EasyNAT COVID-19 RNA Test for Self-Testing Instructions for Use

Before commencing the test, scan the QR code in this guide or on the packaging and watch the how-to-use video. Alternatively, follow the Instructions for Use on the reverse of this document, or visit www.ahpcpharmacyoutlet.com.au and download the Quick Reference Instructions.

Support Helpline: 1800235543

IVD

[PRODUCT NAME]

EasyNAT COVID-19 RNA Test

[SPECIFICATIONS]

Σ1 REF U20252-AZ

[INTENDED USE]

EasyNAT COVID-19 RNA Test is a single-use test kit intended to detect the novel coronavirus SARS-CoV-2 that causes COVID-19. This kit is for home use with self-collected nasal swab samples from individuals aged 14 years and older (self-collected) or individuals aged 2-13 years (collected by an adult). EasyNAT COVID-19 RNA Test is intended to be used by individuals who are suspected of being infected with COVID-19 within the first 14 days of symptom onset.

The assay is only used for an aid for diagnosis of SARS-CoV-2 infection.

Positive results indicate the presence of viral RNA, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider. The EasyNAT COVID-19 RNA Test is intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).

[SUMMARY]

The SARS-CoV-2 belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

[TEST PRINCIPLE]

EasyNAT COVID-19 RNA Test applies isothermal amplification and the nucleic acid lateral flow assay to detect ORF1ab and N gene of SARS-CoV-2 RNA. The assay uses self-driven microfluidic technology to ensure accurate distribution of samples and control the precise flow of liquid during the test, avoiding cross-contamination and ensuring the accuracy of test results. The assay applies cross priming amplification (CPA) and nucleic acid lateral flow assay to qualitatively detect the specific sequence of SARS-CoV-2 RNA. With the self-driven heating module, the assay can perform isothermal amplification reactions through specific amplification primers, probes and DNA polymerase with high strand displacement activity. The assay consists of a module preloaded with nucleic acid amplification reagent and corresponding lateral flow strip. Antigen labeled control material is prefilled in the test cassette as internal control and it will be captured in the control line with specific antibody.

[WARNINGS]

Please make sure to read this Instruction for Use carefully before use. Ustar shall not assume any responsibility for the false results and corresponding consequences due to improper handling of this product or any problems not derived from the performance defects of this product.

IVD This product is for auxiliary diagnosis in vitro only. It shall not be used as the only basis for confirmed diagnosis. Please integrate other test methods or clinical symptoms for comprehensive consideration.

●Testing

This product is for disposable use. Please use it in accordance with this instruction.

1.Do not squeeze or press the test cassette while operating it.
2.Do not move the test cassette while testing.
3.Read test results within 30 minutes after adding the second tube of buffer A, otherwise it may yield false positive result.

●Operation

Treat all the highly infective samples with care during operation and take necessary proactive actions to tackle biological hazards.

1. If the reagent on the test cassette mistakenly enters the eyes or mouth or sprays on the skin, please wash with clean water and seek help from doctors if necessary.
2. Please make sure there is no liquid or other matters affixed on the outside surface of the test cassette before starting the test.
3. Proper sample collection and sample handling are essential for correct results.

●Storage and use

1. This product must be stored at the condition as required in this instruction.
2. Check the expiration date on the package. Do not use the expired product.
3. Before starting the test, please make sure the packaging of the test cassette is not ripped or torn and there is no leakage of the liquid in the test cassette.
4. Please do not use this product for any purposes not described in this instruction.
5. Please store the product properly and prevent children from touching it.
6. The samples should be tested as soon as possible after collection. If not, they could be stored at 2~8℃ for no more than 24 hours
7. It is recommended to start the test within 1 h after sample loading.

●Disposal

1.The pollution level of this kit is PD1.
2.The used product should be sealed in the zip-lock bag, and the completed test kit should be disposed of as per the requirements of standard household waste.

[MATERIALS PROVIDED]

No.	Materials Provided	Quantity	Components
1	Disposable sampling swab	1	9cm plastic stick with flocking swab.
2	Sample tube (Prefilled with lysis buffer)	1	5cm sealed plastic tube containing 500μL lysis buffer (Triton X-100, Tris, pH 8.5)
3	Dripper	1	1.5cm plastic cap
4	Buffer A (Prefilled tubes)	2	6cm plastic tube with twist-off cap containing 290μL buffer A (Triton X-100, pH 8.5)
5	Test cassette	1	11cm plastic test cassette containing DNA Polymerase, RT-Transcriptase, primers and probes. Includes: removable sample hole cap, on-off switch, test interpretation section, and built-in battery (DC 3.7V, 400mAh, 1.48Wh).
6	Zip-lock bag	1	18cm plastic disposal waste bag
7	Instructions for Use	1	A4 size, double-sided paper

Note:

1.The test cassette contains DC 3.7V battery.
2.Do not mix materials from different lots.
3.Do not reuse the materials of the assay.

[LIMITATIONS]

1.The test results are for clinical reference only. Comprehensive consideration of the symptoms, manifestations, medical history, other examinations and treatment effect should be taken into consideration in the clinical diagnosis and treatment.

2.Persons who test positive with the EasyNAT COVID-19 RNA Test should seek follow up care with their physician or healthcare provider and public health reporting could be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses. Persons who test negative and continue to experience COVID-19 like symptoms should carry out a retest or seek health care with their physician or healthcare provider.

3.Inappropriate collection, transport and treatment of samples or low titer of pathogens may yield false negative or invalid result. In this case, retest is recommended

4.This product has been validated for current known mutations. Future mutations of target nucleic acid may yield false negative result.

5.Interference or amplification inhibitors other than presented in **[PERFORMANCE CHARACTERISTICS] 3.2 Interfering substances** that are not verified may yield false negative or invalid result. In this case, retest is recommended

6.Users are advised not to eat, drink or take unnecessary nasal drugs before self-testing.

7.Positive results do not rule out co-infection of bacteria or other viruses.

8.The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

[PERFORMANCE CHARACTERISTICS]

1.Limit of detection

3000 copies/mL

2.Specificity

2.1 Cross-reactivity

Cross-reactivity (organisms tested in the absence of SARS-CoV-2)

The specificity of the assay was evaluated in cross-reactivity testing using 31 commensal organisms. The cross-reactivity testing confirmed that none of the 31 organisms were cross reactive with the EasyNAT COVID-19 RNA Test at the concentrations tested. The 31 commensal organisms are listed below:

Bacteria and viruses	Bacteria and viruses
Bordetella pertussis	*Staphylococcus aureus*
Respiratory Syncytial virus	*Chlamydia pneumoniae*
Adenovirus	*Rhinovirus*
Influenza A virus	*Bocavirus*
Influenza B virus	*Coronavirus* NL63
Parainfluenza virus	*Mycoplasma pneumoniae*
Epstein-Barr virus	*Coronavirus 229E*
Coronavirus OC43	*Coronavirus HKU1*
Legionella pneumophila	*MERS coronavirus*
Streptococcus pneumonia	*SARS CoV-1*
Human Metapneumovirus	*Candida albicans*
Klebsiella pneumonia	*Staphylococcus epidermidis*
Haemophilus influenzae	*Enterovirus EV68*
Mycobacterium tuberculosis	*Streptococcus pyogenes*
Pneumocystis jirovecii (PJP)	*Pseudomonas aeruginosa*
Streptococcus salivarius	/

2.2 Interfering substances

The following substances have no effects on test results of this product.

2.2.1 Endogenous interfering substances: human plasma (1% v/v), human mucoprotein (1% v/v), Human genome DNA (300ng).

2.2.2 Exogenous interfering substances:

Beclomethasone, dexamethasone, flunisolone, triamcinolone acetonide, budesonide, mometasone, fluticasone; histamine hydrochloride; interferon α, zanamivir, ribavirin, oseltamivir, peramivir, arbidol, lopinavir, ritonavir; Mupirocin, levofloxacin, azithromycin, cephalosporin, minocycline, tobramycin. Nasal spray or nose drops: Benfolin, methotrexate, sodium chloride (with preservative) (1% v/v).

3. Variants

The EasyNAT Covid-19 RNA Test can detect the following variants of SARS-CoV-2: Alpha, Beta, Gamma, Delta, Omicron.

4. Clinical performance

Clinical performance of EasyNAT COVID-19 RNA Test was determined by testing 109 positive and 508 negative specimens in General Hospital Jesenice (The Republic of Slovenia) and Clinical Hospital Center Rijeka (The Republic of Croatia). 95.413% of individuals with positive real-time PCR tests are tested positive by EasyNAT COVID-19 RNA Test. 99.803% of individuals with negative real-time PCR tests are tested negative by EasyNAT COVID-19 RNA Test. And the total coincidence rate is 99.028%.

RESULT		RT-PCR		Total
		Positive	Negative	
EasyNAT COVID-19 RNA Test	Positive	104	1	105
	Negative	5	507	512
Total		109	508	617

Relative Sensitivity: 95.413% (95%CI: 89.619% ~ 98.494%)
Relative Specificity: 99.803% (95%CI: 98.908% ~ 99.995%)
Accuracy: 99.028% (95%CI: 97.895% ~ 99.642%)

5. Useability

108 (35 males and 73 females) non-professionals subjects were recruited for Reading and interpretation of the contrived test results. 107 out of 108 volunteers can correctly read and understand the result.

99 non-professional subjects were recruited for self-testing evaluation including 34 positive and 65 unknown subjects. All subjects carried out EasyNAT COVID-19 RNA Test by themselves and the self-test result was compared with professional PCR test.

RESULT		RT-PCR		Total
		Positive	Negative	
EasyNAT COVID-19 RNA Test	Positive	43	0	43
	Negative	1	55	56
Total		44	55	99

Relative Sensitivity:97.73 % (95%CI: 87.98% ~ 99.94%)
Relative Specificity: 100.00% (95%CI: 93.51% ~ 100.00%)
Accuracy: 98.99% (95%CI: 94.50% ~ 99.97%)

Conclusion: EasyNAT COVID-19 RNA Test can be tested by non-professionals themselves and it can be tested in a non-professional environment. The tested personnel can independently complete the entire process of sampling, adding samples, and reading the results

[EXPLANATION OF SYMBOLS]

IVD	*In vitro* diagnostic medical device		Do not re-use
	Use-by date		Consult instructions for use
	Caution		Manufacturer
	Temperature limit	LOT	Batch code
EC REP	Authorized representative in the European Community		Keep dry
	Keep away from sunlight		Do not use if package is damaged
	Date of manufacture		Biological risks
Σ	Contains sufficient for <*n*> tests	REF	Catalogue number

Ustar Biotechnologies (Hangzhou) Ltd.

Manufacturer address: Bldg 1,2&4, 611 Dongguan Road, Binjiang District , Hangzhou, Zhejiang, 310053, China
Sales hotline: +86-571-88939358
Customer service: +86-4008707025
Website: en.bioustar.com
Technical support:+86-4008707025

Sponsored by:

Australia Health Products Central Pty Ltd.

604/3 Waverley St Bondi Junction NSW 2022 Sydney Australia

For support and user assistance call: 1800235543

Contact the 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@tga.gov.au or call 1800 809 361)

[SUPPORT SERVICES]

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 62077244 https://www.health.act.gov.au/
New South Wales Department of Health
1337788 https://www.health.nsw.gov.au/
Northern Territory Department of Health
1800020 080 https://www.health.nt.gov.au/
Queensland Department of Health
134268 https://www.health.qld.gov.au/
South Australian Department of Health
1800253787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health
1800671738 https://www.health.tas.gov.au/
Victorian Department of Health
1800 675 398 https://www.dhhs.vic.gov.au/
Western Australian Department of Health
1800595206 https://www.healthywa.wa.gov.au/

IF You feel UNWELL, DO NOT hesitate to connect with the contacts you need.
For EMERGENCY USE: 000

[INSTRUCTION VERSION AND MODIFICATION DATE]

Approved on May 25th, 2022. Version: A1
Approved on July 19th, 2023. Version: A2

EasyNAT COVID-19 RNA Test (For self-testing)

REF U20252-AZ

Carefully read the instructions before commencing the test.

Materials Provided:

A	Disposable sampling swab	1	9cm plastic stick with flocking swab.
B	Sample tube (Prefilled with lysis buffer)	1	5cm sealed plastic tube containing 500μL lysis buffer (Triton X-100, Tris, pH 8.5)
C	Dripper	1	1.5cm plastic cap
D	Buffer A (Prefilled tubes)	2	6cm plastic tube with twist-off cap containing 290μL buffer A (Triton X-100, pH 8.5)
E	Test cassette	1	11cm plastic test cassette containing DNA Polymerase, RT-Transcriptase, primers and probes. Includes: removable sample hole cap, on-off switch, test interpretation section, and built-in battery (DC 3.7V, 400mAh, 1.48Wh).
F	Zip-lock bag	1	18cm plastic disposal waste bag
G	Instruction for use	1	A4 size, double-sided paper

Materials Required But Not Provided: Timer

Before commencing the test, scan the QR code in this guide or on the packaging and watch the how-to-use video. Alternatively, read the Instructions for Use on the reverse of this document, or visit www.ahpcpharmacyoutlet.com.au and download the Quick Reference Instructions.

Support Helpline: 1800235543

Preparation

1.

Wash or sanitize your hands. Make sure they are dry before starting the test.

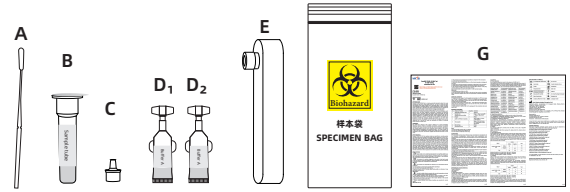
2.

Read the instructions for use, or watch the video before starting the test.

3.

Check the expiration date printed on the package. Do not use if the kit has been damaged or the expiration date has expired.

4.



Open the package and check the kit contents before starting the test.

Specimen Collection

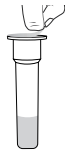
Self collection

Collection by an adult caregiver

A nasal swab sample can be self-collected by an individual aged 14+ years. Children under 14 years of age should be performed by a parent or legal guardian, Do not use the test on children under the age of 2.

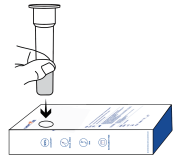
Test Procedure

1.



Carefully tear off the sealing film from the top of sample tube, avoid spilling.

2.

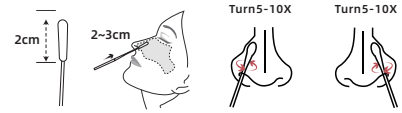


Insert the tube into the hole provided on the kit package. (Or, place the tube in the tube holder.)

3.

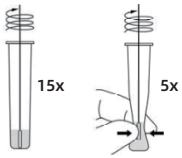
Carefully open the swab packaging at the stick end and remove swab without touching the tip of swab with your hands.

4.



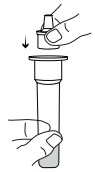
Insert the entire tip of the swab 2 to 3 cm into one nostril. Gently rotate the swab 5 to 10 times brushing against the inside of the nostril. Remove the swab and insert it into the other nostril. Repeat the process by rotating the swab 5 to 10 times brushing the inside of the nostril.

5.



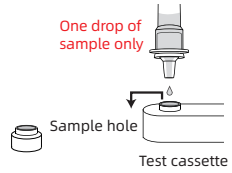
Insert the swab into the base of the sample tube and stir 15 times. Rotate the swab 5 times while squeezing the side of the tube. Remove the swab and place in the disposable specimen bag.

6.



Attach the dripper firmly onto the top of the sample tube.

7.

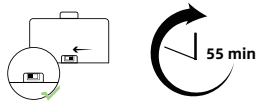


Open the pakaging of the test cassette and place the cassette on a flat and clean surface. Open the cap of sample hole and add only 1 drop of the sample liquid into the sample hole.

8.

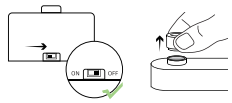
Take out one tube of Buffer A and unscrew the top. Gently squeeze the tube, adding all the liquid into the sample hole. Put the cap back firmly onto the sample hole.

9.



Turn on the switch on the left side of the base of the test cassette. The indicator light will switch on. Set up a timer for 55 minutes.
Note: Do not move the test cassette once the test has started running.

10.



After 55 minutes, turn off the switch at the base of the test cassette. Open the cap of sample hole.

11.

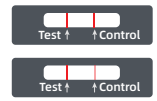
Make sure the test cassette is switched off. Take out the second tube of Buffer A and unscrew the top. Gently squeeze the tube and add all the liquid into the sample hole. Put the cap back firmly onto the sample hole.

12.

The result is valid after 5 minutes and remains valid only for 30 minutes.
Note: Do not read the result after 30 minutes.

Result Interpretation

Positive

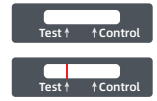


Both the control line (C) and test line (T) appears. This means that the virus that causes COVID-19 has been detected.
Note: Any faint line in the test line region (T) should be considered positive.
A positive test result means it is very likely you have COVID-19. Follow the relevant State or Territory health authority advice and regulations. Follow the local guidelines regarding self-isolation.

Negative

Only the control line (C) and no test line (T) appears. This means that the virus that causes COVID-19 was not detected.
A negative test result indicates that you are unlikely to currently have COVID-19. Continue to follow all applicable rules and protective measures when in contact with others. There may be an infection even if the test is negative.

Invalid



Control line (C) fails to appear. Not enough specimen volume or incorrect operation are the likely reasons for an invalid result. Review the instructions again and repeat the test using a new cassette. If the test results remain invalid, contact your State or Territory Coronavirus testing services.

Safely Dispose of Your Test Cassette Kit.
Once your test is complete, put all of the used test kit contents in the zip-lock bag. Dispose of all contents in your general household waste.

Before commencing the test, scan the QR code in this guide or on the packaging and watch the how-to-use video. Alternatively, follow the Instructions for Use on the reverse of this document, or visit www.ahpcpharmacyoutlet.com.au and download the Quick Reference Instructions.