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CONSUMER COUNCIL

COVID-19
Rapid Antigen Test (RAT) Kits
- Complaint Cases & Tips for Consumers

Media Briefing

9 March 2022

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Background

Current Situation

Panic Buying Arising from Public Anxiety

- Under the fifth wave of the COVID-19 pandemic, whether one's rapid test yields "1 line" or "2 lines" has become the talk of the town, as citizens constantly worry about getting a positive test result.
- There has been a recent surge in panic buying for various goods, from food, daily necessities, to fever relief medicine, lozenges and COVID-19 Rapid Antigen Test (RAT) kits. Empty shelves can be seen in supermarkets, frozen meat stores, pharmacies, personal care stores across the city.
- Panic buying and stockpiling beyond the necessary amount could induce panic in society, resulting in a vicious cycle and causing demand to far outstrip supply. Unscrupulous traders and individuals could also take advantage of the situation.

RAT-related Information Hard to Comprehend

- A profusion of RAT brands from different origins are available on the market and online. Which ones have international accreditation? Which ones are more accurate, with a lower chance of getting a "false negative" or "false positive"? Such information is crucial for consumers yet is complex and difficult to understand.

Briefing Synopsis

- ❑ Complaints relating to RAT kits and case analyses
- ❑ Introduction to the principle of RATs and useful purchasing tips for consumers
- ❑ Demo of the "Approved Rapid Antigen Test (RAT) Kits Search Tool" developed by the Consumer Council

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Part 1
Complaint Figures & Cases

Complaint Figures Relating to Rapid Antigen Tests

	14 Jan – 8 Mar 2022
Sales Practice	6
Late / Non-delivery / Loss	19
Price / Charges Dispute	1
Quality of Goods	13
Expiry Date	4
Wrong Model	1
Variation / Termination of Contract	2
Suspected Spurious Goods	2
TOTAL	**48**

TOTAL AMOUNT INVOLVED	48,937

Note: Apart from 6 resolved cases, the rest are in progress.

Internet Shopping			Retailers	
Chains	Online Shops	Social Media Platform	Chains	Others
5	31	1	9	2
37			11	

- Price per kit vastly varies: $18 - $120
- 13 cases involve certification issues involving accreditation bodies in: EU, Japan, Singapore, UK, Germany, etc.
- Origins:
  Mainland China, Japan, Singapore, Korea, UK, Australia, Hong Kong, etc.

* Based on the information provided by complainants

Complaint Cases – Internet Shopping / Sales Practice

- A consumer ordered 4 boxes of RATs (a total of 8 kits) from an online store on 18 February 2022 at a retail price of $222. The online store claimed that the kits were certified by the European Union (EU) with the CE marking, but the consumer could not find the product in the EU's "common list of COVID-19 rapid antigen tests".
- A consumer ordered 4 boxes of RATs (a total of 8 kits) from an online store on 16 February 2022 at a retail price of $316. Despite the product being advertised as an "officially designated RAT brand by the Singapore Government" both in the promotional images and text, the consumer could not find relevant information on the Singapore Government's official website
- The consumers suspected that the online stores provided incorrect certification information

Complaint Cases – Quality of Goods

- A consumer purchased 1 box of RAT kit from a retail store on 15 February 2022, priced at $88. As the kit did not display any result after using per the instructions, the consumer suspected that the RAT kit did not have any detection properties.
- A consumer purchased 3 boxes of RATs (a total of 15 kits) on 22 February 2022 from a retail store for $585, yet later found that only the expiry date was printed on the box but not the manufacturing date. Upon enquiry, the retailer replied that the manufacturing date was January 2021. The consumer opined that the Omicron and Delta variants had not emerged at the time, and questioned the efficacy of the RAT kits.

Complaint Cases – Expiry Date

- On 10 January 2022, a consumer ordered 4 boxes of RATs (a total of 80 kits) via a retail chain's online store at a total price of $6,500. Upon receiving the product, the consumer found that the goods had a validity period of only 1 year and would expire on 4 May 2022, which is in less than 4 months.
- On 21 February 2022, a consumer purchased 2 boxes of RATs (a total of 4 kits) from a retail store for $480, but later discovered that the products had a validity period of 1.5 years and would expire in July 2022.
- The consumers opined that the test kits were not cheap, yet had an overly short validity period.

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Part 2
Consumer Tips for Buying COVID-19 Rapid Antigen Test (RAT) Kits

1. What is the COVID-19 Rapid Antigen Test? Does it have to be used by trained healthcare professionals?

Antigen tests are one way to screen for disease. The COVID-19 Rapid Antigen Test (RAT) helps to identify whether a sample is infected by detecting the protein (antigens) of the relevant virus in the respiratory sample, thus determining whether one is infected. The general test procedure of RAT:

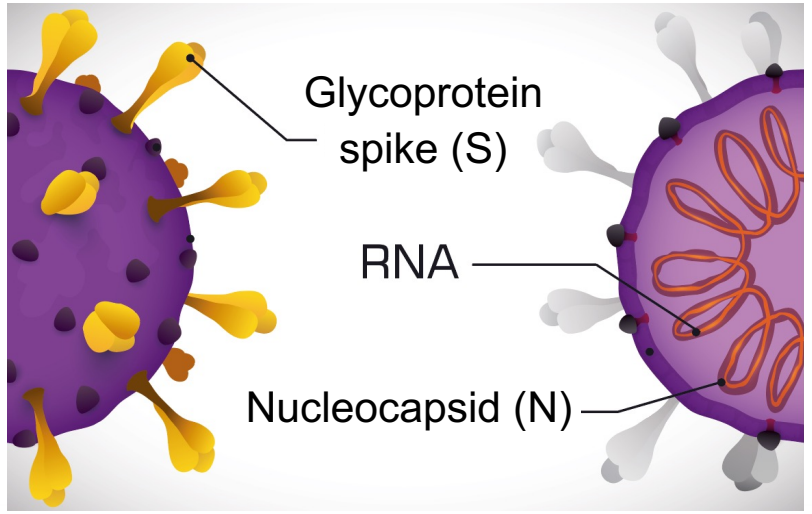
1. Use nasopharyngeal / nasal swabs / deep throat saliva for sample collection
2. Place the swab tip into the buffer solution for antigen extraction
3. Drop the solution into the sample well of the test device
4. Read results after a specific time (usually 15-20 minutes)

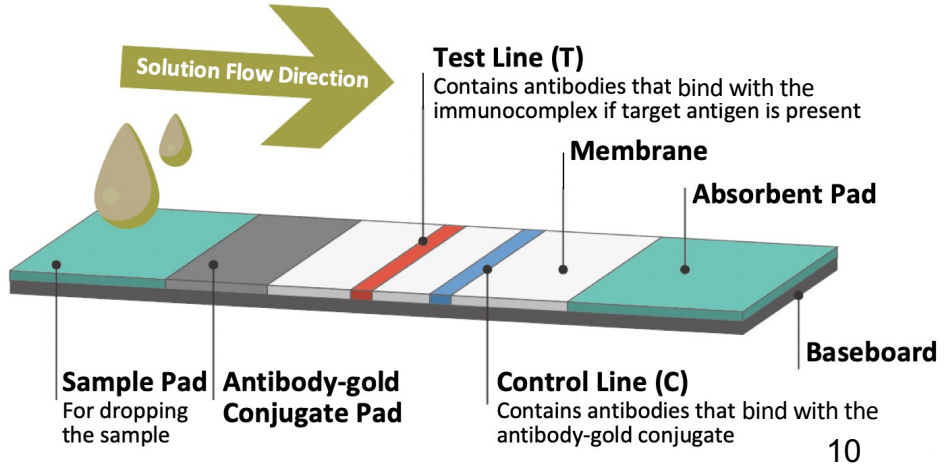
- Currently, most RATs are administered by trained healthcare professionals, but some may also be used by laypersons.
- There are different lists of rapid antigen tests used locally around the world. For example, the EU's "*Common List of COVID-19 Rapid Antigen Tests"* mainly lists those used by healthcare professionals. However, different regions will have different practices/arrangements. For instance, the US Food and Drug Administration includes RATs that can be used by non-professional medical staff in its "*List of SARS-CoV-2 antigen diagnostic tests with Emergency Use Authorization*".

2. How does the RAT work?

An RAT is designed to directly detect SARS-CoV-2 virus proteins (antigens) in respiratory specimens. Current products are more commonly used for detecting nucleocapsid protein.

After dropping the sample into the test device, the buffer solution will flow past the conjugate pad and travel with the antibody-gold conjugate towards the test line (T) and control line (C). If the sample contains the target antigen, it will first bind to the antibody-gold conjugate forming an immunocomplex, which then binds with the antibodies at the test line (T), forming a visible coloured line. If the sample does not contain the target antigen, no colour will appear at the test line. In both instances, when the buffer solution travels past the control line, the antibody-gold conjugate will bind with the antibodies at the control line, forming a visible coloured line.





3. How can consumers select RATs of good quality ?

World Health Organization

The World Health Organization (WHO) recommends RATs to have a

Sensitivity of at least **80%**

Specificity of at least **97%**

4. What are “Sensitivity” and “Specificity” in RATs?

Sensitivity

The sensitivity of a rapid test kit refers to the ability to detect a positive result in an infected person.

For instance, if the same rapid test kit with a sensitivity of 80% is used to test 100 infected people, the result will be that 80 of them get positive results, which are true positives; the remaining 20 people get negative results, which are false negatives.

A false negative test result can give the testee the impression that they are not infected. As a result, they may spread the virus to family members and the community, as well as delaying treatment.

Specificity

The specificity of a rapid test kit refers to the ability to test negative results in non-infected individuals.

For instance, if the same rapid test kit with a specificity of 90% is used to test 100 uninfected people, the result will be that 90 of them get negative results, which are true negatives; the remaining 10 people get positive results, which are false positives.

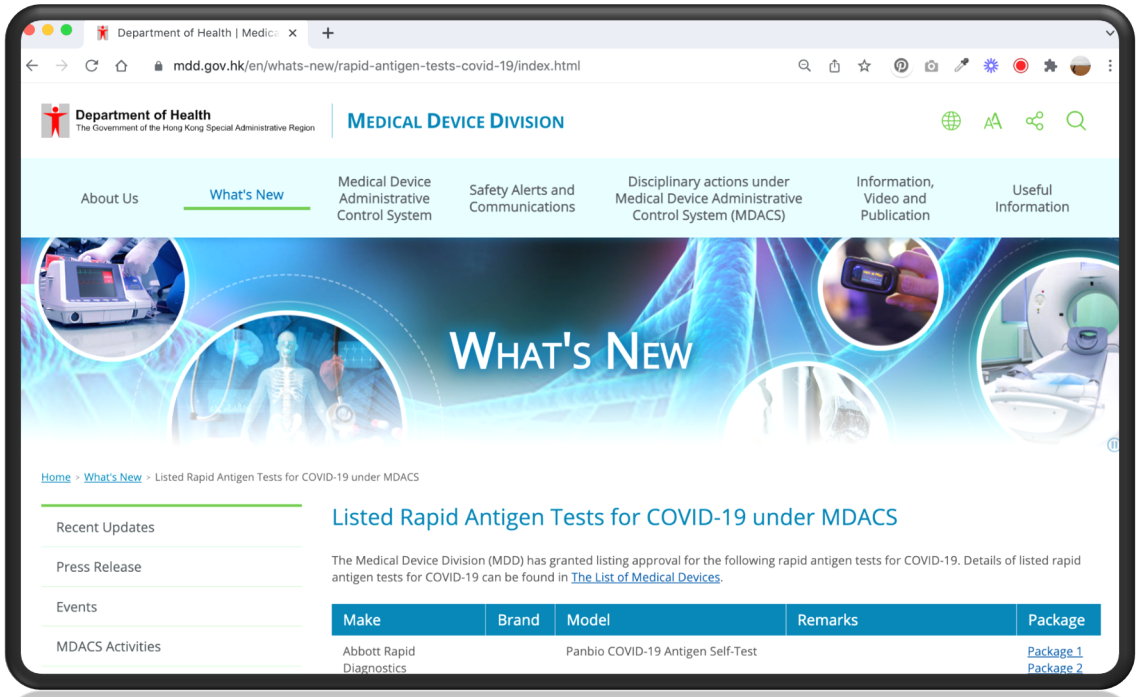
Obtaining a false positive test result can make the testee think they are infected. It may lead to unnecessary quarantining of the testee and close contacts; cause unnecessary anxiety and panic; as well as wasting time and resources for further testing.

5. Does Hong Kong have a relevant certification system?

RAT products are a type of medical device generally classified as Class C In Vitro Diagnostic Medical Devices (IVDMD).

Currently, there is no specific legislation that regulates the manufacture, import, export and sale of medical devices (including COVID-19 RATs) in Hong Kong. The voluntary "Medical Device Administrative Control System" (MDACS) run by the Department of Health (DH) aims to raise public awareness on the importance of medical device safety, as well as to pave the way for developing a long-term statutory regulatory framework. The MDACS includes listed RATs. The listed products meet the requirements of the MDACS in terms of safety, quality and performance. The DH will also monitor the medical device safety alerts issued by overseas regulatory bodies or manufacturers, and handle reports of medical device-related medical incidents as listed in the management system.

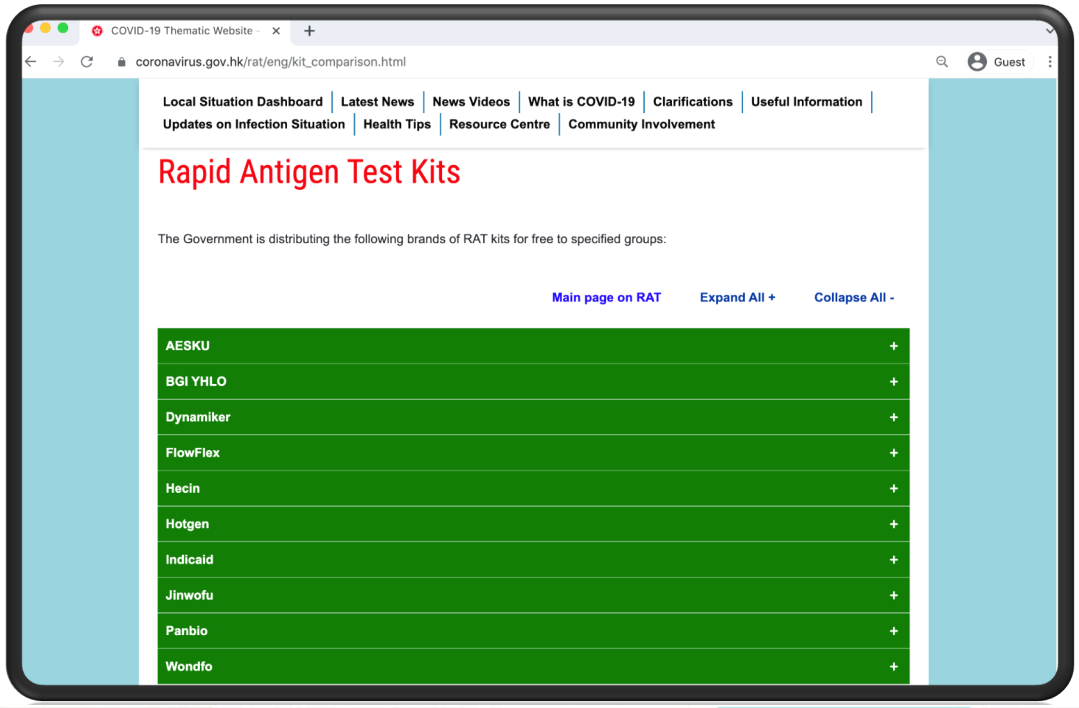
The listed COVID-19 Rapid Antigen Tests can be found at the following website:
https://www.mdd.gov.hk/en/whats-new/rapid-antigen-tests-covid-19/index.html



Hong Kong List

Apart from the COVID-19 Rapid Antigen Tests listed under the MDACS by the Department of Health, the Government has also included on the COVID-19 thematic website a list of the brands of RAT kits for free to specified groups.

https://www.coronavirus.gov.hk/rat/eng/rat.html



6. The Hong Kong Government's COVID-19 thematic webpage lists the rapid antigen tests approved in different regions. How should consumers understand the information?

Mainland China

EU

USA

Mainland China (1)

Regarding the management measures for registering and filing in-vitro diagnostic reagents, these new coronavirus rapid test products are "reagents related to detecting pathogenic pathogen antigens, antibodies, nucleic acids, etc." Therefore, they should be included in the third category of in-vitro diagnostic reagents requiring additional product registration. The National Medical Products Administration (NMPA) will review it, and a medical device registration certificate will be issued upon approval.

Manufacturers must submit the following registration application materials to the drug regulatory authorities:

1) Product risk analysis data;
2) Product technical requirements (the main raw materials in appendix and production process requirements);
3) Product inspection reports (three different production batches of inspection reports must be provided);
4) Clinical evaluation data;
5) Product instructions and label samples;
6) Quality control system documents related to product development and production;
7) Other materials that prove the product's safety and effectiveness.

Mainland China (2)

For the emergency response to public health emergencies with no similar products on the market in China or similar products on low supply that cannot support emergencies, NMPA may implement emergency registration of in-vitro diagnostic reagents.

List: https://www.nmpa.gov.cn/directory/web/nmpa/images/16432483962600 12059.docx

Since the list includes products that detect antigens, antibodies, nucleic acids and other testing methods, consumers should carefully compare the product names when purchasing to ensure that they buy suitable products

	Product Name	Company of Registered Product	Number of Accreditation Certificate Issued by NMPA
50	新型冠状病毒（2019-nCoV）抗原检测试剂盒（胶体金法）	广州万孚生物技术股份有限公司	国械注准 20203400830
51	新型冠状病毒（2019-nCoV）抗原检测试剂盒（乳胶法）	北京金沃夫生物工程科技有限公司	国械注准 20203400831
54	新型冠状病毒（2019-nCoV）抗原检测试剂盒（荧光免疫层析法）	深圳华大因源医药科技有限公司	国械注准 20203400940

EU (1)

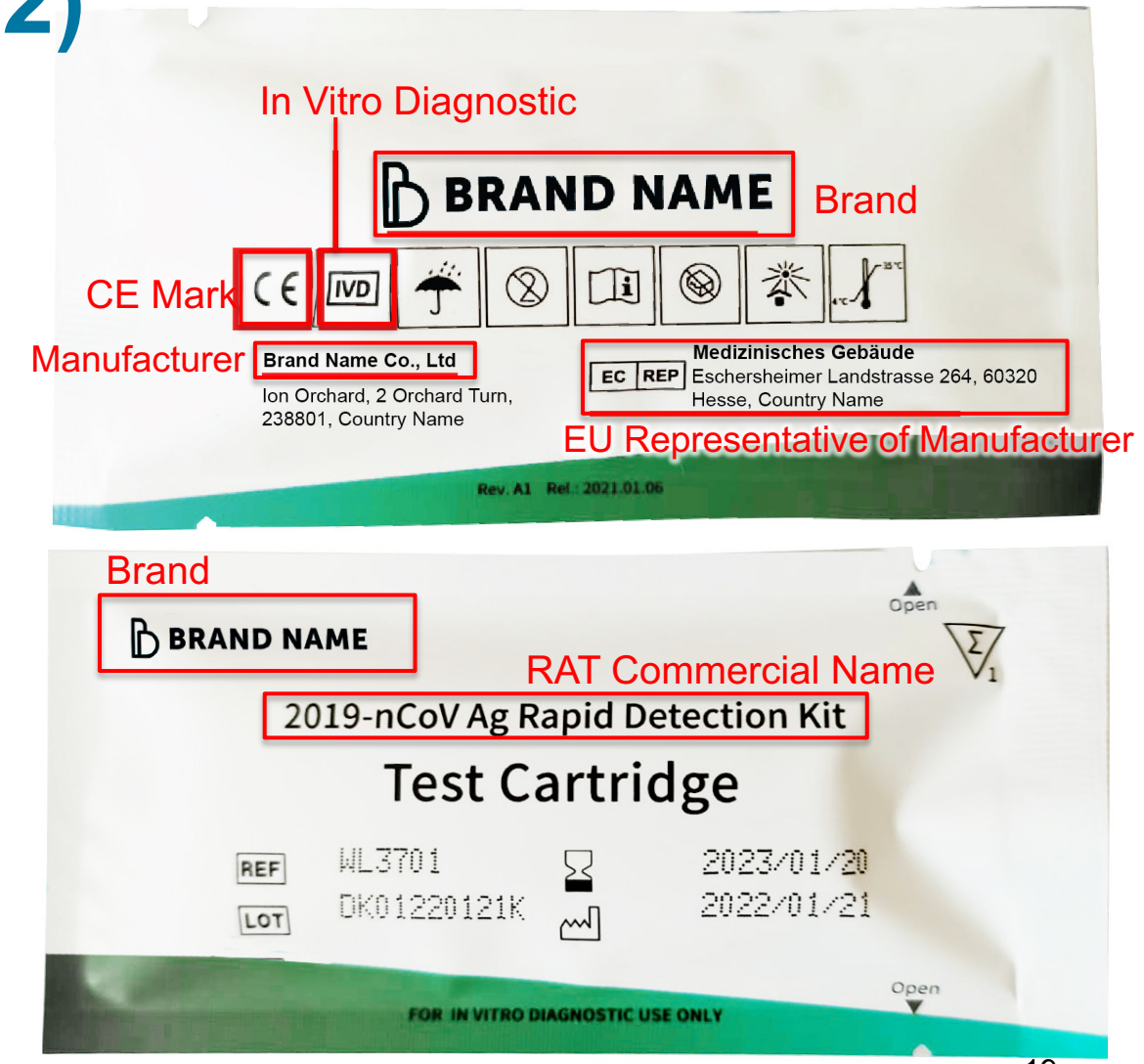
The manufacturer does not need to obtain any license to place the Conformitè Europëenne (CE) Mark on the product label, but needs to meet the following requirements:

1. Complies with all EU regulations applicable to this product
2. Evaluation of the product by a notified body (if applicable)
3. All technical documents are available
4. Draft and sign EU declaration of conformity

However, simply having a CE mark does not mean that the product has been tested for quality by the relevant authorities. The EU adopted a framework on 21 January 2021 in response to the outbreak and for mutual recognition of test results among member states, including the development of a common list of rapid antigen tests. Even though the list is only intended to include rapid antigen tests for use by healthcare professionals, some manufacturers on the list also produce models for use by non-professional healthcare professionals. If the product is for personal testing, such as those sold at retail points, consumers should note whether the product is CE-marked followed by a 4-digit identification number of the notified body, to ensure that the product's design and packaging is suitable for regular consumer use.

EU (2)

- If a product bears the CE mark, consumers may search for the product and manufacturer name in the pdf file* of the "*Common List of COVID-19 Rapid Antigen Tests*" issued by the EU, to confirm whether it has been evaluated.
- The common list is updated regularly: https://ec.europa.eu/health/system/files/2022-03/covid-19_rat_common-list_en_0.pdf



Step 1: Use the search tool of the PDF file reader software to search. It is recommended to search by the manufacturer name first.

Step 2: Enter the manufacturer or brand name and click “Next”.

If the relevant search term can be found, consumers should check that the full name matches the label; if so, you can read the product details.

Enter the manufacturer or brand, then click “next”

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [16]	Completed validation studies	SARS-CoV-2 Target protein	Specimen	
				Nasopharyngeal: Clinical sensitivity: 97.14% (95% CI: 91.88 – 99.41%); Clinical specificity: 99.60% (95% CI: 98.58 – 99.95%)				
Green Cross Medical Science Corp.	GENEDIA W COVID-19 Ag	1144	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 83% at Ct ≤ 25; Manufacturer specificity: 100%	100% sensitivity 90.1% sensitivity 100% specificity NP swab, Anterior nasal swab	DE[2]	Nucleo-protein	Anterior nasal swab, Nasopharyngeal swab	10 May 2021
Guangdong Hecin Scientific, Inc.	2019-nCoV Antigen Test Kit (colloidal gold method)	1747	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 82% at Ct ≤ 25; Manufacturer specificity: 99.07%	96.83% sensitivity 99.39% specificity Nasal swab	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab	10 May 2021
Guangdong Longsee Biomedica Co., Ltd.	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	1216	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	OP swab: sensitivity 95.22%, specificity 99.72% Nasal swab: sensitivity 94.15%, specificity 99.68% NP swab: sensitivity 95.51%, specificity 99.72%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab, Nasal swab	14 July 2021

If the relevant terms can be found, check whether the full name matches the product label

If the name matches, you can refer to the detailed product information

Step 3: Check the key information from the table:

Manufacturer	RAT commercial name	Device ID # [15]	Clinical performance *As reported by independent validation studies*	Clinical performance *Data by manufacturer* [16]	Completed validation studies	SARS-CoV-2 Target protein	Specimen [17]	Included in EU common list since:
Guangdong Longsee Biomedical Co., Ltd.	2019-nCoV Ag Rapid Detection Kit (Immuno-Chromatography)	1216	*Retrospective in vitro study* DE: Positive evaluation by Paul-Ehrlich-Institut (PEI): Sensitivity of 100% at Ct ≤ 25; Manufacturer specificity: 99.5%	OP swab: sensitivity 95.22%, specificity 99.72% Nasal swab: sensitivity 94.15%, specificity 99.68% NP swab: sensitivity 95.51%, specificity 99.72%	DE[2]	Nucleo-capsid protein	Nasopharyngeal swab, Oropharyngeal swab, Nasal swab	14 July 2021

Some information in the table will refer to the country code, for example:

DE = Germany / FR= France / UK = England / CH = Switzerland / NL = Neitherlands / IT = Italy, etc.

The detailed code list can be viewed at:

https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Glossary:Country_codes

EU (3)

Acceptable Product Performance

The EU has certain requirements for the performance of products in the verification research conducted by independent institutions. The following is a summary of the key points:

If the tests are **prospective clinical field studies**, they need to have:

- A sensitivity greater than 80% when tested in symptomatic participants (within the first 7 days after symptom onset) or asymptomatic participants when the diagnosis was confirmed by RT-PCR nucleic acid testing in an independent field study ; or
- A sensitivity of the test for participants with CT values <25 (i.e. a high viral load) should be 90% or greater for independent assessments
- A specificity above 98%.
- At least 100 positive nucleic acid tests participants and at least 300 negative.

If the tests are **retrospective in vitro studies**, they need to have:

- A sensitivity greater than 80% when testing all samples in the reference sample set; or
- A sensitivity of detection 90% or higher for samples with CT values < 25
- A reference sample set composed of at least 50 clinical samples covering the naturally occurring concentration range of 2019-nCoV. The CT value should be in the range of 17 to 36 and divided into 3 groups, with a fairly high viral load (CT value of 17 to 25) accounting for 40%, high viral load (CT value of 25 to 30) accounting for 40%, and medium viral load (CT value of 30 to 36) accounted for 20%.
- A specificity above 98%.

USA (1)

FDA U.S. FOOD & DRUG ADMINISTRATION

In general, before a medical device product is sold in the United States, it needs to go through procedures such as pre-market notification 510(k) or pre-market approval (PMA). Sufficient evidence must be submitted to prove that the product is safe and effective.

On 4 February 2020, in response to the novel coronavirus epidemic, the United States activated the Emergency Use Authorization (EUA) under Section 564 of the local food, drug and cosmetic laws, under the premise that the potential benefits of using the product outweigh the risks, to approve different medical products for the diagnosis and treatment of patients with the novel coronavirus disease. EUA approved products differ from 510(k), or PMA in that EUA only requires that the product may be effective.

The list can be found in the link below and is updated regularly:
https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2#IndividualEUAs

USA (2)

There are different types of products on the list. Products intended for self-testing must be marked with “Over the Counter (OTC) Home Testing”. Consumers should pay attention to ensure that they purchase suitable products.

Date EUA Issued or Last Updated	Entity	Diagnostic (Most Recent Letter of Authorization) and Date EUA Originally Issued	Attributes	Authorized Setting(s)[1]	Authorization Documents[2]
02/18/2022	ACON Laboratories, Inc	Flowflex COVID-19 Antigen Home Test 10/04/2021	Lateral Flow, Visual Read, Over the Counter (OTC) Home Testing, Screening, Single Target	Home, H, M, W	HCP, IFU, IFU (Home Test)
02/17/2022	LumiraDx UK Ltd.	LumiraDx SARS-CoV-2 Ag Test 08/18/2020	Microfluidic Immunofluorescence Assay, Instrument Read, Screening, Single Target	H, M, W	HCP, Patients, IFU
02/16/2022	DiaSorin, Inc.	LIAISON SARS-CoV-2 Ag 03/26/2021	CLIA, Single Target	H, M	HCP, Patients, IFU

7. If the RAT is not on the aforementioned approved lists, does it mean the product is of substandard quality?

If the product is on the approved lists of various regions, in theory they would provide better reassurance. However, it should be noted that in Hong Kong, as the "Medical Device Administrative Control System" is of voluntary nature, manufacturers or agents might not have submitted an application.

Besides, as some products are sold in Hong Kong under a different brand name, they may not be listed in the approved lists of overseas authorities*. In case of doubt, enquire with the trader or the labelled agent or manufacturer. If the reply is unsatisfactory, do not purchase the product.

*Note: The Consumer Council has made every effort to include in and regularly update its Approved Rapid Antigen Test (RAT) Kits Search Tool the names of the products sold in Hong Kong based on the information provided by manufacturers, to serve as reference for consumers.

8. Rumour has it that RAT products manufactured before a certain date last year cannot detect the Omicron variant. Is it true? How can consumers ascertain purchased kits can correctly detect Omicron?

Referencing the information on the EU's *Common List of COVID-19 Rapid Antigen Tests*, most RAT kits target the nucleocapsid (N) protein antigen. Generally speaking, as there is a lower probability of mutation on the N-protein, RAT kits are still able to detect the Omicron variant in theory.

In the EU's common list, a small portion of products have information indicating the coronavirus variants that can be detected. The Council hopes manufacturers could promptly conduct tests and provide the authorities and consumers with data on the detection of different virus strains.

The Public Health Laboratory Services Branch of the Centre of Health Protection (CHP), DH has conducted preliminary evaluation on RAT kits procured by the Government and confirmed that they are effective in detecting the Omicron variant. The evaluation also included RAT kits manufactured prior to the discovery of Omicron variants (i.e. before November 2021). Generally speaking, nucleocapsid protein is less prone to mutation and all the RAT kits procured and distributed by the Government target N protein antigen. As such, the impact of the emergence of Omicron variant on RAT's effectiveness is insignificant.

9. What should I do if the RAT result is positive?

Those tested positive by COVID-19 RAT (including vaguely positive with a faint band showing on the test kit) could take a nucleic acid test for confirmation as needed.

Owing to the relatively high infection risk in the community currently, RAT's positive results are relatively certain. Members of the public tested positive by RAT should be considered positive cases.

Please follow the latest Government guidelines, log onto the CHP's "Declaration System for individuals tested positive for COVID-19 using Rapid Antigen Test" (https://www.chp.gov.hk/ratp) and complete the electronic form to submit information of yourself and household members, as well as the relevant epidemiology information. Individuals should also take all necessary steps to avoid further spreading of the virus.

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Warm Reminder for RAT Kits (1)

Before Purchase

- Refer to the Council's dedicate "***Together, We Fight the Virus!***" webpage: https://www.consumer.org.hk/en/shopping-guide/features/2022-coronavirus-prevention-collection, verify the claimed certification and expiry date of the RAT kits. Do not purchased expired products
- Only buy from reputable traders / online shops
- Online stores may selectively provide information on RAT kits and generally do not disclose the expiry date of the products. Consumers should not fully trust the claims listed on websites, and use payment methods with a chargeback mechanism, such as credit cards
- Check that the packaging is intact when purchasing
- The coronavirus may further mutate and possible antigenic variation may impact the efficacy of the RATs. Therefore, only purchase an appropriate amount of RAT kits and refrain from stockpiling

After Purchase

- Pay attention to the storage instructions and expiry date provided by the manufacturer
- RAT products should normally be stored in a cool and dry place between 2°C to 30°C and away from direct sunlight. It is not necessary to store in a fridge.
- If the kits were stored in a fridge, they should be left at room temperature (15-30°C) for at least 30 minutes before use. Do not open the packaging while letting them return to room temperature.

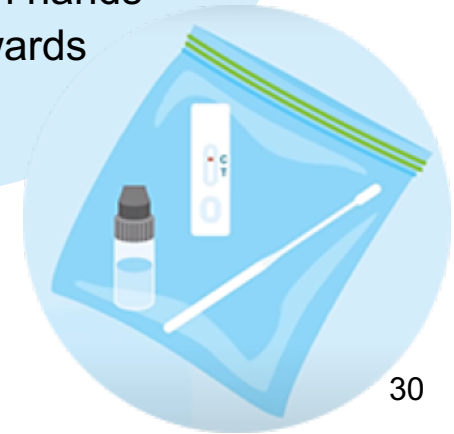
Warm Reminder for RAT Kits (2)

Before Testing

- To avoid affecting the test results, the testee should refrain from rinsing their nose, drinking water, eating, brushing their teeth, rinsing their mouth, smoking or drinking 1-2 hours before the test
- Carefully read the user guide and collect the sample correctly as instructed. Wash your hands before the test.
- Find a clean, well-ventilated spot to do the test. Clear up non-essential items around you. Keep a distance of at least 2 metres from other people.

After Testing

Respiratory specimen is a kind of body fluid and is potentially infectious. Therefore, they should be handled with care and disposed of carefully. After conducting the test, wrap and seal all the product components of the testing kit carefully and dispose properly according to manufacturers' instructions. Wash hands properly afterwards



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Part 3
Approved Rapid Antigen Test (RAT) Kits Search Tool

https://www.consumer.org.hk/en/rapid_antigen_test_search

Fighting the Fifth Wave Together

Do Not Panic Buy
Curb the Vicious Cycle

Keep Calm and Conduct
Compulsory Universal Testing

Beware of Consumer Traps and
Financial Loss from Non-delivery Scams

Use Technology Wisely
Select RAT Kits Smartly

Traders Be Self-disciplined
Tiding Over Tough Times Together

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THE END