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

MATERIALS PROVIDED

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IN THE BOX

- Sterile Swab Stick
- Test Cartridges
- Sample Extraction Tube
- Instructions For Use (IFU)

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

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/

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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.
6. Gently insert the swab 2-3cm into the left nostril or until resistance is felt.
7. Slowly rotate the swab at least 5 times for around 15 seconds.
8. Note: With children, the swab may not reach 3 cm deep and a second person may be needed to hold the child’s head steady.
9. Take the swab from the left nostril and insert it into the tube vigorously at least 20 times.
10. Again, rotate 5 times for 15 seconds.

STEP 3 TEST PROCEDURE

11. Place the swab in the extraction tube liquid.
12. Rotate the swab tip against the walls of the tube vigorously at least 10 times.
13. Hold the extraction tube above the sample well. Squeeze gently so that 2 drops falls into each well.
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.

STEP 4 INTERPRETATION OF TEST RESULTS

Support Services for further information regarding available support services, contact your local Health Department at:

ACT: 02 5124 9213
www.healthy.act.gov.au
NSW: 1300 066 055
www.health.nsw.gov.au
SA: 1300 232 272
www.sahealth.sa.gov.au
TAS: 1300 135 513
www.health.tas.gov.au
VIC: 1300 690 172
www.dhhs.vic.gov.au
WA: 08 9222 4222
www.healthwa.wa.gov.au

eDetails for testing in New South Wales (NSW) and Queensland (QLD):
Influenza A/B, RSV, SARS-CoV-2

**Positive Result**

- RAT-19A:
  - Influenza A Positive
  - Influenza B Positive
  - SARS-CoV-2 Positive
  - RSV Positive

**Negative Result**

- RAT-19A:
  - Influenza A Positive
  - Influenza B Positive
  - SARS-CoV-2 Negative
  - RSV Negative

**Invalid Result**

- RAT-19A:
  - Influenza A Positive
  - Influenza B Positive
  - SARS-CoV-2 Negative
  - RSV Negative

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, RSV consult a medical practitioner for follow-up clinical care.

If results are positive for Influenza A/B or SARS-Cov-2 were not detected within 15 to 20 minutes as weak positive results may not have been followed correctly. The test should be repeated with a new test kit components and a freshly collected sample. If invalid result continue after repeating, please contact HA Tech customer support line for assistance.

If you are positive for Influenza A/B, RSV consult a medical practitioner for follow-up clinical care.

**Positive Result**

- RAT-19A:
  - Influenza A Positive
  - Influenza B Positive
  - SARS-CoV-2 Positive
  - RSV Positive

**Negative Result**

- RAT-19A:
  - Influenza A Positive
  - Influenza B Positive
  - SARS-CoV-2 Negative
  - RSV Negative

**Invalid Result**

- RAT-19A:
  - Influenza A Positive
  - Influenza B Positive
  - SARS-CoV-2 Negative
  - RSV Negative

If you are positive for Influenza A/B, RSV consult a medical practitioner for follow-up clinical care.

If results are positive for Influenza A/B or SARS-Cov-2 were not detected within 15 to 20 minutes as weak positive results may not have been followed correctly. The test should be repeated with a new test kit components and a freshly collected sample. If invalid result continue after repeating, please contact HA Tech customer support line for assistance.

If you are positive for Influenza A/B, RSV consult a medical practitioner for follow-up clinical care.

If results are positive for Influenza A/B or SARS-Cov-2 were not detected within 15 to 20 minutes as weak positive results may not have been followed correctly. The test should be repeated with a new test kit components and a freshly collected sample. If invalid result continue after repeating, please contact HA Tech customer support line for assistance.

If you are positive for Influenza A/B, RSV consult a medical practitioner for follow-up clinical care.
What you need to know before testing

Principle of the test:
The Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 (self-test) is based on the principle of immunochromatography. The test is intended for home use with nasal swab specimens from individuals who have experienced COVID-19-like symptoms during the prior 4 days or Influenza-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 persons 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-year-old.

Intended use:
This kit is not suitable for children under 4-year-old. This kit is not suitable for children under 4-year-old.

Performance characteristics:

In Vitro:
The following inactivated viruses at the limit of detection were used to evaluate the performance of the Respiratory Combo Path 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.

RSV/SARS-CoV-2: Delta and Omicron
Influenza A & Influenza B
Influenza A strains
Influenza B strains

- A/California/07/2009 (H1N1pdm)
- A/Texas/36/2011 (H1N1pdm)
- A/Hong Kong/15/2012 (H3N2)
- A/Perth/16/2013 (Victoria)

- A/Perth/18/2009 (H1N1pdm)
- A/Perth/15/2011 (Victoria)
- A/Hong Kong/128/2014 (Victoria)
- A/Texas/36/2011 (H1N1pdm)

- B/Phuket/307/2013 (Yamagata)
- B/Moscow/10/2010 (Victoria)
- B/Beijing/52/2012 (Yamagata)
- B/Hong Kong/328/2012 (Victoria)

- B/Phuket/307/2013 (Yamagata)
- B/Moscow/10/2010 (Victoria)
- B/Beijing/52/2012 (Yamagata)
- B/Hong Kong/328/2012 (Victoria)

Clinical performance:

Replicate batch of the RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 was correctly identified 97.95% of RSV/SARS-CoV-2/Influenza A/B positive samples. The kit correctly identifies 99.75% of Influenza A samples and 98% of Influenza B negative samples. The kit achieved 97.85% sensitivity and specificity for RSV/SARS-CoV-2/Influenza A/B positive and negative samples.

Analytical specificity:
The reactivity and microbial interference of the following micro-organisms were assessed with the Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19. None of the following micro-organisms were detected: Human adenovirus, Human rhinovirus, Human enterovirus, Human parainfluenza virus 1, Human parainfluenza virus 2, Human parainfluenza virus 3, Human parainfluenza virus 4, Human rhinovirus, Human herpesvirus, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Haemophilus influenzae, Legionella pneumophila, Streptococcus pneumoniae, Streptococcus pyogenes, Staphylococcus aureus, Staphylococcus epidermidis, Candida albicans, Mers-coronavirus, Human coronavirus HU1 and Psidium proviciae.

Analytical sensitivity:
The sensitivity of Detection (LoD) for the Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 was determined to be 10 TCID50/ml for RSV and 40 TCID50/ml for SARS-CoV-2 and 10 TCID50/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, Dextromethorphan, Dexamethasone and Mucinex. This kit is not suitable for children under 4-year-old.

Usage:
The Usability Study of the HA TECH Respiratory Combo Panel RSV/SARS-CoV-2/Influenza A/B Rapid Antigen Test Kit RAT-19 was conducted concurrently with clinical study between March and June 2023 involving a total number of 237 users. The confidence and satisfaction of these users exceeded 95%. The clinical sensitivity established in the hands of lay users was 98.77% for RSV/SARS-CoV-2, 97.14% for Influenza A/B, 95% for Influenza Band 98.87% for RAT-19 achieved 100% clinical specificity for all antigens.

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 results being either equal or missed and mixed strong positives 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.

Limitations:
False negative results are more likely to occur for SARS-CoV-2 if the test is performed after 7 days of symptom onset or 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 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 long period of infection, being in a high risk setting or if there is an occupational risk or other requirements.
False positive 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 unsure 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 identified by the red line, which should always appear at both C on both lines. C. Red line should always appear at both C on both lines. 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. If you are positive for Influenza A/B or RSV consult a medical practitioner for follow-up clinical care.
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What to do after getting a result:
- If the test result is positive or invalid, contact your healthcare provider or local public health department for further testing and appropriate treatment.
- If the test result is negative, no further action is required. However, seek medical attention if symptoms persist or worsen.
- Store the test kit in a cool, dry place and out of reach of children and pets.
- If you are pregnant, have a weakened immune system, are under 1 year old or elderly, or have underlying health conditions, consult a healthcare professional before self-testing. If you are positive for Influenza A/B or RSV consult a medical practitioner for follow-up clinical care.

Support Services:
For further information regarding support services, contact your local state or territory health department as listed below:

- ACT: 02 5124 9213
- NSW: 1300 066 055
- SA: 1300 232 272
- TAS: 1300 135 513
- WA: 08 9222 4222
- NT: 08 9022 8044
- QLD: 13 422 584
- VIC: 1300 650 172
- www.healthywa.wa.gov.au
- www.health.nt.gov.au
- www.health.gov.au
- www.healthy.vic.gov.au

Storage and Stability:
- Store at room temperature.
- Keep away from sunlight.
- Do not use if test kit is damaged or shows signs of being tampered with.
- Avoid eye and skin contact with the solution.
- Do not ingest the solution.
- Keep test kit out of reach of children.

General Information:
- The 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 these users exceeded 95%. The clinical sensitivity established in the hands of lay users was 98.77% for RSV/SARS-CoV-2, 97.14% for Influenza A/B, 95% for Influenza Band 98.87% for RAT-19 achieved 100% clinical specificity for all antigens.
- 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 results being either equal or mixed strong positives 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.