

# COVID-19抗原、抗體、中和抗體檢驗於國內外之 應用經驗

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何美鄉

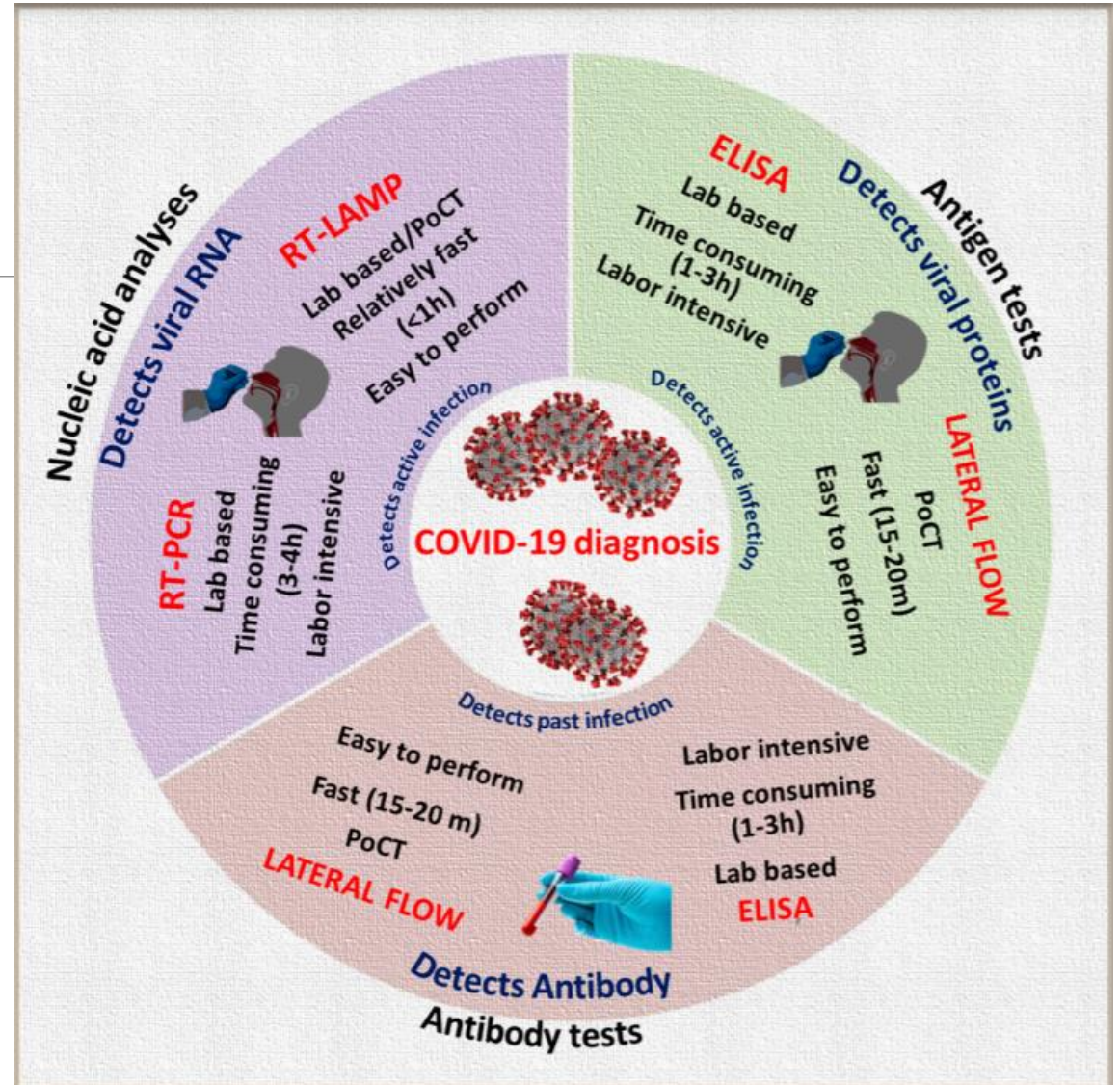
2021.9.24

FOR 新冠肺炎快篩檢驗及應用研討會

# COVID–19

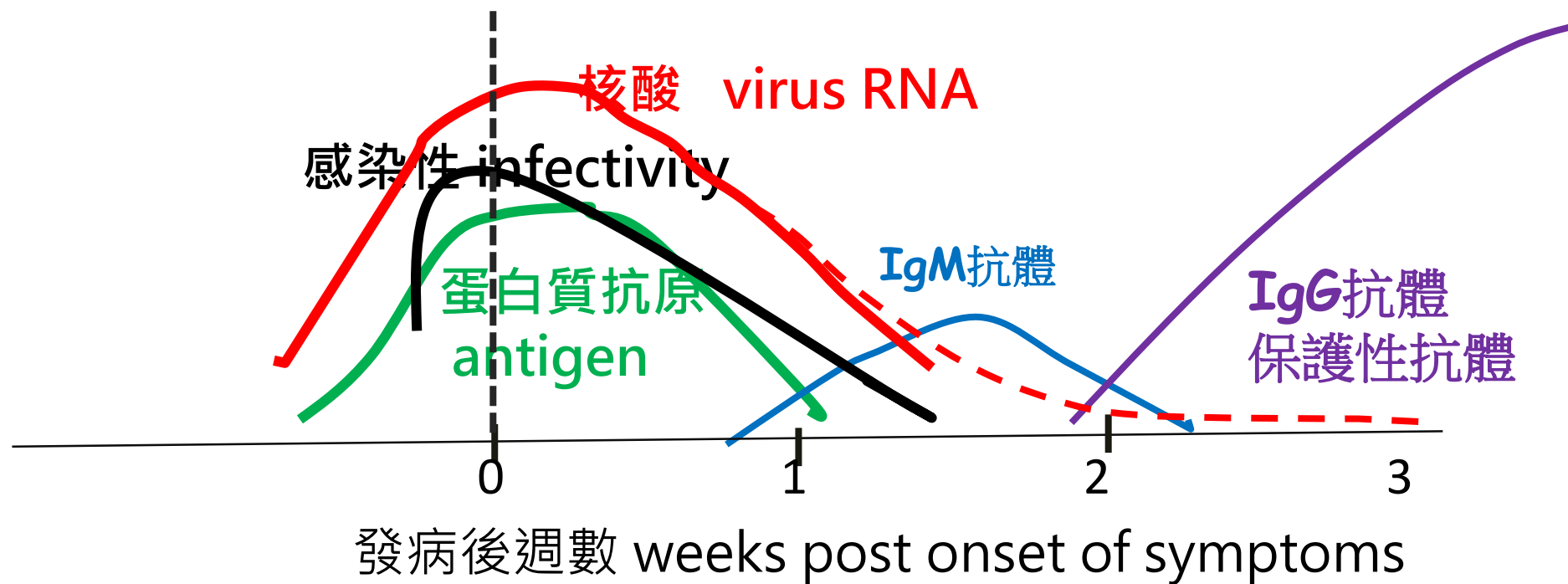
## Diagnostic tests

- In the lab test  
or
- at the point of care /service
- Consider that the **Pathogen is evolving**



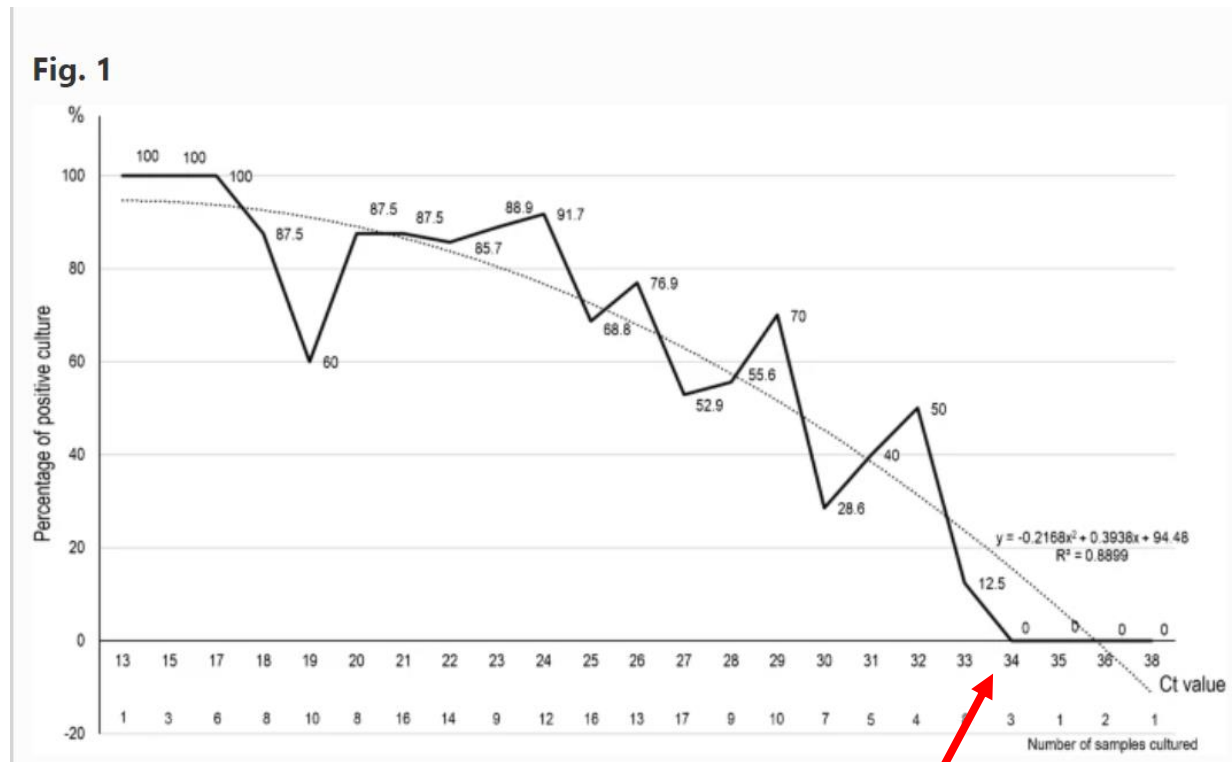
Source: Augustine J. Clin. Med. 2020, 9, 3372; doi:10.3390/jcm9103372

# COVID-19 病人 檢驗試劑的標的 病毒核酸與保護性抗體



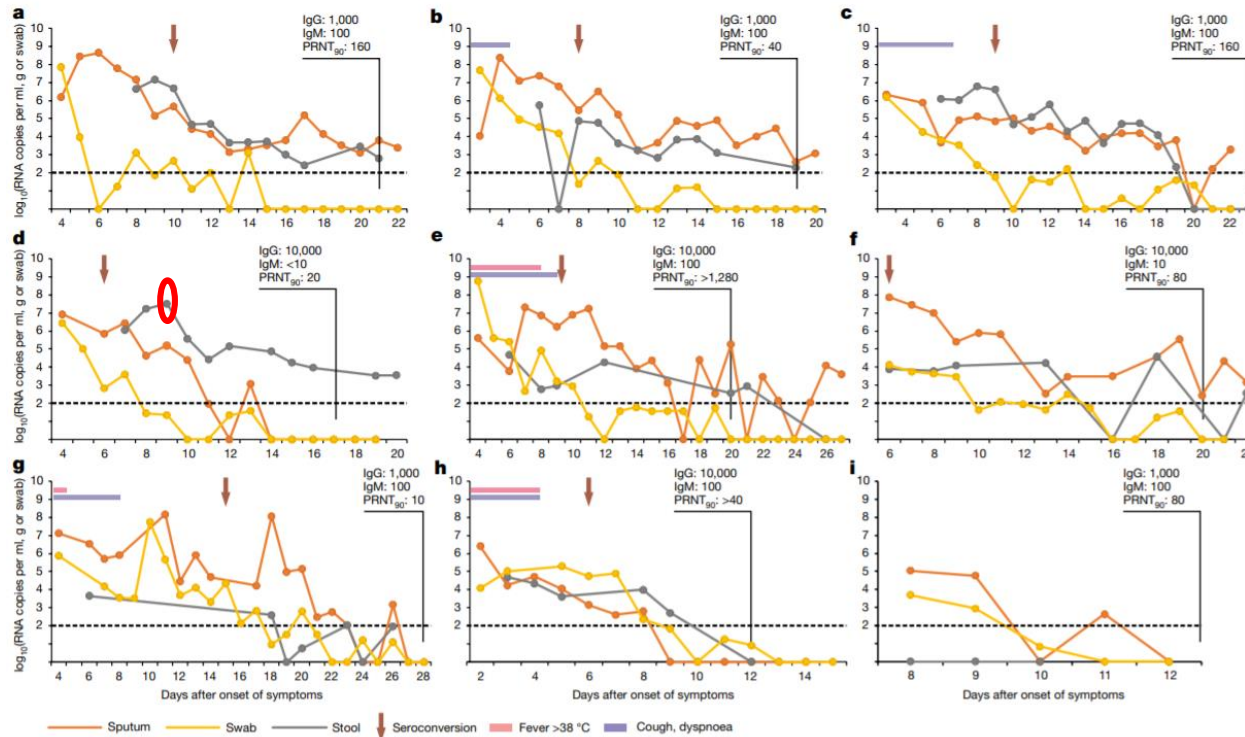
此示意圖，不適用於無症狀感染者;僅適用於有症狀的病人。  
This figure is not applicable for asymptomatic COVID-19 infection

# COVID-19 在病人鼻咽拭子與痰中 Q-PCR CT 值與病毒陽性率的相關性



- CT值 = 33，1 / 8 的機率培養出病毒
- CT 值  $\geq 34$  培養不出活病毒
- Q-PCR 含E GENE
- 183Q-PCR陽性檢體中檢體，129培養出病毒
- 病人檢體含鼻咽拭子，痰

# 病毒量核酸量

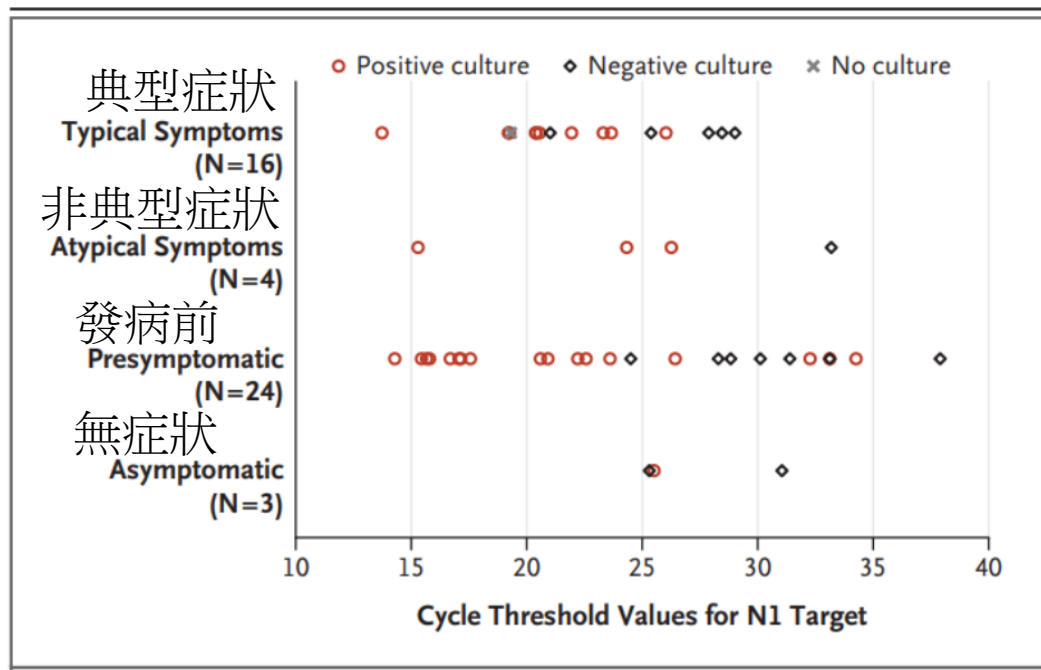


糞便核酸數量：中位數 12,882 copies/g  
(0~600,000 to 30,000,000)

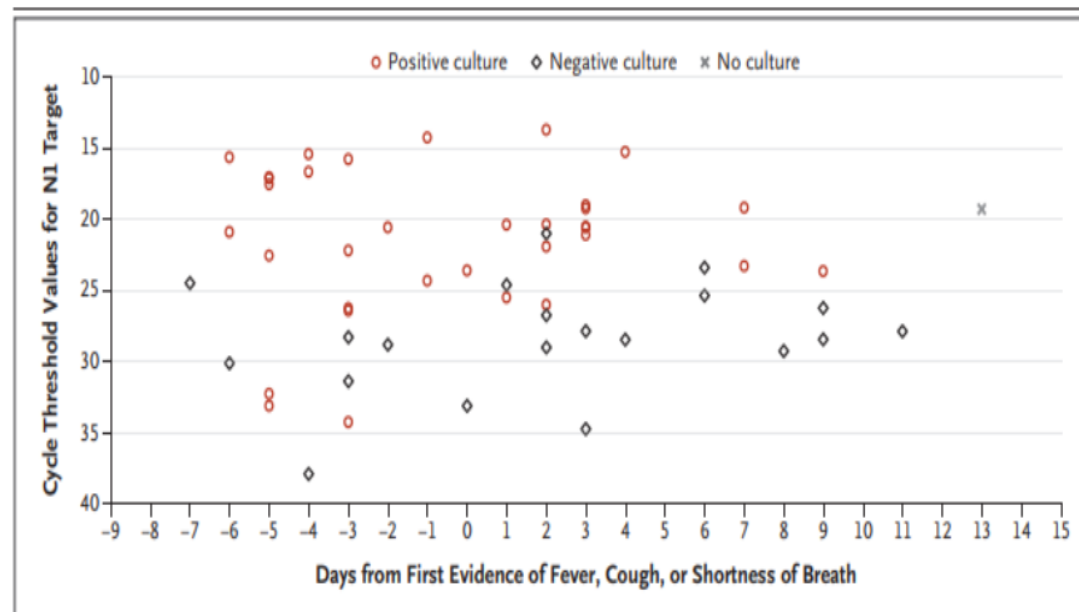
糞便中培養不出病毒

病毒培養：咽喉核酸數量 > 10<sup>6</sup> 才有陽性病毒培養

# COVID-19 在呼吸道中 Q-PCR CT 值與病毒陽性率的相關性



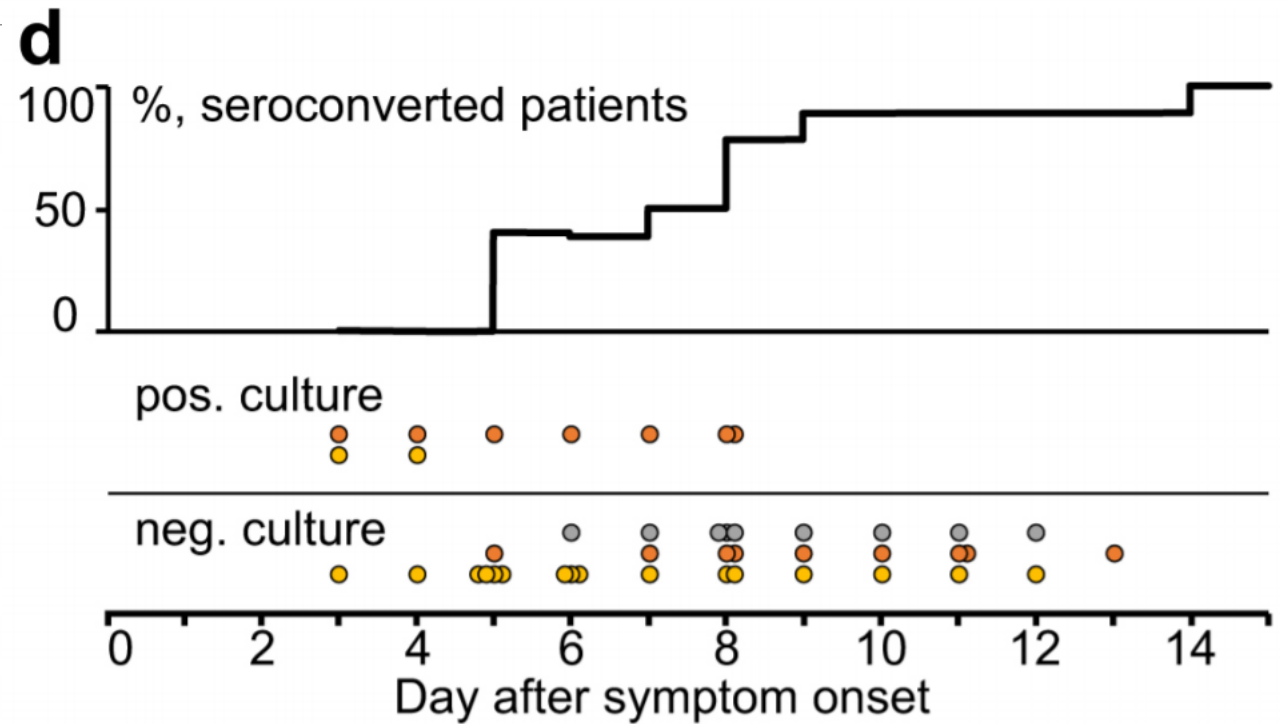
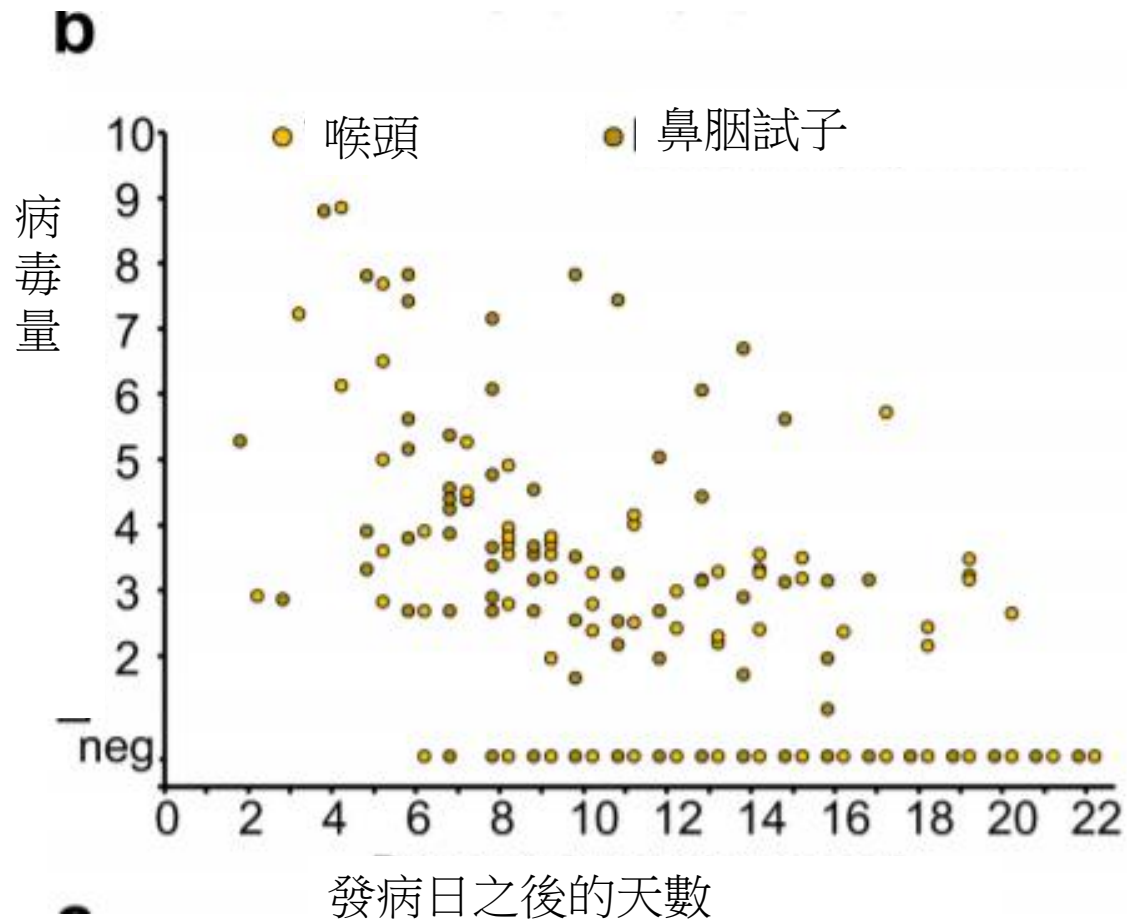
- CT 值  $\geq 34$  培養不出活病毒
- Q-PCR 含N1 GENE
- 感染10天後，不具感染性



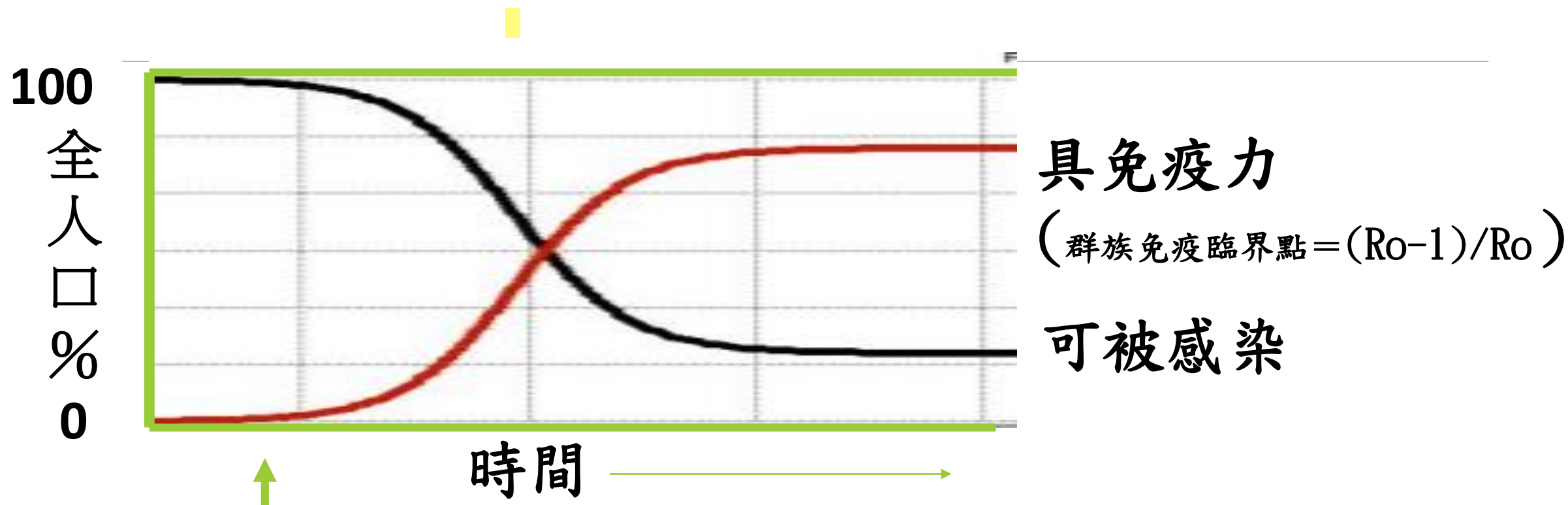


# 發病日的病毒量在鼻咽喉的表皮細胞已達最高

## 發病8天後培養不出病毒



# 疫情的擴散與演進



受疫情影響的各國，都以相當極端的手段，停工、停課、禁航等，來防疫，因為**病人癱瘓醫療體系**。達到群族免疫之前疫情會持續蔓延



# Is there a long-term niche for Ag tests?

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# 案例

## EU Digital COVID Certificate

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Is a digital proof that a person has either

- been vaccinated against COVID-19 or
- **received a negative test result** or
- recovered from COVID-19

COVID -19 Diagnostic tests

WHO sensitivity >80% specificity >97%

EU sensitivity >90% specificity >97%

# 案例

## Singapore

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- Vaccination one dose 81%, two doses 79%
- Despite rising confirmed cases, the severe case number remains low
- Singapore reported daily 1,178 new cases of Covid-19 this week
- Of the more than 13,000 people infected over the last four weeks the health ministry said, 98 per cent had no or mild symptoms.

Facing uncertainty

- Beginning 9/18 ART (Antigen Rapid Test) sold in vending machine

# 案例

## Entry to US (non-US Nationale)

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Before Nov 2021

- a negative COVID-19 test, taken within three (3) calendar days of departure, or
- proof of recovery from the virus within the last 90 days.

November and onwards

- Fully vaccinated
- a negative COVID-19 test, taken within three (3) calendar days of departure

# 案例

## USA Aug 28, 2021

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If the United States were an international destination, more than 80% of states would qualify for a Level 4 “Do Not Travel” designation by the Centers for Disease Control and Protection (CDC).

For travel within the U.S., CDC guidance depends on an individual’s vaccination status. The agency recommends that Americans delay all travel until they are fully vaccinated. If that is not possible, the CDC asks that unvaccinated travelers take a Covid-19 viral test one to three days before departure. Then, during the trip, travelers should practice social distancing and wear a face mask while indoors in public settings and in crowded venues. Lastly, the CDC recommends that unvaccinated travelers get a viral test three to five days after returning home and self-quarantine for one week.

# 案例

## Korea

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Fully Vaccinated are exempt from quarantine

Tests for all entries; Tests accepted LAMP, NAAT, NEAR, PCR, SDA and TMA tests.

Vaccination status 70% 42%

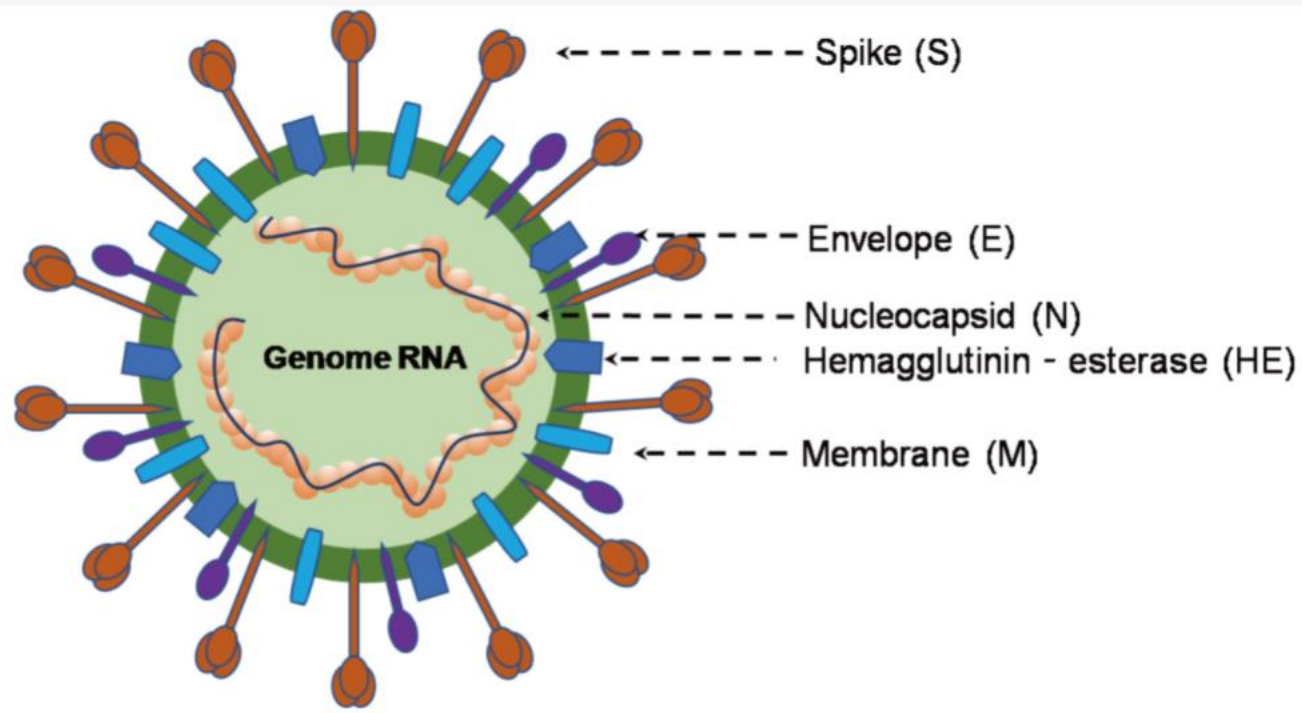


# Testing for neutralization antibody

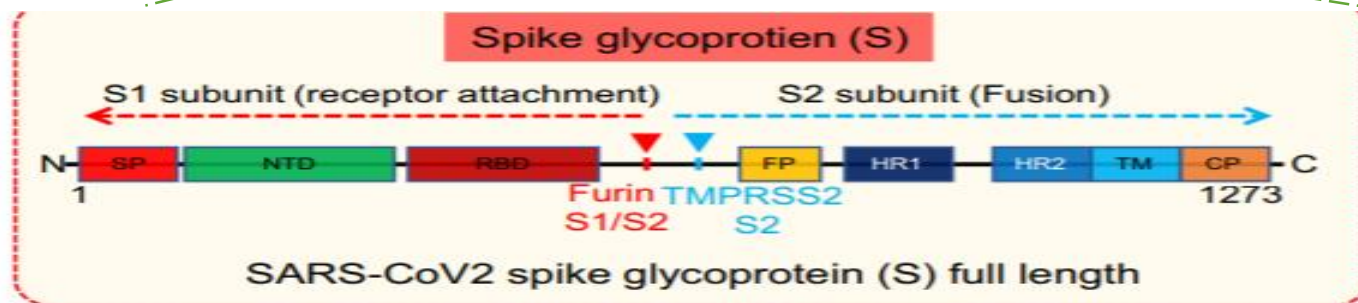
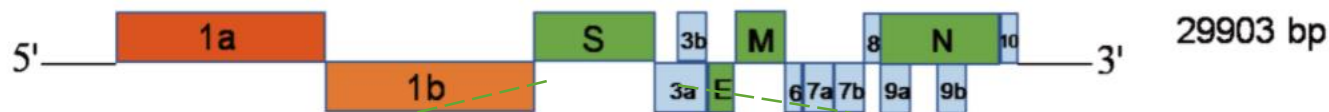
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- Laborious work
- necessary for vaccine efficacy/effective evaluation
- Replaced by surrogate antibody (IgG to S protein or to RBD)
- Need for P3 lab continue?

A



B



# SARS-CoV-2

## Antibody vaccine vs natural infection

- Antibody induced by gene-based or subunit protein-based vaccines
  - Anti-S or anti-RBD
- Natural infection
  - Anti-N
  - N-terminus cross reactive with many coronavirus
  - C-terminus more specific for SARS-CoV-2

# Diagnosis at Point of care/service (DIY)

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Action taken after confirmed diagnosis

- Immediate treatment
  - Effective drug available
- Traffic control
- Isolation
  - Infection remains life threatening to substantial fraction of population

# Diagnostic Test done the Lab

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- can be done in Large scale
- more efficient / economical

In situations

- collective data needed
- Evaluation of vaccine, drug, and control strategy
- Following the evolution of pathogen (molecular tests only)

# General problem with DIY diagnostic test

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- A number of COVID-19 tests available on the UK market failed to replicate their stated performance in technical and in use validation and real-world evidence collection.
- Information about the true performance of COVID-19 test products is not easily accessible to consumers
- Consumers without access to information that would allow them to make informed choices about the tests they purchase.

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Thank You!!