Biolink

Biopen®

COVID-19 & Influenza A/B

Antigen Nasal Test Kit for Self-testing

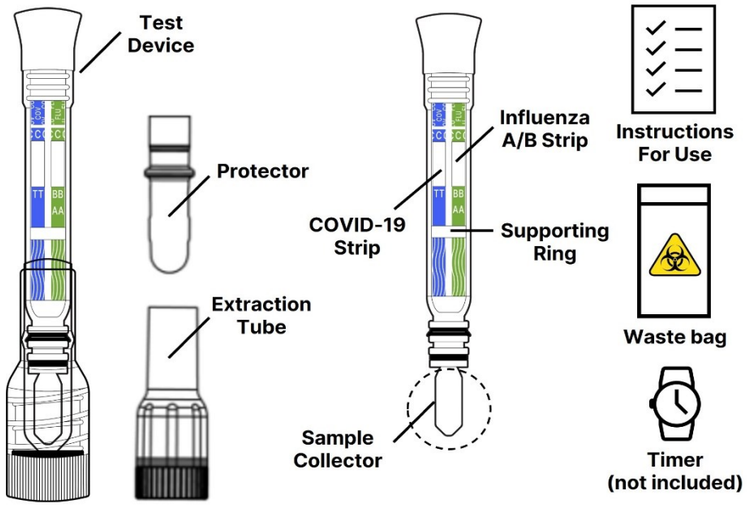
Quick Reference Instructions

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

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

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

PACKAGE CONTENTS



STORAGE AND STABILITY

1. Store the COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing at 2-30°C when not in use.
2. DO NOT FREEZE.
3. Kit contents are stable until the expiration dates marked on outer packaging and container.
4. Shelf Life: 24 months. Do not use kit or components beyond the expiration date.

NOTE

!!! Children aged between 2 and 18 years old must be supervised or tested by an adult when carrying out the test.

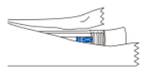
!!! Do not use this test on anyone under 2 years of age.

!!! Caution should be taken when inserting the sample collector into the nasal cavity.

INTENDED USE

The COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing is an in vitro immunoassay. The assay is intended for home testing (or self-testing). Children aged between 2 and 18 years old must be supervised or tested by an adult when carrying out the test. The assay is an in vitro immunochromatographic assay for the qualitative detection of SARS-CoV-2, Influenza A, and Influenza B viral nucleoprotein antigens 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 (within the first 4 days of the onset of symptoms). The assay obtains a preliminary result only, aiding in the diagnosis of COVID-19 and/or Influenza A/B. This test has not been cleared for use in asymptomatic individuals.

BEFORE THE TEST



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

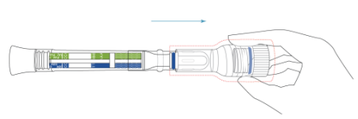
2. Remove the test device from its pack. For the best results, the assay should be performed within 1 hour.

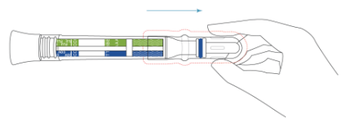
3. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

NASAL SWAB COLLECTION

1. Take the test device out of the extraction tube.

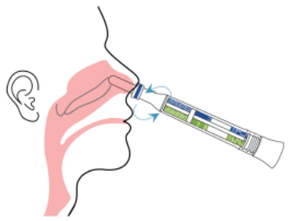
2. Remove the protector.

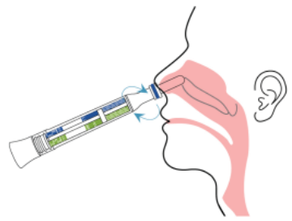




3. Gently insert the sample collector until resistance is met (about 1-2 cm into the nostril). Rotate the collector five times against the nasal wall and remove it from the nostril.

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.

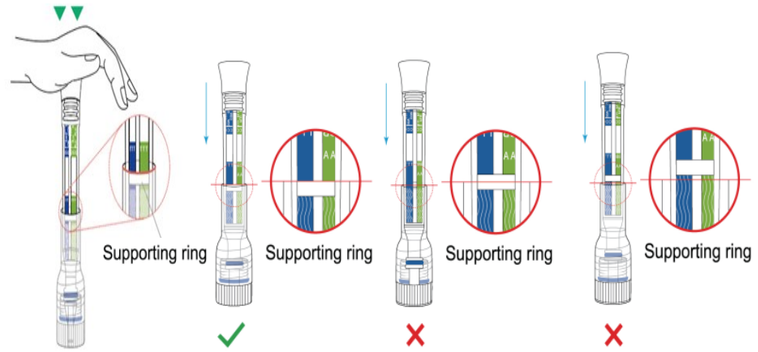
Note:

- Caution should be taken when inserting the sample collector into the nasal cavity.
- With children, the maximum depth of insertion into the nostril may be less than 2cm, and you may need to have a second person to hold the child's head while swabbing.
- This test may feel slightly uncomfortable or tickly, but it should not hurt. Do not insert the collector any deeper if you feel strong resistance.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

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.

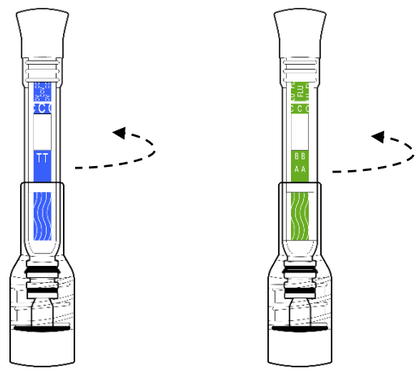
2. Read the results at **15 minutes**. Do not read the results after 30 minutes.

3. The used test kit should be placed into a waste bag and discarded as general waste. Please follow the local regulations for household waste disposal.

READING THE RESULTS

IMPORTANT

- **Look around all sides of the test device to read results from all test strips:**



WARNING

- **You may test positive for more than one disease.**
- **Keep track of which strips show positive, negative, and/or invalid results.**
- **The shade of lines may vary. If a faint or weak line appears, it should be considered a positive result.**
- **Details on how to read each individual strip are shown below.**

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

INTERPRETATION OF THE RESULTS

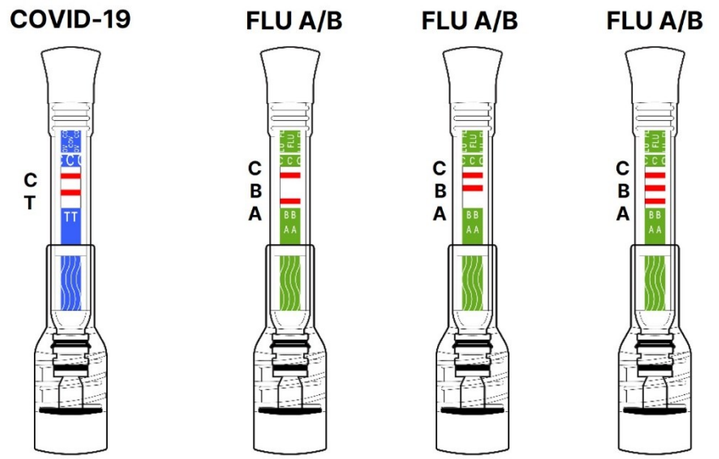
Look around all sides of the test device to read the results of each test strip independently from each other. Read the results at 15 minutes. Do not read the results after 30 minutes:

POSITIVE RESULTS

If you get POSITIVE results for COVID-19, follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if necessary. If unwell, please consult a medical practitioner for follow up clinical care.

If you get POSITIVE results for Influenza A/B, please consult a medical practitioner for follow up clinical care.

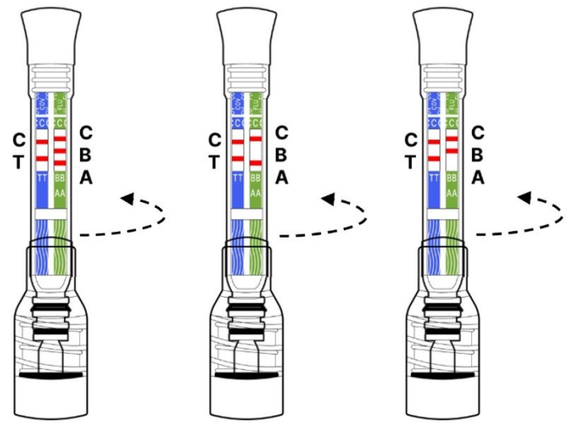
Please follow all public health advice on limiting the spread of COVID-19 and Influenza.



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

MIXED POSITIVE RESULTS

It is possible to test positive for more than one disease – look around all sides of the test device:



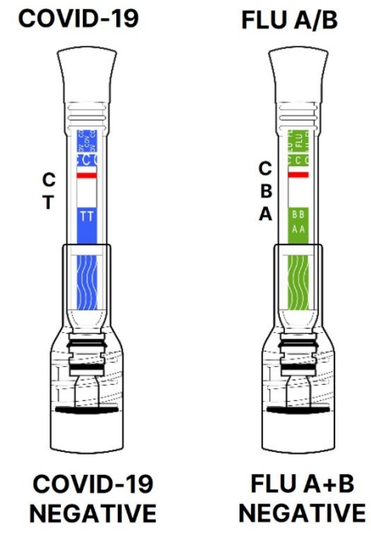
NOTE: The shade of lines may vary, but even if a faint or weak line appears, the test should be considered positive.

NEGATIVE RESULTS

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), or Influenza A/B (Flu A/B). 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 and Influenza.

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



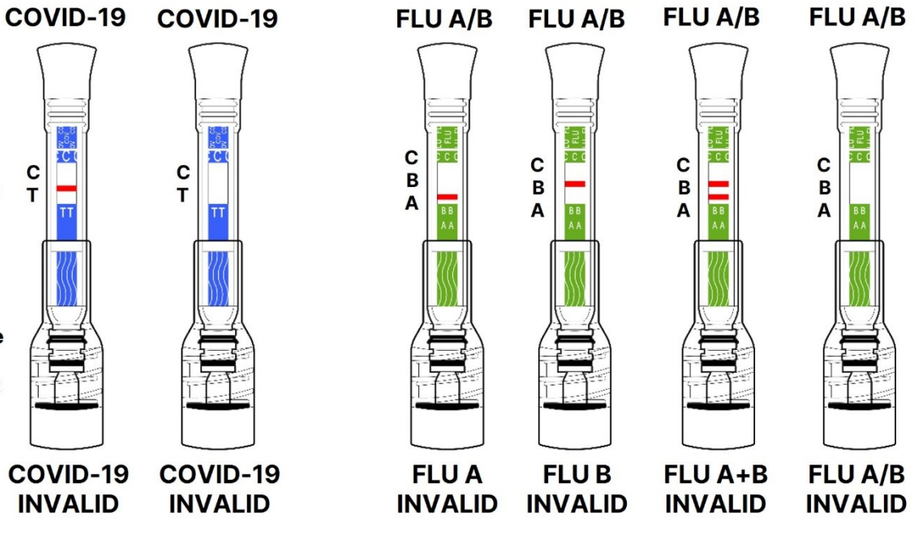
If symptoms persist, repeat testing and consult a medical practitioner for follow-up clinical care.

INVALID RESULTS

When no red line appears in the control region (C) for all three tests, the test is invalid:

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

If invalid result continues after repeating, please contact the provided contact number for assistance.

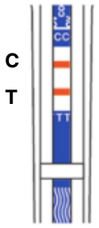


NOTE: Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the control line (C) failure.

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).

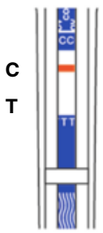
COVID-19 RESULTS



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

A positive test result means it is very likely patients currently have COVID-19 disease. **Please follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if necessary. If unwell, please consult a medical practitioner for follow up clinical care.**

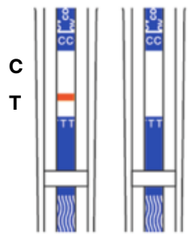
NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens. **The shade of lines may vary. If a faint or weak line appears, it should be considered a positive result.**



<u>COVID-19 Negative</u>: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

A negative result for COVID-19 does not mean a person does not have COVID-19. If a person has symptoms, they should follow the guidance from the local state or territory health departments, and if unwell seek medical assistance.

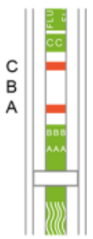
NOTE: A negative result does not mean you are not infected with SARS-CoV-2. If you are unwell, please consult a medical practitioner for follow up care and continue to follow all public health advice on limiting the spread of COVID-19. If symptoms persist, test again within at least 24 hours and no more than 48 hours between tests as SARS-Cov-2 antigen present in COVID-19 cannot be precisely detected in all phases of an infection.



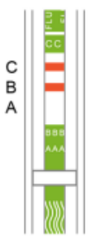
<u>COVID-19 Invalid</u>: No colored band appears in the control region (C), whether a test band(s) is present or not.

NOTE: Results from any test which has not produced a control band at the specified read time must be discarded. **Please review the procedure and repeat with a freshly collected sample and a new test. If the problem persists, please report repeated invalid results to the sponsor.**

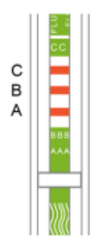
INFLUENZA RESULTS



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



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

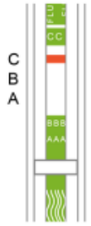


<u>Influenza A+B Positive</u>: One colored band appears in the control region (C), and two other colored bands appear in both A region (A) and B region (B).

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.

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 have a positive Influenza A and/or B result, please consult a medical practitioner for follow up clinical care.**

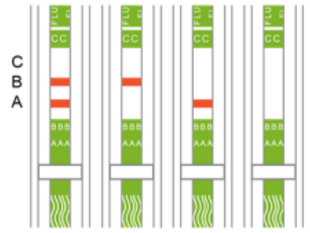
NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype. **The shade of lines may vary. If a faint or weak line appears, it should be considered a positive result.**



<u>Influenza A+B Negative</u>: Only one colored band appears in the control region (C), and band appears neither in the A region (A) nor B region (B).

A negative test result means it is unlikely patients have influenza A/B disease. Please continue to observe local hygiene and safety measures.

NOTE: A negative result does not mean a person does not have influenza, and if symptoms persist, the person should seek medical attention and further testing if required.



<u>Influenza A or B Invalid</u>: No colored band appears in the control region (C), whether a test band(s) is present or not. Results from any test which have not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

PRINCIPLE

The COVID-19 & Influenza A/B Antigen Nasal Test Kit detects SARS-CoV-2 and Influenza A&B viral nucleoprotein antigens through visual interpretation of color development on the internal strip. AntiSARS-CoV-2 monoclonal antibody (mAb) and Influenza A&B antibodies are immobilized at the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 mAb and Influenza A&B 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 antibodies on the conjugate pad. Consequently, the antigen-antibody complex will be captured by the anti-SARS-CoV-2 mAb or Influenza A&B 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 viral and Influenza A&B 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.

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 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 in the extraction tube before testing.
- Caution should be taken when inserting the sample collector into the nasal cavity.
- 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.
- Do not use this test on anyone under 2 years of age.
- 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.
- Dispose all parts of the used test kit into the waste bag, then discard the waste bag in the general waste.

LIMITATIONS

1. 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. The intensity of color in a positive band should not be evaluated as “quantitative or semi-quantitative”.
2. 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.
3. Failure to follow the test procedure and interpretation of results may negatively affect and / or falsify the test result.
4. Negative results do not completely rule out an infection with SARS-CoV-2 viral and Influenza A&B virus.
5. A negative result does not rule out infection with another type of respiratory virus.
6. Recommended repeat testing (e.g. within 1-3 days) if ongoing suspicion of infection, high risk setting/occupation or other requirement.
7. This test does not discriminate between SARS-coronavirus and SARS-CoV-2 (COVID-19). Positive results may be due to present infection with SARS-CoV.
8. 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 symptoms) and in asymptomatic individuals.
9. Negative results may not mean a person is not infectious and if symptoms are present the person must seek immediate further testing.

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QUALITY CONTROL

Internal Procedural Controls: The COVID-19&Influenza A/B 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.

PERFORMANCE

ANALYTICAL SENSITIVITY

The limit of detection (LOD) of COVID-19&Influenza A/B Antigen Nasal Test Kit for Self-testing, defined as the concentration of influenza virus and SARS-CoV-2 virus that produces positive COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing results approximately 95% of the time, was identified by evaluating different concentrations of inactivated Flu A, inactivated Flu B and inactivated SARS-CoV-2 in the COVID-19 & Influenza A/B Antigen Nasal Test Kit for Self-testing.

The LOD on different SARS-CoV-2 variants for COVID-19 Test were summarized in the table below:

SARS-CoV-2	Inactivated Virus LOD ($TCID_{50}$/mL)
Wild type	$1\times10^{2.4}$
Alpha (B.1.1.7)	$1\times10^{2.5}$
Delta (B.1.617.2)	$5\times10^{1.5}$
Omicron (B.1.1.529.1)	$1\times10^{2.25}$
Omicron (B.1.1.529.2)	1×10^{2}

The LOD on different influenza viral strains for Influenza A/B Test were summarized in the table below:

Influenza A (H1N1)	Inactivated Virus LOD ($TCID_{50}$/mL)	Live Virus LOD ($TCID_{50}$/mL)
A/Michigan/45/2015	1.0×10^{4}	10
A/California/07/2009	1.53×10^{4}	15.3
A/Brisbane/02/2018	1.3×10^{4}	26
A/Victoria/2570/2019	1.3×10^{4}	13
A/Wisconsin/588/2019	1.05×10^{4}	21
A/Sydney/5/2021	1.13×10^{4}	22.5

Influenza A (H3N2)	Inactivated Virus LOD ($TCID_{50}$/mL)	Live Virus LOD ($TCID_{50}$/mL)
A/Singapore/INFIMH-16-0019/2016	1.4×10^{4}	28
A/Hong Kong/4801/2014	4.1×10^{4}	41
A/Hong Kong/2671/2019	1.33×10^{4}	26.5
A/Hong Kong/45/2019	1.6×10^{4}	16
A/Switzerland/9715293/2013	2.23×10^{4}	22
A/Darwin/6/2021	8.0×10^{3}	8
A/Darwin/9/2021	1.15×10^{4}	23

Influenza B (Yamagata lineage)	Inactivated Virus LOD ($TCID_{50}$/mL)	Live Virus LOD ($TCID_{50}$/mL
B/Massachusetts/2/2012	7.8×10^{4}	39
B/Phuket/3073/2013	2.7×10^{5}	135

Influenza B (Victoria lineage)	Inactivated Virus LOD ($TCID_{50}$/mL)	Live Virus LOD ($TCID_{50}$/mL
B/Colorado/06/2017	1.9×10^{5}	100
B/Brisbane/60/2008	3.9×10^{4}	19.5
B/Washington/02/2019	8.75×10^{4}	35
B/Austria/1359417/2021	5.0×10^{4}	25

CLINICAL EVALUATION

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

COVID-19 Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	RT-PCR Negative	Total
COVID-19 & Influenza A/B Antigen Nasal Test Kit	**Positive**	192	1	**193**
	Negative	8	500	**508**
	Total	**200**	**501**	**701**

Diagnostic Sensitivity: 96.0% (92.3%~98.0%) *
Diagnostic Specificity: 99.8 % (98.9%~100.0%)*
Overall Agreement: 98.7 % (97.6%~99.3%)*
***95% Confidence Interval**

Influenza A Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	RT-PCR Negative	Total
COVID-19 & Influenza A/B Antigen Nasal Test Kit	**Positive**	99	3	**102**
	Negative	4	595	**599**
	Total	**103**	**598**	**701**

Diagnostic Sensitivity: 96.1% (90.4%~98.5%) *
Diagnostic Specificity: 99.5 % (98.5%~99.8%) *
Overall agreement: 99.0 % (98.0%~99.5%) *
***95% Confidence Interval**

Influenza B Antigen Rapid Test vs. RT-PCR

		RT-PCR Positive	RT-PCR Negative	Total
COVID-19 & Influenza A/B Antigen Nasal Test Kit	**Positive**	79	2	**81**
	Negative	5	615	**620**
	Total	**84**	**617**	**701**

Diagnostic Sensitivity: 94.0 % (86.8%~97.4%) *
Diagnostic Specificity: 99.7 % (98.8%~99.9%) *
Overall agreement: 99.0% (98.0%~99.5%) *
***95% Confidence Interval**

USABILITY STUDIES

159 people self-sampled and self-tested using the COVID-19/Influenza A&B Antigen Test Kit and were also tested with a PCR.

COVID-19 Test

The tests correctly identified 90.0% (27/30) of positive samples and 100.0% (129/129) of negative samples.

Influenza A Test

The tests correctly identified 92.0% (23/25) of positive samples and 99.3% (133/134) of negative samples.

Influenza B Test

The tests correctly identified 100.0% (7/7) of positive samples and 99.3% (151/152) of negative samples.

USER COMPREHENSION STUDIES

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

CROSS REACTIVITY STUDIES

The COVID-19 & Influenza A/B Antigen Nasal Test Kit presented no cross-reactivity with these 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	Epstein-Barr virus
Adenovirus 2	Enterovirus EV70
Adenovirus 3	Enterovirus EV71
Adenovirus 4	Enterovirus A16
Adenovirus 5	Enterovirus A24

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

CROSS REACTIVITY STUDIES (CONTINUED)

Adenovirus 7	Enterovirus B1
Adenovirus 55	Echovirus 6
HCoV-229E	Respiratory syncytial virus B
HCoV-OC43	Rhinovirus A30
HCoV-NL63	Rhinovirus B52
HCoV-HKU1	*Bordetella parapertussis*
MERS-CoV	*Bordetella pertussis*
SARS-CoV	*Candida albicans*
SARS-CoV-2	*Chlamydia pneumoniae*
Influenza A (H1N1) pdm09	*Group C Streptococcus*
Influenza A (H1N1)	*Hemophilus influenzae*
Influenza A (H3N2)	*Legionella pneumophila*
Influenza B Victoria lineage	*Mycoplasma pneumoniae*
Influenza B Yamagata lineage	*Mycobacterium tuberculosis*
Human metapneumovirus	*Staphylococcus aureus*
Norovirus	*Staphylococcus epidermidis*
Parainfluenza virus 1	*Streptococcus agalactiae*
Parainfluenza virus 2	*Streptococcus pneumoniae*
Parainfluenza virus 3	*Streptococcus pyogenes*
Parainfluenza virus 4	*Pseudomonas aeruginosa*
Respiratory syncytial virus A	*Staphylococcus salivarius*

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

The high concentrations of either virus did not interfere with the detection of the other two 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 syn-drome 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 is damaged

CE CE Marking according to IVD Medical Devices Directive 98/97/EC

STATE & TERRITORY HEALTH DEPARTMENTS

Australian Capital Territory Coronavirus hotline
☎ (02)62077244(8:00am-8:00pm daily) ⊕ http://health.act.gov.au/

New South Wales Department of health
☎ 137788 ⊕ http://health.nsw.gov.au/

Northern Territory Department of health
☎ (National helpline): 1800020080 ⊕ http://health.nt.gov.au/

Queensland Department of Health
☎ 13COVID or 134268 ⊕ http://health.qld.gov.au/

South Australian Department of Health
☎ (9am to 5pm daily): 1800253787 ⊕ https://www.sahealth.sa.gov.au/

Tasmanian Department of Health
☎ (coronavirus): 1800671738 ⊕ http://health.tas.gov.au/

Victorian Department of Health
☎ (24/7): 1800675398 ⊕ http://www.dhhs.vic.gov.au/

Western Australian Department of Health
☎ 13COVID (8:00am to 6:00pm. Mon-Fri) or 1800595206
⊕ http://healthwa.gov.au/

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50,
Moganshan Road,
Gongshu District, Hangzhou,
310011 Zhejiang, P.R. China
contact@diareagent.com

Manufactured for:
Emergence Technology Pty Ltd.
6/3 Hill St, Toorak, VIC 3142
Australia

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