Biopen®

Biolink

COVID-19, Influenza A/B & RSV

Antigen Nasal Test Kit for Self-testing

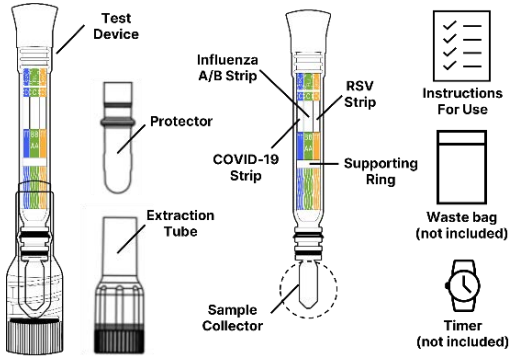
Quick Reference Instructions

Scan QR Code for video or visit www.biolink.net.au/v/abcrsv

Customer Support Helpline 1800 728 439
Customer Service Hours: 9AM-7PM AEST, 7 Days a week.

CAREFULLY READ THE INSTRUCTIONS BEFORE PERFORMING THE TEST

PACKAGE CONTENTS



STORAGE AND STABILITY

- **DO NOT FREEZE.**
- Store at 2-30°C when not in use.
- Do not use kit or components beyond the expiration date.
- Kit contents are stable until the expiration dates on packaging and box.

INTENDED USE

The COVID-19, Influenza A/B & RSV Antigen Nasal Test Kit for Self-testing is an in vitro immunoassay. The assay is intended for home testing (or self-testing). **Children aged 2-18 years old should have the samples collected and tested by an adult.** The assay is an in vitro immunochromatographic assay for the qualitative detection of nucleoprotein antigens of SARS-CoV-2 (COVID-19), Influenza A, and Influenza B, and fusion protein antigen of Respiratory Syncytial Virus (RSV) in nasal swab specimens collected from patients against the respiratory infection for COVID-19 (**within the first 7 days of the onset of symptoms**) and influenza A/B and RSV (**within the first 4 days of the onset of symptoms**). The assay obtains a preliminary result only, aiding in the diagnosis of COVID-19, Influenza A/B and/or RSV. This test has not been cleared for use in asymptomatic individuals.

PRINCIPLE

The COVID-19, Influenza A/B & RSV Antigen Nasal Test Kit detects nucleoprotein antigens of SARS-CoV-2, Influenza A, Influenza B and fusion protein antigens of RSV through visual interpretation of color development on the internal strips. AntiSARS-CoV-2 monoclonal antibody (mAb) and Influenza A/B and RSV antibodies are immobilized at the test region of the nitrocellulose(NC) membrane. Anti-SARS-CoV-2 mAb and Influenza A/B and RSV antibodies conjugated to colored particles are immobilized on the conjugated pad. During testing, target antigens, if present in the nasal secretions, will be released into the extraction buffer. As the specimen migrates along the strip by capillary action and then interacts with reagents on the sample pad, the target antigens will bind to anti-SARS-CoV-2 mAb or Influenza A/B or RSV antibodies on the conjugate pad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 mAb or Influenza A/B or RSV antibodies immobilized at the test region. Excess colored particles will be captured at the control region of the NC membrane. The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2, Influenza A/B and/or RSV viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that a proper volume of specimen has been added and membrane wicking is working.

QUALITY CONTROL

Internal Procedural Controls: The COVID-19, Influenza A/B & RSV Antigen Nasal Test Kit for Self-testing has built-in (procedural) controls. Each test device has an internal standard zone to ensure proper sample flow. The user should confirm that the colored band located at the "C" region is present before reading the result.

WARNINGS AND PRECAUTIONS

- Read the Package Insert prior to use.
- Directions should be read and followed carefully.
- The test components are packed in foil pouches to protect them from moisture during storage. Check each foil pouch before opening it. Do not use any component that has holes in the film, or if the pouch has not been completely sealed. Improper storage of test items or components can lead to incorrect results.
- Do not use kit or components beyond the expiration date.
- If samples and test components are not brought to room temperature before the test, the test sensitivity may be reduced. Incorrect or unsuitable sampling and storage can lead to false negative test results.
- For in vitro diagnostic use.
- Use a separate test for each person, the test can only be used once.
- Use only the supplied test components. Do not replace the buffer with any other liquid.
- Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use.
- Do not puncture the membrane of the extraction tube before testing.
- Do not use the test if you have a nosebleed. If your nose bleeds after swabbing, apply pressure to your nose and consult your health professional. Do not insert the swab again.
- If you have a nose piercing, sample the other nostril. If pierced on both sides, remove the piercing on one side before sampling.
- Avoid eye, skin and mucous membrane contact with the buffer. In the event of contact with buffer, rinse with plenty of water.
- Do not ingest.
- Keep out of the reach of children. Small test components can pose a choking hazard.
- Testing results should not be the sole basis for treatment or other management decisions.

LIMITATIONS

- False negative results may occur if testing is not performed within the first 4 days of symptom onset for Influenza A/B and RSV, and within the first 7 days of symptom onset for COVID-19.
- A positive result cannot necessarily determine whether a person is infectious.
- The tests are less reliable in the later phase of infection (more than 7 days after the onset of COVID-19 symptoms or more than 4 days after the onset of Influenza A/B and/or RSV symptoms) and in asymptomatic individuals.
- The test is suitable for personal use and may only be used for the qualitative detection of the SARS-CoV-2 and Influenza A/B viral nucleoprotein antigens and RSV fusion protein antigens. The intensity of color in a positive band should not be evaluated as "quantitative or semi-quantitative".
- As with all diagnostic tests, a clinical diagnosis must not be based on the results of a single test, but rather be made by the doctor after all clinical and laboratory results have been evaluated.
- Failure to follow the test procedure and interpretation of results may negatively affect and / or falsify the test result.
- Negative results do not completely rule out an infection with SARS-CoV-2, Influenza A/B, and/or RSV.
- A negative result does not rule out infection by another type of respiratory virus.
- Recommended repeat testing (e.g. within 1-3 days) if ongoing suspicion of infection, high risk setting/occupation or other requirement.
- This test does not discriminate between SARS-coronavirus (SARS-CoV) and SARS-CoV-2 (COVID-19). Positive results may be due to present infection with SARS-CoV.
- Negative results may not mean a person is not infectious and if symptoms are present the person must seek immediate further testing.

NOTE

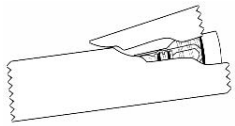
- Caution should be taken when inserting the sample collector into the nasal cavity.
- Do not use test kit on children under 2 years of age.
- For children, the maximum depth of insertion into the nostril may be less than 2cm, and you may need a second person to hold the child's head while swabbing.

BEFORE THE TEST

1. Bring devices, reagents, and specimens to room temperature (15~30°C) before use.

2. Remove the test device from its pack. For the best results, the assay should be performed within 2 hours.

3. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

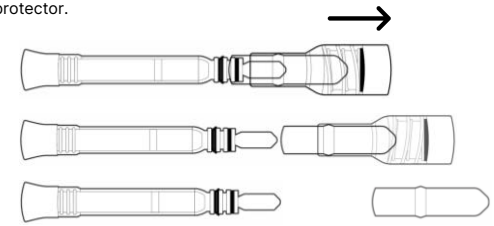


NASAL SWAB COLLECTION

WARNING:

- **Inaccurate test results may occur if the nasal swab specimen is not properly collected.**
- **Do not insert the collector any deeper if you feel strong resistance.**
- **This test may feel slightly uncomfortable or tickly, but it should not hurt.**

1. Take the test device out of the extraction tube and remove the protector.

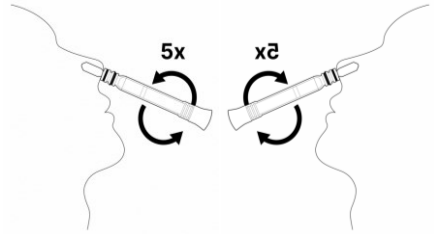


2. Make sure not to touch the sample collector on any surface.

3. Gently insert the sample collector until resistance is met (about 1-2 cm into the nostril). Rotate the collector five times against the nasal wall and remove it from the nostril.

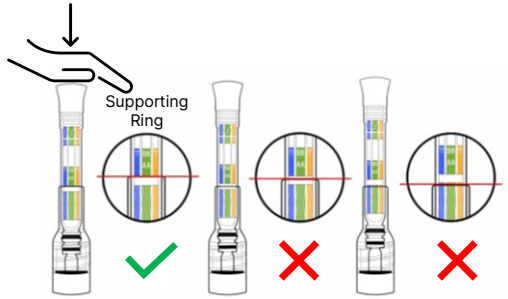
4. Pull the swab out of the nose while twisting it slightly.

5. Repeat the sample collection procedure for the other nostril to ensure that sufficient specimen is collected from both nasal cavities.



PROCESSING THE SAMPLE

1. Place the test device vertically into the extraction tube until the top edge of the extraction tube reaches the top of the supporting ring.

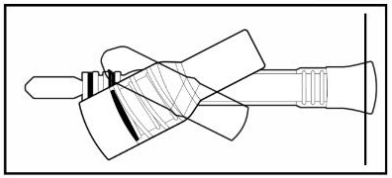


WARNING: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.

2. Read the results at **15 minutes**. Do not read the results after 30 minutes.

INTERPRETATION OF RESULTS
See Page 2

3. The used test kit should be placed into a waste bag (**not provided**) and discarded as general waste. Please follow the local regulations for household waste disposal.

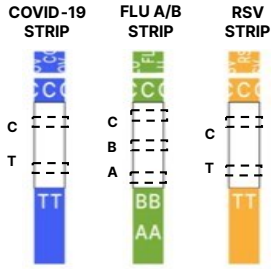


INTERPRETATION OF RESULTS

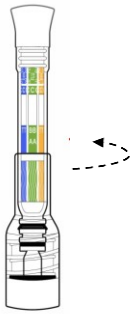
Look around all sides of the test device to read the results of each test strip independently of each other. Read the results at 15 minutes. Do not read the results after 30 minutes:

READING THE TEST STRIPS

Look for red lines in the dotted areas on each strip:

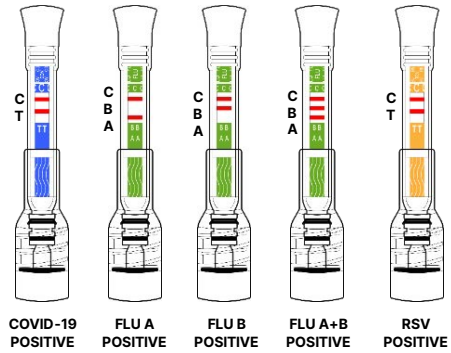


NOTE: The shade of lines may vary, but even if a faint or weak line appears, the test should be considered positive.



Look around all sides of the test device and keep track of your results

POSITIVE RESULTS



COVID-19 POSITIVE | FLU A POSITIVE | FLU B POSITIVE | FLU A+B POSITIVE | RSV POSITIVE

NOTE: The shade of lines may vary, but even if a faint or weak line appears, the test should be considered positive.

COVID-19 Positive: Two colored bands appear on the strip. One band appears in the control region (C) and another band appears in the test region (T).

Influenza A Positive: One colored band appears in the control region (C), and another colored band in the A region (A).

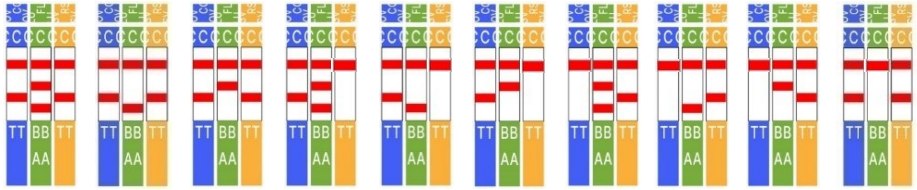
Influenza B Positive: One colored band appears in the control region (C), and another colored band in the B region (B).

Influenza A+B Positive: One colored band appears in the control region (C), and two other colored bands appear in both A region (A) and B region (B).

RSV Positive: Two colored bands appear on the strip. One band appears in the control region (C) and another band appears in the test region (T).

MIXED POSITIVE RESULTS

It is possible to test positive for more than one disease at the same time.
Diagrams below show all possible combinations of mixed positive results:



COVID-19 FLU A+B RSV POSITIVE | COVID-19 FLU A RSV POSITIVE | COVID-19 FLU B RSV POSITIVE | COVID-19 FLU A+B POSITIVE | COVID-19 FLU A POSITIVE | COVID-19 FLU B POSITIVE | FLU A+B RSV POSITIVE | FLU A RSV POSITIVE | FLU B RSV POSITIVE | COVID-19 RSV POSITIVE

NOTE: The shade of lines may vary, but even if a faint or weak line appears, the test should be considered positive.

WHAT TO DO IF YOU TEST POSITIVE FOR COVID -19?

A positive test result means that SARS-CoV-2 has been detected in your sample. There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens.

While isolation is no longer a legal requirement in Australia, if you test positive for COVID-19, staying at home protects the people in your community. Anyone diagnosed with COVID-19 can pass the virus onto others. If you test positive, you should not visit high-risk settings like hospitals and aged and disability care settings:

- for at least 7 days or until symptoms have gone
- unless seeking immediate medical care

To help protect those around you, we recommend:

- practicing good hygiene
- wearing a mask outside the home
- working from home where possible
- following your local health department's advice when leaving home
- avoiding contact with people who are at higher risk of severe disease
- avoiding going to school, public areas, or travel on public transport, in taxis or ride-share services
- If you have any appointments you cannot miss (visit to a doctor, family violence service or police), let them know in advance that you have COVID-19

If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the Australian Healthdirect helpline on 1800 022 222.

WHAT TO DO IF YOU TEST POSITIVE FOR INFLUENZA A/B?

A positive test result means that the virus that causes influenza A or influenza B was detected in your sample, and it is very likely that you have influenza A or influenza B. If you get positive results for Influenza A/B, please consult a medical practitioner for follow up clinical care.

There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens or identify any specific influenza virus subtypes. If unwell, please consult a medical practitioner for follow up clinical care.

Co-infection with influenza A and B is rare. The positive results for both A and B should be considered an invalid result, and another test should be performed. If the test is again positive for both influenza A and B, the specimen should be re-tested by another method prior to reporting of results.

WHAT TO DO IF YOU TEST POSITIVE FOR RSV?

If you get positive results for RSV, please consult a medical practitioner for follow up clinical care. There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens or identify any specific RSV subtype. If unwell, please consult a medical practitioner for follow up clinical care.

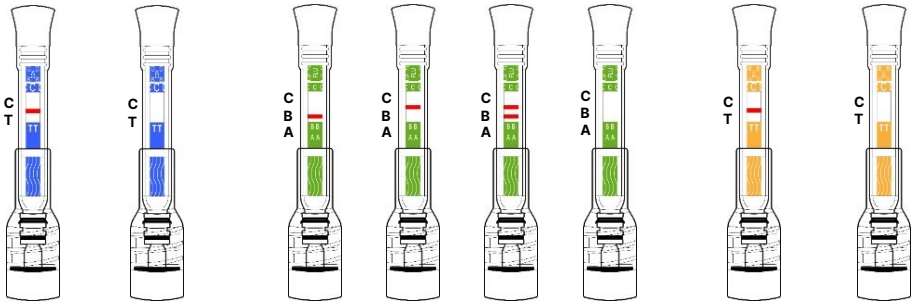
Please follow all public health advice on limiting the spread of COVID-19, Influenza, and RSV.

INVALID RESULTS

If you get an INVALID result, insufficient sample volume or incorrect procedural techniques are the most likely reasons for the control line (C) failure.

Review the test procedure and repeat the test using a freshly collected sample and a new test device.

If an invalid result continues after repeating, please contact the provided Customer Service Helpline number for assistance.



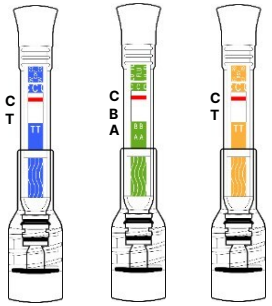
COVID-19 INVALID | COVID-19 INVALID | FLU A INVALID | FLU B INVALID | FLU A+B INVALID | FLU A/B INVALID | RSV INVALID | RSV INVALID

No red line appears in the control region (C) for COVID-19 (SARS-CoV-2). The test is invalid even if there is a line on the region (T).

No red line appears in the control region (C) for Flu A/B. The test is invalid even if there is a line on the region (A), (B), or (A) and (B).

No red line appears in the control region (C) for RSV. The test is invalid even if there is a line on the region (T).

NEGATIVE RESULTS



COVID-19 NEGATIVE | FLU A+B NEGATIVE | RSV NEGATIVE

Red lines appear only in the control region (C), and no line in the region (A), (B) and (T)

A negative result does not mean you are not infected with SARS-CoV-2 (COVID-19), Influenza A/B (Flu A/B), or RSV.

If you are unwell, please consult a medical practitioner for follow up care and continue to follow all public health advice on limiting the spread of COVID-19, Influenza A/B, and RSV.

If symptoms persist, repeat testing within 1-3 days. For COVID-19, repeat testing within at least 24 hours and no more than 48 hours between tests as SARS-CoV-2 antigen present in COVID-19 cannot be precisely detected in all phases of infection.

If symptoms persist, seek medical attention and further testing if required.

PERFORMANCE

ANALYTICAL SENSITIVITY

The limit of detection (LOD) of COVID-19, Influenza A/B & RSV Antigen Nasal Test Kit for Self-testing, defined as the concentration of SARS-CoV-2, Influenza A/B, and/or RSV virus antigens that produces positive test results approximately 95% of the time, was identified by evaluating different concentrations of inactivated SARS-CoV-2, inactivated Flu A, inactivated Flu B and inactivated RSV using the COVID-19, Influenza A/B & RSV Antigen Nasal Test Kit for Self-testing. Representative LODs for different analytes tested are summarized in the tables below:

COVID-19	Inactivated virus LOD ($TCID_{50}$/mL)
Wild type	$1\times10^{2.4}$

Additional COVID-19 variants tested include Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), Omicron (BA.1), Omicron (BA.2), Omicron (BA.4), Omicron (BA.5), Omicron (BA.2.76).

INFLUENZA A	LOD ($TCID_{50}$/mL)
Influenza A (H1N1)	**Inactivated virus**
A/Sydney/5/2021	1.40×10^{4}
Influenza A (H3N2)	**Inactivated virus**
A/Darwin/9/2021	9.13×10^{3}

Additional Influenza A (H1N1) variants tested include A/Michigan/45/2015, A/California/07/2009, A/Brisbane/02/2018, A/Victoria/2570/2019, and A/Wisconsin/588/2019. Additional Influenza A (H3N2) variants tested include A/Singapore/INFIMH-16-0019/2016, A/Hong Kong/4801/2014, A/Hong Kong/2671/2019, A/Hong Kong/45/2019, A/Switzerland/9715293/2013, and A/Darwin/6/2021.

INFLUENZA B	LOD ($TCID_{50}$/mL)
Influenza B (Yamagata lineage)	**Inactivated virus**
B/Massachusetts/2/2012	7.63×10^{4}
Influenza B (Victoria lineage)	**Inactivated virus**
B/Austria/1359417/2021	4.13×10^{4}

Additional Influenza B (Yamagata lineage) variants tested include B/Phuket/3073/2013. Additional Influenza B (Victoria lineage) variants tested include B/Colorado/06/2017, B/Brisbane/60/2008, B/Washington/02/2019.

RSV	Inactivated virus LOD ($TCID_{50}$/mL)
Type A	9.0×10^{3}
Type B	2.4×10^{3}

CLINICAL EVALUATION

The results of all clinical data are summarized in following tables:

COVID-19 Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
COVID-19	**Positive**	105	3	**108**
	Negative	3	514	**517**
	Total	**108**	**517**	**625**

Diagnostic Sensitivity: 97.2% (92.0%~99.1%) *
Diagnostic Specificity: 99.4 % (98.3%~99.8%)*
Overall Agreement: 99.0 % (97.9%~99.6%)*
***95% Confidence Interval**

Influenza A Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
Influenza A	**Positive**	66	6	**72**
	Negative	4	549	**553**
	Total	**70**	**555**	**625**

Diagnostic Sensitivity: 94.3% (86.2%~97.8%) *
Diagnostic Specificity: 98.9 % (97.7%~99.5%) *
Overall agreement: 98.4 % (97.1%~99.1%) *
***95% Confidence Interval**

Influenza B Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
Influenza B	**Positive**	35	5	**40**
	Negative	3	582	**585**
	Total	**38**	**587**	**625**

Diagnostic Sensitivity: 92.1 % (79.2%~97.3%) *
Diagnostic Specificity: 99.1 % (98.0%~99.6%) *
Overall agreement: 98.7% (97.5%~99.4%) *
***95% Confidence Interval**

RSV Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
RSV	**Positive**	42	6	**48**
	Negative	4	573	**577**
	Total	**46**	**579**	**625**

Diagnostic Sensitivity: 91.3 % (79.7%~96.6%) *
Diagnostic Specificity: 99.0 % (97.8%~99.5%) *
Overall agreement: 98.4% (97.1%~99.1%) *
***95% Confidence Interval**

USABILITY STUDIES

190 lay users took part in the COVID-19, Influenza A/B & RSV Antigen Test Kit and were also tested with a PCR. Results are summarized below.

COVID-19

The tests correctly identified 97.1% (34/35) of positive samples and 100.0% (155/155) of negative samples.

COVID-19 Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
COVID-19	**Positive**	34	0	**34**
	Negative	1	155	**156**
	Total	**35**	**155**	**190**

Influenza A

The tests correctly identified 87.5% (28/32) of positive samples and 100.0% (158/158) of negative samples.

Influenza A Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
Influenza A	**Positive**	28	0	**28**
	Negative	4	158	**162**
	Total	**32**	**158**	**190**

Influenza B

The tests correctly identified 88.2% (30/34) of positive samples and 100.0% (156/156) of negative samples.

Influenza B Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
Influenza B	**Positive**	30	0	**30**
	Negative	4	156	**160**
	Total	**34**	**156**	**190**

RSV

The tests correctly identified 93.5% (29/31) of positive samples and 100.0% (159/159) of negative samples.

RSV Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	Negative	Total
RSV	**Positive**	29	0	**29**
	Negative	2	159	**161**
	Total	**31**	**159**	**190**

USER COMPREHENSION STUDIES

190 lay users were asked to interpret tests results, including weak positives and mixed results for SARS-CoV-2, Influenza A/B & RSV, and 100% of the test subjects correctly identified all test results.

CROSS REACTIVITY STUDIES

The COVID-19, Influenza A/B & RSV Antigen Nasal Test Kit presented no cross-reactivity with the below microorganisms at specified concentrations. Potentially cross-reacting microorganisms may be present in the nasal samples have been validated, and only SARS-CoV showed false positive results with SARS-CoV-2 test, and due to the high homology between SARS-CoV and SARS-CoV-2, this unfavorable risk cannot be ruled out.

Adenovirus 1	*Chlamydia pneumoniae*
Adenovirus 2	Enterovirus A24
Adenovirus 3	Enterovirus B1
Adenovirus 4	Echovirus 6
Adenovirus 5	HCoV-229E
Adenovirus 7	HCoV-OC43
Adenovirus 55	HCoV-NL63
Epstein-Barr virus	MERS-coronavirus
Enterovirus EV70	Human metapneumovirus
Enterovirus EV71	Norovirus
Enterovirus A16	Parainfluenza virus 1
Parainfluenza virus 2	*Group C Streptococcus*
Parainfluenza virus 3	*Haemophilus influenzae*
Parainfluenza virus 4	*Legionella pneumophila*
Respiratory syncytial virus A	*Mycoplasma pneumoniae*
Respiratory syncytial virus B	*Mycobacterium tuberculosis*
Rhinovirus A30	*Staphylococcus aureus*
Rhinovirus B52	*Staphylococcus epidermidis*
Bordetella parapertussis	*Streptococcus agalactiae*
Bordetella pertussis	*Streptococcus pneumoniae*
Candida albicans	*Streptococcus pyogenes*

INTERFERING SUBSTANCES STUDIES

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated at specified concentrations. None of them were found to affect the test performance of the kit.

3 OTC nasal sprays	Guaiacol glyceryl ether
3 OTC mouth washes	Mucin
3 OTC throat drops	Whole blood
4-acetamidophenol	Mupirocin
Acetylsalicylic acid	Oxymetazoline
Albuterol	Phenylephrine
Chlorpheniramine	Phenylpropanolamine
Dexamethasone	Zanamivir
Dextromethorphan	Adamantanamine
Diphenhydramine	Oseltamivir phosphate
Doxylamine succinate	Tobramycin
Flunisolide	Triamcinolone

COMPETITIVE INHIBITION STUDIES

High concentrations of each virus did not interfere with the detection of the other viruses at lower concentrations and no competitive inhibition was observed.

LITERATURE REFERENCES

1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35-48 (2017).
2. Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697-1699 (2013).

MEDICAL DEVICE INCIDENT REPORT

You can contact the Therapeutic Goods Administration (TGA) to report poor performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361 (08:30am to 5:00pm Monday to Friday).

SAFETY INFORMATION

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 to protect yourself. Test kit solutions should only be used as directed. Do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes. Keep out of the reach of children and pets before and after use. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.

GLOSSARY OF SYMBOLS

REF	Catalog number	2℃ 30℃	Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use by
	Manufacturer	Σ	Contains sufficient for <n> tests
	Do not reuse		Do not use if package damaged

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