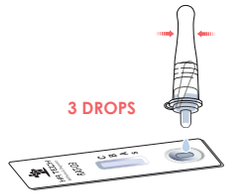
Close the nozzle firmly onto the tube. Squeeze the tube around the swab tip at least 5 times.

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



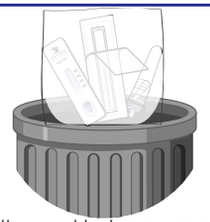
Hold the extraction tube above the sample well. Squeeze gently so that 3 drops fall into the well.

13

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

Caution: Results read after 20 minutes may be inaccurate.

14



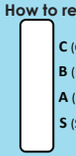
Place the used test components into a small plastic bag which can be sealed and dispose of in general waste. Wash your hands with soap and water.

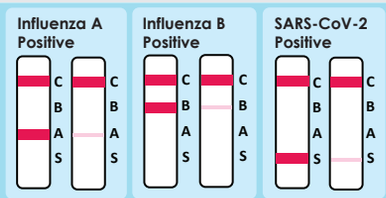
Please read the next page for further information about the test and your results.

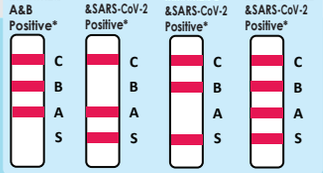
STEP 4 INTERPRETATION OF TEST RESULTS

Positive Result

How to read the test:







A coloured line is visible at the control line (C) and any of the test lines (A/B/S). The result is considered positive even if the line is faint.

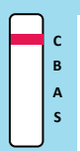
If you are positive for SARS-CoV-2, follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if required. If unwell seek medical assistance. If you are positive for Influenza A/B, consult a medical practitioner for follow-up clinical care.

***NOTE:** Co-infection with Influenza A, B and/or SARS-CoV-2 is rare. If results are positive for more than one antigen i.e., Flu A, B and/or SARS-CoV-2, the person should be re-tested. The result is considered positive even if the line is faint.

Negative Result

A coloured line is visible at the control line (C) only. It indicates that antigens from Influenza A/B or SARS-CoV-2 were not detected from the collected specimen.

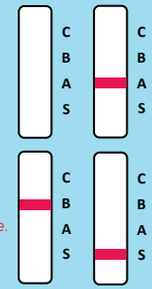
CAUTION: You should re-test after 24-48 hours if you have symptoms. A negative result may not mean that the person is not infectious. if symptoms persist or if unwell, please consult a medical practitioner for follow-up clinical care.



Invalid Result

No visible coloured line appears at control line (C) after performing the test. The results are invalid even if there is a line at the test lines (B), (A) and (S).

An invalid result indicates an error has occured with the test. The instructions may not have been followed correctly or the particular test device may have been defective. The test should be repeated with a new test kit components and a freshly collected sample.



SARS-COV-2 & INFLUENZA A/B COMBO RAPID ANTIGEN TEST KIT RAT-03 (SELF-TEST)

Instructions for Use

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BioPharma & Diagnostics

What you need to know before testing

Intended use:

The SARS-CoV-2 & Influenza A/B Combo Rapid Antigen Test Kit (RAT-03) is intended to aid the diagnosis of COVID-19 and Influenza A/B in symptomatic patients through qualitative detection of SARS-CoV-2, Influenza A and B nucleocapsid protein antigens based on principal of immunochromatography.
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 or Influenza-like symptoms within the last 4 days.

Principle of the test:

The SARS-CoV-2 & Influenza A/B Combo Rapid Antigen Test Kit is a qualitative immunoassay for the detection of SARS-CoV-2 & Flu A/ B antigen in nasal swab. During testing, antigen in the specimen reacts with anti-SARS-CoV-2 antibody-coated particles and with anti-Influenza A antibody-coated particles as well as with anti-Influenza B antibody-coated particles in the reaction pad to produce the immune complex. The complex migrates along the membrane by capillary action to the test region. The complex then respectively reacts with antibodies. If the specimen does not contain antigen of SARS-CoV-2, Influenza A/ B, no colored line will appear in the test region, indicating a negative result.

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.
- Users between 4-9 years must have sampling and collection performed by an adult. Users between 9-18 years require the guidance of an adult. This kit is not suitable for children under 4 year old.
- 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.
- The chemicals in the extraction solution may be hazardous to the skin and eye as per the table below. No personal protective equipment is recommended for use.

Chemical name	GHS hazard category	GHS code	Concentration
ProClin® 300	Skin sensitiser sub-category 1A	May cause an allergic skin reaction (H317)	0.03%

If the reagent solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice.
https://www.poisonsinfo.nsw.gov.au/ or 131-126.

- Store the test kit out of reach of children and pets.

Performance Characteristics:

Inclusivity (Variants):
Evaluation using inactivated virus at the limit of detection demonstrated that the performance of the SARS-CoV-2 & Influenza A/B Combo Rapid Antigen Test Kit (RAT-03) 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. The following Influenza strains were also evaluated at the limit of detection to confirm performance was not affected:

Influenza A strains	Influenza B strains
A/South Australia/34/2019	B/Austria/1359417/2021 (Victoria)
A/Perth/179/2022	B/Colorado/6/2017 (Victoria)
A/Victoria/4144/2022	B/Victoria/27/2020 (Yamagata)
A/Sydney/1297/2022	B/Sydney/701/2019 (Yamagata)
A/South Australia/333/2022	B/Brisbane/37/2018 (Yamagata)
A/Tasmania/309/2022	B/Brisbane/5/2020 (Victoria)
A/Victoria/2570/2019	B/Victoria/28/2020 (Victoria)
A/Darwin/6/2018	B/Darwin/11/2021 (Victoria)
A/Victoria/2455/2019	B/Phuket/3073/2013 (Victoria)
A/Brisbane/02/2018	
A/Darwin/6/2021	
A/Darwin/24/2021	
A/Tasmania/503/2020	
A/Darwin/726/2019	

Clinical performance:
The SARS-CoV-2 & Influenza A/B Combo Rapid Antigen Test Kit RAT-03 (Self-Test) achieved 98.77%, 97.14% and 96.43% clinical sensitivity for SARS-CoV-2, Influenza A and Influenza B respectively for the RT-PCR positive samples of the respective targets. The kit achieved 100% clinical specificity for all three targets SARS-CoV-2, Influenza A and Influenza B for the respective RT-PCR negative samples.

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

Analytical Sensitivity:
The Limit of Detection (LoD) was determined to be 40 $TCID_{50}$/mL for SARS-CoV-2, 1.5 x 10^3 $TCID_{50}$/mL for Influenza A and 5.0 x 10^3 $TCID_{50}$/mL for Influenza B.

Endogenous and exogenous Interfering Substances:
The following substances were spiked into samples and tested with the SARS-CoV-2 & Influenza A/B Combo Rapid Antigen Test Kit. No interference with results was observed.
Substance: Benzocaine, Blood, Dexamethasone, Menthol, Mucin, Naso GEL, Phenylephrine, Afrin Oxymetazoline, CVS Nasal Spray (Cromolyn), Alkalol, Sore Throat Phenol Spray, Tobramycin, Mupirocin, Fluticasone, Tamiflu (Oseltamivir phosphate, Budenoside, Biotin, Acetylsalicylic Acid, Diphenhydramine, Dextromethorphan and Mucinex.

Usability:

A total of 167 lay users were recruited in Sydney between December 2022 January 2023 to participate in the usability study. 65 confirmed SARS-CoV-2 positive samples, 37 Influenza A/B samples, and 65 unknown samples were used in the study. In total, there were 20 Influenza A samples, 17 Influenza B samples, and 68 SARS-Cov-2 samples as 3 additional positives were picked up by RT-PCR from the unknown samples. The estimated sensitivity (positives over true positives) and specificity (negatives over true negatives) in the hands of lay users are within the 80% sensitivity (98.53% for SARS-CoV-2, 95% for Influenza A, and 88.24% for Influenza B) and 98% Specificity (100% for SARS-CoV-2, Influenza A, and Influenza B) requirements set by TGA, and demonstrates that sensitivity and specificity was maintained in the hands of lay users.
The overall success of steps completed by all the participants enrolled in the study was determined by the personnel conducting the study. Collectively, subjects performed 2129/2171 steps correctly. Most steps had greater than 95% satisfactory performance rate.

What to know after reading your result

Limitations:

- False negative results are more likely to occur for SARS-CoV-2 if the test is performed after 7 days of symptoms onset and for Influenza if the test is performed after 4 days of symptoms onset.
- False negative results 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 result should be treated as presumptive only and may not mean you are not infectious. If you are experiencing any flu or COVID-19-like symptoms you should consult a medical practitioner for follow-up clinical care.
- 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 you are positive for SARS-CoV-2, follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if required. If unwell seek medical assistance. If you are positive for Influenza A/B, consult a medical practitioner for follow-up clinical care.
- The test contains an internal quality control zone indicated by the 'C'. A red line should always appear at the 'C'. If the control line does not appear, the test result is invalid, and the testing should be repeated by using new test kit components and a freshly collected sample. Please contact HA TECH customer support line if repeated invalid test results are obtained.

COVID-19 & Influenza 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.
- Place the used test kit components into a small plastic bag which can be sealed and dispose of in general waste.

To help slow the spread of COVID-19 and Influenza 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

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

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

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

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

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

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

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

Index of Symbols

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.

General Information

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www.ha-tech-ltd.com

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