REF GCFC-525SKa-H1/GCFC-525SKa-H2/ GCFC-525SKa-H4/GCFC-525SKa-H5/ GCFC-525SKa-H6/GCFC-525SKa-H10

HEALGEN®

INSTRUCTIONS FOR USE

Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test

For Self-Testing

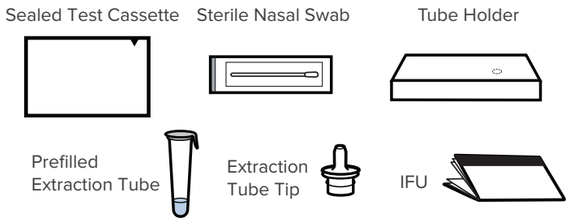
For *in vitro* diagnostic use only

Please scan the QR code or use the URL below to access a digital version of the instructions, an on-line instructional video and information about accessing support services.

https://healgen.au/human-health/infectious-disease-respiratory/rapid-check-covid-19-flu-ab-antigen-test/

Carefully read the instructions before performing the test.

Materials Provided



Required but not provided: Timer or clock.

Preparing for The Test

NOTE:

- **Do not open the test contents until ready for use.**

If the test cassette is open for an hour or longer, invalid test results may occur.

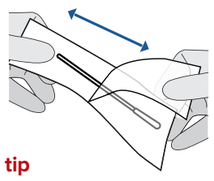
- **Allow the test device and reagents to come to room temperature [15-30°C(59-86°F)] prior to testing.**

1. **Check the test's expiration date printed on the outer test packaging.**
2. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.
3. Turn over the test kit box to locate the perforated hole.

4. Insert the extraction tube into the tube holder. Ensure that the tube is stable and upright.
5. Tear off the sealing film on the extraction tube gently to avoid spilling the liquid.

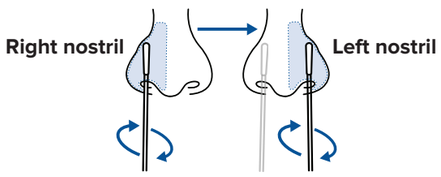
Sample Collection

1 Remove the swab from the pouch. Carefully insert the sterile swab no more than 3/4 inch (1.5 cm) into the nostril.



Be careful not to touch the swab tip (soft end) with hand.

2 Slowly rotate the swab **at least 5 times** against the nostril wall **for at least 15 seconds**. Remove the swab and repeat in the other nostril using the same swab.

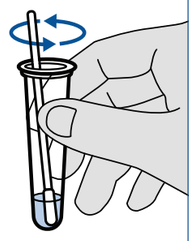


5x for 15 seconds, each nostril

Note: If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

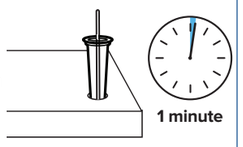
Running The Test

3 Immerse the swab into the prefilled extraction tube and swirl the swab in the buffer. Ensure the sample is mixed thoroughly by **making at least 6 circles.**



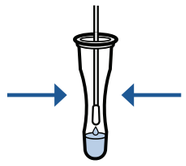
Sample must be mixed in the extraction buffer within 1 hour of sample collection.

4 Leave the swab in the extraction tube for **1 minute**. A timer is recommended for this step.



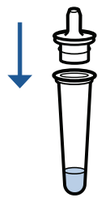
5 After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess sample in the swab.

Remove and discard the swab.



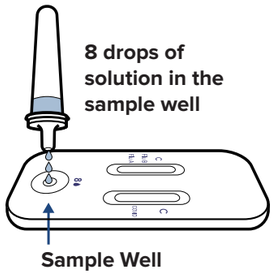
6 Hold the tube upright and insert the extraction tube tip into tube opening. Ensure a tight fit to prevent leaking.

Note: Return the Tube to the tube holder before proceeding to the next step.



7 Remove test cassette from sealed pouch and lay it on a flat surface.

8 Invert the extraction tube and **squeeze 8 drops** of test sample into the sample well. Then discard the tube.



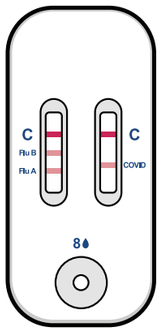
Sample must be applied to the test cassette within one hour of completing step 3.

9 Start timer. Read results at 15 minutes.

Do not interpret results before 15 minutes or after 20 minutes, as this may result in false or invalid results.

Interpreting Your Results

Control line = **C**
Flu B line = **Flu B**
Flu A line = **Flu A**



C = Control line

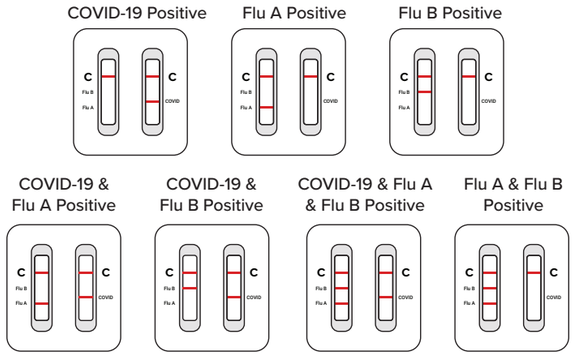
COVID = COVID-19 line

- Look for lines next to 'C' (Control), 'Flu B', 'Flu A' and 'COVID'.
- Look closely! Any faint line is still a line.

Make sure there is a visible line next to 'C' in both result windows. If one or both 'C' lines are missing, the result is INVALID. Repeat with a new test and sample.

Positive Test Result

POSITIVE



If you see a line at any one, or multiple, of the 'COVID', 'Flu A' or 'Flu B' areas, it means that your test result is positive and the virus annotated next to the positive line was detected in your sample. Consult your healthcare provider to discuss your positive test result.

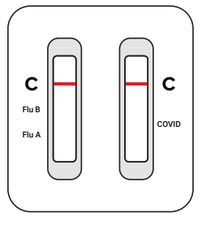
NOTE: Any pink or purple line in the correct, indicated locations, no matter how faint, should be considered an indication of a positive result.

What you need to do:

- If you tested positive for COVID-19 and/or Influenza A/B, please consult a medical practitioner for follow-up clinical care.
- If you have a POSITIVE result, staying at home protects the people in your community.
- If you test positive, you should not visit high-risk settings like hospitals, and aged & 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 to avoiding contact with people, who are at higher risk of severe disease, wearing a mask outside the home, working from home where possible, avoiding going to school, public areas, or travel on public transport, in taxis, or ride-share services, practicing good hygiene, and following your local health department's advice when leaving home.
- If you feel unwell or need COVID-19 and/or Influenza advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222.
- **If you have symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.**
- If you experience only mild symptoms, or no symptoms at all (asymptomatic). You can manage these symptoms with over-the-counter medication.
- Follow the guidance from your local state or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- If you are worried about your child's symptoms, contact your GP as soon as possible. A GP or nurse will treat your child based on their age, symptoms, and past medical history. If they are showing severe symptoms, call triple zero (000) immediately.

Negative Test Result

NEGATIVE



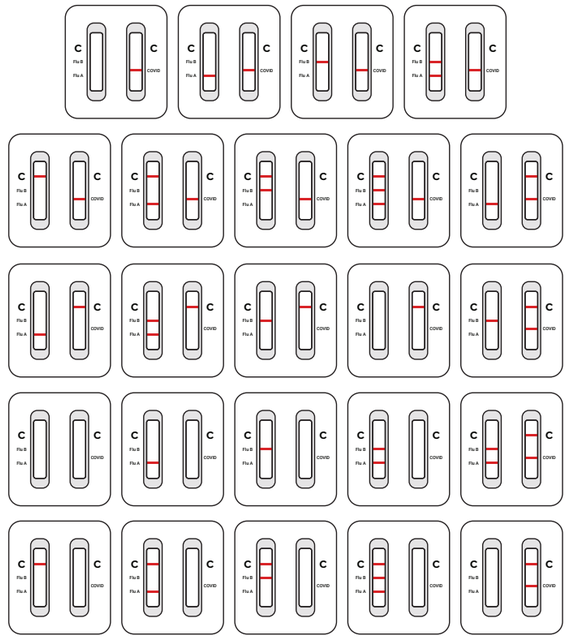
If you do not see a line at 'COVID', 'Flu A' or 'Flu B' It means you may not have COVID-19, Flu A or Flu B virus.

What you need to do:

- Negative results do not completely rule out SARS-CoV-2, Infulenza A or Infulenza Binfection. Please continue to comply with all applicable rules regarding contact with others and protective measures.
- If symptoms are developed the individual must have a laboratory PCR test performed even with a negative test.
- If symptoms develop persist or become more severe, follow the guidance from you local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- If it is suspected, repeat the test after 1 - 3 days, as the coronavirus/Influenza virus cannot be precisely detected in all phases of an infection.

Invalid Test Result

INVALID



If a control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, **THE TEST HAS FAILED** and is considered invalid.

What you need to do:

An invalid test result means that the test is unable to determine if you are infected with influenza or SARS-CoV-2 (COVID-19) or not. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If an invalid result is produced, please review the procedure and repeat with a new test.. If the test results remain invalid, contact the sponsor hotline for further guidance.

After Testing

1 After the test is complete, place all the components in a plastic bag and tightly sealed, then dispose in household waste or rubbish bin.

2 Wash and dry your hands thoroughly again.

Index of Symbols

	Consult instructions for use		Tests per kit		Keep away from sunlight
IVD	For *in vitro* diagnostic use only		Use-by date (Expiration date)		Do not re-use
	Store at 36~86°F/2~30°C	LOT	Batch code	REF	Catalogue number
UDI	Unique device identifier		Keep dry		Manufacturer
	Do not use if package is damaged				

HEALGEN®

Healgen Scientific, LLC.
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1 713-733-8088 Fax: +1 713-733-8088
Website: www.healgen.com

Australian Sponsor:
Compliance Management Solutions Pty Ltd.
3/85 Curzon Street
North Melbourne VIC 3051
Australia.

For Customer Support Helpline: Call 0415 860 461 9am-7pm (AEST), 7 days per week for information on the correct use of this test and for interpretation of the test results.

Revision Date: 2025-11-25

Intended Use

The Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test is a lateral flow immunochromatographic assay for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen in anterior nasal swab samples. The test is intended for use in symptomatic individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset and / or Influenza A+B within the first 4 days of symptom onset.
It is intended to aid in the rapid diagnosis of SARS-CoV-2, influenza A and/or influenza B infections. This test provides only a preliminary test result. Therefore, any reactive specimen with
the Healgen® Rapid CheckTM COVID-19/Flu A&B Antigen Test must be confirmed with alternative testing method(s) and clinical findings.
It is intended for Self-testing use.

Summary And Explanation

COVID-19 and influenza are acute and highly contagious viral infections of the respiratory tract. The causative agents of the diseases are immunologically diverse, single-strand RNA viruses known as SARS-CoV-2 viruses and influenza viruses, respectively. There are three types of influenza viruses: A, B and C. Type A viruses are the most prevalent and are associated with more serious disease whereas Type B infection is generally milder. Type C virus has never been associated with a large epidemic of human disease.
A patient can be infected with a single virus or co-infected with SARS-CoV-2 and one or more types of influenza viruses. These viral infections occur more often during the respiratory illness season (this includes the fall and winter seasons) and the symptoms generally appear 3 to 7 days after the infection. Transmission for all of these viruses occurs through coughing and sneezing of aerosolized droplets from infected people, who may be either symptomatic or asymptomatic. For symptomatic patients, the main symptoms include fever, fatigue, dry cough, and loss of taste and smell. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea were also associated symptoms.

Principle of The Test

The Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test is an immunochromatographic assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein antigens extracted from COVID-19, influenza virus types A and B with anterior nasal swab samples.
The test device is a plastic housing, known as a cassette, containing two test strips, each composed of the following parts: sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pads contain colloidal gold conjugated with monoclonal antibodies (mAb) specific for SARS-COV-2, Influenza A, and Influenza B target proteins. When the test sample is added into the sample well (S) of the cassette, mAb conjugates dried in the reagent pad are dissolved and interact with the viruses' proteins in the sample (if present). These complexes migrate along the test strip and across the reaction lines on the membrane. The reaction line contains a second antibody specific to available target protein-mAb complexes with each of the virus antigens of the test, resulting in visible test lines for the viruses in the sample.
Reactions for each virus occur independently at their respective locations on the test reaction membrane. If the sample contains influenza type A or B antigens, a pink-to-red test line (A or B) will develop; if SARS-CoV-2 antigens are present, a pink-to-red test line (T) will develop. The procedural control line (C) must always appear on both strips for the test to be valid.

Materials

Materials Provided

	GCFC-525SKa-H1	GCFC-525SKa-H2	GCFC-525SKa-H4	GCFC-525SKa-H5	GCFC-525SKa-H6	GCFC-525SKa-H10
Sealed Test Cassette(s)	1	2	4	5	6	10
Sterile Nasal Swab(s)	1	2	4	5	6	10
Pre-filled Extraction Tube(s)	1	2	4	5	6	10
Extraction Tube Tip(s)	1	2	4	5	6	10
Tube Holder	1	1	1	1	1	1
Instructions For Use	1	1	1	1	1	1

Materials Required but Not Provided

Clock or timer

Warnings And Precautions

1. Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate or invalid results.
2. **Do not use the test if you have had symptoms for more than 7 days or no symptoms at all.**
3. **Do not use under 2 years of age.**
4. Do not use the test kit after its expiration date.
5. The test can only be used once.
6. The test is less reliable in the later phase of infection and in asymptomatic individuals.
7. Test for children should be under the supervision of an adult.
8. Do not use the test if the pouch is damaged or open.
9. Swabs, tubes and test cassettes are for single use only.
10. Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
11. When collecting a sample, only use the swab provided in the kit.
12. Inadequate or inappropriate sample collection, storage, or transport may yield false test results.
13. Testing should be performed in an area with good lighting.
14. **Keep the testing kit and kit components away from children and pets before and after use. Avoid contact with your skin, eyes, nose, or mouth. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your skin, eyes, nose, or mouth, flush with large amounts of water. If irritation persists, contact Australian Poisons Information Centre for medical advice: 131 126.**

Hazard Category (mixture)	Hazard Class	GHS Hazard Statement for mixture	Hazardous Ingredients (%)*
2	Skin irritation	Causes skin irritation (H315)	Tris (2.4%) 1, 2-Benzisothiazolin-3-One (0.04%)
2	Eye irritation	Causes eye irritation (H320)	1, 2-Benzisothiazolin-3-One (0.04%) Tris (2.4%) Ethylenediamine ethoxylated propoxylated polymer (S9) (0.75%)

Storage And Stability

- Store the test kit between 36-86°F (2-30°C) in a place out of direct sunlight.
- DO NOT FREEZE.
- Do not use test device and reagents after expiration date.
- Test cassettes that have been outside of the sealed pouch for more than 1 hour should be discarded.

Limitations

1. The Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test is for in vitro diagnostic use, and should only be used for the qualitative detection of influenza A, B and/or SARS-CoV-2 in nasal swab specimens.
2. The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.
3. SARS-CoV-2 and Influenza self-testing are for use as an aid for diagnosis only and individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.
4. A negative test result may occur if the level of antigen in the sample is below the detection limit of the test or if the sample is collected, handled or transported improperly.
5. A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention and further testing by PCR if required.
6. Negative result do not rule out infection with another type of respiratory virus.
7. A positive result cannot necessarily determine whether a person is infectious.
8. Positive results do not rule out co-infection with other respiratory pathogens.
9. Persons with risk factors for severe disease from respiratory pathogens (e.g., young children, elderly individuals, chronic lung disease, heart disease, compromised immune system, diabetes, and other conditions) should contact a healthcare provider; users should also contact a healthcare provider if symptoms persist or worsen.
10. This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
11. Incorrect test results may occur if a specimen is incorrectly collected or handled.
12. This device is a qualitative test and cannot provide information on the amount of virus present in the specimen.
13. Exposure to hand sanitizer may cause false negative results with this test.
14. Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive influenza test results after vaccination.
15. This test does not distinguish between SARS-CoV and SARS-CoV-2.
16. Recommend repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
17. The test is less reliable when used in the condition of later phase of infection. If testing is not performed within the first 7 days symptom onset, false SARS-CoV-2 negative results may occur. If testing is not performed within the first 4 days symptom onset, false influenza negative results may occur.

Performance Characteristics

Clinical Study

Clinical Study: COVID-19

A total of 1329 subjects were enrolled in the study, all of whom were tested with the candidate and reference (RT-PCR) kits. Through PCR testing, 177 positive and 1152 negative cases were confirmed. Test results of the candidate kit and the reference kit are summarized in 2×2 table below.

COVID-19		RT-PCR Kit		Total	Overall Sensitivity (95% CI)	Overall Specificity (95% CI)	Overall Accuracy (95% CI)
		Positive	Negative				
Healgen® Rapid Check™ COVID-19/ Flu A&B Antigen Test	Positive	170	10	180	96.05% (92.06%-98.07%)	99.13% (98.41%-99.53%)	98.72% (97.96%-99.20%)
	Negative	7	1142	1149			
Total		177	1152	1329			

Clinical Study: Flu A

For the 1331 subjects who successfully completed antigen testing, 125 Flu A true positive samples, 1198 Flu A true negative samples, 1 Flu A false positive samples and 7 Flu A false negative samples have been found. The diagnostic sensitivity and specificity were calculated as below:

Flu A		RT-PCR Kit		Total	Overall Sensitivity (95% CI)	Overall Specificity (95% CI)	Overall Accuracy (95% CI)
		Positive	Negative				
Healgen® Rapid Check™ COVID-19/ Flu A&B Antigen Test	Positive	125	1	126	94.70% (89.46%-97.41%)	99.92% (99.53%-99.99%)	99.40% (98.82%-99.70%)
	Negative	7	1198	1205			
Total		132	1199	1331			

Clinical Study: Flu B

For the 1350 subjects who successfully completed antigen testing, 129 Flu B true positive samples, 1209 Flu B true negative samples, 1 Flu B false positive samples and 11 Flu B false negative samples have been found. The diagnostic sensitivity and specificity were calculated as below:

Flu B		RT-PCR Kit		Total	Overall Sensitivity (95% CI)	Overall Specificity (95% CI)	Overall Accuracy (95% CI)
		Positive	Negative				
Healgen® Rapid Check™ COVID-19/ Flu A&B Antigen Test	Positive	129	1	130	92.14% (86.48%-95.56%)	99.92% (99.53%-99.99%)	99.11% (98.45%-99.49%)
	Negative	11	1209	1220			
Total		120	1210	1350			

Usability

Lay users in different age distribution, different education level and different gender participated in usability study conducted in the self-testing environment. Compared to RT-PCR, the clinical performance of COVID-19/Flu A&B Antigen Test in hands of lay persons showed a sensitivity of 92.0% (N=75) and a specificity of 99.0% (N=1044) for COVID-19 Antigen, a sensitivity of 92.6% (N=54) and specificity of 99.9% (N=1090) for influenza A antigen and a sensitivity of 90.5% (N=42) and a specificity of 99.9% (N=1102) for influenza B antigen.

Analytical Sensitivity (Limit of Detection)

1. Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2, Influenza A and Influenza B at which ≥95% of all (true positive) replicates test positive.

	Virus Strains	LoD ($TCID_{50}$/mL)
SARS-CoV-2	USA-WA1/2020 (UV inactivated)	$3.95x10^2$
	USA-WA1/2020 (Heat inactivated)	$3.09x10^3$
	USA/COR-22-063113/2022 (BA.5, Omicron variant)	$1.095x10^3$
	JN.1 (Omicron variant)	$1.57×10^2$
Flu A (H3N2)	Darwin/6/21	$2.09x10^2$
Flu A (H1N1)	Victoria/4897/22	$2.02x10^2$
	A/California/07/2009 pdm09	$1.05x10^3$
	Guangdong-Maonan/SWL 1536/19 (PROtrol inactivated)	$5.62x10^1$
Flu B (Yamagata)	Florida/04/06	$1.46x10^1$
Flu B (Victoria)	Washington/02/19	$1.58x10^3$
	Washington/02/19 (PROtrol inactivated)	$1.75x10^4$

Analytical Reactivity/Inclusivity

The analytical inclusivity study demonstrated the performance of Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test for Self-testing was not affected by different SARS-CoV-2 variants and influenza viral strains summarised as below:

SARS-CoV-2:
Omicron (JN.1)

Influenza A (H1N1):
A/California/04/2009, A/Brisbane/02/2018, A/Michigan/45/2015, A/GuangdongMaonan/SWL1536/2019, A/NY/03/2009, A/Indiana/02/2020, A/Wisconsin/588/2019, A/Sydney/5/2021, A/Hawaii/66/2019, A/Victoria/4897/2022, A/Wisconsin/67/2022, A/Ohio/09/2015

Influenza A (H3N2):
A/Tasmania/503/2020, A/New York/21/2020, A/Alaska/01/2021, A/Hong Kong/45/2019, A/Darwin/6/2021, A/HongKong/2671/2019, A/Indiana/08/2011, Darwin/9/2021, Cambodia/E0826360/20

Influenza B (Yamagata lineage):
B/Texas/06/2011, B/Utah/09/2014, B/Florida/04/2006, B/Wisconsin/01/2010

Influenza B (Victoria lineage):
B/Colorado/06/2017, B/Brisbane/60/2008, B/Washington/02/2019, B/Texas/02/2013, B/Michigan/01/2021, Austria/1359417/21

Analytical Specificity (Cross-Reactivity)

The analytical specificity/interference of the Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test was evaluated by testing various commensals and pathogenic microorganisms in the absence (cross-reactivity) and presence (microbial interference) of SARS-CoV-2/Flu A/Flu B at 3x LoD. Each organism was tested in replicates of three (3) with or without SARS-CoV-2/ FluA/FluB present in the sample. No cross-reactivity and no microbial interference was observed for any of the listed organisms:

ID	Organism	ID	Organism	ID	Organism
SARS	SARS-CoV-1	EV68	Enterovirus Type (e.g. 68), Species D Type 68	MT	Mycobacterium tuberculosis avirulent, Strain
MERS	MERS-coronavirus	RSVA	Respiratory syncytial virus A, Strain A-2	NM	Neisseria meningitidis, serogroup A
OC43	Human coronavirus OC43	RSVB	Respiratory syncytial virus B, Strain CH93(18)-18	NS	Neisseria sp. Elongata Z071
229E	Human coronavirus 229E	RV	Rhinovirus 1A, Strain N/A	PJ	Pneumocystis jirovecii, Strain W303-Pji
NL63	Human coronavirus NL63	BP	Bordetella pertussis, Strain A639	PA	Pseudomonas aeruginosa, Strain N/A
AV1	Adenovirus, Type 1 (Adenoid 71)	CA	Candida albicans, Strain Z006	SA	Staphylococcus aureus Protein A producer, e.g.,
AV7	Adenovirus Type 7, Type 7A (Species B)	CP	Chlamydia pneumoniae, Strain Z500	SE	Staphylococcus epidermidis (PCI 1200)
CMV	Cytomegalovirus, Strain AD-169	CB	Corynebacterium xerosis	SS	Streptococcus salivarius, Strain C69 [S30D]
EBV	Epstein Barr Virus, Strain B95-8	EC	Escherichia coli, Strain mcr-1	SPN	Streptococcus pneumoniae, Strain Z022
hMPV	Human Metapneumovirus (hMPV), Strain TN/91-316	HI	Hemophilus influenzae, type b; Eagan	SPY	Streptococcus pyogenes, Strain MGAS 8232
P1	Parainfluenza virus 1, Strain	LB	Lactobacillus sp., Lactobacillus Acidophilus,	ME	Measles, Strain Edmonston
P2	Parainfluenza virus 2, Strain Greer	LP	Legionella spp pneumophila, Strain	MU	Mumps (Isolate 1)
P3	Parainfluenza virus 3, Strain C243	MC	Moraxella catarrhalis, Strain 59632	MP	Mycoplasma pneumoniae, Strain PI 1428
P4	Parainfluenza virus 4, Strain N/A				

Our Test Results indicated there is the cross reactivity between HCoV-HKU1 and SARS-CoV-2 at the concentration of 10μg/ml in detection of HCoV-HKU1 recombinant nucleocapsid protein.

Competitive Interference

The Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test showed no competitive interference from the analytes co-existed in the specimens.

Interfering Substances

Test results will not be interfered by following substances at certain concentrations:
Human Whole Blood (EDTA tube), Leukocytes, Throat Lozenges (Menthol/Benzocaine), Mucin, Zinc (Therazinc throat Spray), Naso GEL (NeilMed), Nasal Drops (Phenylephrine), Nasal Spray (Oxymetazoline), Nasal Spray (Cromolyn), Nasal Corticosteroid (Dexamethasone), Nasal Corticosteroid (Fluticasone Propionate), Nasal gel (Galphimia glauca, Histanium hydrocloricum, Luffa operculate, Sulfur), Homeopathic allergy relief (Histaminum hydrochloricum), Zicam nasal spray (Galphimia glauca, Luffa operculata), Nasal spray (Alkalol), Sore Throat Phenol Spray, Tobramycin, Mupirocin, Anti-viral drug (Remdesvir), Tamiflu (Oseltamivir), FluMist (Quadrivalent/Live), Zanamivir, Biotin, Body & Hand Lotion, Body Lotion (with 1.2% dimethicone), Hand Lotion, Hand Sanitizer with Aloe (62% ethyl alcohol), Hand Sanitizer cream lotion, Hand Sanitizer(80% ethanol), Hand soap liquid gel.

Technical Support

For Customer Support Helpline: Call 0415 860 461 9am-7pm (AEST), or 9am-8pm (AEDT), 5 days per week for information on the correct use of this test and for interpretation of the test results.

Information regarding available support services can also be obtained by contacting your local state and territory health department at:

Australian Capital Territory Department of Health	(02) 6207 724	www.covid19.act.gov.au
New South Wales Department of Health	1800 020 080	www.nsw.gov.au/covid-19
Northern Territory Department of Health	1800 490 484	www.coronavirus.nt.gov.au
Queensland Department of Health	13 42 68	www.covid19.qld.gov.au
South Australian Department of Health	1800 253 787	www.sahealth.sa.gov.au
Tasmanian Department of Health	1800 671 738	www.coronavirus.tas.gov.au
Victorian Department of Health	1800 675 398	www.coronavirus.vic.gov.au
Western Australian Department of Health	1800 595 206	www.healthywa.wa.gov.au/

Report Performance or Usability Issues:
Contact TGA to report poor performance or usability issues in the self-test environment.
Report an issue via the Users Medical Device Incident Report, email: **iris@health.gov.au** or call 1800 809 361

Revision Date: 2025-11-25