SARS-CoV-2檢驗與篩檢

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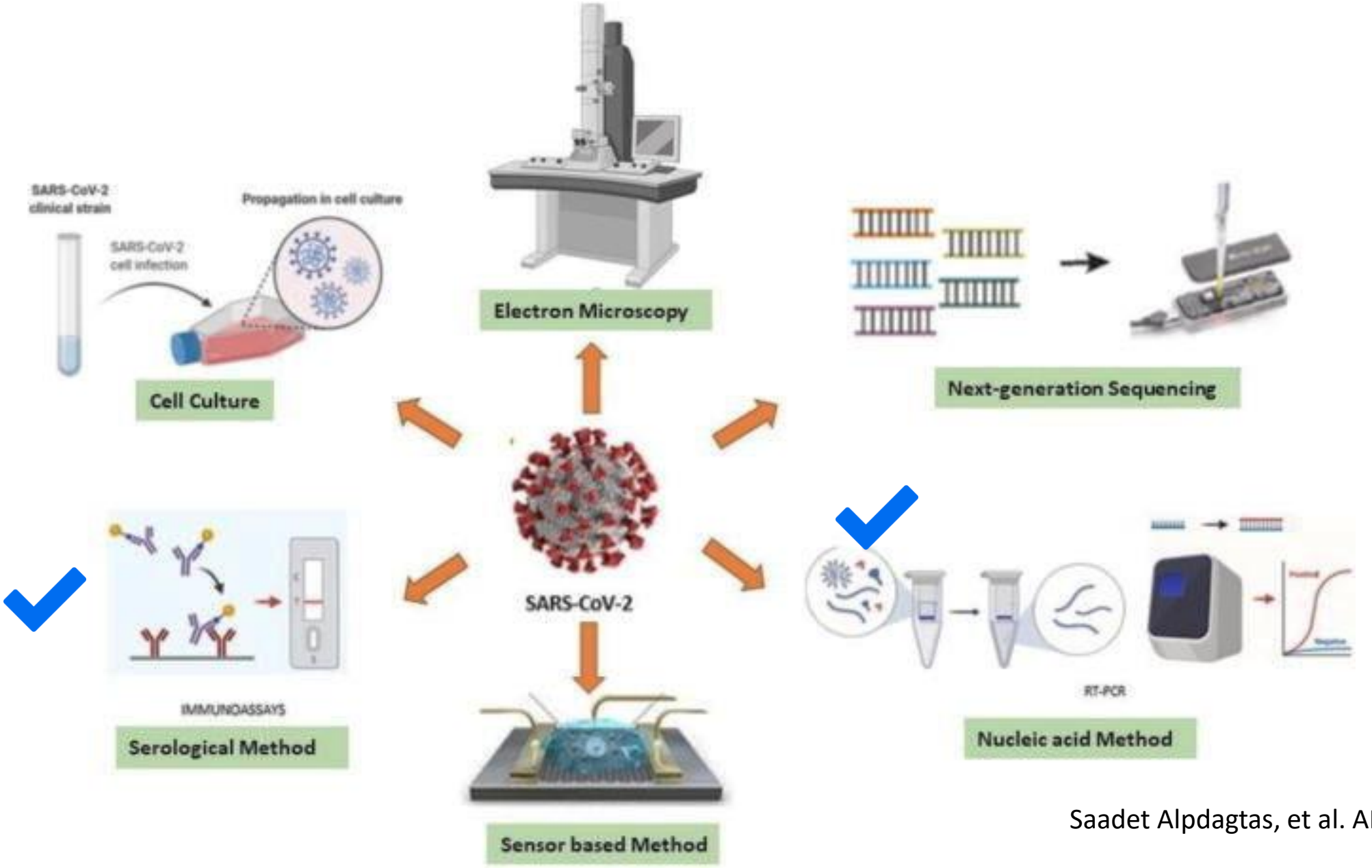
盧柏樑

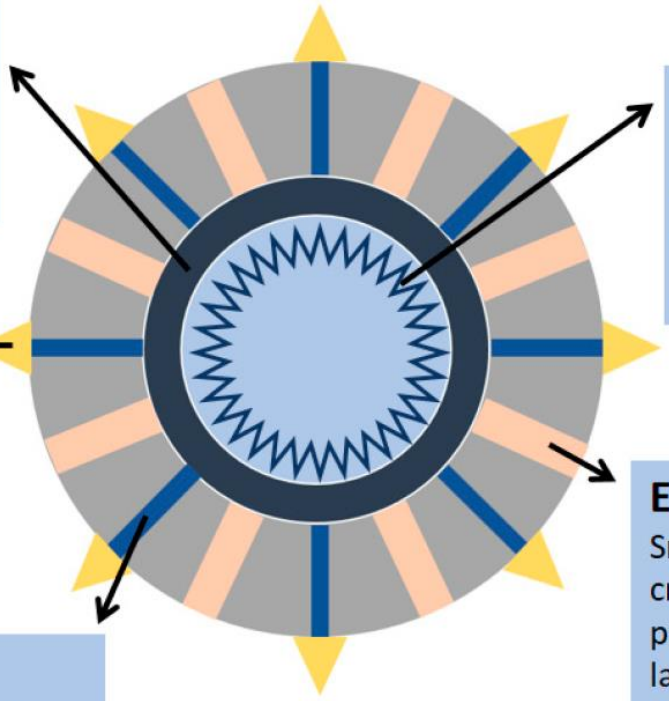
Diagnostic methods for RNA viruses



Saadet Alpdagtas, et al. APL Bioeng 2020

SARS-CoV-2 structural proteins and genomic component

Nucleocapsid Protein (N)
It encapsulates the viral genome and enhances the efficiency of RNA transcription and viral replication. The N protein has been detected through FICA.



Viral RNA
The nucleic acid component of SARS-CoV-2. Certain genes (*RdRP* and *ORF1ab*) can be amplified by RTFQ-PCR, dPCR, mPCR and LAMP assays.

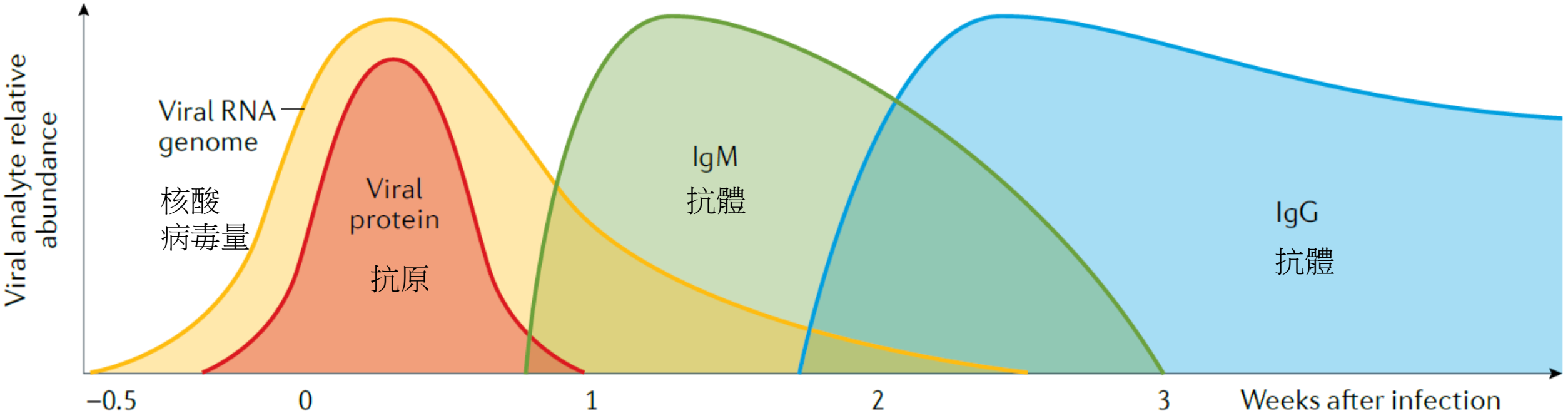
Surface "spike" Glycoprotein (S)
Main target of neutralizing antibodies. It has been used for designing and developing S protein-based vaccines and therapeutics.

Envelope Protein (E)
Small integral protein involved in critical viral functions and pathogenicity. SARS-CoV-2 strains lacking E protein are promising vaccine candidates.

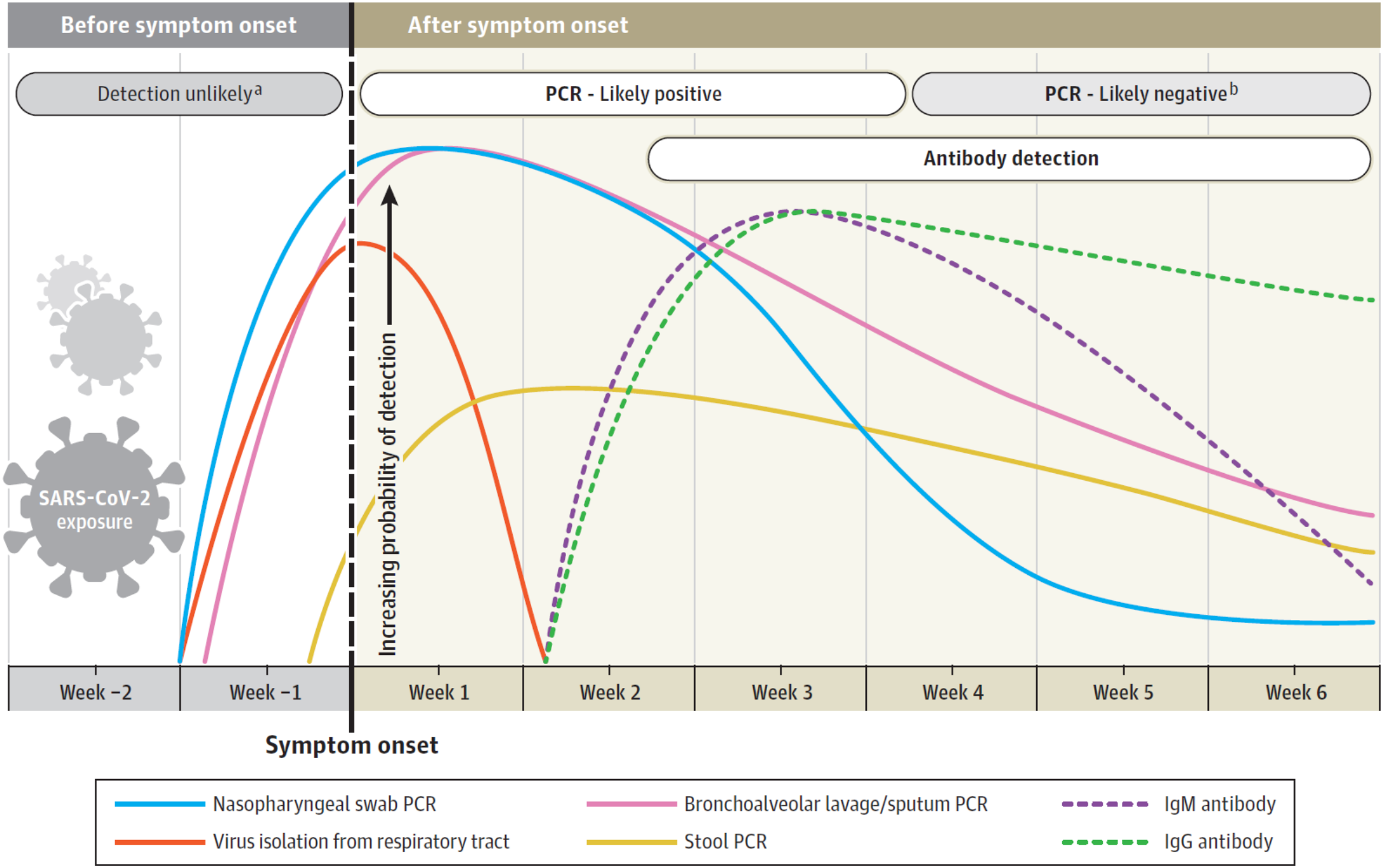
Matrix Protein (M)
Substitutions in this protein may result in changing viral antigenicity. The gene that encodes for M protein has been detected by NTS.

Zhou, P, et al. Nature 2020; Udugama, B, et al. ACS Nano 2020; Sexton, N.R, et al. J. Virol. 2016; Duan, L, et al. Front. Immunol. 2020; Hu, Y, et al. Bioinform. 2003 ; Schoeman, D.; Fielding, B.C. Virol. J. 2019

Viral analyte (RNA, protein and antibody) dynamics



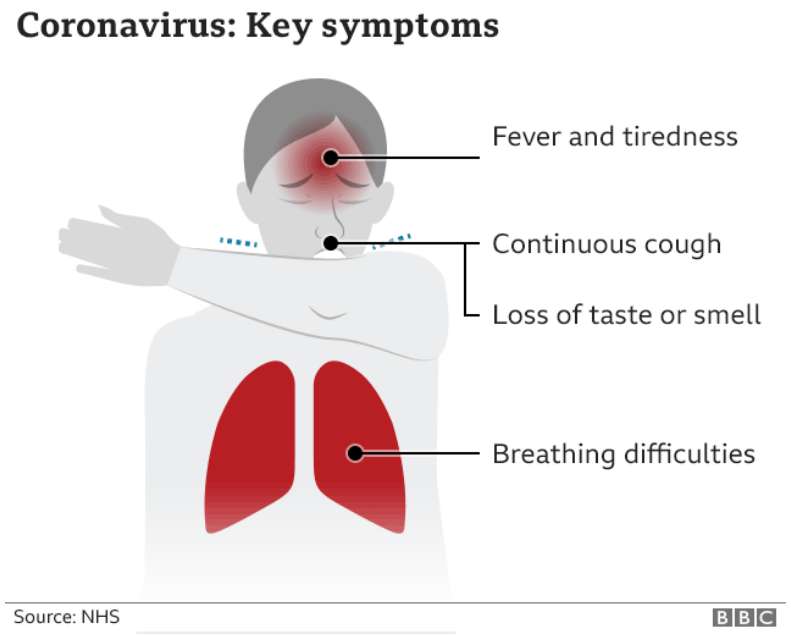
Tim R. Mercer and Marc Salit, Nature Reviews Genetics 2021

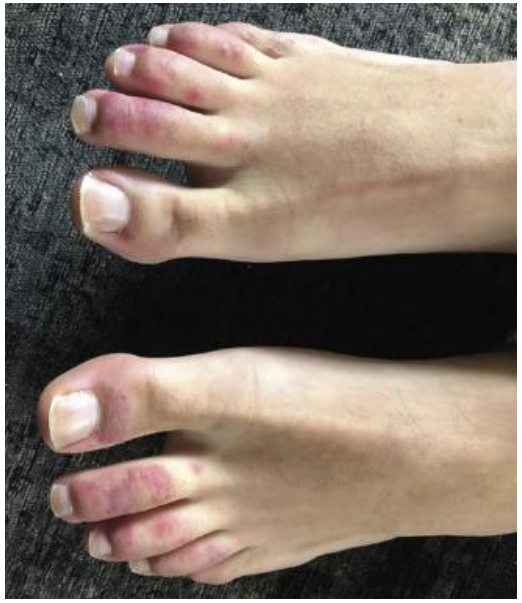


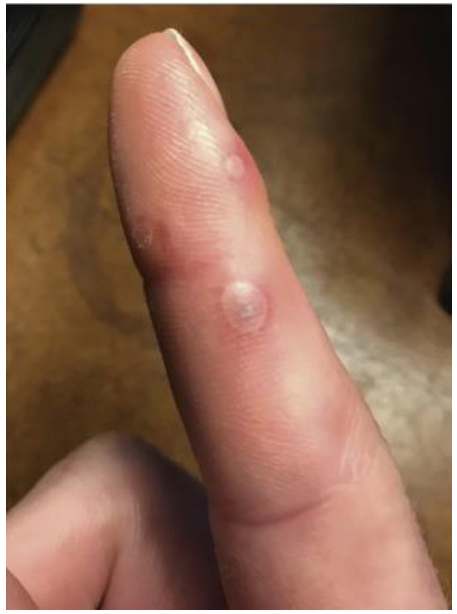
Nandini Sethuraman, et al. JAMA 2020

Diagnostic approach： Whom to test ?

- Symptomatic patients
  - If possible, all symptomatic patients with suspected infection
  - Resp. symptoms, loss of taste or smell, pernio-like lesions…







1. Esther E. Freeman, et al. J Am Acad Dermatol. 2020
2. Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19, updated December 23, 2020

Diagnostic testing for SARS-CoV-2

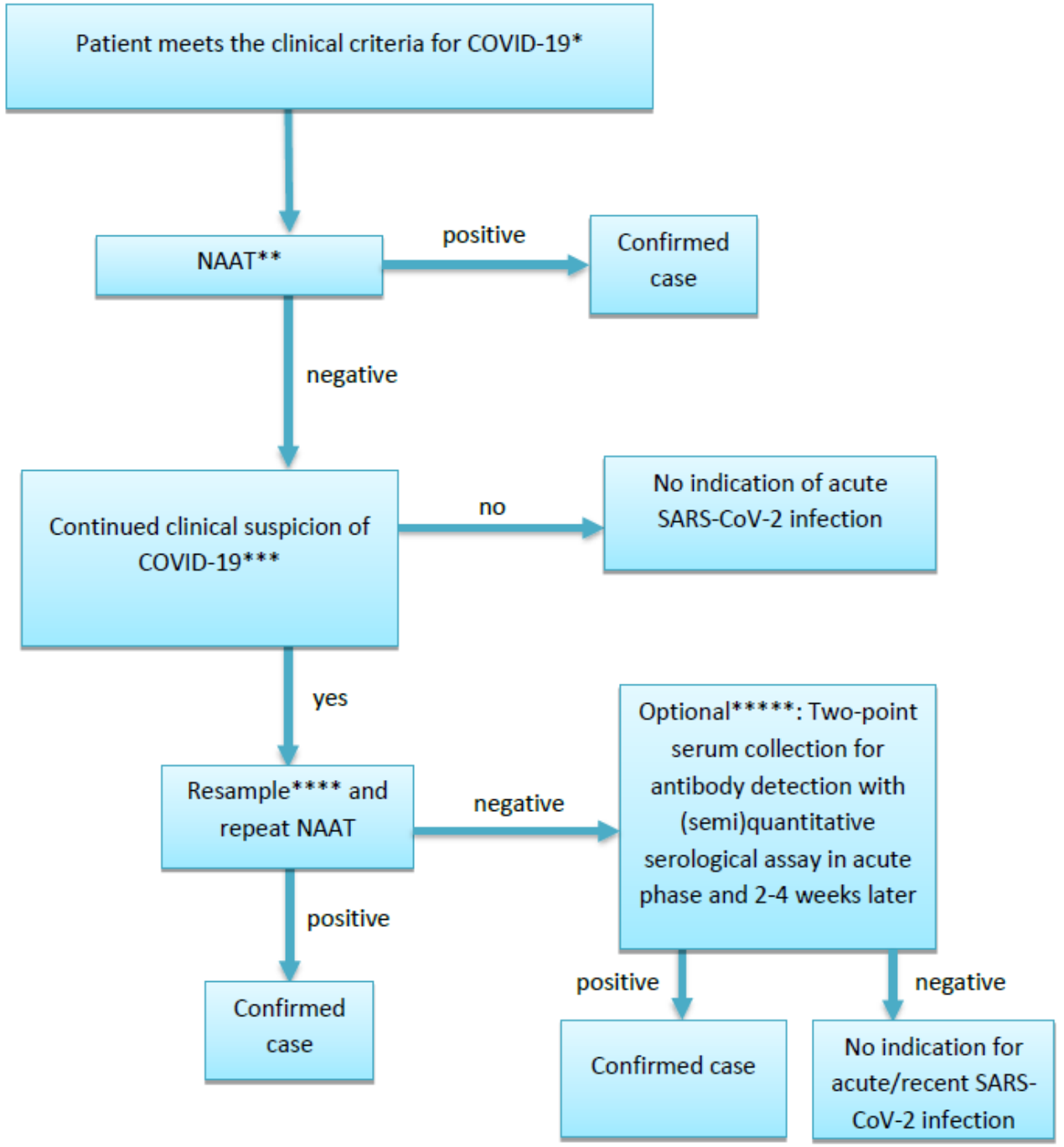
Interim guidance

11 September 2020

World Health Organization

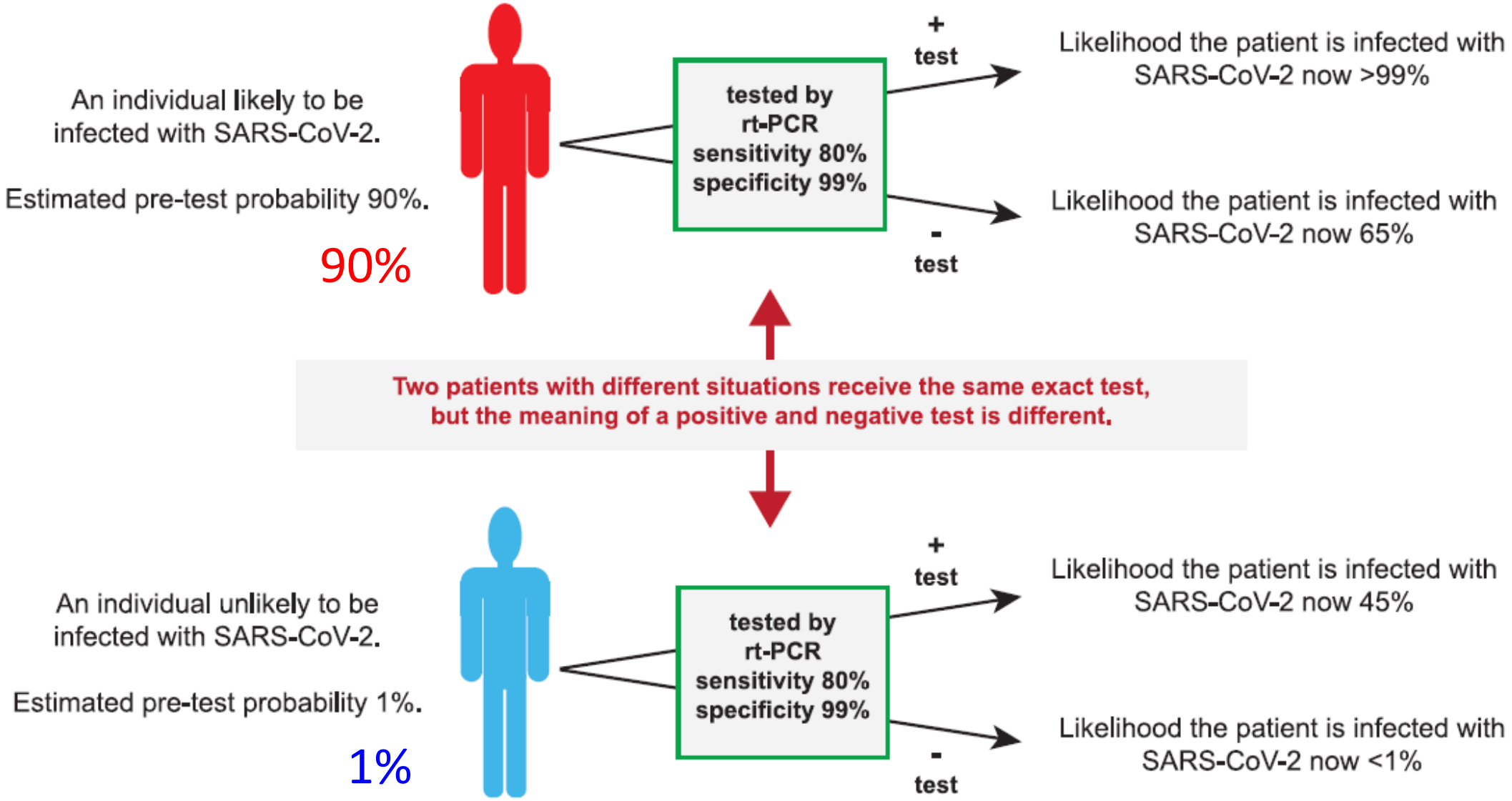
Diagnostic flow diagram for the detection of acute SARS-CoV-2 infection in individuals with clinical suspicion for COVID-19

依序做 PCR, PCR, 抗體

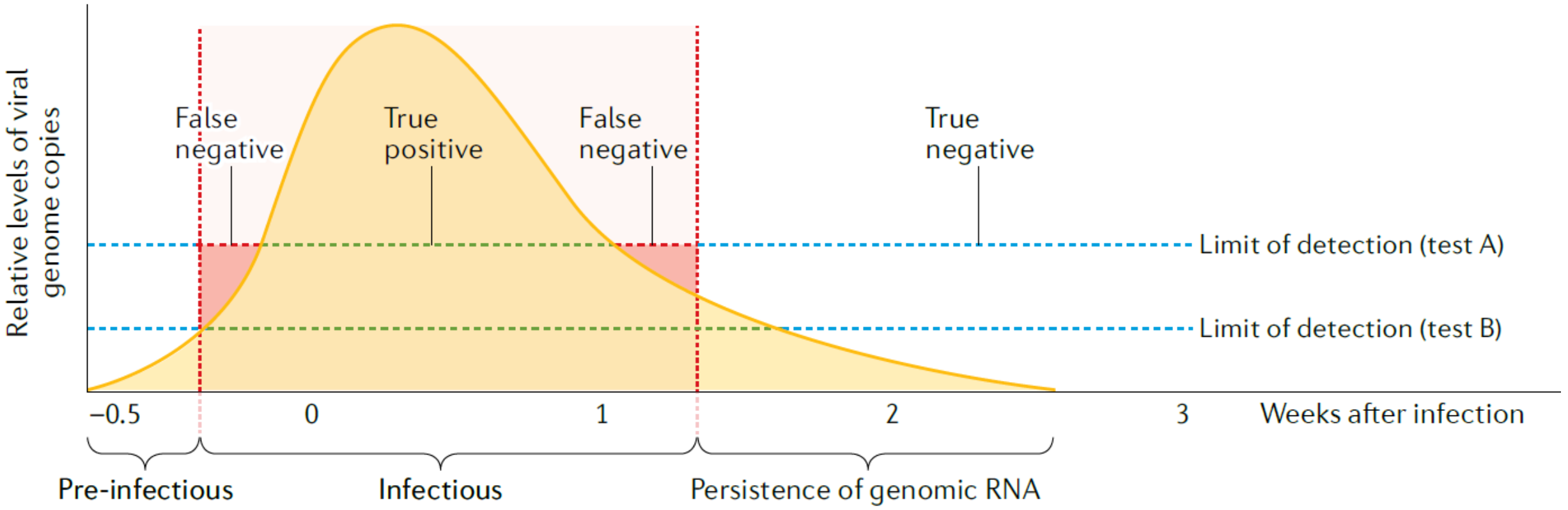


Pre-test probability that the disease is present

Edward C. Stites and Craig B. Wilen. Med (N Y) 2020



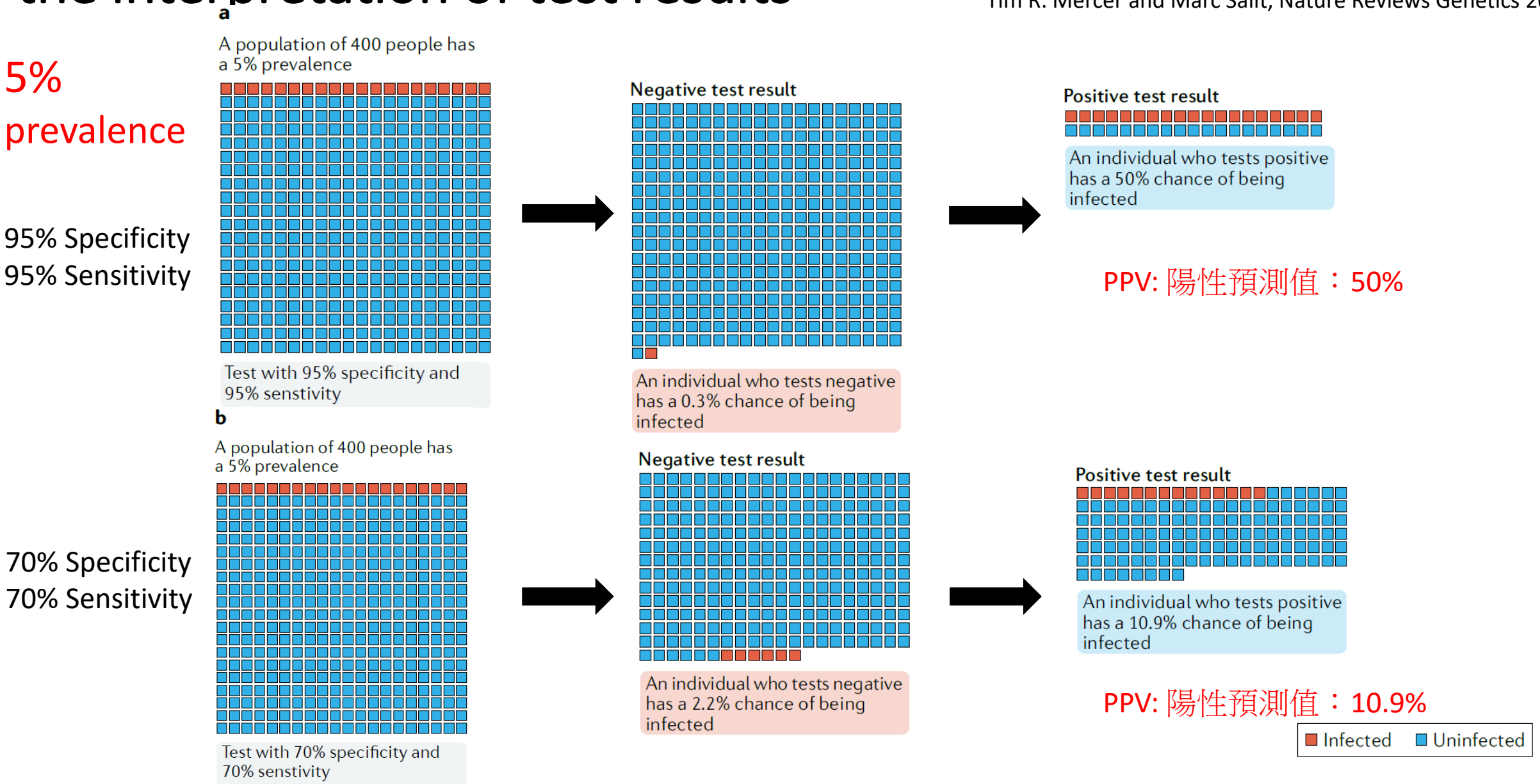
Analytical sensitivity is dependent on test performance and viral dynamics



Tim R. Mercer and Marc Salit, Nature Reviews Genetics 2021

How test sensitivity, specificity and disease prevalence influence the interpretation of test results

Tim R. Mercer and Marc Salit, Nature Reviews Genetics 2021



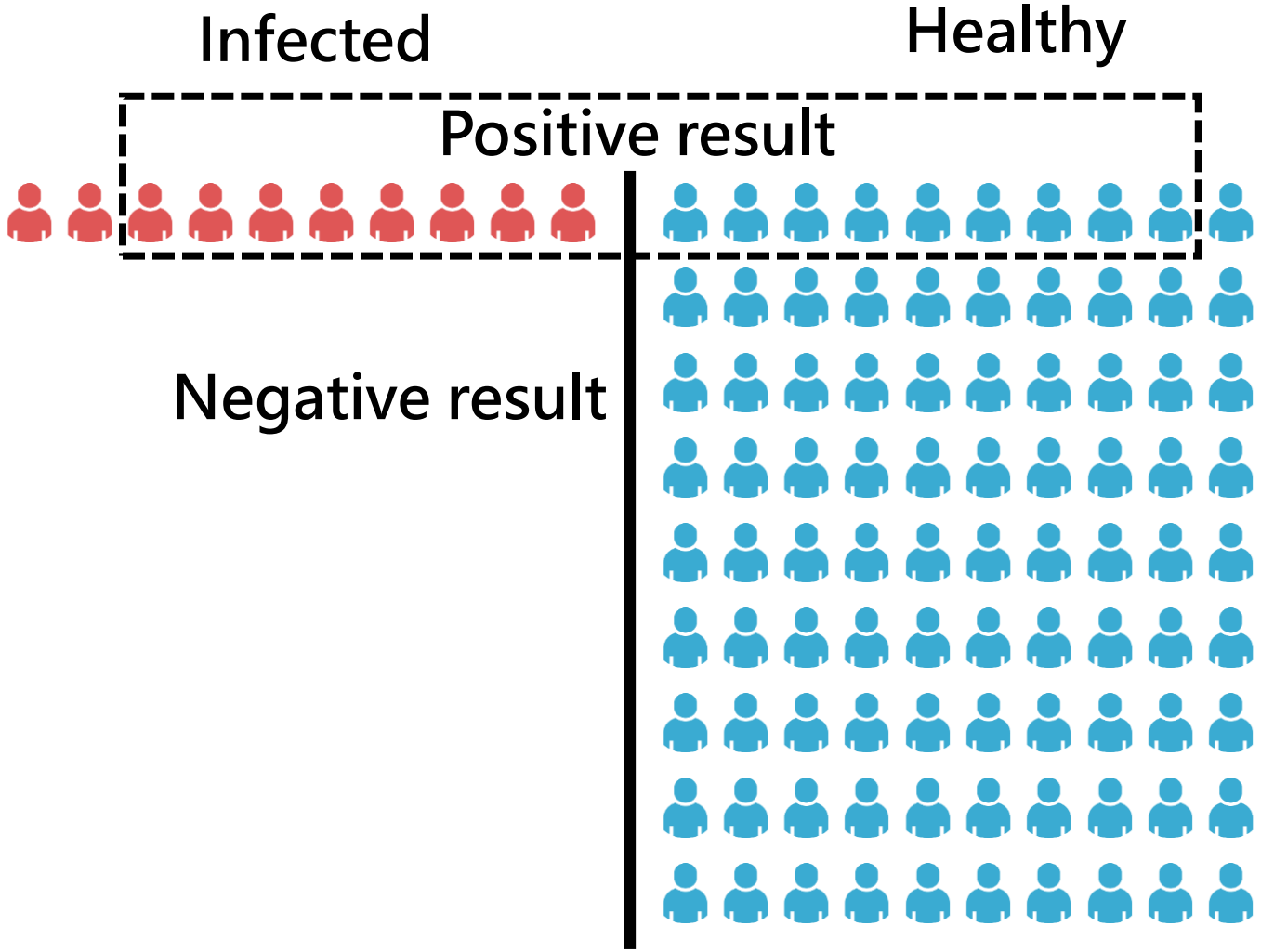
Diagnostic approach: Whom to test?

- Asymptomatic testing for SARS-CoV-2 needs clear goals and protocols
- Select asymptomatic patients
  - Close contact with index case
  - individuals at risk for severe disease (eg, long-term care facilities, cancer patients…)
  - hospitalized patients at locations where prevalence is high
- Screening program
  - depends on population prevalence of infection, the different tests, different people's willingness to accept personal inconvenience…

1. Infectious Diseases Society of America Guidelines on the Diagnosis of COVID-19, updated December 23, 2020
2. CDC Guidance for Expanded Screening Testing to Reduce Silent Spread of SARS-CoV-2. https://www.cdc.gov/coronavirus/2019-ncov/php/testing/expanded-screening-testing.html
3. European Society for Blood and Marrow Transplantation. COVID-19 anbd BMT. https://www.ebmt.org/covid-19-and-bmt

Disease prevalence= 10%

Diagnostic assay sensitivity 80%, specificity：90%



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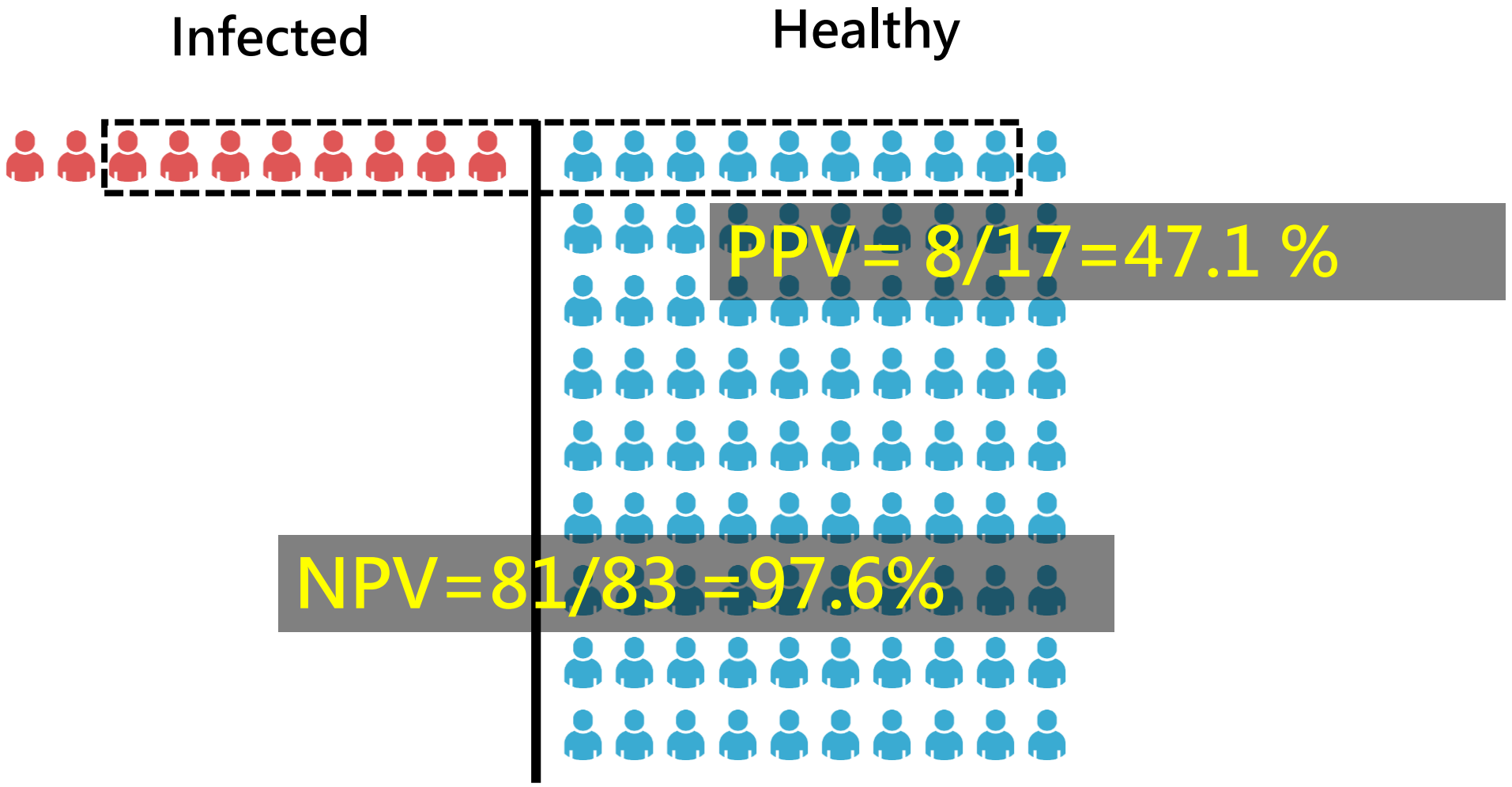

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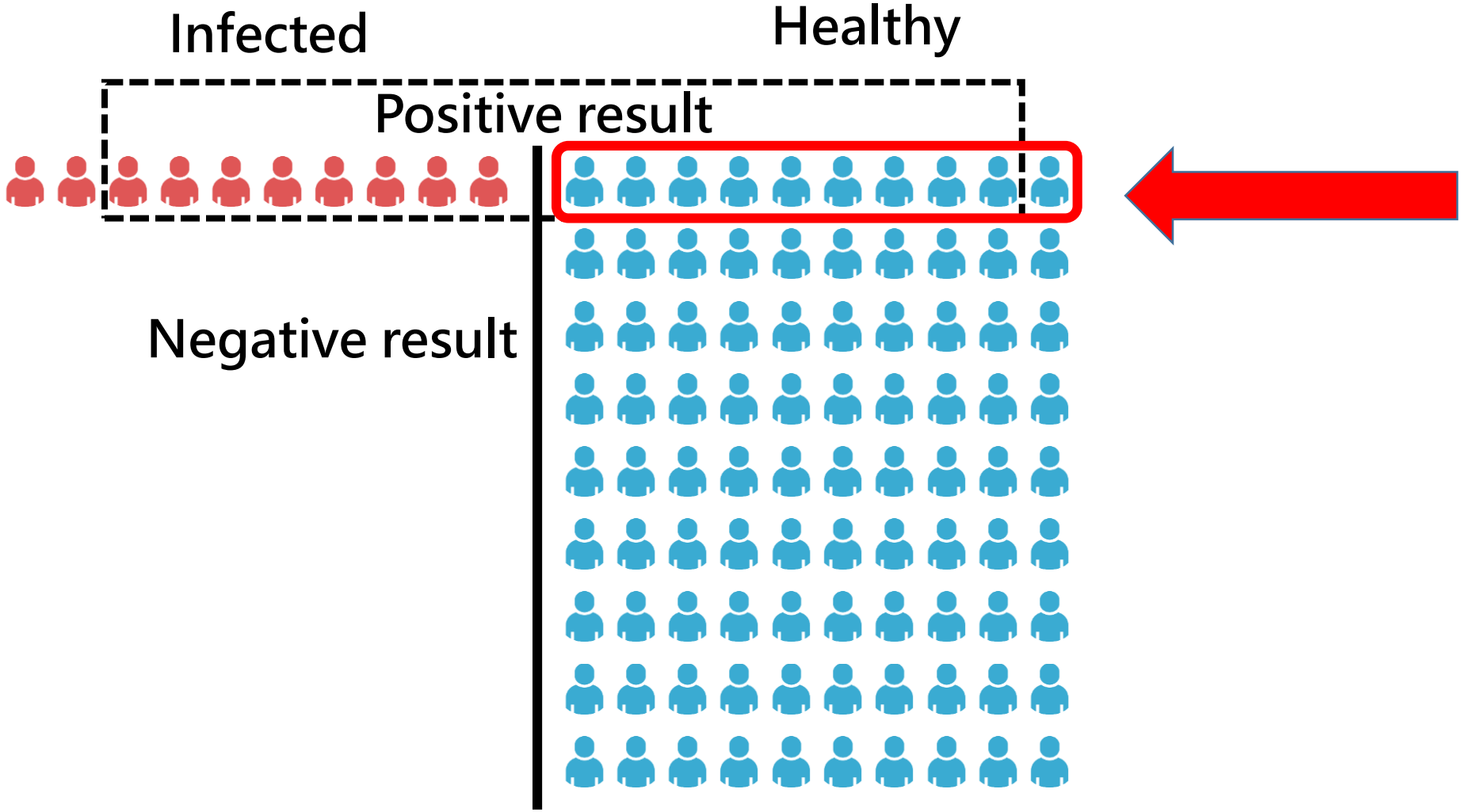
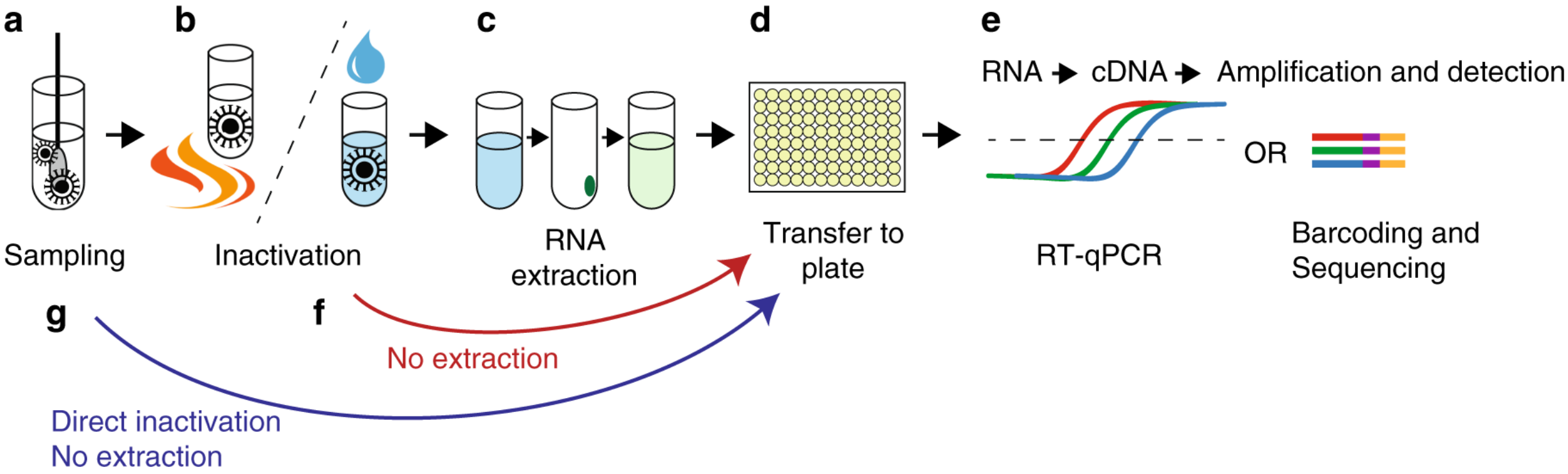


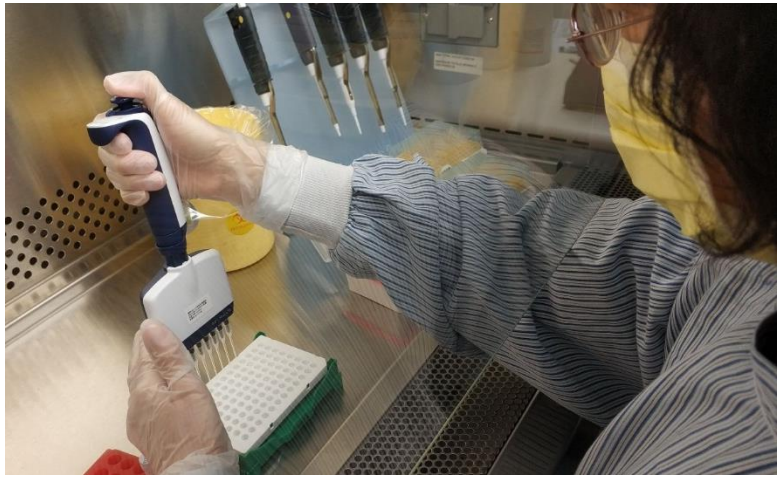
Schematic overview of SARS-CoV-2 RT-PCR testing procedure



Ioanna Smyrlaki, et al. Nat commun 2020

初期面臨問題

以人工萃取RNA,傳統分生檢驗方法,面臨以下問題:
(1)疫情影響可能試劑短缺
(2)耗時且人力需求量大
(3)檢驗初期非特異性結合干擾問題



diagnostics

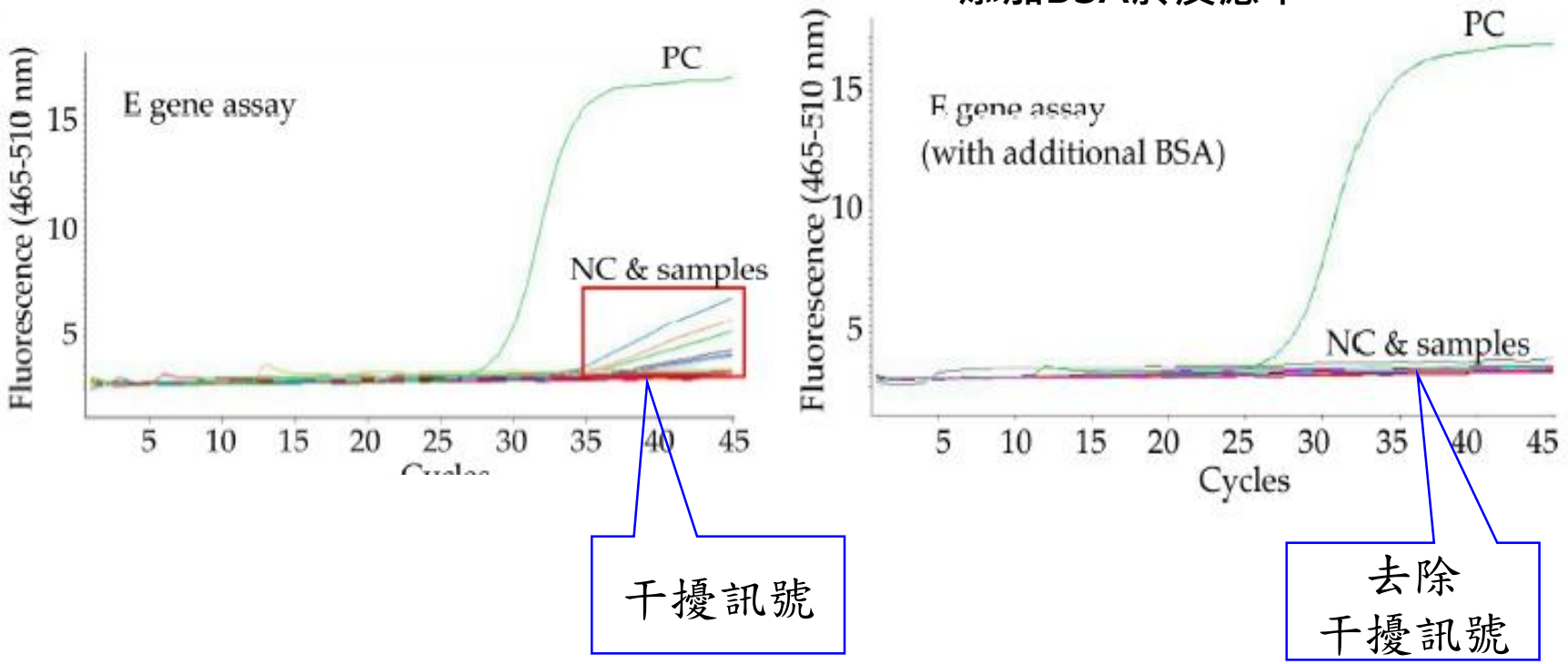
MDPI

Communication

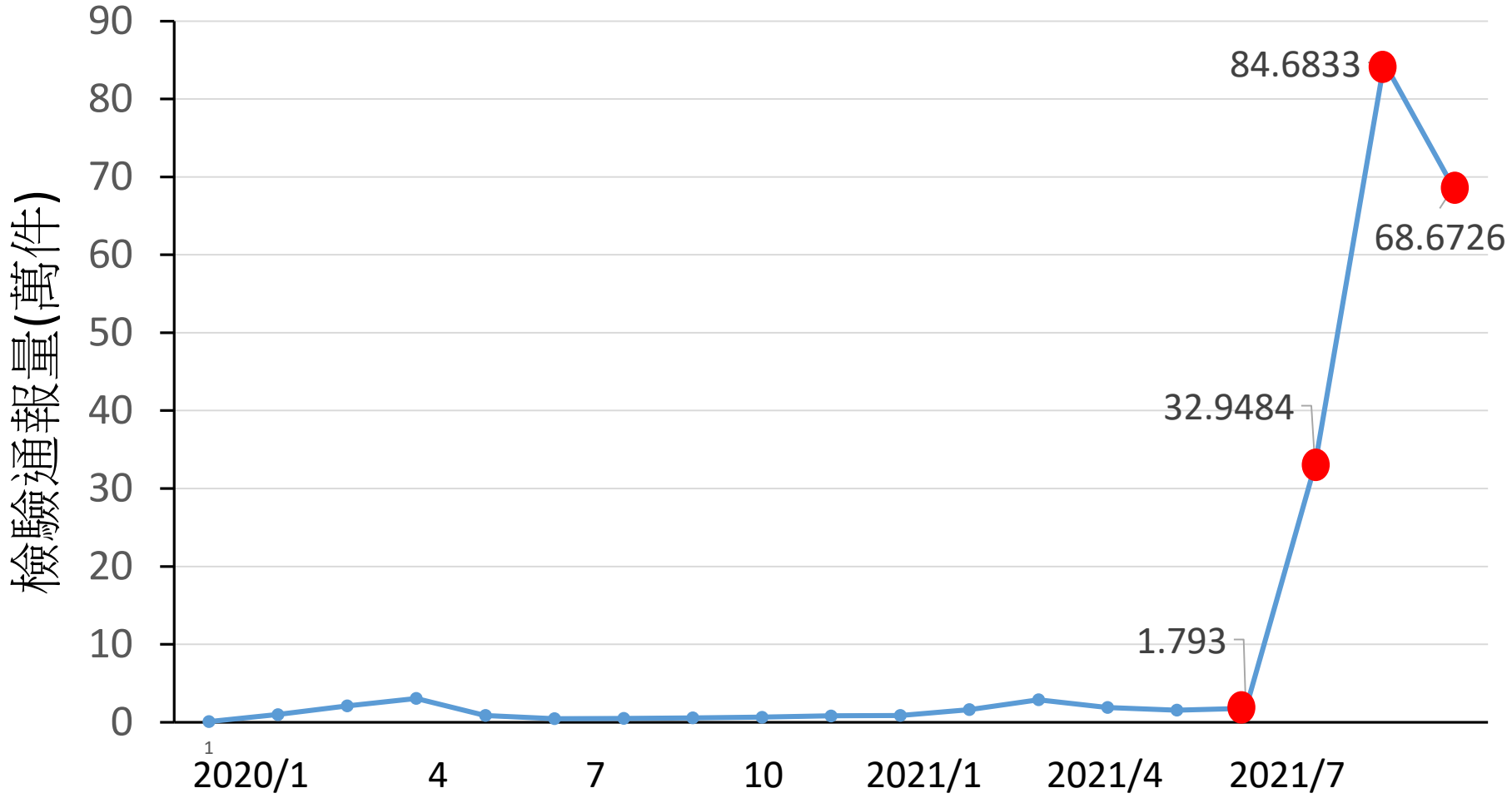
Optimization of the CDC Protocol of Molecular Diagnosis of COVID-19 for Timely Diagnosis

Chao-Ju Chen [1], Li-Ling Hsieh [1], Shu-Kai Lin [1], Chu-Feng Wang [1], Yi-Hui Huang [1], Shang-Yi Lin [1,2,3] and Po-Liang Lu [1,2,3,*]

-試劑量減半流程測試
-添加BSA於反應中

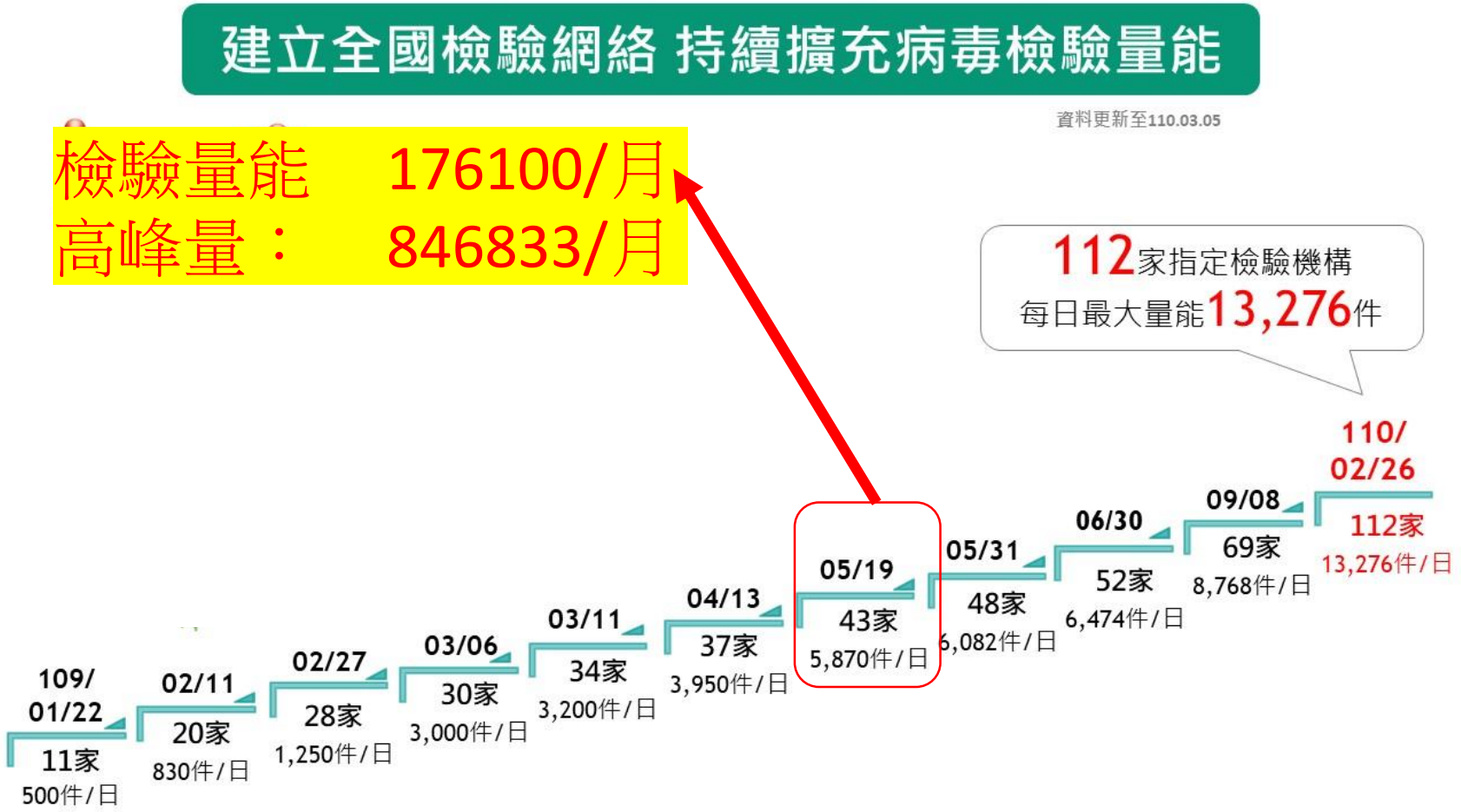


全國新型冠狀病毒通報檢驗量



資料來源：政府資料開放平台

想像一下，如果檢驗量的高峰點是在2020年5月



建立高通量自動化以提升檢測量能

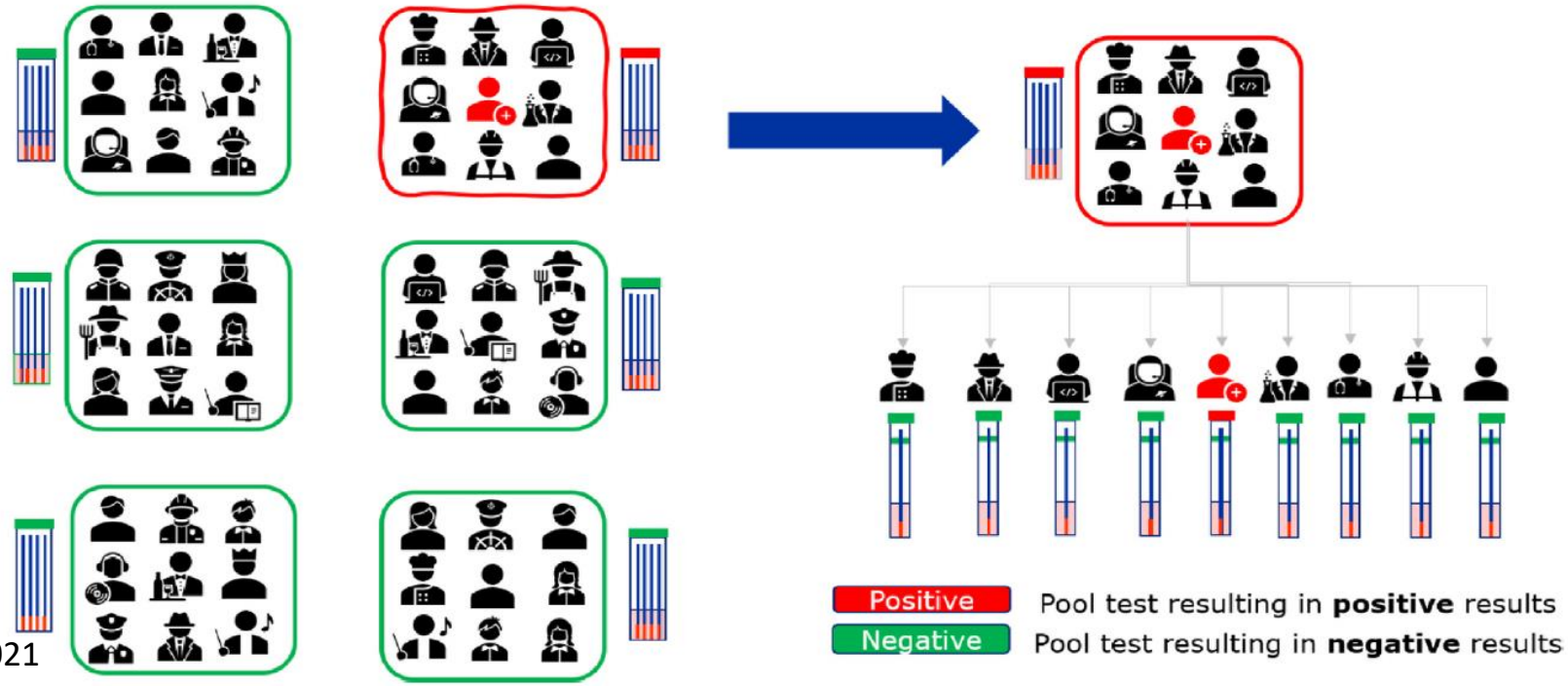
全自動化cobas® 6800 系統

將檢體簡易處理後即可上機，在儀器內自動完成核酸萃取及PCR

- 每批可處理94支檢體
- 檢驗效率：第一批檢體(自上機到結束)需時3小時，第二批以後後每1.5小時可完成檢測
- 24小時可檢測約1400支檢體

Pooled Testing Strategies for SARS-CoV-2 diagnosis

- increase testing capacity, lower the cost per test, and conserve reagents during times of sudden and heavy inflow of test requests, pandemic surveillance, large-scale population testing.
- The larger the pool size, the higher the probability of false negatives



Nadja Grobe, et al. Clin Microbiol Infect 2021
Daniel EA, et al. Diagn Microbiol Infect Dis. 2021

嚴重特殊傳染性肺炎核酸檢測池化(pooling)方式操作步驟

110/6/28

操作步驟

1. 各待測檢體先依常規流程完成前處理(例如有些實驗室會先移液分管)。
2. 將各待測檢體以每五支為一組，取等體積混合成一管(一個 pool)。每個 pool 中各檢體須取的體積量請依各檢測平台所投入之檢體總體積計算。例如單一檢體投入體積為 300 ul，則將每個 pool 視為單一檢體時，亦須投入 300 ul 進行檢驗，因此各 pool 所含的 5 支檢體每支須取 60 ul (使總和為 300 ul)；若再考慮分注時的誤差，建議可多取 10 %的體積(例如每支取 66 ul)，5 支混合後每個 pool 含 330 ul，再取 300 ul 進行檢驗。

備註：若各單位所使用的檢測平台原廠有提供 pooling 之操作步驟，亦可自行參考，依該步驟執行，惟每個 pool 所含的檢體上限為 5 支。

結果判讀

1. 若單一 pool 的檢驗結果呈現陰性，則該 pool 內的 5 支檢體均核發陰性報告。
2. 若單一 pool 的檢驗結果呈現陽性，則該 pool 內的 5 支檢體均須個別重新檢測，再依各檢體的檢驗結果核發報告。

Taiwan CDC accessed by 2021/10/06

快速核酸檢測工具

檢測工具	操作時間	一次可檢測的檢體量	說明
Xpert Xpress SARS-CoV-2 (Cepheid)	1 小時	1-4 tests	• 已有相當多的實證顯示檢驗效能與標準做法相當 • 很貴
ID NOW COVID-19 assay (Abbott)	15 分鐘	1 test	• 檢測速度非常快 • 無法提供Ct值 • 效能略低於標準做法，但仍算是相對可靠的診斷工具
Liat System (Roche)	20-30 分鐘	1 test	• 較新出來的工具 • 初步研究評估效能與Xpert類似 • 可同時檢測流行性感冒病毒

Rapid molecular assays 檢測效能

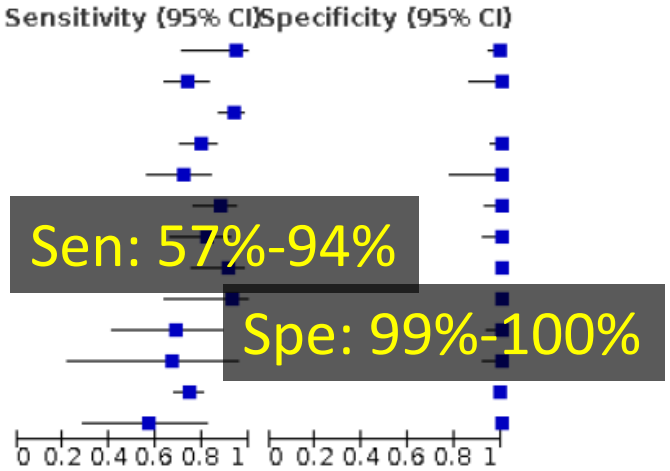
Cochrane Database Syst Rev. 2020 Aug 26;8(8):CD013705.

Figure 10. Forest plot by test brand for molecular assays. A&E: accident and emergency; IFU: instructions for use

Abbott - ID NOW (Isothermal PCR)

Study	TP	FP	FN	TN	IFU compliant	Sensitivity (95% CI)	Specificity (95% CI)
Ghofrani 2020	16	1	1	95	No	0.94 [0.71, 1.00]	0.99 [0.94, 1.00]
Smithgall 2020 [A]	65	0	23	25	No	0.74 [0.63, 0.83]	1.00 [0.86, 1.00]
Rhoads 2020	90	0	6	0	No	0.94 [0.87, 0.98]	Not estimable
Moore 2020	94	0	25	79	No	0.79 [0.71, 0.86]	1.00 [0.95, 1.00]
Mitchell 2020	33	0	13	15	No	0.72 [0.57, 0.84]	1.00 [0.78, 1.00]
Zhen 2020 [A]	50	0	7	50	No	0.88 [0.76, 0.95]	1.00 [0.93, 1.00]
SoRelle 2020	32	0	7	44	No	0.82 [0.66, 0.92]	1.00 [0.92, 1.00]
Cradic 2020(a)	30	0	3	151	No	0.91 [0.76, 0.98]	1.00 [0.98, 1.00]
Cradic 2020(b)	12	0	1	169	Unclear	0.92 [0.64, 1.00]	1.00 [0.98, 1.00]
Lephart 2020 [A]	11	0	5	59	Yes	0.69 [0.41, 0.89]	1.00 [0.94, 1.00]
Jin 2020	4	0	2	46	Yes	0.67 [0.22, 0.96]	1.00 [0.92, 1.00]
Harrington 2020	139	2	47	336	Yes	0.75 [0.68, 0.81]	0.99 [0.98, 1.00]
Thwe 2020	8	0	6	147	Yes	0.57 [0.29, 0.82]	1.00 [0.98, 1.00]

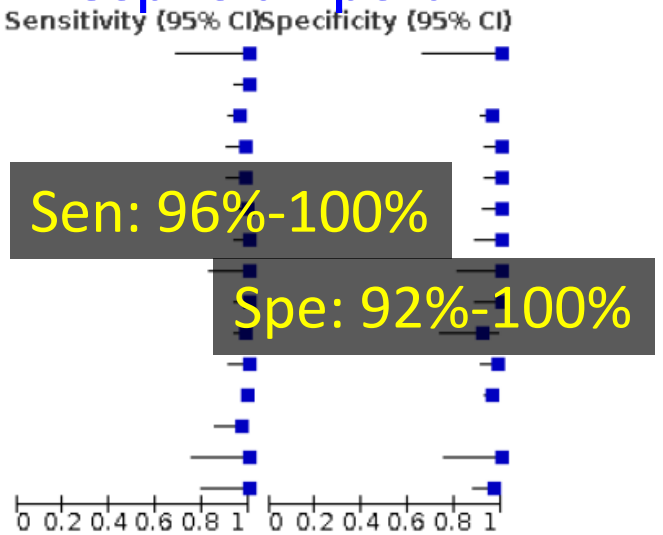
Abbott ID NOW



Cepheid - Xpert Xpress (Automated RT-PCR)

Study	TP	FP	FN	TN	IFU compliant	Sensitivity (95% CI)	Specificity (95% CI)
Goldenberger 2020	10	0	0	9	No	1.00 [0.69, 1.00]	1.00 [0.66, 1.00]
Chen 2020a	55	0	0	0	No	1.00 [0.94, 1.00]	Not estimable
Hou 2020	147	5	6	127	No	0.96 [0.92, 0.99]	0.96 [0.91, 0.99]
Stevens 2020	53	0	1	50	No	0.98 [0.90, 1.00]	1.00 [0.93, 1.00]
Zhen 2020 [B]	57	0	1	50	No	0.98 [0.91, 1.00]	1.00 [0.93, 1.00]
Wong 2020	118	0	1	43	No	0.99 [0.95, 1.00]	1.00 [0.92, 1.00]
Wolters 2020	58	0	0	30	No	1.00 [0.94, 1.00]	1.00 [0.88, 1.00]
Dust 2020	20	0	0	18	Unclear	1.00 [0.83, 1.00]	1.00 [0.81, 1.00]
Jokela 2020	60	0	0	30	Unclear	1.00 [0.94, 1.00]	1.00 [0.88, 1.00]
Smithgall 2020 [B]	87	2	1	23	Unclear	0.99 [0.94, 1.00]	0.92 [0.74, 0.99]
Moran 2020	42	1	0	60	Unclear	1.00 [0.92, 1.00]	0.98 [0.91, 1.00]
Loeffelholz 2020	219	11	1	250	Unclear	1.00 [0.97, 1.00]	0.96 [0.93, 0.98]
Broder 2020	34	0	1	0	Yes	0.97 [0.85, 1.00]	Not estimable
Lieberman 2020	13	0	0	13	Yes	1.00 [0.75, 1.00]	1.00 [0.75, 1.00]
Lephart 2020 [B]	16	2	0	56	Yes	1.00 [0.79, 1.00]	0.97 [0.88, 1.00]

Cepheid Xpert



The performance of the cobas® Liat® SARS-CoV-2 & Influenza A/B assay is equivalent to the cepheid® Xpress SARS-CoV-2 assay for SARS-CoV-2 detection.

FDA grants first emergency use ok for at-home COVID-19 test

Credit: Lucira Health

SARS-CoV-2 antigen-detecting rapid diagnostic tests

	Sample type	Time of sample collection*	Result reading	Sensitivity, specificity†	Comments
Abbott BinaxNOW, USA	Nasal swab	0–7 days	Visual, 15 min	97%, 99%	WHO Emergency Use Listing; US FDA Emergency Use Authorization; app for results; influenza A and B tests available
Abbott Panbio, USA	Nasal swab, nasopharyngeal swab	0–7 days	Visual, 15–20min	93%, 99%	WHO Emergency Use Listing; US FDA Emergency Use Authorization pending
Access Bio CareStart, USA	Nasal swab, nasopharyngeal swab	0–5 days	Visual, 15–20min	88%, 100%	US FDA Emergency Use Authorization
BD Veritor, USA	Nasal swab	0–5 days	Instrument, 30 min	84%, 100%	US FDA Emergency Use Authorization
LumiraDx, UK	Nasal swab	0–12 days	Instrument, 12 min	98%, 97%	US FDA Emergency Use Authorization
Quidel Sofia SARS Antigen Fluorescent Immunoassay, USA	Nasal swab, nasopharyngeal swab	0–5 days	Instrument, 20 min	97%, 100%	US FDA Emergency Use Authorization; does not differentiate between SARS-CoV and SARS-CoV-2
Quidel Sofia Flu and SARS Antigen Fluorescent Immunoassay, USA	Nasal swab, nasopharyngeal swab	0–5 days	Instrument, 20 min	95%, 100%	US FDA Emergency Use Authorization
SD Biosensor, South Korea	Nasal swab, nasopharyngeal swab	Not stated	Visual, 15–30min	97%, 100%	WHO Emergency Use Listing

Data from the Foundation for Innovative New Diagnostics.[2] SARS-CoV=severe acute respiratory syndrome coronavirus. FDA=Food and Drug Administration. *Days after symptom onset. †Data from manufacturers.

Rosanna W Peeling,et al. Lancet Infect Dis 2021

Rapid antigens performance with SARS-CoV-2 variants *in vitro* study

快速抗原檢驗
對變異株有效

Dilution in Saliva

Test	Virus Lineage	Dilution Levels (RNA copies/mL) [a]				
		1:10 (10^8/mL)	1:100 (10^7/mL)	1:1000 (10^6/mL)	1:10,000 (10^5/mL)	1:100,000 (10^4/mL)
Test I	B.1.1 (Non-VOC)	5	4	2	Neg.	Neg.
	B.1.1.7 (Alpha)	5	3	1	Neg.	Neg.
	B.1.351 (Beta)	5	4	2	Neg.	Neg.
	P.1 (Gamma)	5	3	1	Neg.	Neg.
	B.1.617.2 (Delta)	5	4	2	Neg.	Neg.
Test II	B.1.1 (Non-VOC)	5	4	2	1	Neg.
	B.1.1.7 (Alpha)	5	3	2	1 [b]	Neg.
	B.1.351 (Beta)	5	4	2	1	Neg.
	P.1 (Gamma)	5	3	1	Neg.	Neg.
	B.1.617.2 (Delta)	5	3	1	Neg.	Neg.
Test III	B.1.1 (Non-VOC)	5	3	2	Neg.	Neg.
	B.1.1.7 (Alpha)	5	3	1	Neg.	Neg.
	B.1.351 (Beta)	5	3	2	Neg.	Neg.
	P.1 (Gamma)	5	3	2	Neg.	Neg.
	B.1.617.2 (Delta)	5	2	1	Neg.	Neg.
Test IV	B.1.1 (Non-VOC)	5	4	3	1	Neg.
	B.1.1.7 (Alpha)	5	3	2	Neg.	Neg.
	B.1.351 (Beta)	5	4	2	1	Neg.
	P.1 (Gamma)	5	3	2	Neg.	Neg.
	B.1.617.2 (Delta)	5	4	2	Neg.	Neg.

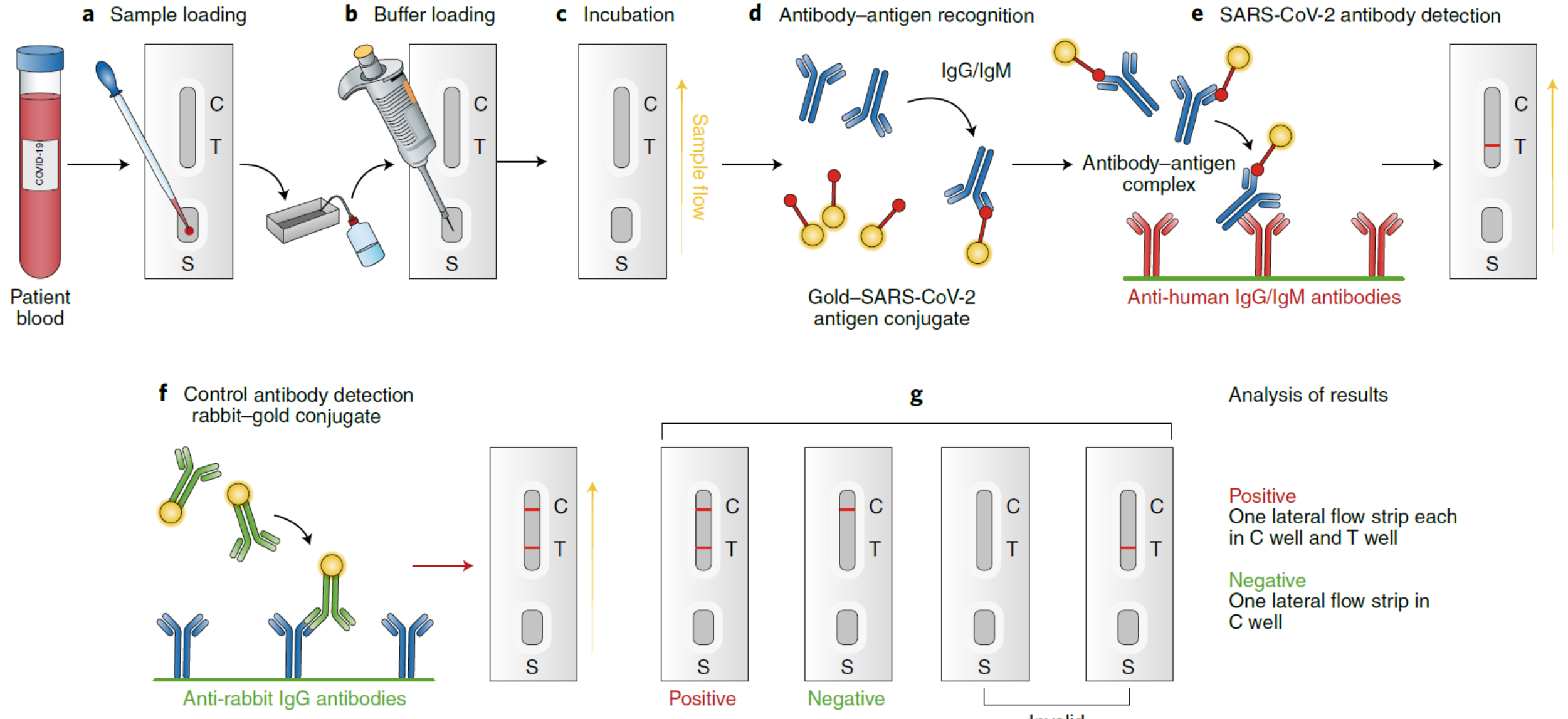
Sabrina Jungnick, et al. Microorganisms 2021

Detection of SARS-CoV-2 antibodies

- Multiple isotypes of antibodies, and the developed tests most commonly measure IgM and/or IgG
- As the antibody response requires time to develop, these tests are less useful for the diagnosis of an acute, active infection.
  - advantageous for documenting a previous infection
  - useful in epidemiological studies
- Combining real-time PCR and serological testing significantly increases positive viral detection rates

1. Hou, H. et al. *Clin. Transl. Immunol.* 2020.
2. Padoan, A. et al. *Clin. Chim. Acta* 2020
3. Long, Q. X. et al. *Nat. Med.* 2020
4. Weissleder, R., et al. Sci. Transl. Med. 2020

SARS-CoV-2 serological testing



Bhavesh D. Kevadiya, et al. Nature Materials 2021

Automated COVID-19 antibody test

FACT SHEET FOR HEALTHCARE PROVIDERS
Abbott Laboratories Inc. **March 1, 2021**
AdviseDx SARS-CoV-2 IgG II

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the AdviseDx SARS-CoV-2 IgG II.

You should not interpret the results of this test as an indication or degree of immunity or protection from infection.

This test detects human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus using only human serum (including collected using a serum separator tube) and plasma (acid citrate dextrose, sodium citrate, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin in a separator tube, and sodium

開放民眾自費進行COVID-19血清抗體檢驗及配套措施討論會議說明

發

中央流行疫情指揮中心今(23)日表示，因應民眾因求學、工作、出國及其他個人因素等，而有血清抗體檢驗需求，指揮中心醫療應變組議，邀集傳染病防治醫療網指揮官、臨床醫療及檢驗專家等進行專業溝通及討論，說明如下：

1.民眾如有血清抗體檢驗需求，將可至經各地方衛生局審核通過之提供自費COVID-19血清抗體檢驗服務之醫事機構進行檢驗。為使提供自費血清抗體檢驗服務醫事機構及民眾有所依循，指揮中心參考歐美等國際檢驗指引及建議，血清抗體檢驗主要適用時機為評估個人是否曾經遭受感染產生抗體。由於一般抗體檢測結果不完全等同於對COVID-19免疫力（或保護力）之高低或有無，醫事機構在接受民眾進行自費血清抗體檢驗前後，應詳細說明其檢測方式及結果代表之意義，以利正確解讀。

2.為防範疾病傳播風險及保障民眾健康，民眾於自費抗體檢驗前，需經醫師評估，如具發燒、呼吸道症狀、味覺嗅覺喪失、不明腹瀉等疑似COVID-19 症狀、TOCC風險或有疑慮者，應先進行核酸檢驗等措施。若無上述相關症狀或評估無疑慮者，由醫師開立檢驗處方執行自費抗體檢驗。

3.檢驗試劑以使用通過衛生福利部食品藥物管理署許可之SARS-CoV-2人類抗體檢測試劑抗體，並須於檢驗報告中載明檢驗抗原種類(如：S蛋白等)及抗體項目(如：IgG、Total Ig等)、使用之試劑廠牌及檢測方法(如：CLIA或ELISA)、檢驗結果(如檢測數值及判讀標準)等資訊。

4.自費檢驗收費標準，依據醫療法第21條規定：「醫療機構收取醫療費用之標準，由直轄市、縣(市)主管機關核定之」，及醫療法第22條第2項規定：「醫療機構不得違反收費標準，超額或擅立收費項目收費」。

指揮中心提醒，不論血清抗體檢驗結果為陽性或陰性，仍應遵守防疫新生活原則，維持社交距離、落實手部衛生、咳嗽禮節及佩戴口罩等個人防護措施等，以降低感染風險，確保自身健康。

網紅「四叉貓」自費驗疫苗抗體惹議，指揮中心：未開放一般人檢驗

文 / 中央社

2021-09-17　　瀏覽數 16,750+

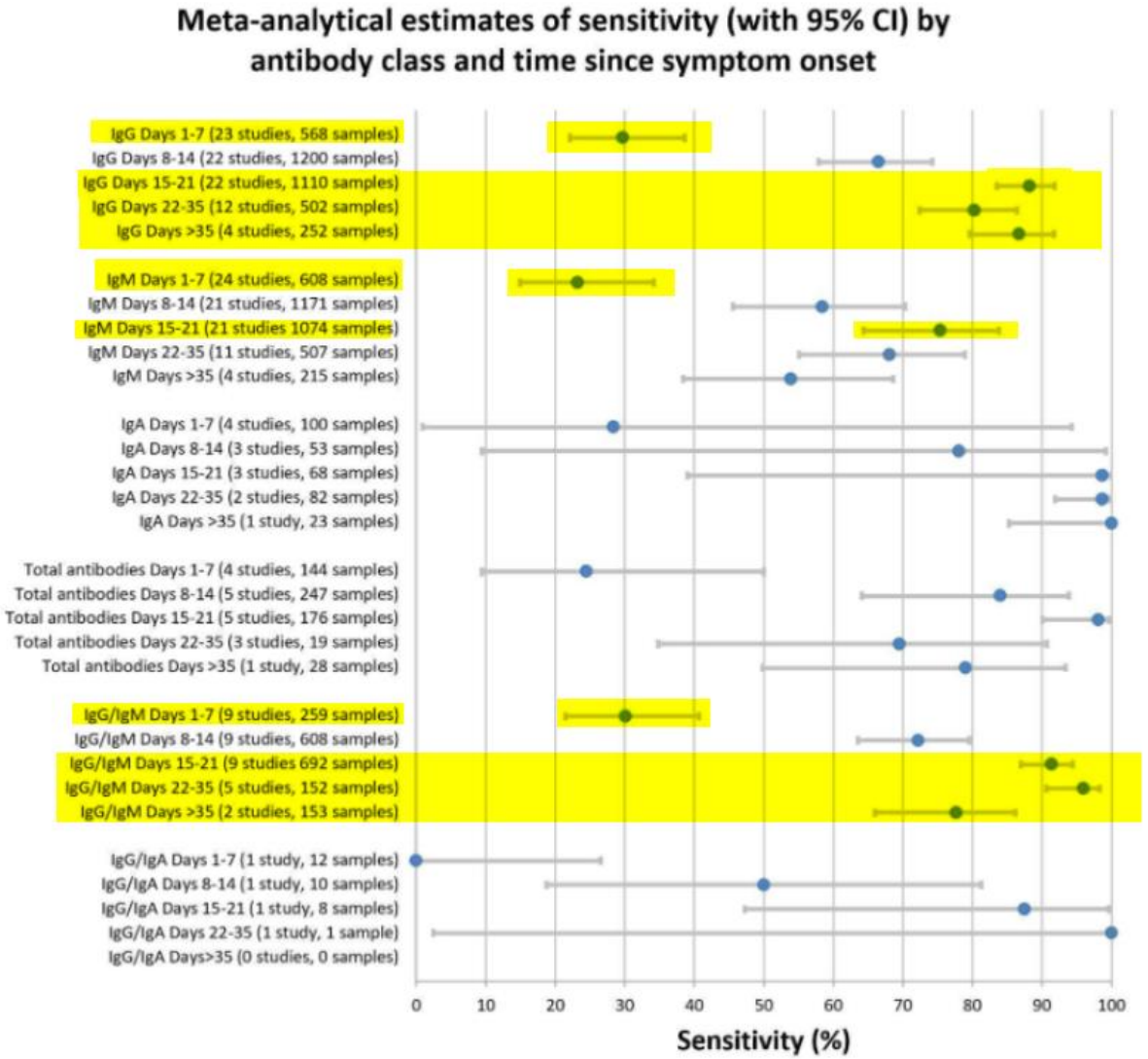
1. 一般自費抗體結果不完全等同疫苗保護力
2. 需報告須載明檢測標的(如: S蛋白)及抗體項目(如: IgG)
3. 自費收費標準依地方主管機管核定 (目前已開放公費，自費等待收費標準核定中)

Meta-analytical estimates of sensitivity (with 95% CI) by antibody class and time since onset of symptoms

Cochrane Database Syst Rev . 2020 Jun 25;6(6):CD013652.

- The sensitivity of antibody tests is too low in the first week since symptom onset.
- Antibody tests are likely to have a useful role for detecting previous SARS-CoV-2 infection if used 15 or more days after the onset of symptoms.

Figure 3. Meta-analytical estimates of sensitivity (with 95% CI) by antibody class and time since onset of symptoms



國內現有相關檢測試劑 – EUA 專案核准

- 醫療用核酸、抗原及抗體檢測試劑: 共180款 (110.10.28更新)
- 家用快篩試劑: 共19款 (110.07.01 更新)

Update date：110/10/28

專案輸入新冠病毒檢驗試劑相關產品資訊清單

The imported COVID-19 IVD granted emergency use authorization by Ministry of Health and Welfare (MOHW), Taiwan

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造廠名稱 Manufacturer	檢驗標的 Target
1	2020/3/30	SARS-COV-2 Antibody Test COVID-19 IgG/IgM Rapid Test	廣州萬孚生物技術有限公司 Guangzhou Wondfo Biotech Co., Ltd	抗體檢測 Antibody
2	2020/4/8	Xpert Xpress SARS-CoV-2 test	Cepheid Inc.	核酸檢測 Nucleic acid
3	2020/4/8	Abbott RealTime SARS-CoV-2 Amplification Reagent Kit Abbott RealTime SARS-CoV-2 Control Kit	Abbott Molecular Inc.	核酸檢測 Nucleic acid
4	2020/4/24	2019-nCoV Ab TEST CASSETEE	英諾特(唐山)生物技術有限公司 Innovita (Tangshan) Biological Technology Co. Ltd	抗體檢測 Antibody

Update date：110/10/28

專案製造新冠病毒檢驗試劑相關產品資訊清單

The domestic COVID-19 IVD granted emergency use authorization by Ministry of Health and Welfare (MOHW), Taiwan

序號 No.	核准日期 Approval date	試劑名稱 Commercial Name	製造商名稱 Manufacturer	檢驗類型 Target
1	2020/4/30	瑞基新型冠狀病毒 (orf 1ab)檢測試劑 POCKIT Central SARS-CoV-2 (orf 1ab) Premix Kit 瑞基自動化核酸分析儀 POCKIT Central Nucleic Acid Analyzer 瑞基萃取耗材組 POCKIT Central Cartridge Set (B) 瑞基新型冠狀病毒(orf 1ab)檢測試劑陽性對照組 POCKIT Central SARS-CoV-2 (orf 1ab) P(+) Control Reagent	瑞基海洋生物科技股份有限公司 GeneReach Biotechnology Corporation	核酸檢測 Nucleic acid
2	2020/5/11	列特博新型冠狀病毒 RNA 檢測試劑組 LabTurbo AIO COVID-19 RNA Testing Kit 列特博 AIO 核酸萃取試劑組 LabTurbo Viral DNA/RNA AIO extraction Kit	諾貝爾生物有限公司 Taigen Bioscience Corporation	核酸檢測 Nucleic acid

Summary

- No test is perfect when it comes to the attributes of accuracy, accessibility, affordability, and timeliness of results.
  - Probabilistic test interpretation is an important role in test interpretation
- The interpretation of a test for SARS-CoV-2 will depend on a combination of the accuracy of the test and the estimated risk of COVID-19 prior to performing the test
  - RT-PCR and rapid antigen detection tests are useful for diagnosis of acute SARS-CoV-2 infection.
  - Serological tests identify previous exposure to the virus

COVID-19檢測試劑怎麼分？

	核酸檢測	抗原檢測	抗體檢測
原理	偵測體內 病毒核酸片段	偵測體內 病毒抗原	偵測體內 病毒抗體
用途	疑似感染之 篩檢及確診	迅速找出疑 似陽性個案 阻斷感染源	了解是否過去曾 感染(但打疫苗後 也會檢測陽性)
使用時機	早期篩檢或 確診	大量快速 初步篩檢	疫情調查使用

我國目前核准抗體檢測類之新冠肺炎篩檢試劑皆為專供專業人士使用，民眾自行使用之安全、有效性皆未被驗證。

有關家用新冠肺炎快篩試劑相關資訊可至衛生福利部食品藥物管理署「家用快篩試劑專區」查詢。

家用快篩試劑專區

中央流行疫情指揮中心

2021.11.05