HA TECH
BioPharma & Diagnostics

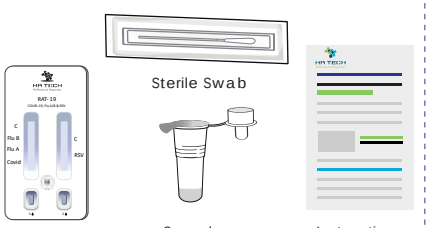
Respiratory Combo Panel RSV/ SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 (Self-Test) (Nasal Swab)
Instructions for Use

IFU-19
V1.5

MATERIALS PROVIDED

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

IN THE BOX



HA TECH CUSTOMER SUPPORT

Customer support: **+61 (0)431 581 133**
Hours: 9am-7pm (AEST) or
9am-8pm (AEDT)
7 days per week

SCAN FOR VIDEO GUIDE

Scan this QR code to access a video of these instructions. For further information please visit our website:
https://www.ha-tech-ltd.com/rapid-test-kits/
(or call us on: +61(0)431 581 133)
This service is available 9am-7pm (AEST) or 9am-8pm(AEDT), 7 days per week.

SCAN ME

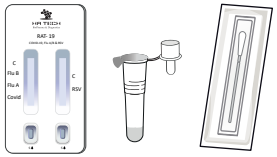
Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

STEP 1 PREPARATION

1

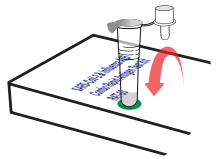
Wash your hands with soap and water for at least 20 seconds before the test.

2



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

3



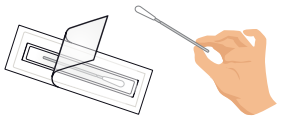
Take the extraction tube and place it in the tube holder marked on the box.

4

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

STEP 2 SAMPLE COLLECTION

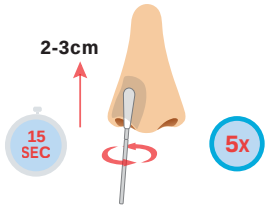
5



Remove the swab from its packaging.

Caution: Be careful not to touch the swab tip.

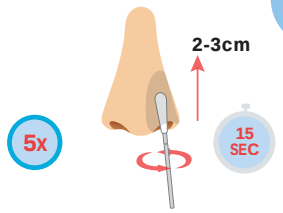
6



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



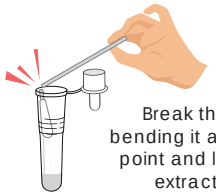
Remove the swab from the **LEFT** nostril and insert into the **RIGHT** nostril. Again, rotate **5 times** for **15 seconds**.

STEP 3 TEST PROCEDURE

8

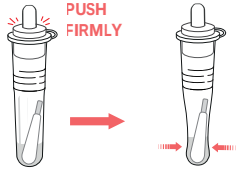
Place the swab in the extraction tube liquid. Rotate the swab tip against the walls of the tube vigorously at least 10 times.

9



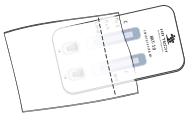
Break the swab by bending it at the notched point and leave it in the extraction tube.

10



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

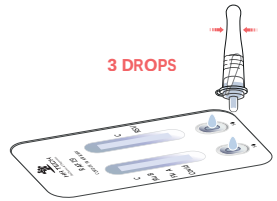
11



Take the cartridge out of the 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



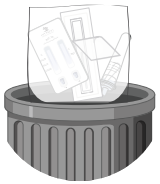
Hold the extraction tube above the sample well. Squeeze gently so that 3 drops falls into each well.

13

Set a timer for 15 minutes. Read the results between15 to 20 minutes as weak positive specimens take time to become visible.

Caution: Results read after 25 minutes may be inaccurate.

14

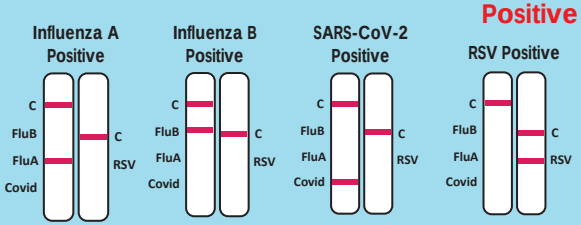


Place the used test components into a small plastic bag which can be sealed and dispose of in general waste. Wash your hands with soap and water.

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

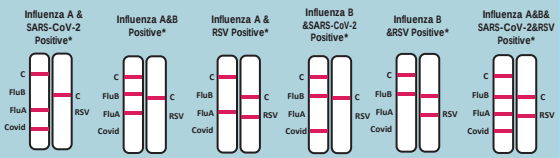
STEP 4 INTERPRETATION OF TEST RESULTS

Positive Result



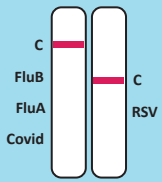
If you are positive for SARS-CoV-2, follow the guidance from your local State or Territory Health Department for reporting of positive results & confirmation testing if required. If unwell seek medical assistance. If you are positive for Influenza A/B, RSV consult a medical practitioner.

Co-infection



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

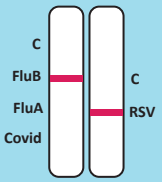
Negative Result



A coloured line is visible at the control line (C) only.

Negative result indicates that antigens from RSV, Influenza A/B or SARS-Cov-2 were not detected from the collected specimen. If you have symptoms, please re-test after 24-48 hours. If symptoms persist, consult a medical practitioner.

Invalid Result



No visible coloured line appears at control line (C) in either windows after performing the test. The results are invalid even if there is a line at the test lines (FluA), (FluB) and (Covid) and (RSV).

An invalid result indicates an error has occured with the test. The instructions may not have been followed correctly. The test should be repeated with a new test kit components and a freshly collected sample. If the invalid result continues after repeating, please contact HA TECH customer support line for assistance.

Respiratory Combo Panel RSV/ SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 (Self-Test) (Nasal Swab)

Instructions for Use

HA TECH
BioPharma & Diagnostics

What you need to know before testing

Intended use:

The HA TECH Respiratory Combo Panel RSV/ SARS-CoV-2/ Influenza A/B Rapid Antigen Test Kit RAT-19 is intended to aid the differential diagnosis of Respiratory Syncytial Virus (RSV), SARS-CoV-2 and Influenza A/B in symptomatic patients through qualitative detection of the nucleocapsid protein of RSV, SARS-CoV-2, Influenza A and B antigens based on the 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/RSV-like symptoms within the last 4 days.
The Respiratory Combo Panel RSV/ SARS-CoV-2/ Influenza A/B Rapid Antigen Test Kit RAT-19 is intended to be used by layperson as a self-test and does not require any special training for sample collection and performing the test. Users between 4-18 years require the guidance of an adult. This kit is not suitable for children under 4 years old.

Principle of the test:

The Respiratory Combo Panel RSV/ SARS-CoV-2/ Influenza A/B Rapid Antigen Test Kit RAT-19 is a qualitative chromatographic immunoassay for the detection of Respiratory Syncytial Virus (RSV), SARS-CoV-2 and Influenza A/B antigen in the sample. In the test procedure, the applied specimen will migrate through the conjugate release pad, which contains conjugated antibodies that are specific to the nucleocapsid protein of the targets (RSV/SARS-CoV-2/Influenza A/B). The specimen, together with the conjugated antibody bound to the target antigen, will migrate along the membrane through capillary action and react with immobilized antibody. The immobilized antibodies bound to the antigen-conjugated antibody complex develop the test lines (Flu A), (Flu B), (Covid) or (RSV) depending on the types of antigens present in the sample while the immobilized antibodies that bound to the conjugated antibody will form the control line at (C) indicating the test is valid and the flow is complete. If the specimen does not contain antigen of RSV, SARS-CoV-2 or Influenza A/ B, there will be no antigen-conjugated antibody complex captured by immobilized antibody on the membrane and hence, no test line at (Flu A), (Flu B), (Covid) or (RSV) will be observed.

Warnings:

- Each test can only be used once. Do not re-use any kit contents.
- Test results should be read between 15 and 20 minutes. Interpretation of results before 15 minutes can cause weak positives to be missed. Interpretation of results after 25 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 years 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 eyes 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 eyes, 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):
The following inactivated viruses at the limit of detection were used to evaluate the performance of the Respiratory Combo Panel RSV/ SARS-CoV-2/ Influenza A/B Rapid Antigen Test Kit RAT-19 and it was confirmed that the performance of the product was not affected.
SARS-CoV-2 : Delta and Omicron
Influenza A & Influenza B
Influenza A strains
A/South Australia/34/2019, A/Perth/179/2022, A/Victoria/4144/2022, A/Sydney/1297/2022, A/South Australia/333/2022, A/Tasmania/309/2022, A/Victoria/2570/2019, A/Darwin/6/2018, A/Victoria/2455/2019, A/Brisbane/02/2018, A/Darwin/6/2021, A/Darwin/24/2021, A/Tasmania/503/2020, A/Darwin/726/2019
Influenza B strains
B/Austria/1359417/2021 (Victoria), B/Colorado/6/2017 (Victoria), B/Victoria/27/2020 (Yamagata), B/Sydney/701/2019 (Yamagata), B/Brisbane/37/2018 (Yamagata), B/Brisbane/5/2020 (Victoria), B/Victoria/28/2020 (Victoria), B/Darwin/11/2021 (Victoria), B/Phuket/3073/2013 (Victoria)
Respiratory syncytial virus (RSV) : RSV A and RSV B

Clinical performance:
Respiratory Combo Panel RSV/ SARS-CoV-2/ Influenza A/B Rapid Antigen Test Kit RAT-19 correctly identified 97.95% of SARS-CoV-2 RT-PCR positive samples and 100% of SARS-CoV-2 negative samples. For Influenza A, the kit correctly identified 97.83% of Influenza A RT-PCR positive samples and 100% of Influenza A negative samples. For Influenza B, the kit correctly identified 96.00% of Influenza B RT-PCR positive samples and 100% of Influenza B negative samples. The kit achieved 97.87% clinical sensitivity for RSV RT-PCR positive samples and 100% clinical specificity for RSV RT-PCR negative samples.

Analytical specificity:
The potential cross-reactivity and microbial interference of the following micro-organisms was assessed with the Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 with no cross-reactivity or microbial interference detected. Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Adenovirus, Enterovirus, Human Metapneumovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3 , Parainfluenza virus 4 , Enterovirus D68 , Mumps virus , Rhinovirus , Herpes virus , *Mycobacteria tuberculosis , Chlamydia pneumoniae, Haemophilus influenzae , Legionella pneumoniae , Streptococcus pneumoniae , Streptococcus pyogenes , Streptococcus aureus, Bordetella pertussis , Mycoplasma pneumoniae, Candida albicans,* MERS-coronavirus , SARS-coronavirus, Human coronavirus HKU1*, and Pneumosystis jirovecii.*

Analytical Sensitivity:
The Limit of Detection (LoD) for HA TECH Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 (self-test) was determined to be 159 $TCID_{50}$/ml for RSV , 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 potentially interfering substances were also tested with the Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 (self-test) and no interference was observed: Benzocaine, Blood, Mucin, Mometasone furoate, Lidocaine, Azelastine, Oxymetazoline Hydrochloride, Saline nasal spray, Budenoside, Sodium cromoglycate, Fluticasone propionate, Zanamivi, Menthol, Naso GEL, Phenylephrine, Afrin Oxymetazoline, CVS Nasal Spray (Cromolyn), Alkalol, Sore Throat Phenol Spray, Tobramycin, Mupirocin, Tamiflu (Oseltamivir phosphate), Biotin, Acetylsalicylic Acid, Diphenhydramine, Dextromethorphan, Dexamethasone and Mucinex .

Usability:
The Usability Study of the HA TECH Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 (self-test) was conducted concurrently with clinical study between March and June 2023 involving a total number of 237 users. The confidence and satisfaction of the users exceeded 95%. The clinical sensitivity established in the hands of lay users were 98.77% for SARS-CoV-2, 97.14% for Influenza A, 95% for Influenza B and 96.87% for RSV. RAT-19 achived 100% clinical specificity for all targets in the hands of the lay users.

Additional user Interpretation Study of the HA TECH Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 (self-test) was conducted parallelly . The inter-reader variability was low with all negative, strong positive, weak positive and mixed strong positive results having less than 5% discordance in interpretation. Overall, the result of the usability study supports the use of the HA TECH Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 for self-testing.

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 Influeza, RSV 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 24-48 hours after your first test) if there is a current suspicion of infection, exposure in a high-risk setting, or 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 and RSV consult a medical practitioner for follow-up clinical care.
- The test contains an internal quality control zone indicated by the 'C'. Red line should always appear at both 'C' on both cassettes. If the two control lines do 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.

RSV,COVID-19 & Influenza Safety Information:

To help slow the spread of RSV, COVID-19 and Influenza and protect yourself and others:

- 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 disposed in general waste.
- 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.

Helpline Contact Information:

For **assistance** regarding the use of the kit or any other related questions, please call the **HA TECH Customer Support Line** available **9am-7pm (AEST)** or **9am-8pm (AEDT), 7 days per week** on **+61 (0)431 581 133**.

Therapeutic Goods Administration (TGA) Contact Information:

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 (8.30 am to 5.00pm, Monday to Friday)

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.nsw.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

In Vitro Diagnostic Use

Tests per Kit

Batch Number


See Instruction for Use


Manufacturer


Do Not Reuse

Catalog #


Store between 2~30°C


Keep Dry


Keep away from sunlight


This Side Up


Expiry Date

Authorised Representative

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 proper storage conditions, the items in the kit are stable until the expiration date.

General Information

HA Tech Pty Limited
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www.ha-tech-ltd.com

Sponsor:
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