philosys [Video Tutorial]

Manufactured by PHILOSYS Co., Ltd.

Gmate® COVID-19 Ag Saliva Instructions for Use

PRODUCT NAME

Gmate® COVID-19 Ag Saliva (Model No. AG-020)

INTENDED USE

The Gmate® COVID-19 Ag Saliva is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in human Saliva sample from individuals who are suspected of COVID -19 within the first seven days of the onset of symptoms.
Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status.
follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
Positive results do not rule out bacterial infection or co-infection with other viruses. Detected substances may not be the definite cause of disease. Negative results do not rule out SARS- CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with PCR, if necessary for patient management. This test is to aid in the diagnosis of Covid 19. This test is intended to be used for self testing.

COMPONENTS

1. Test Device
2. Buffer & Filter Cap
3. Sample Collection Tube & Cap & Sample Collection Funnel
4. Instruction Manual & Quick Guide

MATERIAL NEEDED BUT NOT PROVIDED

1. Timer

STORAGE AND EXPIRY

Store in the sealed pouch at 4-30℃, avoid heat and sunlight.
avoid using expired products.
It must be used within 1 hour if opened (Humidity ≤60%, Temp: 20℃-30℃). Do not freeze.

WARNINGS AND LIMITATIONS

1. Children and adolescents between 2 - 15 years of age must be tested under the supervision of a parent or legal gurdian.
2. Do not use on anyone under 2 years of age.
3. As a disposable product, this test cannot be reused.
4. The test can only be performed using a saliva sample.
5. The test can only qualitatively detect the presence of SARS-CoV-2 antigens in human saliva. It cannot determine the specific amount of antigens found in the samples. Additionally, the strength of the test line and the potency of the SARS-CoV-2 antigens found in the sample are not correlated.
6. Do not use if the product is past its expiration date or its package has been damaged.
7. Only use the buffer that comes included with the product. Do not mix or use other diluents, as that may produce incorrect results.
8. If testing is not performed within the first 7 days of symptom onset, there is a risk of false-negative results.
9. The test can be less reliable in the later phase of infection and in asymptomatic individuals.
10. Recommend repeat testing 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.
11. A negative result does not rule out infection with another type of respiratory virus. Monitor for symptoms, repeat testing in 1-3 days, and if symptoms persist to contact state / territory for further advice.
12. A positive result cannot necessarily determine whether a person is infectious
13. Possible reasons for false negative results: The use of incompatible extracting buffers, delayed sample transfers, improper sample collection, non-standardized sample treatment procedures, low virus titer in the samples and other errors may cause false negative results.
14. Possible reasons for false positive results:
    - Improper sample collection, the use of incompatible buffers, and non-standardized elution procedures may all cause false positive results.
    - Cross-contamination of samples may cause false positive results.
15. Possible reasons for invalid results:
    - The test cannot be carried out successfully if the necessary sample volume is not collected.
    - The test card is considered invalid if the package is damaged.
    - If problem persists, contact state / territory for further advice and seek medical assistance if unwell.

PERFORMANCE CHARACTERISTICS

1. Analytical Sensitivity (Limit of detection)

The LoD of the Gmate® COVID-19 Ag Saliva is 40 $TCID_{50}$ /ml

2. Variants

The Gmate® COVID-19 Ag Saliva detects the Alpha(B.1.1.7), Beta(B.1.351), Gamma(P.1), Delta(B.1.617.2) variants

3. Analytical Specificity (Cross-reactivity)

By testing 26 viruses and 12 other microorganisms, except for the Human SARS-coronavirus nucleoprotein, other viruses and microorganisms have no effect on the test results.

Virus tested	
HCoV-NL63	Adenovirus Type55
HCoV-OC43	Echovirus
HCoV-229E	Influenza virus A (H1N1)
HCoV-HKU1	Influenza virus A(H3N2)
MERS	Influenza virus B Strain
Human SARS-coronavirus Nucleoprotein	Parainfluenza Type 1
(Positive)	Parainfluenza Type 2
Adenovirus Type3	Parainfluenza Type 3
Adenovirus Type7	Parainfluenza Type 4
Adenovirus Type1	Respiratory syncytial virus (RSV) type A
Adenovirus Type5	Respiratory syncytial virus (RSV) type B
Adenovirus Type8	Rhinovirus A16
Adenovirus Type11	Human Metapneumovirus (hMPV) 16 Type A1
Adenovirus Type21	

Other microorganism	
Candida albicans	Hemophilus influenzae
Legionella pneumophila	Bordetella pertussis
Streptococcus pneumoniae Pseudomonas	Pneumocystis
aeruginosa	Chlamydia Pneumoniae
Staphylococcus epidermidis	Streptococcus Pyogene
Mycopla Pneumoniae	Mycobacterum Tuberculosis

4. Interfering substances

The results showed that it was not interfered by the concentration of the following drugs:

Arbidol Hydrochloride Hydrate	Watermelon frost buccal tablets
Zanamivir	Beclomethasone
Meropenem	Dexamethasone acetate
Oseltamivir	Metronidazole Tablets
Ritonavir	Sodium chloride
Peramivir trihydrate	Alpha-interferon
Triamcinolone	Phenylephrine hydrochloride
Nalidixic acid	Acetaminophen
Amoxicillin Capsules	Gentamicin procaine vitamin B12 granules
Aspirin	Flunisolide
Ibuprofen	Cefalexin
Acetylsalicylic acid	Cefradine
Hydrocortisone	Levofloxacin
Vancomycin hydrochloride	Ribavirin
Histamine hydrochloride	Biotin
Ceftriaxone sodium	Cydiodine Buccal Tablets
Benzocaine	Wuweibencao Bacteriostatic oral fluid
obramycin	Mucin
Lopinavir	Blood (human)
Azithromycin	HAMA

5. Clinical Performance

[Professional study]

The Gmate® COVID-19 Ag Saliva was established with 620 patients who were suspected of SARS-CoV-2. RT-PCR is used as the reference method for the Gmate® COVID-19 Ag Saliva.

SARS-CoV-2 Antigen Saliva Rapid Test	RT-PCR		Total
	Positive	Negative	
Positive	115	2	117
Negative	5	498	503
Total	120	500	620

PPA: 95.83%（95%CI：90.62%-98.21%）/ NPA: 99.60%（95%CI：98.55%-99.89%）/ OPA: 98.87%（95%CI：97.69%-99.45%）
EXPLANATION OF TERMS:
PPA: Positive Percent Agreement = True Positives / True Positives + False Negatives
NPA: Negative Percent Agreement = True Negatives / True Negatives + False Positives.
OPA: Overall Percent Agreement = True Positives + True Negatives / Total
CI: Confidence Interval

[Layperson study]

The Gmate® COVID-19 Ag Saliva was compared to RT-PCR molecular test. Subjects self-sampled and self-tested using the Gmate® COVID-19 Ag Saliva.
Gmate® COVID-19 Ag Saliva correctly identified 93.33% (28 out of 30 people) of positive samples and 100% (70 out of 70 people) of negative samples.

TECHNICAL SUPPORT

For Customer Support Call: **1800 241 881** (Monday to Sunday, 9am – 7pm)

REPORTING ISSUES

Report any performance or usability issues to TGA by e-mail (iris@tga.gov.au) or call **1800 809 361**.

REPORTING ISSUES

For support services, contact your local state and territory health departments listed below.

ACT: 02 5124 9213 www.health.act.gov.au	NT: 08 8922 8044 www.health.nt.gov.au	SA: 1300 232 272 www.sahealth.sa.gov.au	VIC: 1300 650 172 www.dhhs.vic.gov.au
NSW: 1300 066 055 www.health.act.gov.au	QLD: 13 432 584 www.health.qld.gov.au	TAS: 1300 135 513 www.health.tas.gov.au	WA: 08 9222 4222 www.healthywa.wa.gov.au

MANUFACTURER

Sponsored by MD SOLUTIONS AUSTRALASIA
Unit 1, 16-8 Tennyson St Williamstown North VIC 3016

Manufactured by PHILOSYS Co., Ltd.
28-5, Gwangwol-gil, Okgu-eup, Gunsan-si, Jeollabuk-do, 54172, Republic of Korea

CE IVD

EC REP **Obelis SA**
Boulevard Général Wahis 53 1030 Brussels, Belgium

INSTRUCTIONS OF SYMBOL

	Consult instructions for use		Keep dry
4℃ 30℃	Temperature limit	LOT	Batch code
	For single use	IVD	In vitro diagnostic medical device
	Manufacturer		Date of manufacture
	Use-by date	Σ	Contains sufficient for <n> tests
EC REP	European representative		Keep away from sunlight
CE	CE mark		Don't use the product when the package is damaged

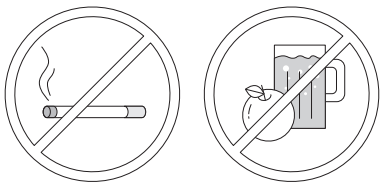
Gmate® COVID-19 Ag SALIVA

COVID-19 Antigen Saliva Test Quick Guide

• Children and adolescents between 2 - 15 years of age must be tested under the supervision of a parent or legal gurdian.
• Do not use on anyone under 2 years of age.

Test Procedure

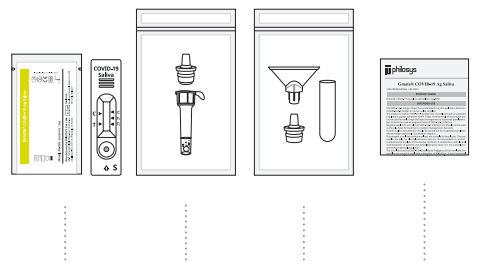
1 Rinse your mouth 30 minutes before collecting sample.
You should not eat, drink or smoke after the mouth wash.



2 Wash your hands thoroughly before taking the test.

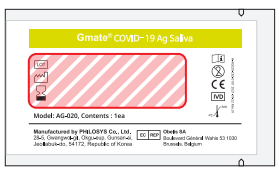
When using the product, use disposable gloves or other types of protective material.

3 Check the components before taking the test.

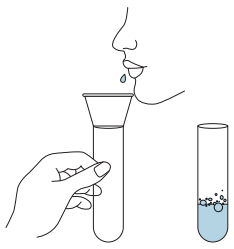


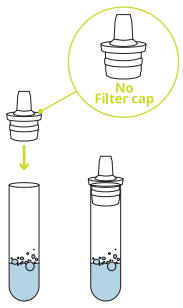
Test Device | Buffer & Filter Cap | Sample Collection Tube & Cap & Sample Collection Funnel | Instruction Manual & Quick Guide

4 Check the expiration date printed on the front cover of the testing device pouch. Do not use an expired test device. Tear open the pouch and inspect the test device before use.

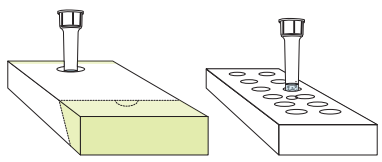


5 Open the sample collection pouch. Connect the funnel with the sample collection tube for easier sample collection. Spit gently into the tube until half of the tube is filled. Afterwards, close the tube with the provided cap.

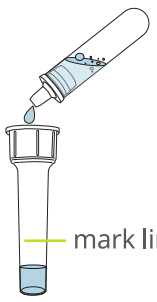


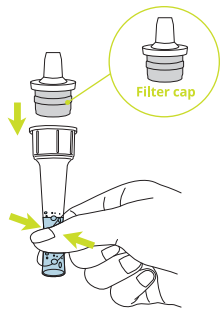


6 Open the buffer & the filter cap pouch. Take the lid off the buffer and place it on the printed slot of the package.

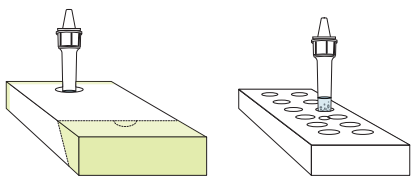


7 Pour the collected saliva sample into the buffer tube until you reach the marked line.
Press the filter cap to close the tube.
Press the bottom of the tube 10 times so that the buffer and saliva can be mixed well.

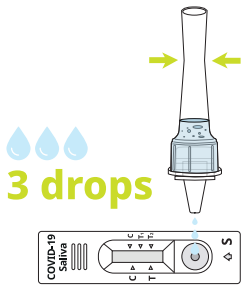




8 Leave the buffer tube in its place for 5 minutes to ensure the sample and the solution are well mixed.



9 Take out the test devie from the pouch and place it on a flat and clean surface.
Put **THREE (3)** drops into the well of the test device.



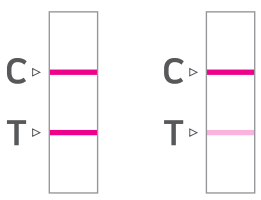
Be careful not to pour all the sample into the testing device.

10 Wait for 15 minutes to check the results.

Check the result after 15 minutes.
Do not read the test after 20 minutes.

Test Result Analysis

Positive Result
[Two red-colored lines appear in the **C** and **T** regions respectively.]

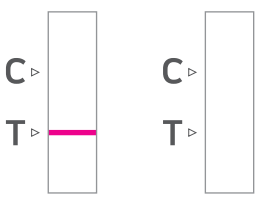


If you get a positive test result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Negative Result
[One red-colored line appears only in the **C** region.]

NO COVID-19 virus antigen was found in the sample. However, a negative result does not rule out COVID-19.
Monitor for symptoms, repeat testing in 1-3 days, and if symptoms persist to contact state / territory for further advice.

Invalid Result
[A red-colored line **does not** appear in the **C** region.]



You will need to re-test with a new test kit and sample. Review the test procedure carefully.
If problem persists, contact state / territory for further advice and seek medical assistance if unwell.

• **Even if the lines are faint, the test result is considered valid.**

Carefully place the test kit and all conponents into plastic bag provided and dispose in normal household waste.

[Video Tutorial]

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Operating hour Monday - Sunday (9am - 7pm)

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