COVID-19社區化的診斷策略

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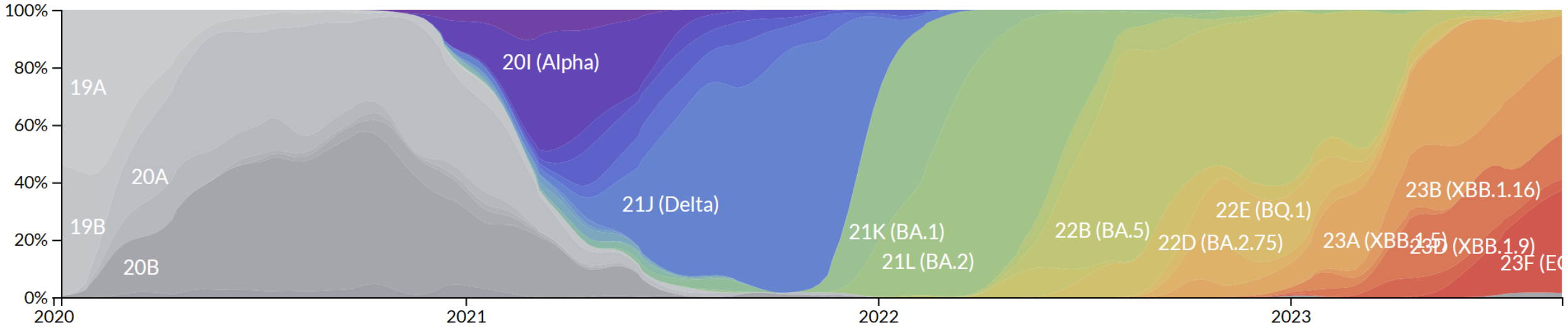
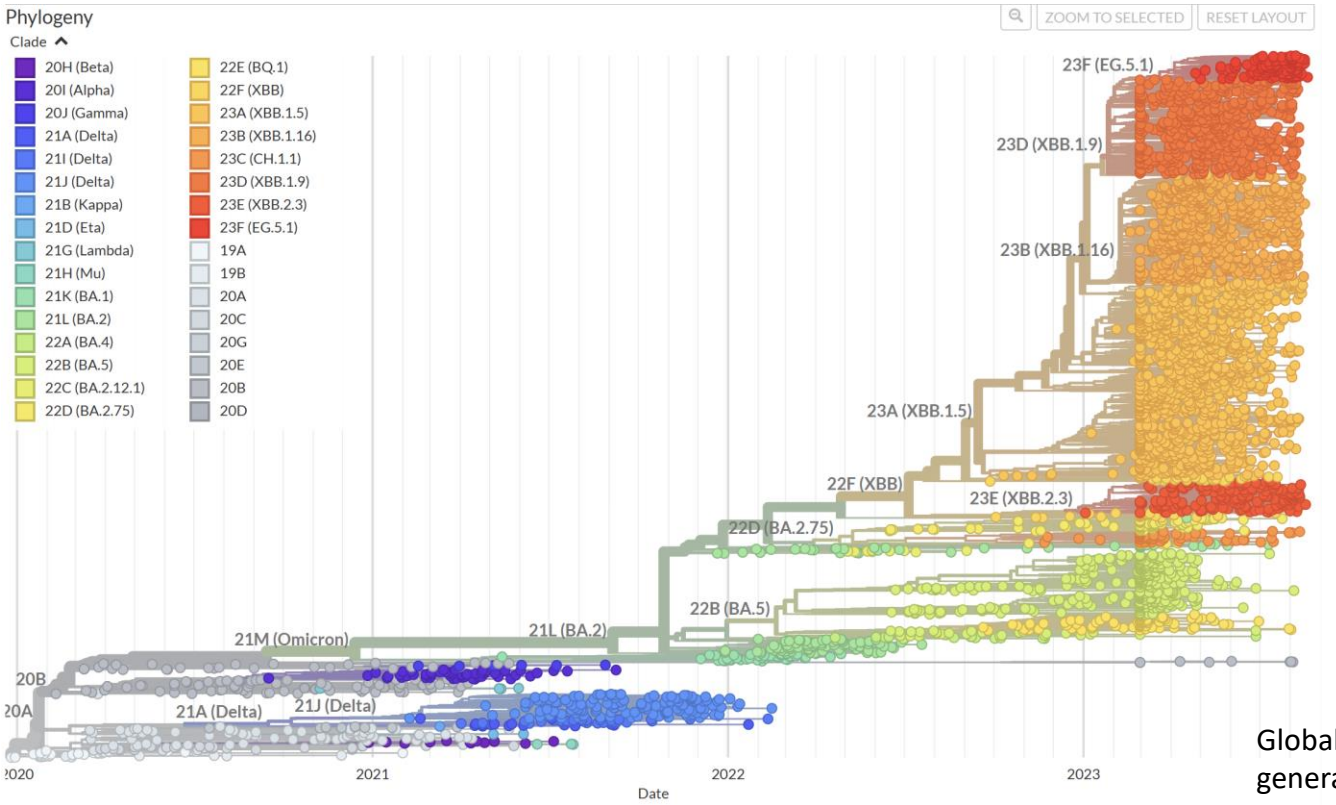
演講大綱

- 新冠流行現狀與檢驗考量
- 核酸檢測及抗原快篩
- **Omicron**變異株對檢驗的影響
- 醫療機構篩檢策略
- 呼吸道病毒檢測及監測計畫

Frequencies (colored by Clade)





Globally representative genome samples of SARS-CoV-2 between Dec 2019 and Aug 2023 generated by nextstrain.org accessed by 30 Aug 2023

3/20起

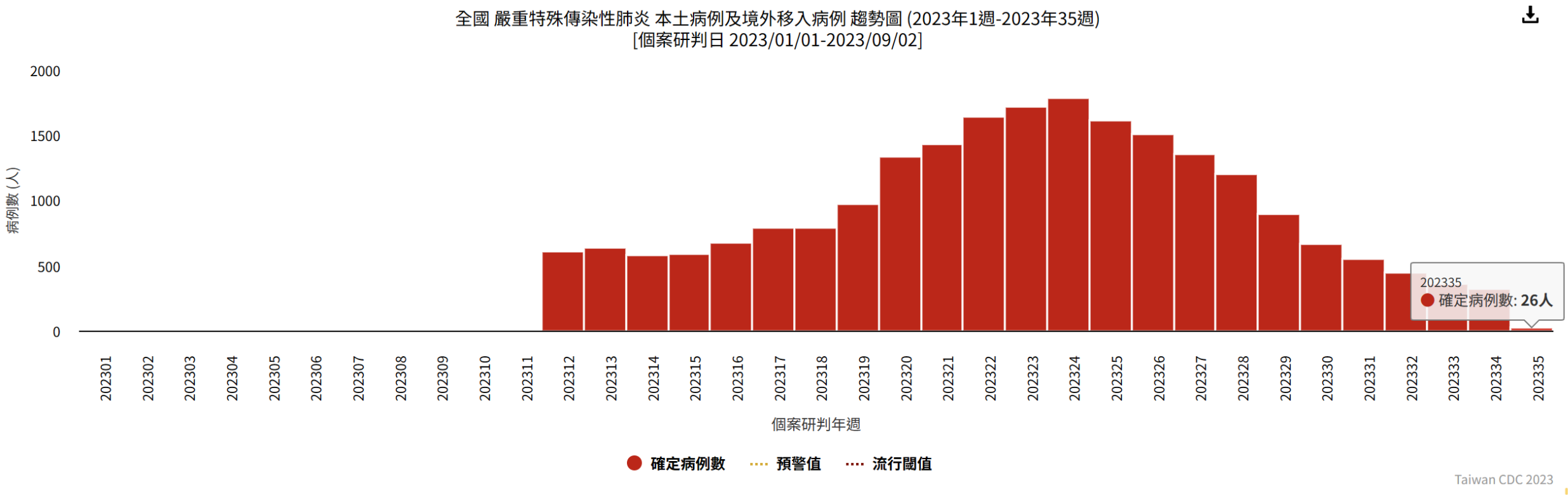
嚴重特殊傳染性肺炎病例定義調整

通報項目	嚴重特殊傳染性肺炎
臨床條件	發燒（≧ 38°C）或有呼吸道症狀後14 日（含）內，出現肺炎需氧氣治療或其他併發症，因而住院（含急診待床）或死亡者
檢驗條件	具有下列任一個條件： 一.臨床檢體（如鼻咽或咽喉擦拭液、痰液或下呼吸道抽取液等）分離並鑑定出新型冠狀病毒 二.臨床檢體新型冠狀病毒分子生物學核酸檢測陽性 三.臨床檢體新型冠狀病毒抗原檢測陽性（醫事人員執行抗原快篩） (刪除家用快篩及家用PCR陽性)
通報定義	符合臨床條件及檢驗條件
疾病分類	確定病例:符合臨床條件及檢驗條件

- 新制實施日後7天，爲新舊定義切換之緩衝期，相關資訊系統仍提供舊制期間確診之民衆補上傳自主疫調及醫療院所補通報，以維護於舊制期間確診之民衆權益。3/20~3/26新舊病例定義切換緩衝期，醫療院所可補通報舊制期間確診民眾

台灣嚴重特殊傳染性肺炎趨勢

趨勢圖 | 地理分佈 | 圖表 | 同期比較 | 境外移入 | 疾病小百科



傳染病統計資料查詢系統 (cdc.gov.tw) accessed on 29 Aug 2023

8/15起 0+n自主健康管理調整為5*天

對象

- 未符合COVID-19病例定義(併發症)之SARS-CoV-2篩檢陽性輕症或無症狀民眾
- 距離發病日未滿5天但已完成治療之確診(併發症)者

建議遵守事項

- 具重症風險因子者(65歲以上長者、孕產婦、具慢性病或免疫不全/免疫低下病史者等)於快篩陽性後儘速就醫，以利及時開立口服抗病毒藥物
- 有症狀時，建議在家中休息，並儘量避免非必要的外出；外出時請全程佩戴口罩
- 出現警示症狀，儘速撥打119、或由同住親友接送或自行前往等方式就醫

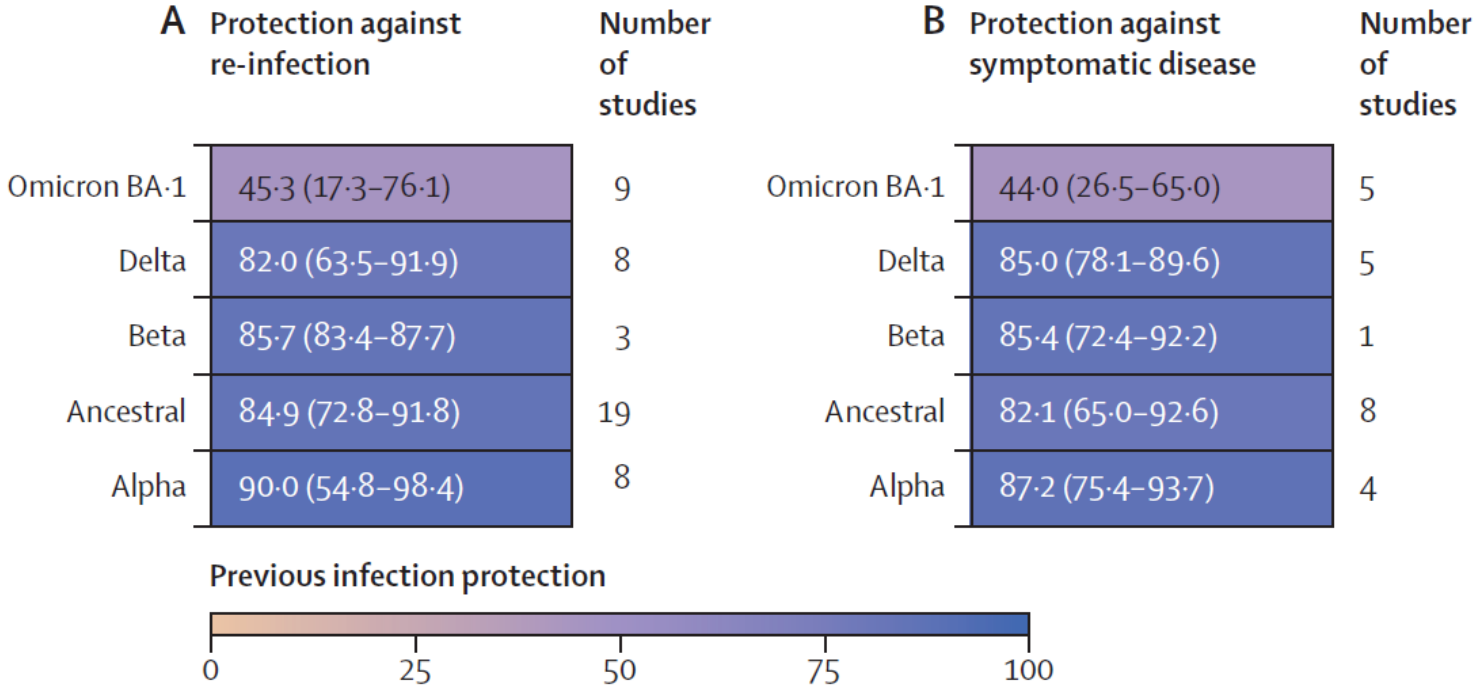
其他建議遵守事項

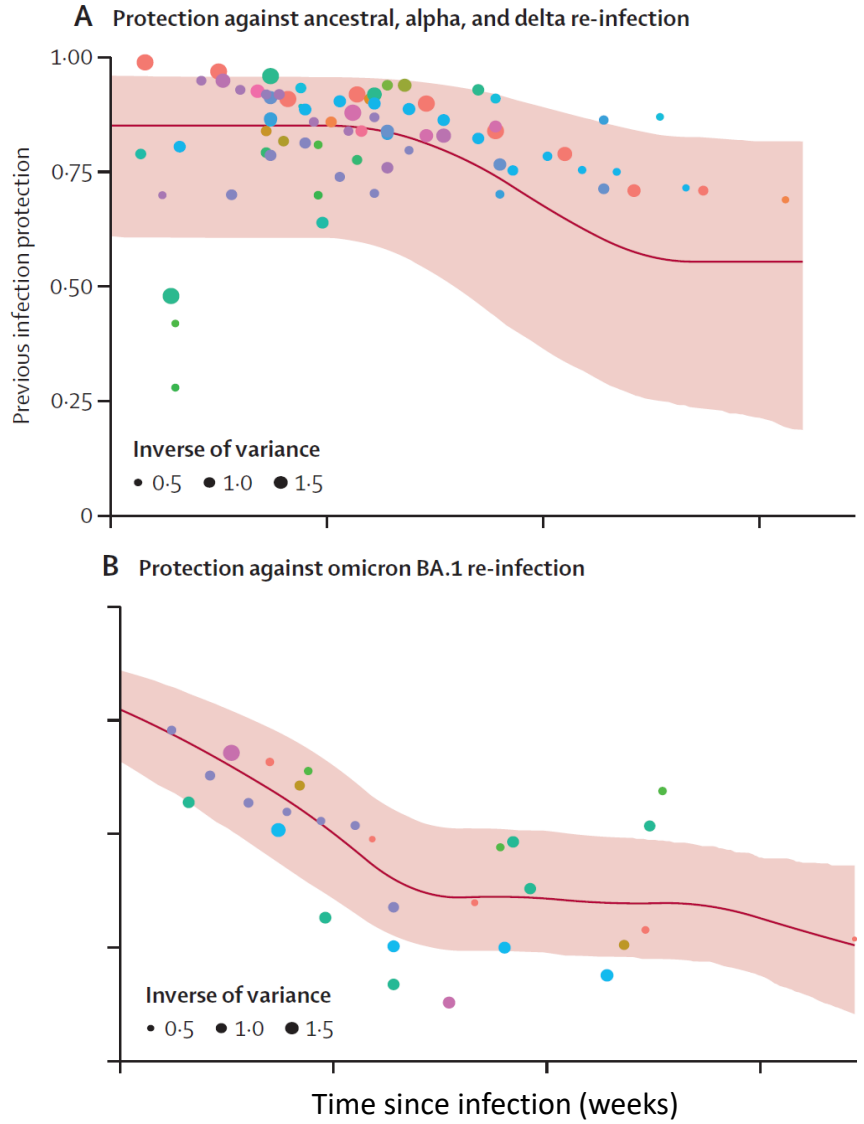
- 如須前往醫療院所，請遵守公布之醫療應變措施
- 同戶同住者日常生活請採取適當防護，並避免與篩檢陽性者共食

＊ 自發病日或採檢日(無症狀者適用)起，進行自主健康管理至自行呼吸道檢體快篩檢測陰性或距發病日或採檢陽性日已達5天(無需採檢)。

2023/08/01 衛生福利部疾病管制署

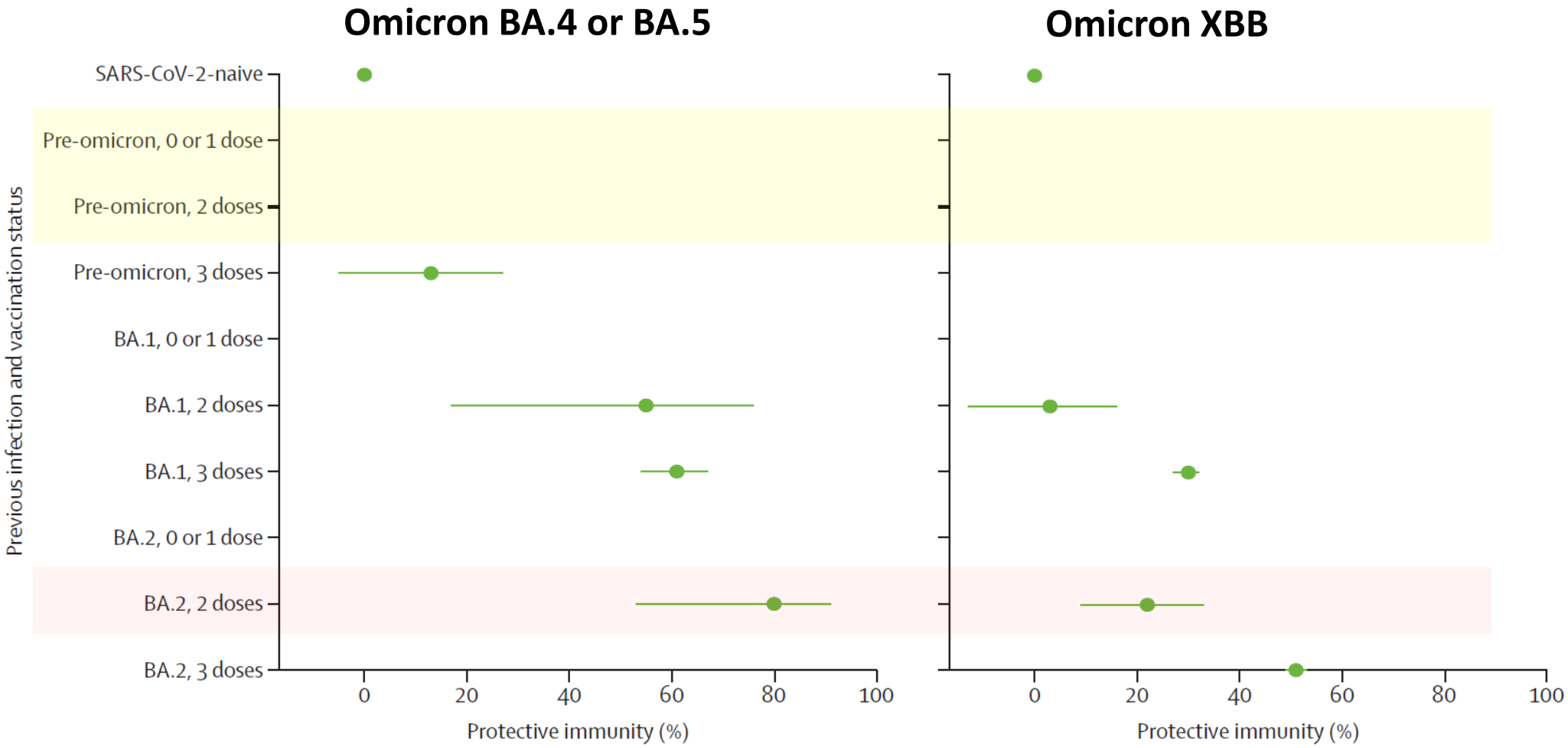
過去感染新型冠狀病毒對於再次感染的保護力分析：
a systematic review and meta-analysis: global protection by variant





COVID-19 Forecasting Team, Lancet 2023

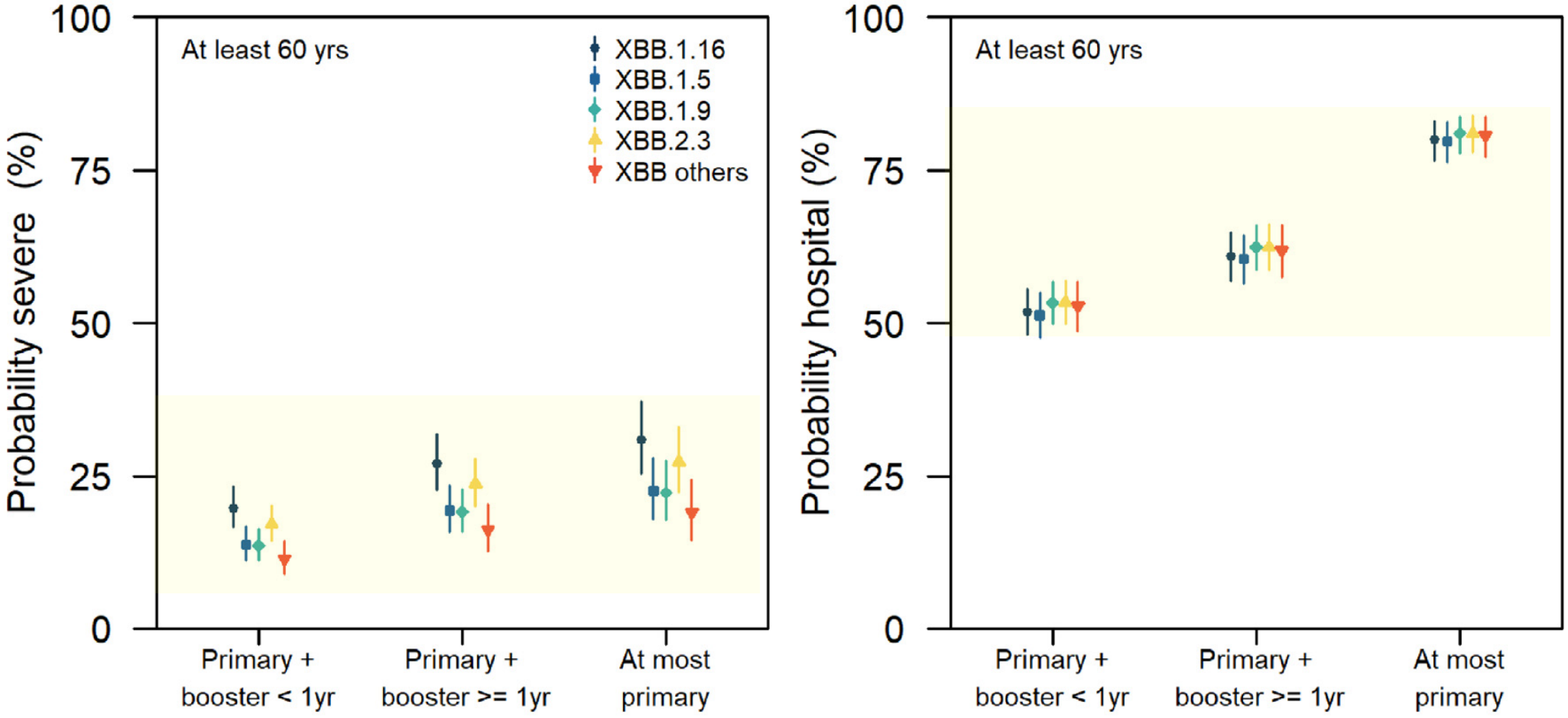
過去感染Omicron病毒及施打疫苗對於XBB變異株的保護力較BA.4或BA.5差



Celine Y Tan, et al. Lancet Infect Dis 2023

年紀大的族群仍需小心!!

Severity of SARS-CoV-2 Omicron XBB subvariants in Singapore

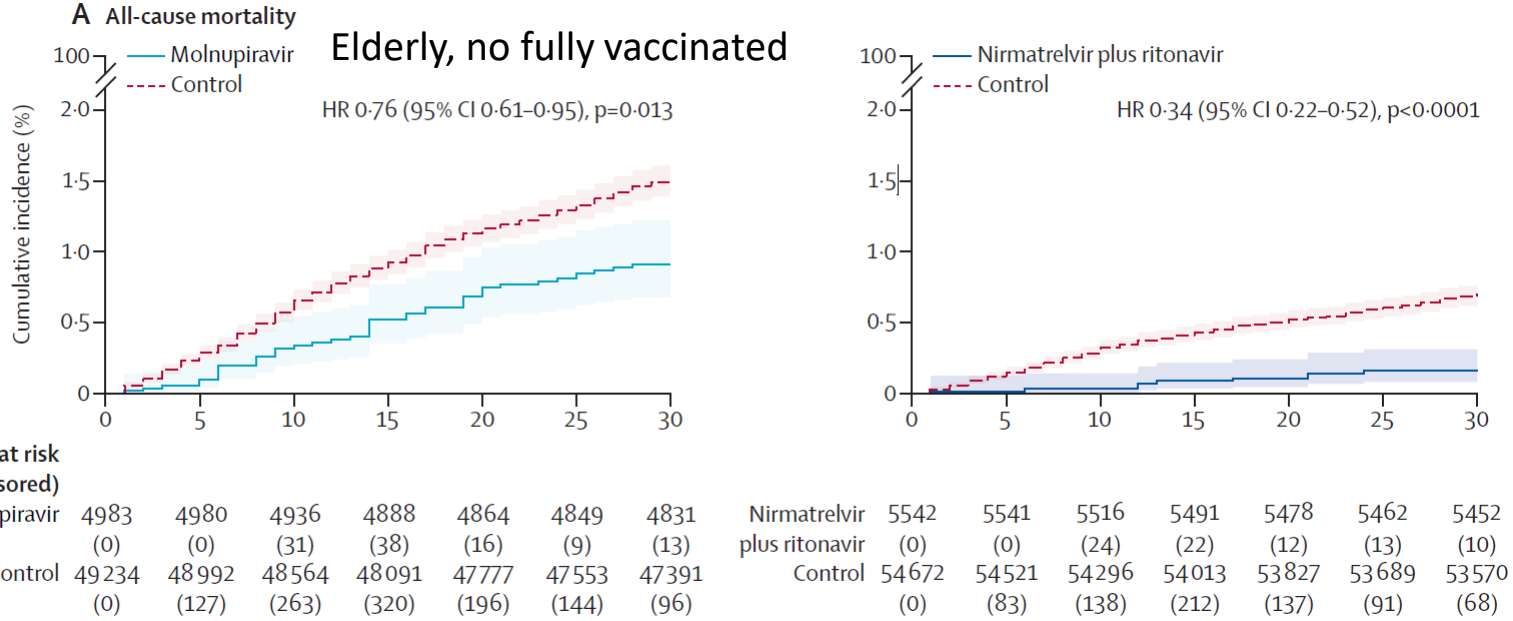


Rachael Pung, et al. The Lancet Regional Health -Western Pacific 2023

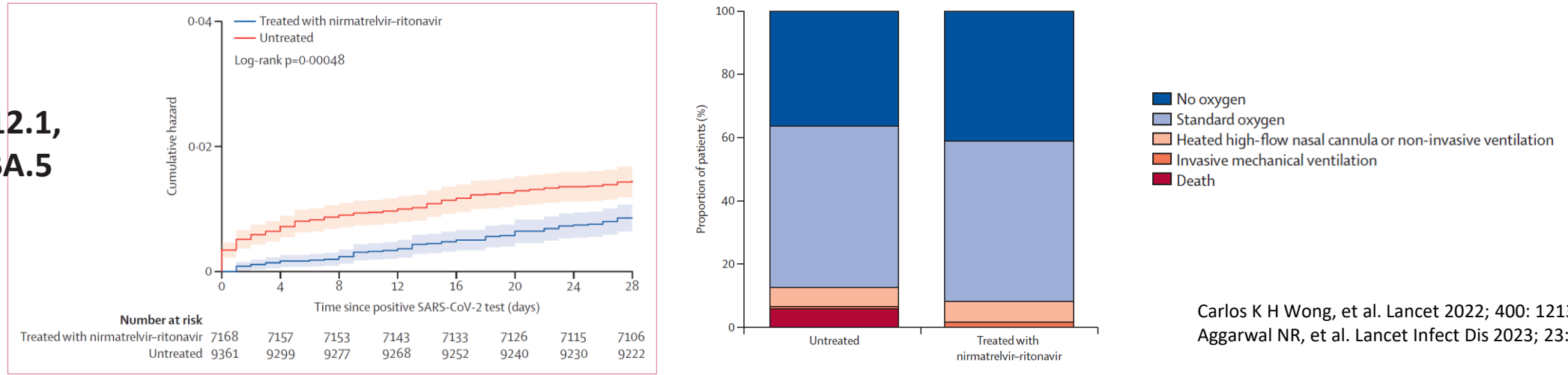
即時檢驗的好處：提供適當的治療，改善預後

During Omicron subvariants surge, anti-viral agents reduced disease severity

BA.2.2



BA.2, BA2.12.1, BA.4, and BA.5



Carlos K H Wong, et al. Lancet 2022; 400: 1213–22
Aggarwal NR, et al. Lancet Infect Dis 2023; 23: 696–705

即時檢驗的好處：提供適當的治療，改善預後

During Omicron BA.2/4/5/XBB surge, anti-viral agents still reduced disease severity

- **Aged ≥ 60 years**. Almost 95% received ≥ 3 doses of mRNA vaccines; 5.4 % had preceding infection. Overall 26.5% of infections occurred during the Omicron XBB period

Clinical characteristics, infection-related parameters and receipt of nirmatrelvir-ritonavir	Category	Hospitalisation, adjusted odds-ratio, 95%CI[†]	Severe COVID-19, adjusted odds-ratio, 95%CI[†]
Treatment	Control (untreated)	1.00	1.00
	Received nirmatrelvir-ritonavir	0.65(0.50,0.85) **NNT=3**	0.86(0.48,1.55) **NNT=7**
Reinfection	Not reinfected	1.00	1.00
	Reinfected	0.62(0.51,0.75)	0.35(0.20,0.59)
Vaccination status[‡]	Unvaccinated/partially vaccinated	1.00	1.00
	Fully vaccinated	0.43(0.34,0.55)	0.34(0.22,0.53)
	Boosted	0.23(0.18,0.28)	0.15(0.10,0.22)
	Doubly boosted	0.13(0.11,0.16)	0.06(0.04,0.09)

Wee LE, et al. Clin Microbiol Infect. 2023

新型冠狀病毒檢驗的時機

診斷 (diagnosis)

確認目前是否感染，用於有COVID-19感染症狀或無症狀但是高度懷疑或接觸COVID-19確診的人

篩檢 (screening)

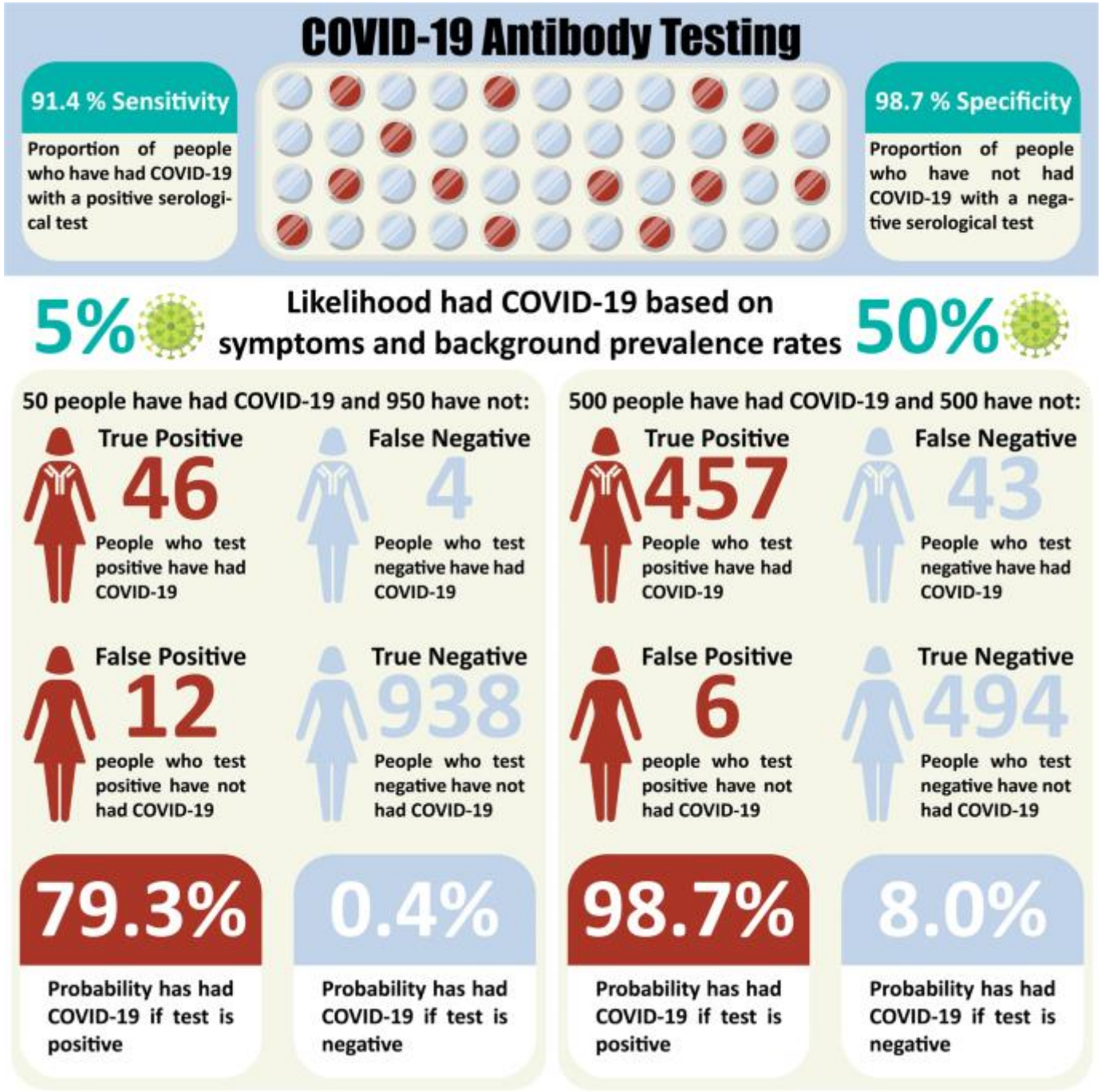
無症狀但是懷疑或不確定、接觸COVID-19確診的人

公衛監測需求(Public health surveillance)

監測群體COVID-19感染的狀況、盛行率等，由於監測的指標為群體，因此多半已去識別化的方式進行，例如基因型監測或廢水監測

症狀導向篩檢策略

- 有症狀表示檢驗前機率高
- 無症狀表示檢驗前機率低
  - 謹慎進行無症狀篩檢!



Journal of Assisted Reproduction and Genetics (2021) 38:539–541

新冠病毒感染症狀的轉變

World Health Organization list of covid-19 symptoms

Common

- Fever
- Cough
- Tiredness
- Loss of taste or smell

目前發生比例較低

Less common

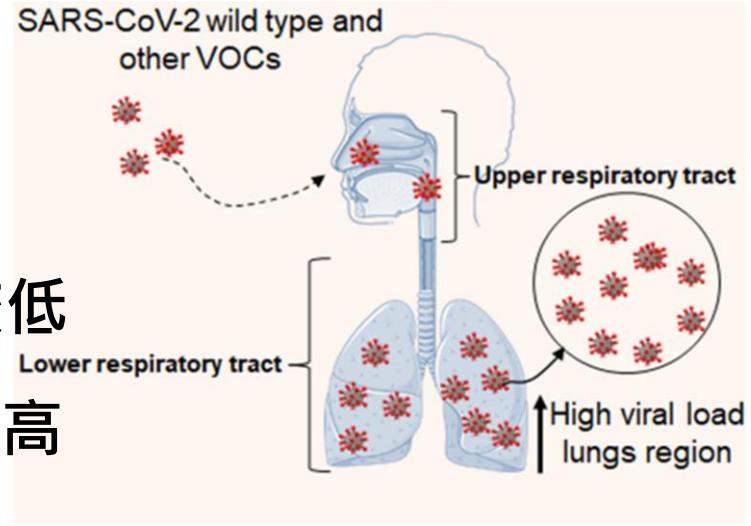
- Sore throat

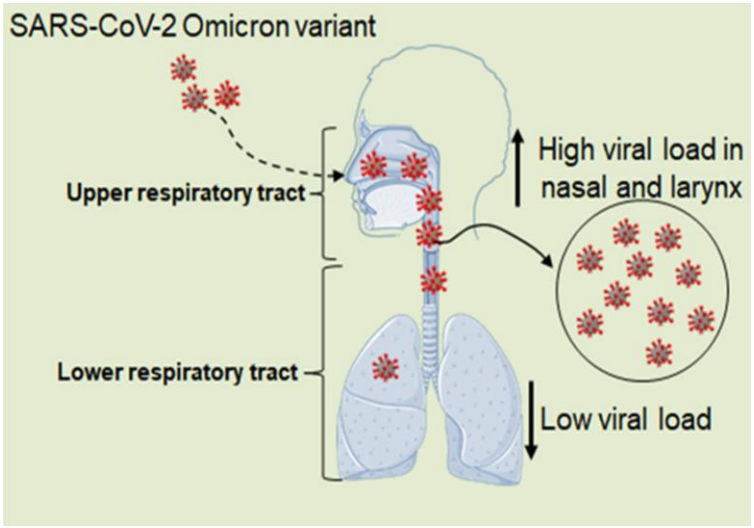
目前發生比例較高

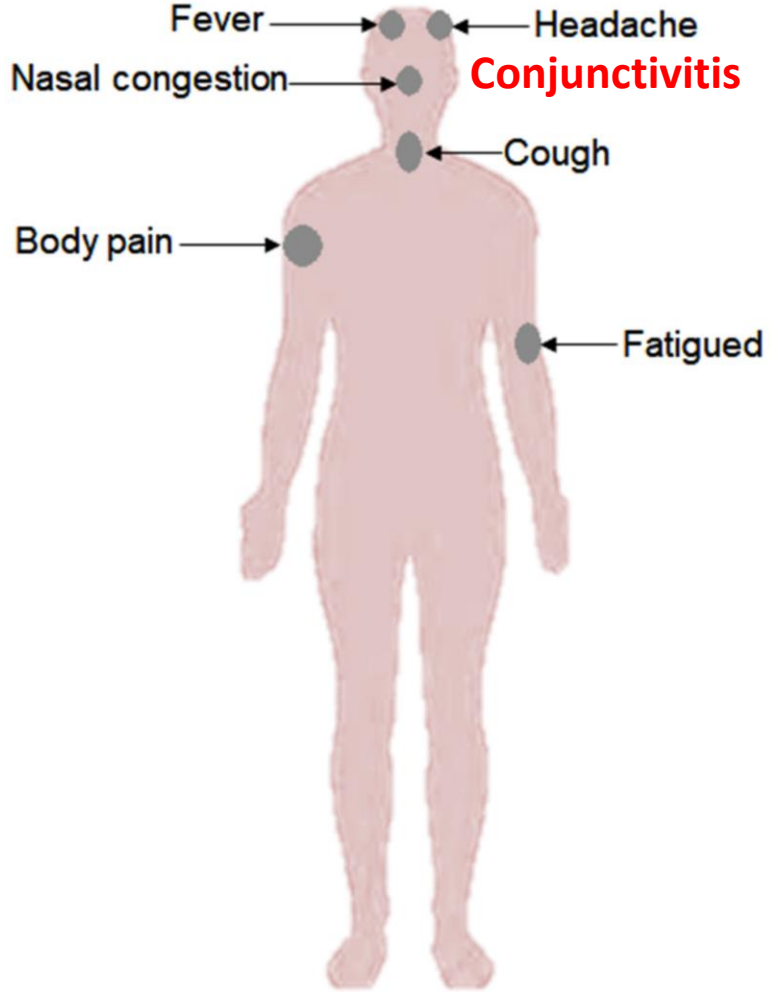
- Headache
- Aches and pains
- Diarrhoea
- Rash on skin or discoloration of fingers or toes
- Red or irritated eyes

Most serious

- Chest pains
- Confusion
- Loss of speech or mobility
- Difficulty breathing[1]



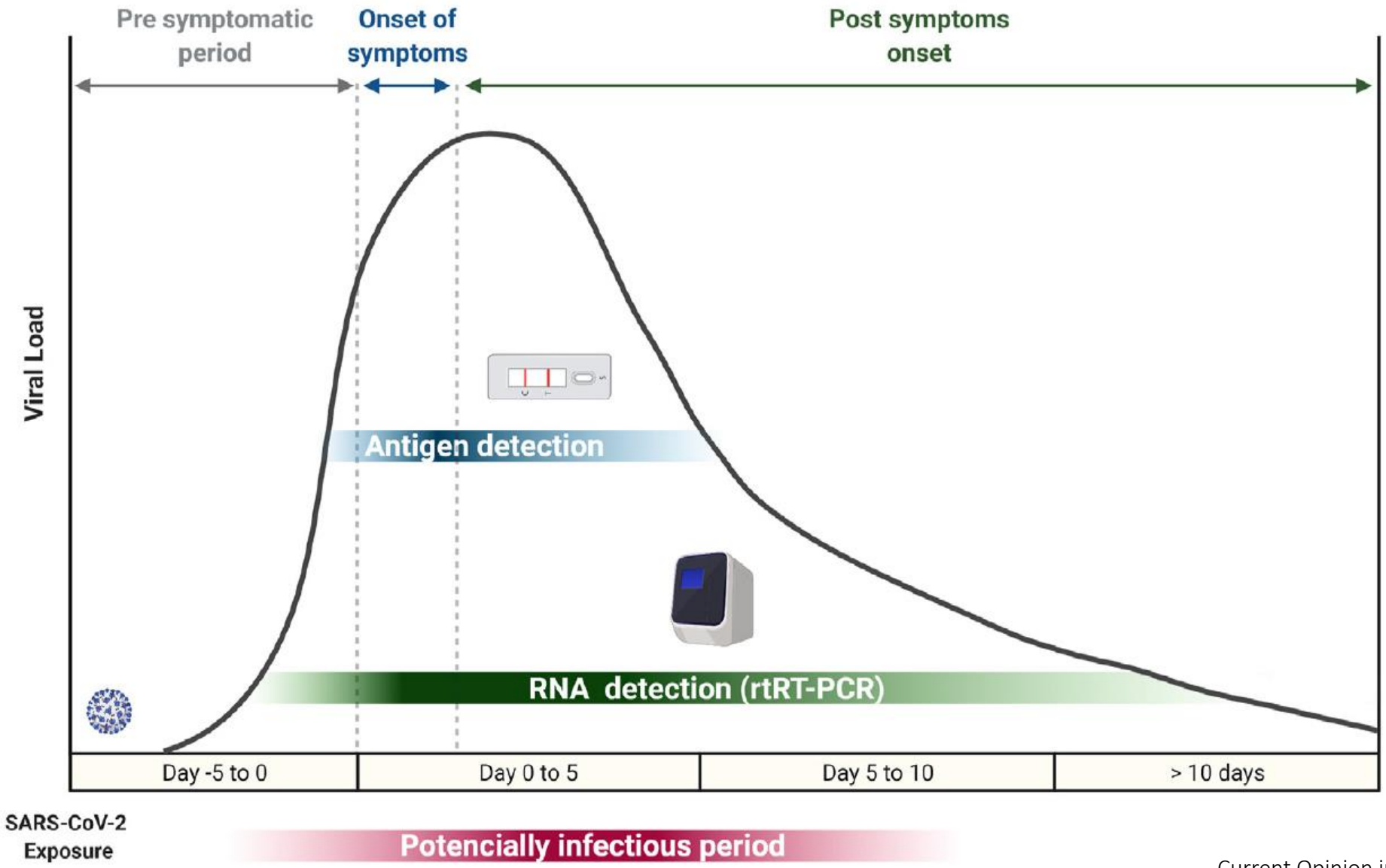




General symptoms of Omicron variant

1. BMJ 2023;380:p3 2. Srijan Chatterjee, et al. Virus 2023 3. Karina-Doris Vihta KD, Clin Infec Dis 2023

診斷工具 PCR vs. Rapid Antigen Test



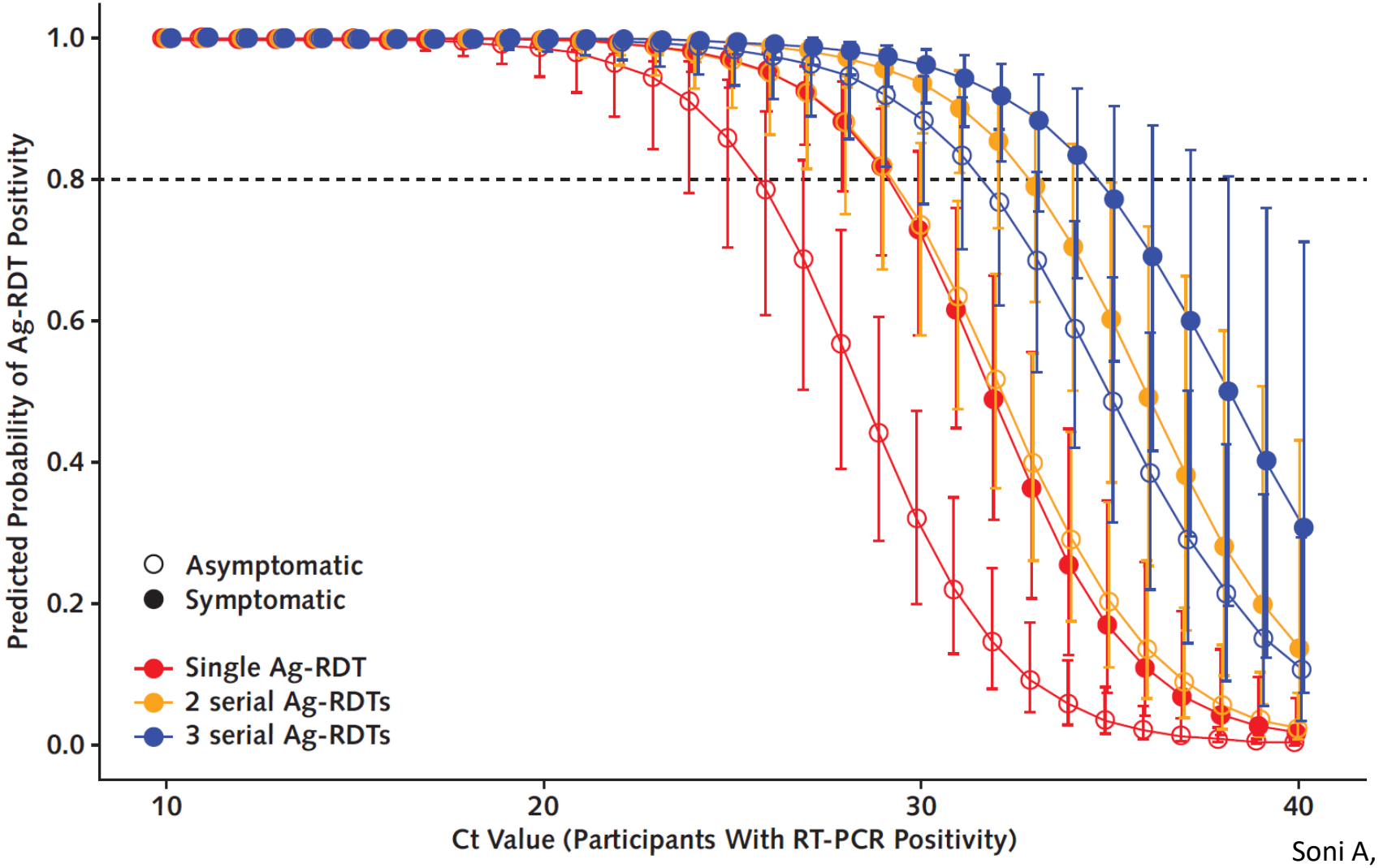
Current Opinion in Pharmacology 2022, 62:152–158

核酸及抗原檢測的比較

	原理	優點	缺點
核酸檢測	偵測病毒的核酸片段(黃金準則)	• 高敏感性及特異性的檢驗方法 • 再感染或復發的評估工具	• 技術門檻高 • 需要特定的設備及實驗室要求 • 檢驗時間較久
抗原檢測	偵測病毒抗原	• 快速提供結果 • 便宜 • 不一定需要專門的技術人員執行	• 敏感性較核酸檢驗差 • 檢驗品質不易掌握(尤其家用快篩)

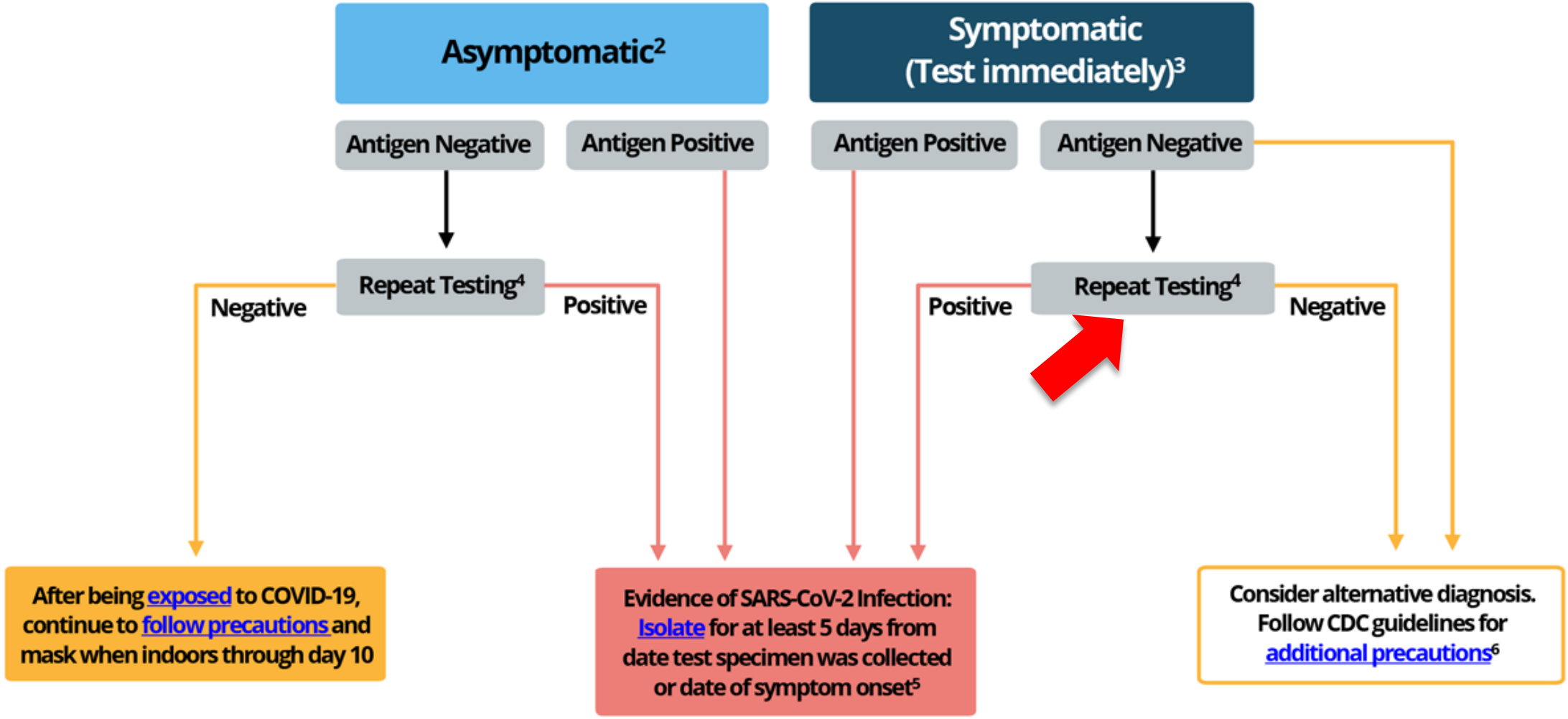
重複採檢及症狀與否影響抗原快篩檢驗準確度

Predicted probability of Ag-RDT positivity: symptom status and serial testing



Soni A, et al. Ann Intern Med. 2023.

Recommendations to Healthcare Providers on Interpreting Antigen Test Results for Diagnostic Purposes



https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

The New Normal: Delayed Peak SARS-CoV-2 Viral Loads Relative to Symptom Onset and Implications for COVID-19 Testing Programs

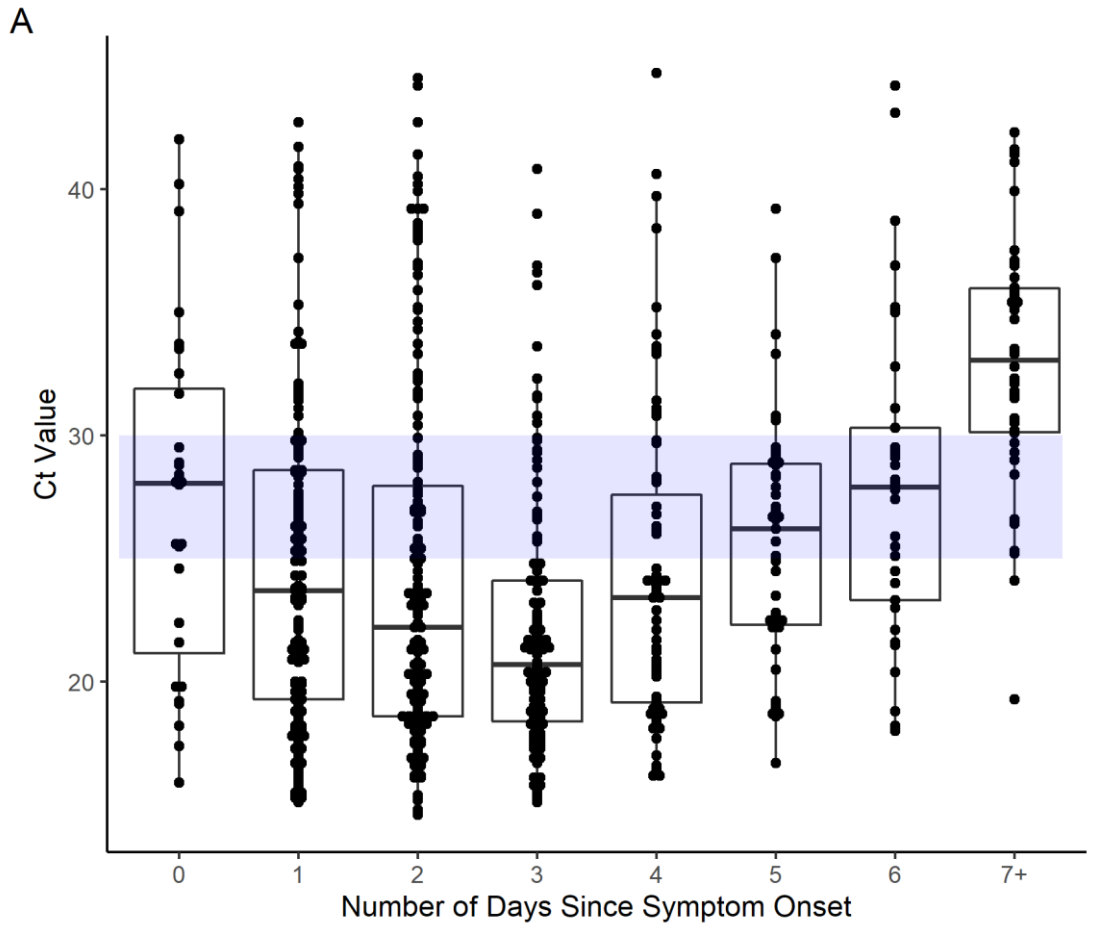


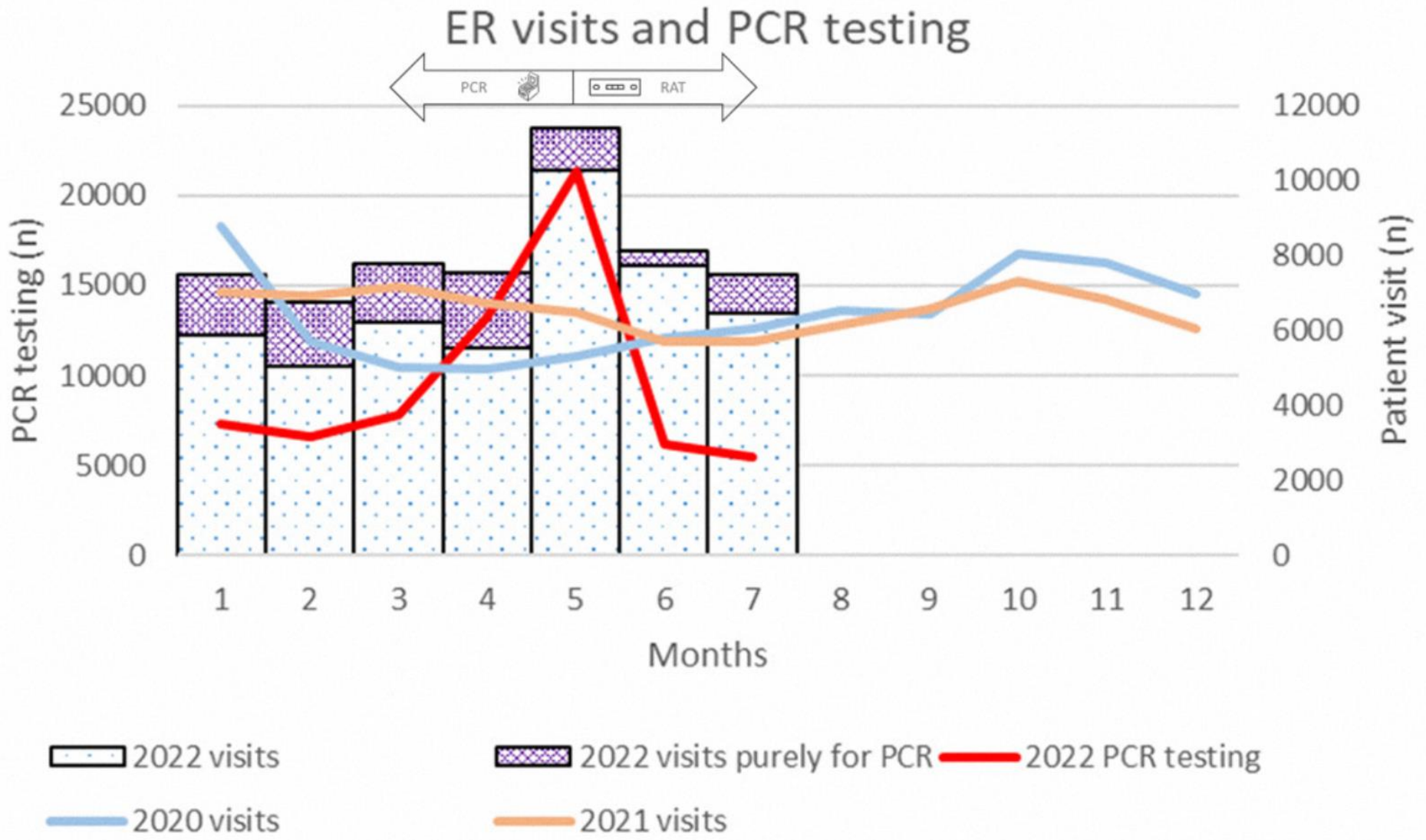
Table 1. SARS-CoV-2 Cycle Threshold (Ct) values, number/percent of samples with Ct values no more than Ct 25 or Ct 30, and nucleoprotein antigen concentrations, grouped by days since symptom onset.

Days Since Symptom Onset	Ct, median (IQR)	Ct ≤ 25, n (%)	Ct ≤ 30, n (%)	Ag conc (pg/mL), median (IQR), n
0, n=28	28.0 (21.2-31.9)	10 (35.7)	20 (71.4)	10.4 (0.5-199.4), n=20
1, n=136	23.7 (19.3-28.6)	76 (55.9)	113 (83.1)	48.1 (3.4-1407.9), n=106
2, n=155	22.2 (18.6-28.0)	99 (63.9)	122 (78.7)	298.1 (5.6-4121.6), n=111
3, n=117	20.7 (18.4-24.1)	92 (78.6)	106 (90.6)	714.2 (138.1-5939.2), n=87
4, n=67	23.4 (19.1-27.6)	45 (67.2)	54 (80.6)	251.8 (25.9-4509.0), n=48
5, n=43	26.2 (22.3-28.9)	19 (44.2)	37 (86.0)	26.5 (3.9-1205.5), n=31
6, n=33	27.9 (23.3-30.3)	11 (33.3)	24 (72.7)	24.8 (1.6-302.0), n=27
0-6, n=579	23.1 (19.1-28.4)	352 (60.8)	476 (82.2)	156.7 (6.7-2890.1), n=430
7+, n=42	33.0 (30.1-36.0)	2 (4.8)	10 (23.8)	1.1 (0.2-19.1), n=28

Ct, cycle threshold; IQR, interquartile range; Ag, antigen; Conc, concentration

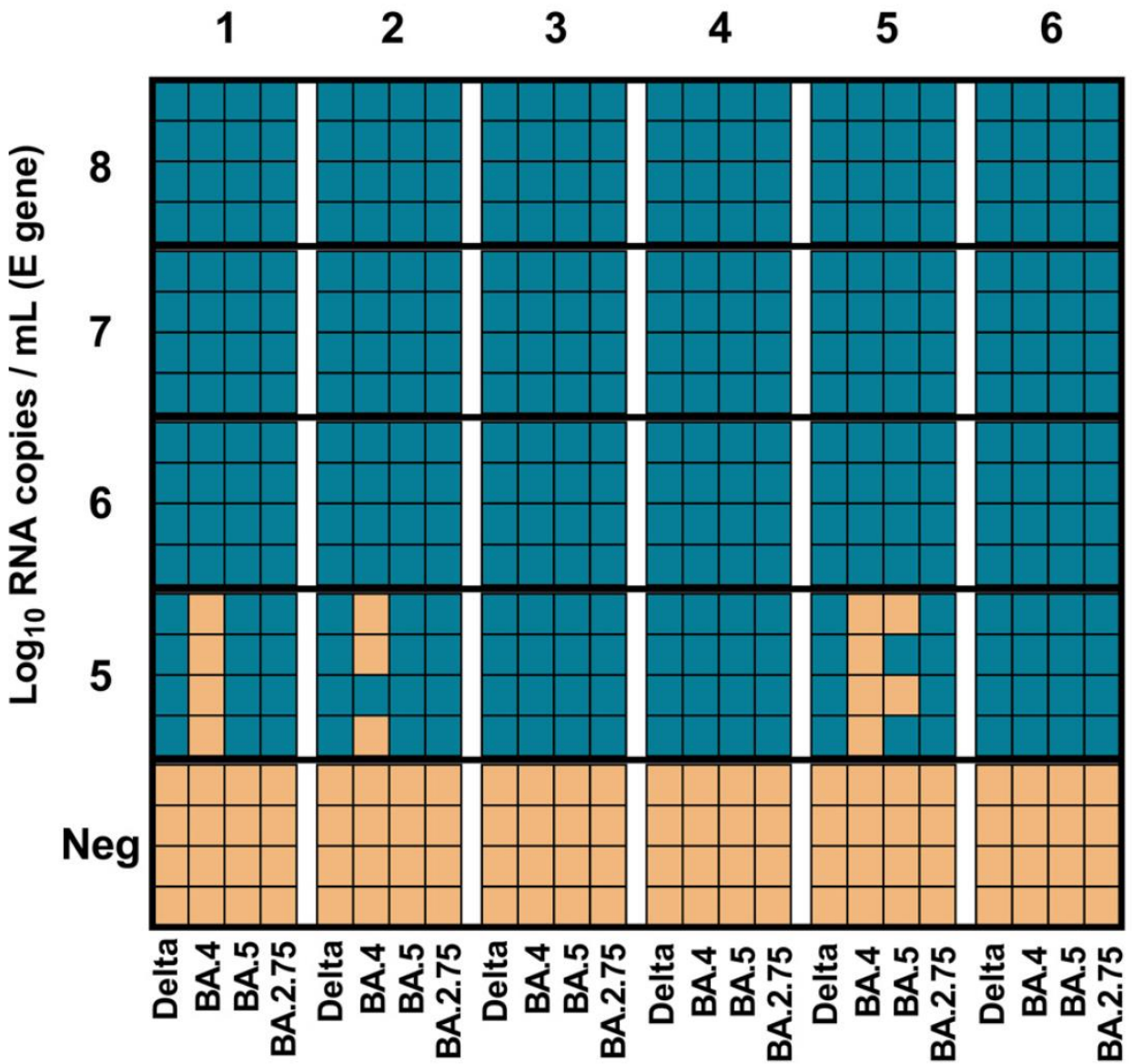
Frediani JK, et al. medRxiv. 2023 May 10:2023.05.09.23289735

台灣PCR政策調整後，舒緩醫療量能



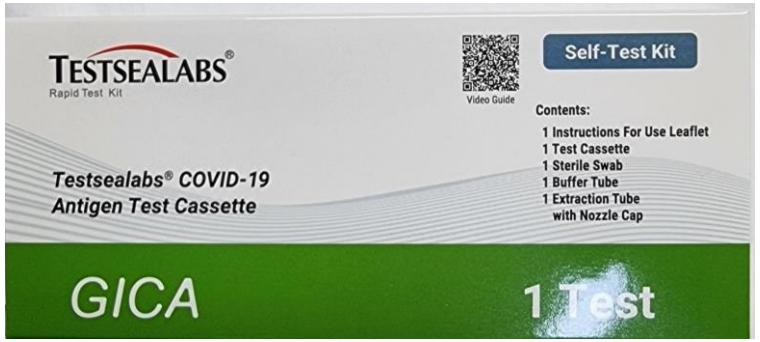
Hsin Chi, et al. Front Public Health. 2023

Assigned lateral flow antigen test kit



	Ct (N gene)			
	Delta	BA.4	BA.5	BA.2.75
8	18.7	19.7	18.3	19.4
7	22.0	22.0	22.0	22.2
6	25.3	25.7	25.0	25.9
5	29.0	29.0	28.7	29.3

Detected
Not Detected



Mackenzie C, et al. J Clin Microbiol. 2022

英國大規模新冠病毒快篩及PCR檢測的一致性比較
through the Alpha-, Delta- and Omicron-dominant waves

- Nov 4, 2020, and March 21, 2022
- assessed 75,382 pairs of LFD and RT-PCR tests

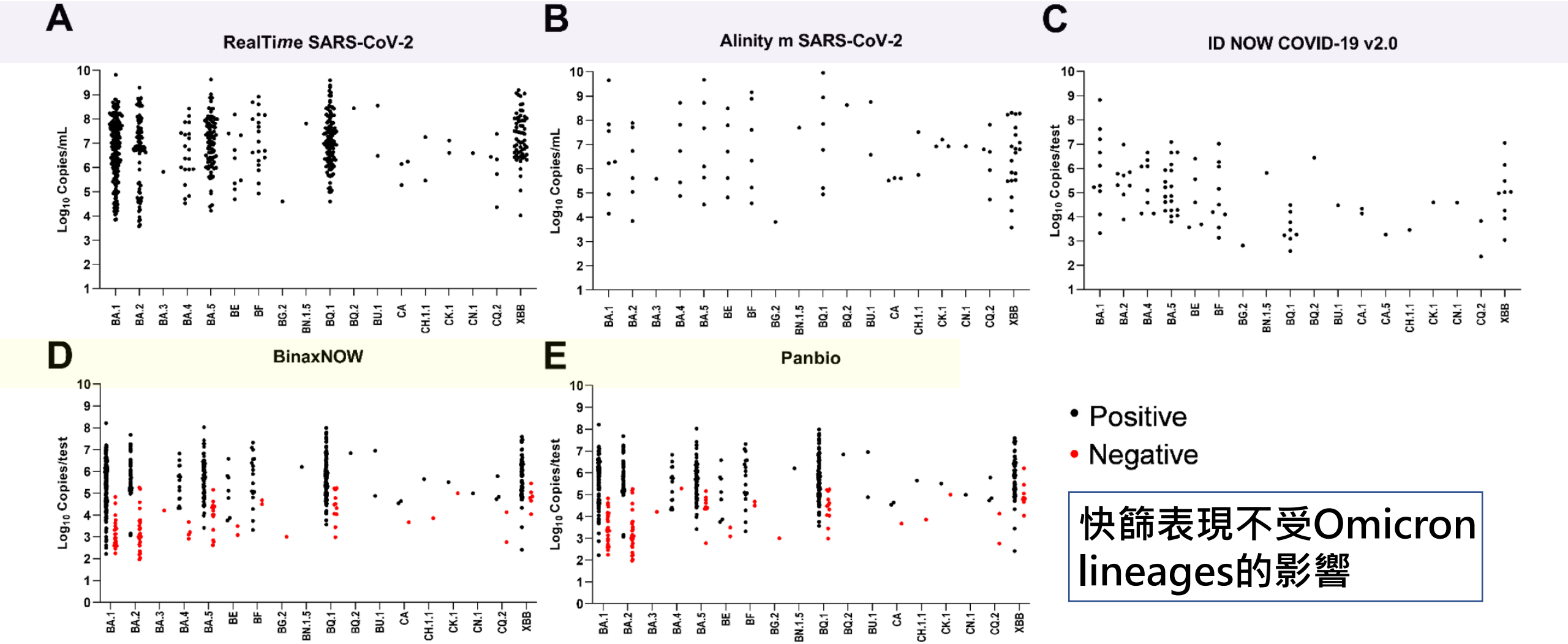
	Index case symptom status	Number of index cases	Estimated percentage of index cases detectable by LFDs (95% CI)
Alpha	Symptomatic	60 322	76·5% (69·2–85·5)
Delta	Symptomatic	198 707	80·5% (73·7–86·9)
Omicron	Symptomatic	67 633	80·1% (74·6–85·3)
Alpha	Asymptomatic	3590	51·1% (15·3–67·0)
Delta	Asymptomatic	13 153	57·2% (31·3–80·8)
Omicron	Asymptomatic	3969	64·9% (54·5–80·1)

Pango lineages: alpha (B.1.1.7), delta (B.1.617.2), and omicron (BA.1 or BA.2). LFD=lateral flow device.

Table 3: **Estimated index cases detectable by LFDs by dominant circulating variant and symptom status among case–contact pairs with probable SARS-CoV-2 transmission**

Eyre DW, et al. Lancet Infect Dis. 2023

Molecular and rapid antigen test results for omicron lineages



快篩表現不受Omicron lineages的影響

Anderson M, et al. J Clin Virol. 2023

抗原快篩對於Omicron亞型變異株仍有不錯的表現

	BinaxNOW			Panbio		
Variant	Tested, *n*=	Positive, *n*=	Positive,%	Tested, *n*=	Positive, *n*=	Positive,%
BA.1	165	163	98.8	101	93	92.1
BA.2	69	65	94.2	69	64	92.8
BA.3	1	0	0	1	0	0
BA.4	16	16	100	16	15	93.8
BA.5	81	72	88.9	81	70	86.4
BE	5	5	100	5	5	100
BF	17	15	88.2	17	15	88.2
BG.2	QNS	QNS	QNS	QNS	QNS	QNS
BN.1.5	1	1	100	1	1	100
BQ.1	105	92	87.6	105	91	86.7
BQ.2	1	1	100	1	1	100
BU.1	2	2	100	2	2	100
CA	2	2	100	2	2	100
CH.1.1	1	1	100	1	1	100
CK.1	2	1	50	2	1	50
CN.1	1	1	100	1	1	100
CQ.2	4	3	75	4	3	75
XBB	60	54	90	60	51	85
Total	533	494	92.7	469	416	88.7

*BinaxNOW and Panbio rapid antigen test results are shown for specimens with a viral load >4 $\log_{10}$ copies/test.
n, number of samples; QNS, Insufficient volume for testing.

XBB快篩的敏感性仍不錯，分別為90%及85%

Anderson M, et al. J Clin Virol. 2023

家用新型冠狀病毒抗原檢驗試劑針對XBB變異株評估情形

專案製造家用新型冠狀病毒抗原檢驗試劑評估結果

序號	產品名稱	防疫核准字號	申請業者名稱	評估結果
1	福爾威創家用新型冠狀病毒抗原快速檢驗套組	1106809622	泰博科技股份有限公司	有評估資料，評估無影響
2	飛確 RV2 家用新型冠狀病毒抗原快速檢驗試劑	1106810589	寶齡富錦生技股份有限公司	有評估資料，評估無影響
3	台塑生醫家用新型冠狀病毒抗原快速檢驗試劑	1106028306	台塑生醫科技股份有限公司	有評估資料，評估無影響
4	凌越家用新型冠狀病毒抗原快速檢測試劑	1106033071	凌越生醫股份有限公司	有評估資料，評估無影響
5	速可安家用新冠病毒抗原自我檢測套組	1110801588	安特羅生物科技股份有限公司	有評估資料，評估無影響
6	飛確 RV2 家用新型冠狀病毒抗原快速檢驗試劑	1110804717	寶齡富錦生技股份有限公司	有評估資料，評估無影響
7	長興家用 COVID-19 抗原快速檢測試劑套組	1110708839	長興材料工業股份有限公司	有評估資料，評估無影響
8	普生家用新型冠狀病毒抗原快速檢測試劑	1110605099	普生股份有限公司	有評估資料，評估無影響
9	嘉瑞 COVID-19 抗原家用檢驗試劑	1110711909	瑞智生化科技股份有限公司	有評估資料，評估無影響
10	安必測新冠肺炎抗原家用快篩套組	1111609550	安盛生科股份有限公司	有評估資料，評估無影響

專案輸入家用新型冠狀病毒抗原檢驗試劑評估結果

序號	產品名稱(英文)	產品名稱(中文)	防疫核准字號	申請業者名稱	評估結果
1	SARS-CoV-2 Antigen Self Test Nasal	羅氏家用新冠病毒抗原自我檢測套組(鼻腔)	1106016908	台灣羅氏醫療診斷設備股份有限公司	有評估資料，評估無影響
2	QuickVue AT-Home OTC COVID-19 Test	快得利家用新冠肺炎快篩套組	1106017376	新富偉生物科技股份有限公司	輸入之產品均已逾有效期限
3	InteliSwab COVID-19 Rapid Test	欣大因特利家用型新冠抗原快篩試劑	1106810236	瑞亞生醫股份有限公司	輸入之產品均已逾有效期限
4	Panbio COVID-19 Antigen SELF-TEST	亞培家用新冠病毒抗原檢測套組	1106019149	亞培快速診斷設備股份有限公司	有評估資料，評估無影響
5	Humasis COVID-19 Ag Home test	伏麻西斯家用新冠病毒抗原自我檢測套組	1106017614	冷泉港生物科技股份有限公司	有評估資料，評估無影響
		禾美司家用新冠病毒抗原快篩	1106018224	瑞麟生物科技有限公司	有評估資料，評估無影響
		護瑪思家用新冠病毒抗原快篩檢測組	1110710361	索瑪沛思生物科技股份有限公司	有評估資料，評估無影響
		“優美思”家用新冠病毒抗原快篩檢測套組	1110011033	艾慕思生物科技股份有限公司	未曾輸入
6	BIOCREDIT COVID-19 Ag Home Test Nasal	百快家用新冠病毒抗原快篩檢測組	1106811670 1110806023	新城藥品股份有限公司	有評估資料，評估無影響
		銳偵 家用新冠肺炎抗原快速檢測試劑	1106608063	弘朗生物科技有限公司	有評估資料，評估無影響
7	Celltrion DiaTrust COVID-19 Ag Home Test	安心篩家用新冠病毒抗原自我檢測套組	1106017675	高登環球生醫有限公司	有評估資料，評估無影響
		賽特瑞恩家用型新冠肺炎抗原快篩劑套組	1106021656	因思銳國際股份有限公司	輸入之產品均已逾有效期限
		台灣賽特瑞恩家用型新冠肺炎抗原快篩試劑	1111610417	台灣賽特瑞恩有限公司	未曾輸入

序號	產品名稱(英文)	產品名稱(中文)	防疫核准字號	申請業者名稱	評估結果
8	GenBody COVID-19 Ag Home Test	基因巴帝居家用新冠病毒抗原快篩檢測套組	1106019360 1106036358	森昌有限公司	有評估資料，評估無影響
		捷保定新冠病毒居家用抗原快篩檢測試劑	1110801477	嘉碩生醫電子股份有限公司	有評估資料，評估無影響
9	Gmate COVID-19 Ag Saliva	福吉美家用新型冠狀病毒唾液抗原快速檢驗套組	1111604349	福又達生物科技股份有限公司	輸入之產品均已逾有效期限
10	BD kit for rapid detection of SARS-CoV-2	BD家用新型冠狀病毒抗原快速檢測套組	1110709493	新加坡商必帝股份有限公司台灣分公司	輸入之產品均已逾有效期限
11	InnoScreen COVID-19 Antigen Rapid Test Device (Self-Test)	英諾千 新冠病毒居家用抗原快速檢測試劑(自我檢測)	1110710989	醫全實業股份有限公司	有評估資料，評估無影響
12	Indicaid covid-19 rapid antigen at-home test	妥析新冠病毒快速抗原家用檢測試劑盒	1110805905	永芯生技股份有限公司	產品已無庫存
		明傑新冠肺炎家用抗原快篩	1111610782	明傑企業社	未曾輸入
13	STANDARD Q COVID-19 Ag Home Test	標準生技醫藥家用新冠病毒抗原快篩檢測組	1110711723	標準生技醫藥股份有限公司	有評估資料，評估無影響
		白千層家用新冠病毒抗原快篩檢測組	1110711573	白千層有限公司	有評估資料，評估無影響

資料統計至：112年8月10日

https://www.fda.gov.tw/TC/siteContent.aspx?sid=12697

COVID-19快篩EUA到期

- 食藥署: 以專案輸入或製造的快篩或檢驗試劑，都將於**6月30日全數到期**，得重新申請正式醫材許可證，才能在國內販售使用。
- 食藥署副署長陳惠芳表示，目前已有15家業者已向食藥署申請正式的醫材許可證；其中抗原快篩有9件，5件家用快篩、4件是專業用，另有4件核酸，2件抗體。

- 申請醫療器材許可證審核時間需要約3個月，食藥署接獲申請後就會儘快加速審查。
- 目前已有2款產品已取得國內的正式醫材許可證。分別為**Biofire RP panel**以及**寶齡富錦**生技股份有限公司所生產的「飛確 RV2新型冠狀病毒抗原快速檢驗試劑」。

COVID-19快篩EUA將到期 限期交報告否則不能賣

2023/6/28 15:14（6/28 15:18 更新）

中央通訊社

過期試劑的評估：小心使用

Unexpired and expired rapid antigen kits at various viral concentrations

2.32×10^2 $TCID_{50}$/mL (10 X LOD)

效期內

過期五個月

2.32×10^3 $TCID_{50}$/mL (LOD)

效期內

過期五個月

Vaeth MJE, et al. Microbiol Spectr. 2023

醫療機構入院篩檢還需要？

https://www.theglobeandmail.com/canada/british-columbia/article-ubc-pilot-project-offering-rapid-tests-to-screen-students-in-residence/

醫療機構全面性無症狀新冠篩檢的反思

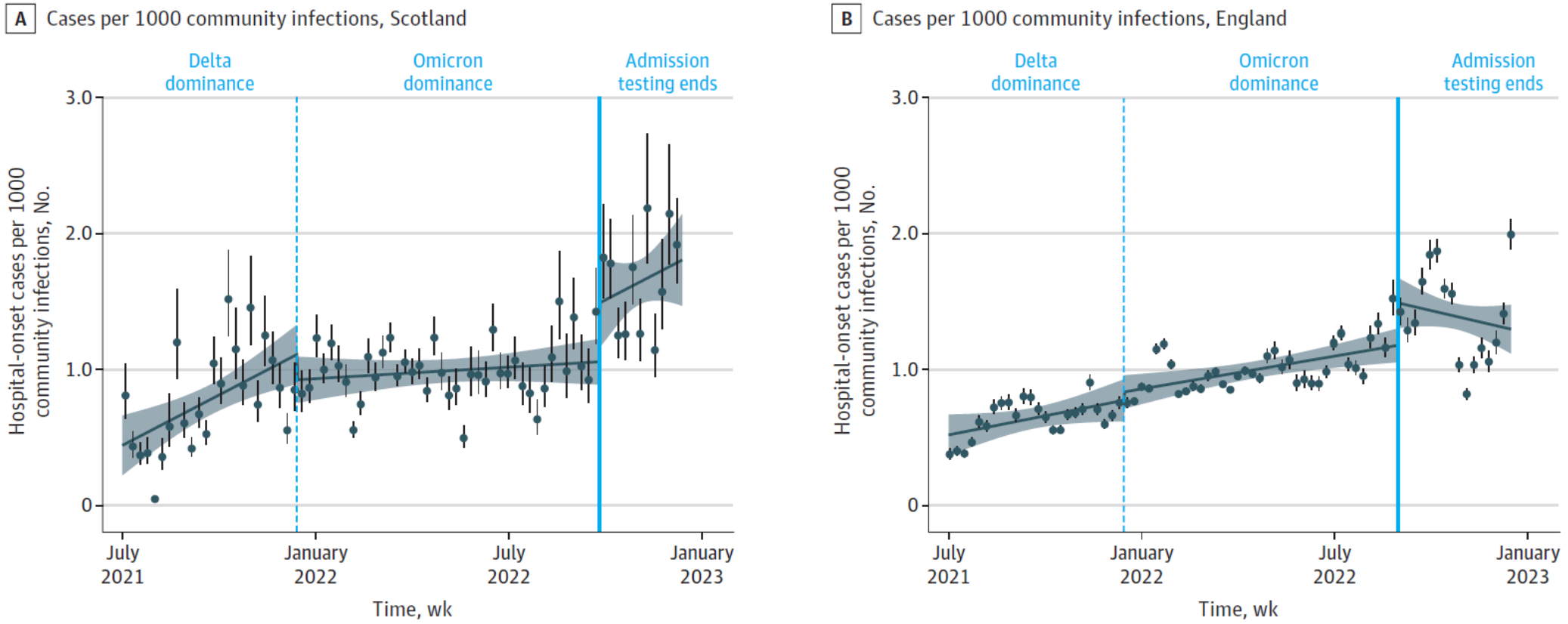
- 大量檢驗量能的耗損
- 僞陽性：
  - 不必要的隔離需求、延長住院天數、延遲患者真正所需的治療、接受無謂的抗病毒藥物治療、床位需求增加、增加醫療成本支出、造成病人不便
- 偽陰性：
  - 病人忽視基本感控要求

*Society for Healthcare Epidemiology of America (SHEA) recommended against “routine universal use of asymptomatic screening for SARS-CoV-2 in healthcare facilities”

Thomas R Talbot, et al. Infect Control Hosp Epidemiol. 2023

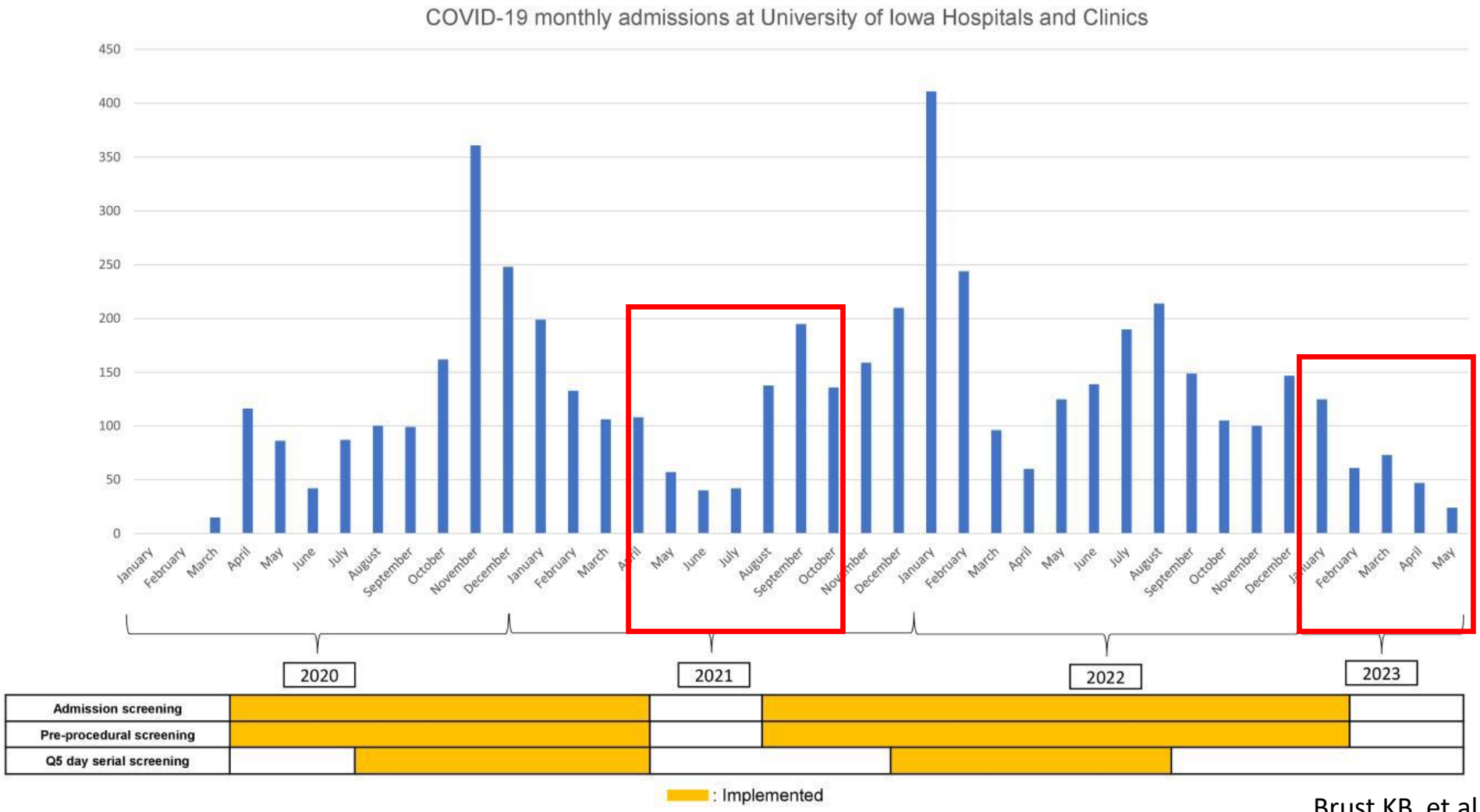
取消入院篩檢與院內新冠感染的關係：
英格蘭及蘇格蘭經驗

Figure. Weekly New Hospital-Onset COVID-19 Cases in Scotland and England per 1000 Estimated Community COVID-19 Infections and per New Admissions for Community-Onset COVID-19 Infection



Theodore R Pak, at al. JAMA Intern Med. 2023

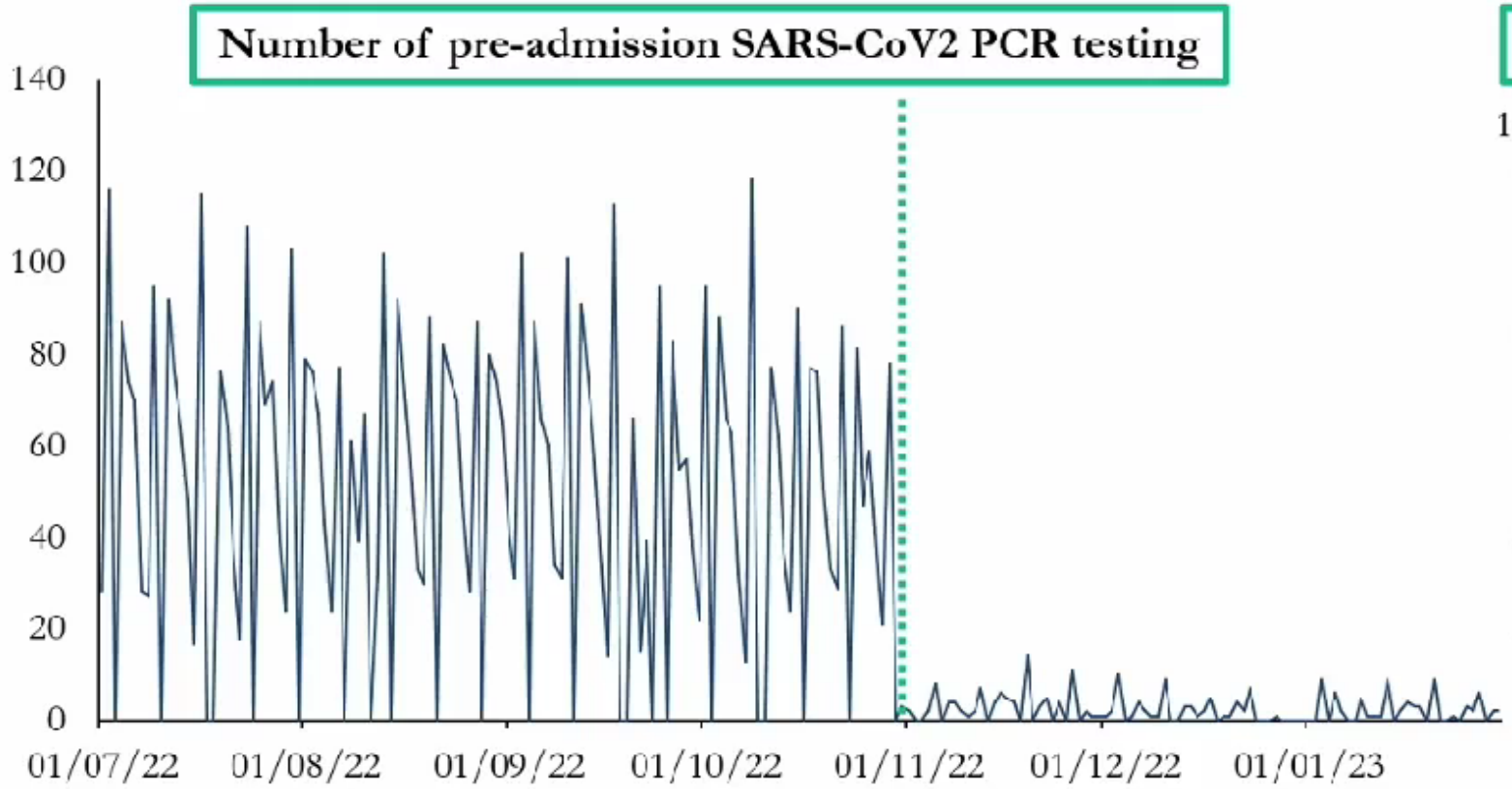
取消入院篩檢與院內新冠感染的關係：美國經驗

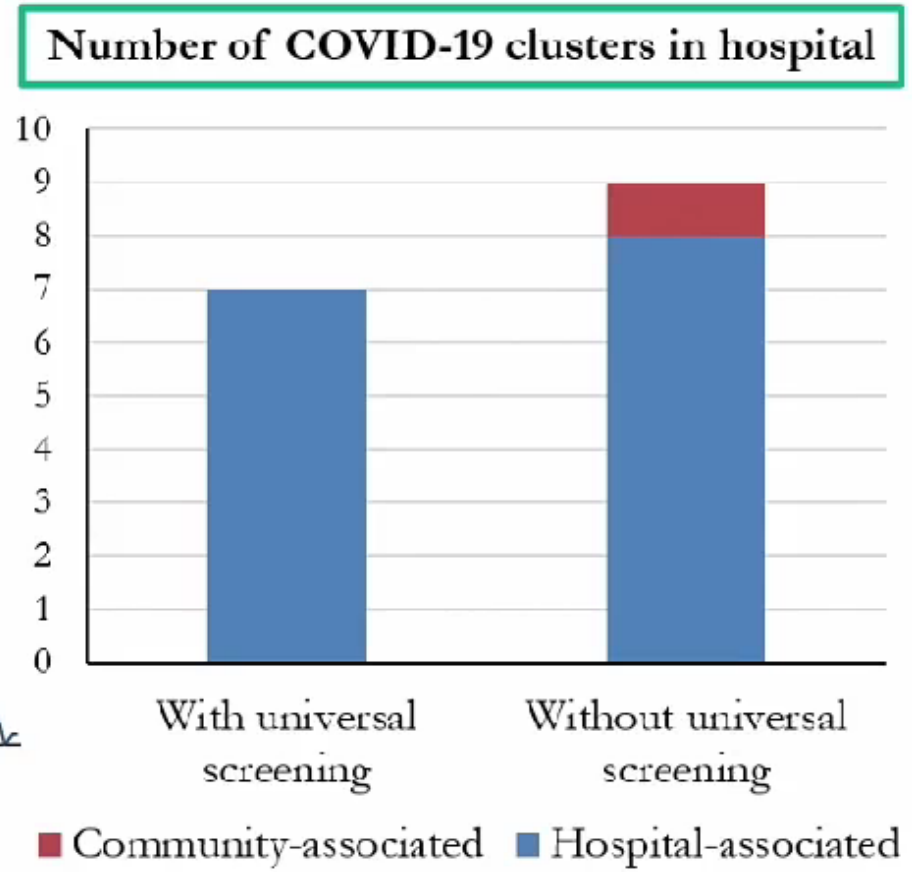


Brust KB, et al. Clin Infect Dis 2023

取消入院篩檢與院內新冠感染的關係：
日本經驗

- 取消全面性入院篩檢並未顯著增加院內感染的個案





PCR, polymerase chain reaction. Honda H, et al. *Infect Control Hosp Epidemiol* 2023 [In press]

SHEA建議：
感染風險評估後再進行無症狀篩檢策略

- 社區新冠感染的盛行率
- 易感受族群
  - 例如，骨髓移植患者、未施打疫苗老人
- 某些設施規劃
  - 例如，療養急慢性照護機構
- 可能會造成院內傳播的醫療處置
  - 例如，可能產生大量氣霧的處置

Thomas R Talbot, et al. Infect Control Hosp Epidemiol. 2023

COVID-NET :: Entire Network :: 2020-22 :: Weekly Rate

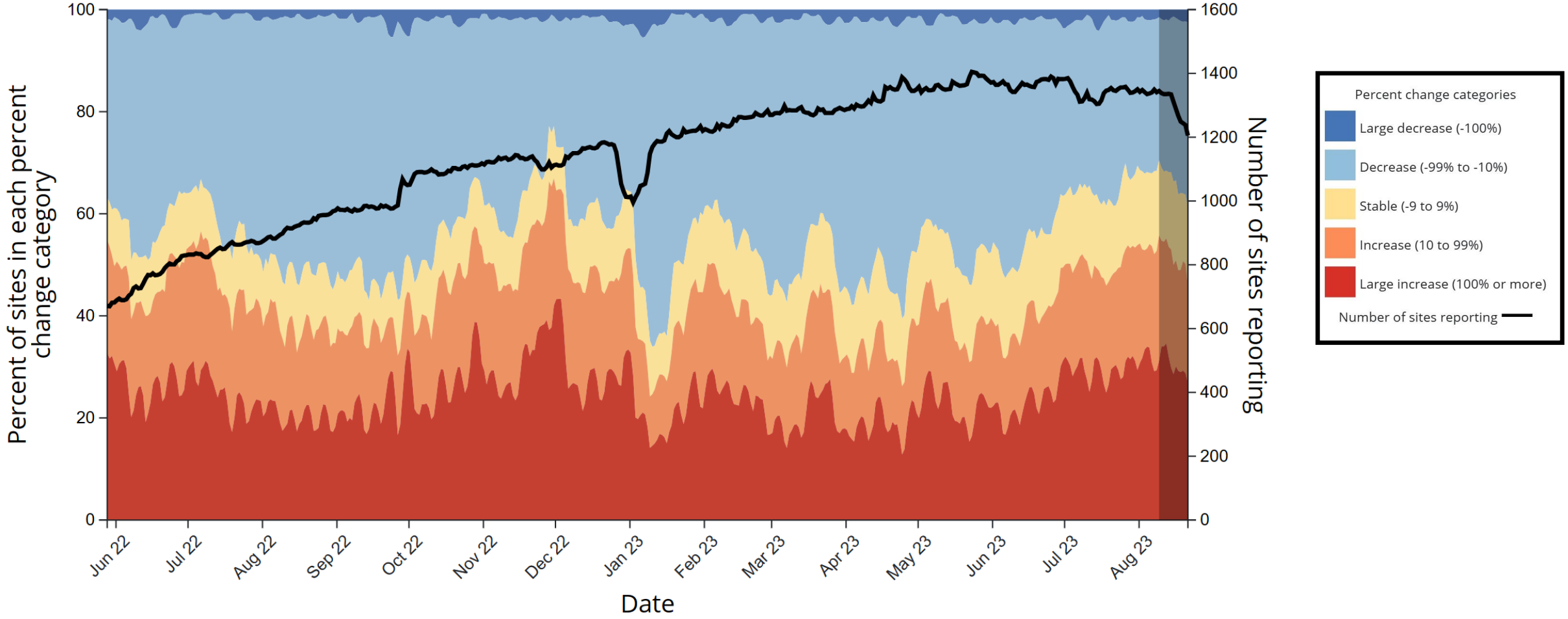
To zoom, hold down Alt key and click and drag to create a rectangle. Double click to reset zoom.

Rates per 100,000 population

Year: 2020-22
Week Ending: Aug 12, 2023
MMWR Week: 32
0-4 yr: 1.5
5-17 yr: 0.2
18-49 yr: 0.6
50-64 yr: 1.3
65+ yr: 7.1
per 100,000 population

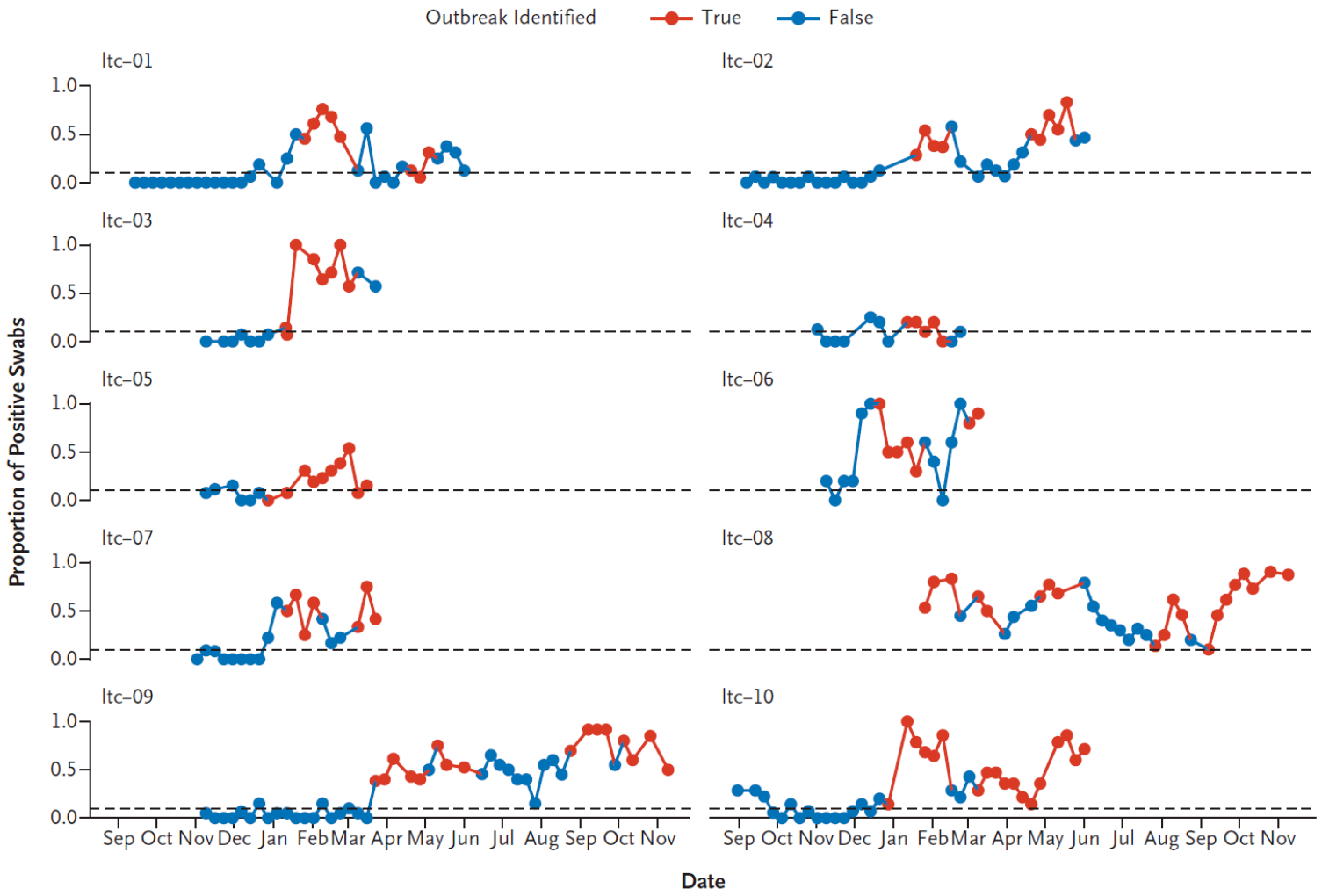
美國汙水監測系統

Percent of sites in each percent change category over time, United States*



長照中心的環境監測：及早預測群突發

Graphical Representation of Swab Positivity for SARS-CoV-2 Over Time



8間長照機構，採集樣本超過10%陽性，五天後會發生群突發

Michael Fralick, et al. NEJM Evid 2023; 2 (3)

長照中心的環境監測：及早預測群突發

Graphical Representation of Swab Positivity for SARS-CoV-2 Over Time

Table 3. Percentage of Swabs Positive for SARS-CoV-2 in the Days Leading Up to and the Days Following the Declaration of an Outbreak.*

Characteristic	Days Before Outbreak	Days Before Outbreak	Days Before Outbreak	Days After Outbreak	Days After Outbreak
Time period	21–15	14–8	7–1	1–7	8–14
No. of swabs	357	335	357	267	281
Positive (%)	31 (26–35)	36 (31–42)	39 (34–44)	55 (49–61)	40 (35–46)
Quantification threshold	37 (35.5–38.2)	38.1 (36.4–39.3)	37.6 (35.3–38.7)	37.2 (35.1–38.7)	37.7 (35.9–38.8)

* Swab positivity is expressed as percentage (95% confidence interval), and quantitative reverse transcriptase polymerase chain reaction (RT-qPCR) quantification cycle (Cq) is expressed as median (interquartile range), unless otherwise noted. SARS-CoV-2 denotes severe acute respiratory syndrome coronavirus 2.

Table 4. Test Characteristics of Floor Swabs to Identify a Current Outbreak.*

Threshold	Sensitivity	Specificity	NPV	PPV
10%	0.94 (0.88–0.97)	0.53 (0.45–0.6)	0.94 (0.87–0.97)	0.57 (0.49–0.64)
20%	0.86 (0.78–0.91)	0.64 (0.57–0.71)	0.88 (0.81–0.92)	0.61 (0.53–0.69)
30%	0.78 (0.69–0.85)	0.76 (0.69–0.82)	0.84 (0.77–0.89)	0.68 (0.6–0.76)
40%	0.67 (0.57–0.75)	0.8 (0.73–0.85)	0.79 (0.72–0.84)	0.69 (0.59–0.77)
50%	0.56 (0.47–0.65)	0.87 (0.81–0.92)	0.75 (0.69–0.81)	0.74 (0.64–0.83)

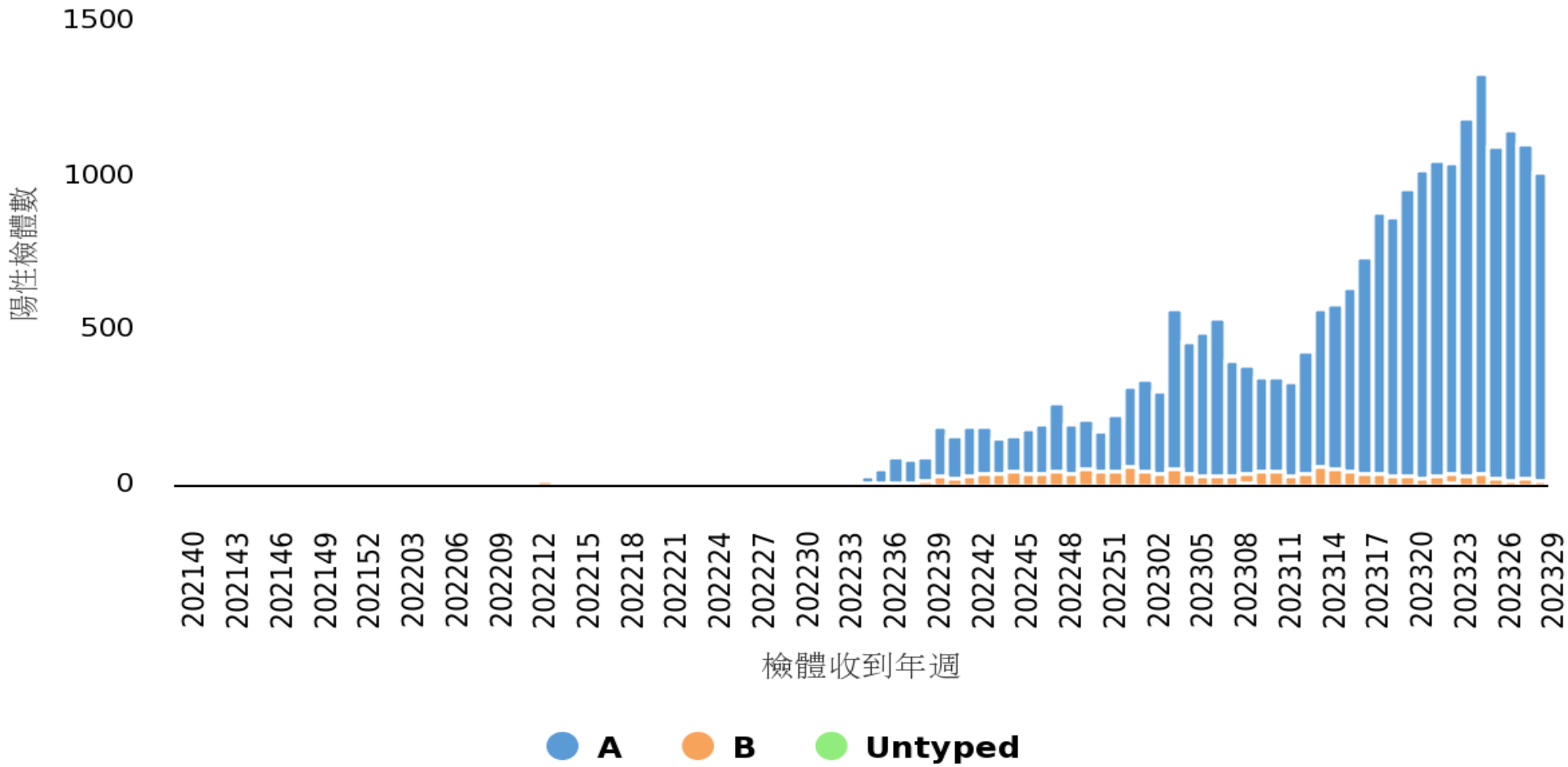
* Data are given as mean (95% confidence interval). NPV denotes negative predictive value; and PPV, positive predictive value.

秋冬挑戰 influenza

- **致病原**
  流感病毒(Influenza virus)，可分為A、B、C及D四種型別，其中只有A型及B型可以引起季節性流行，目前主要流行的季節性流感病毒為A(H3N2)與A(H1N1)亞型，以及B/Victoria與B/Yamagata種系等4類。
- **潛伏期**
  通常為1-4天，平均為2天。出現併發症的時間約在發病後的1-2週內。
- **臨床症狀**
  主要症狀為發燒、頭痛、肌肉酸痛、疲倦、流鼻水、喉嚨痛及咳嗽等，部分患者伴有腹瀉、嘔吐等症狀。多數患者在發病後會自行痊癒，**少數患者可能出現嚴重併發症**，如肺炎、腦炎、心肌炎及其他嚴重之繼發性感染或神經系統疾病等。
- **高危險族群**

  包括65歲以上長者、嬰幼兒及孕婦、免疫功能不全者，以及罹患氣喘、糖尿病、心血管、肺臟、肝臟、腎臟等慢性疾病或BMI≧30者。

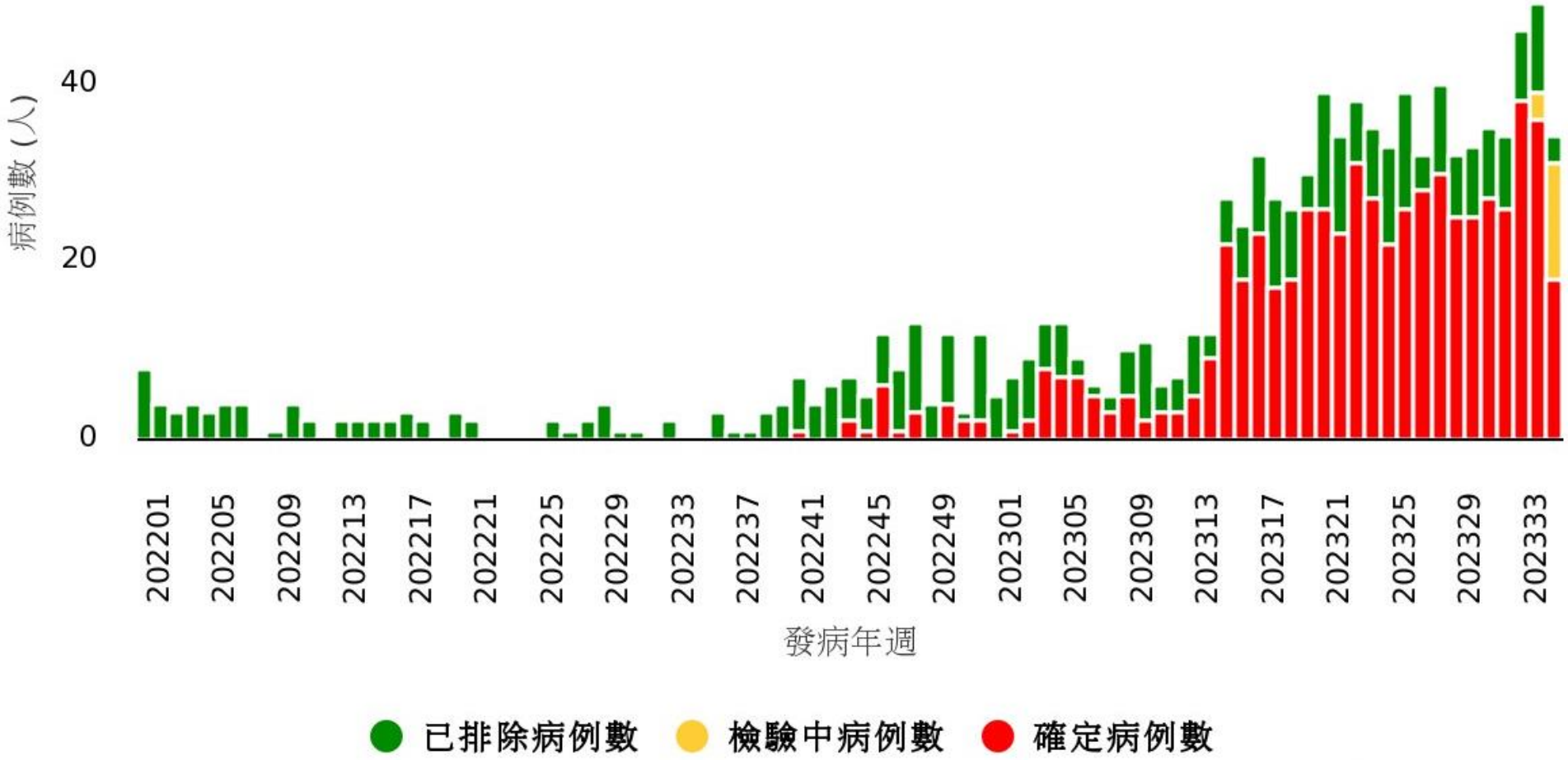
台灣流感陽性件數趨勢 (2021/1-2023/7)



Taiwan CDC 2023 (LARS)

台灣流感速訊2023年第 29週 (2023/7/16 – 2023/7/22)

全國流感併發重症本土病例及境外移入病例
2022/1/2-2023/9/2



今年累積個案數：**592**

死亡數：**132**

傳染病統計資料查詢系統 (cdc.gov.tw) accessed by 2 Sep 2023

新冠合併流感病毒共同感染，死亡率增加

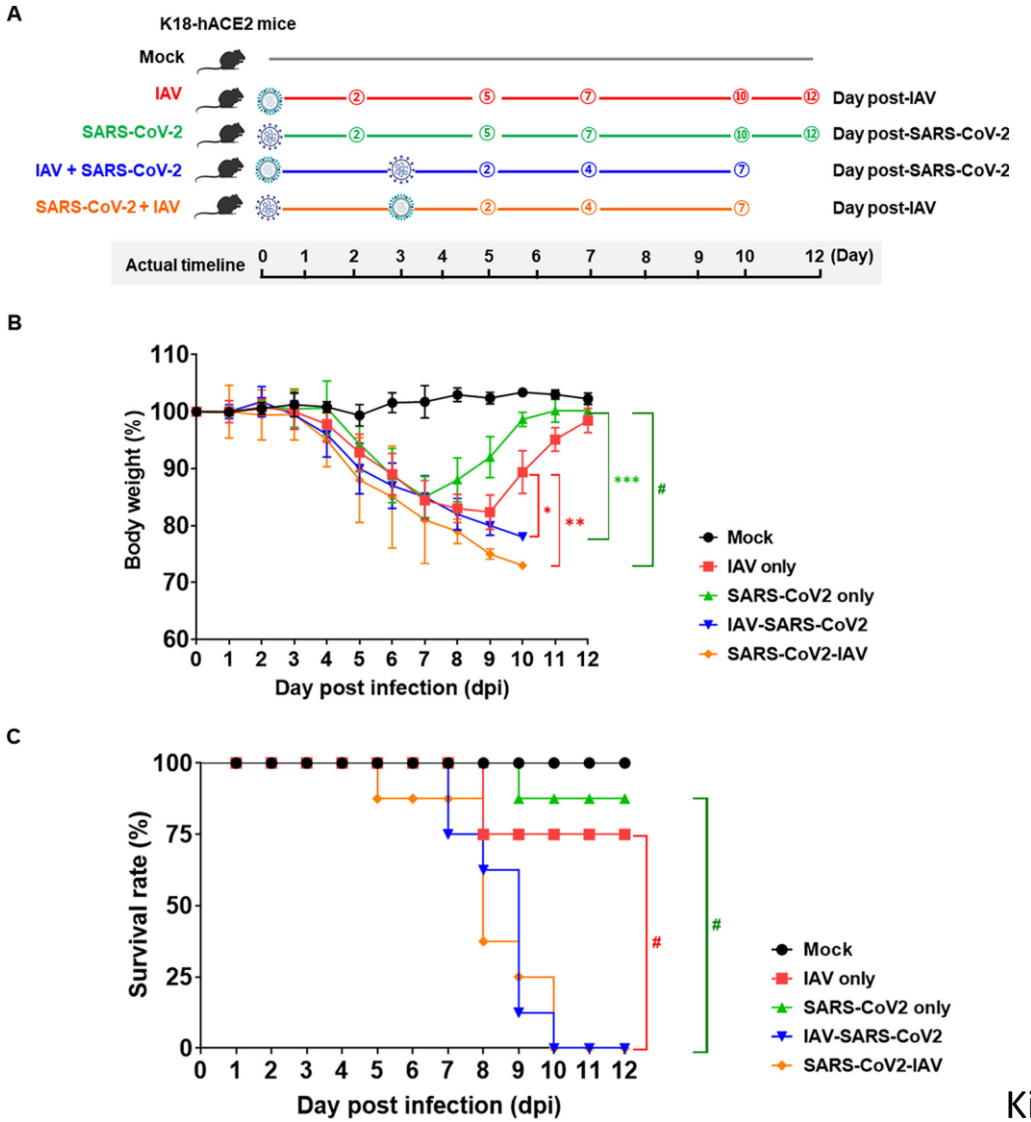
	Unweighted		Weighted	
	OR (95% CI)	p value	OR (95% CI)	p value
Invasive mechanical ventilation				
Adenovirus	1·22 (0·72–1·99)	0·44	0·64 (0·18–1·68)	0·42
Influenza virus	1·68 (1·14–2·45)	0·0073	4·14 (2·00–8·49)	0·0001
Respiratory syncytial virus	1·05 (0·68–1·59)	0·82	0·78 (0·15–2·70)	0·73
In-hospital mortality				
Adenovirus	1·60 (1·03–2·44)	0·033	1·53 (0·67–3·33)	0·29
Influenza virus	1·49 (1·04–2·12)	0·027	2·35 (1·07–5·12)	0·031
Respiratory syncytial virus	1·20 (0·84–1·72)	0·31	0·60 (0·69–2·10)	0·47

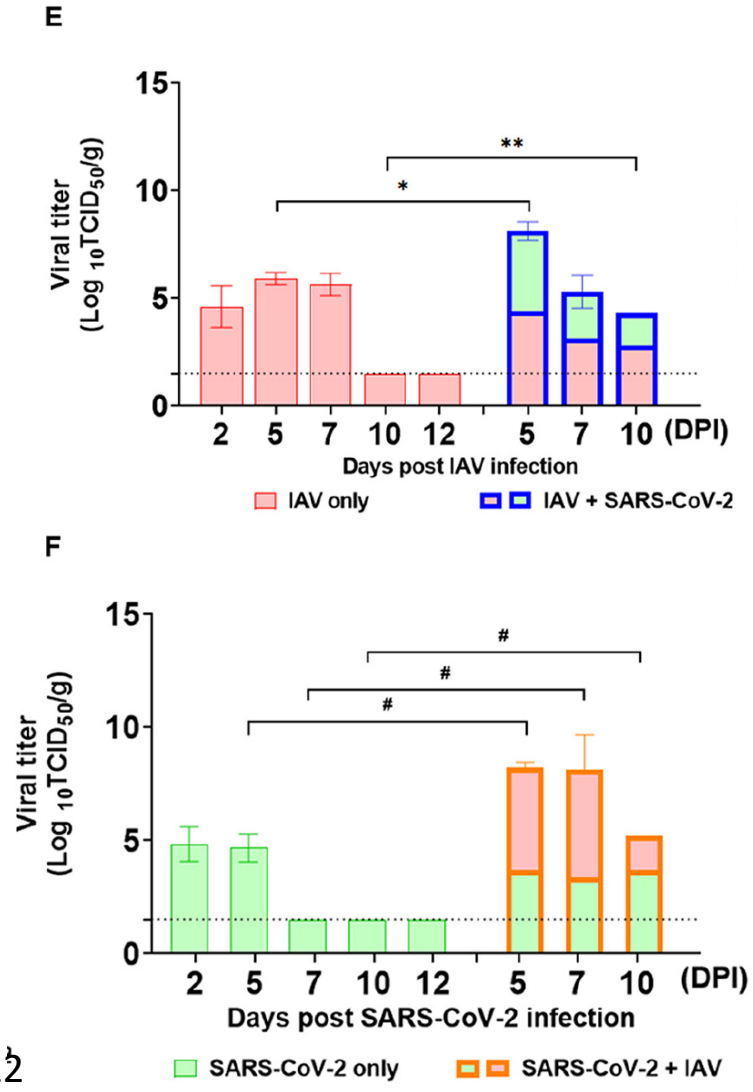
Model is adjusted for the following confounders: age, sex, number of comorbidities, treatment with corticosteroids, days since the start of the pandemic, co-infection, and 4C Mortality Score. OR=odds ratio.

Table: **Multivariable model of the effect of co-infection compared with SARS-CoV-2 monoinfection**

Swets MC, et al. Lancet. 2022.

新冠合併流感病毒共同感染，死亡率增加





Kim EH, et al. J Virol. 2022

即時檢驗的好處，流感患者也同樣受益

五天內用藥比例 mPOCT vs. Control: 99% vs. 62%, p<0.01

第七天的臨床狀況mPOCT較好

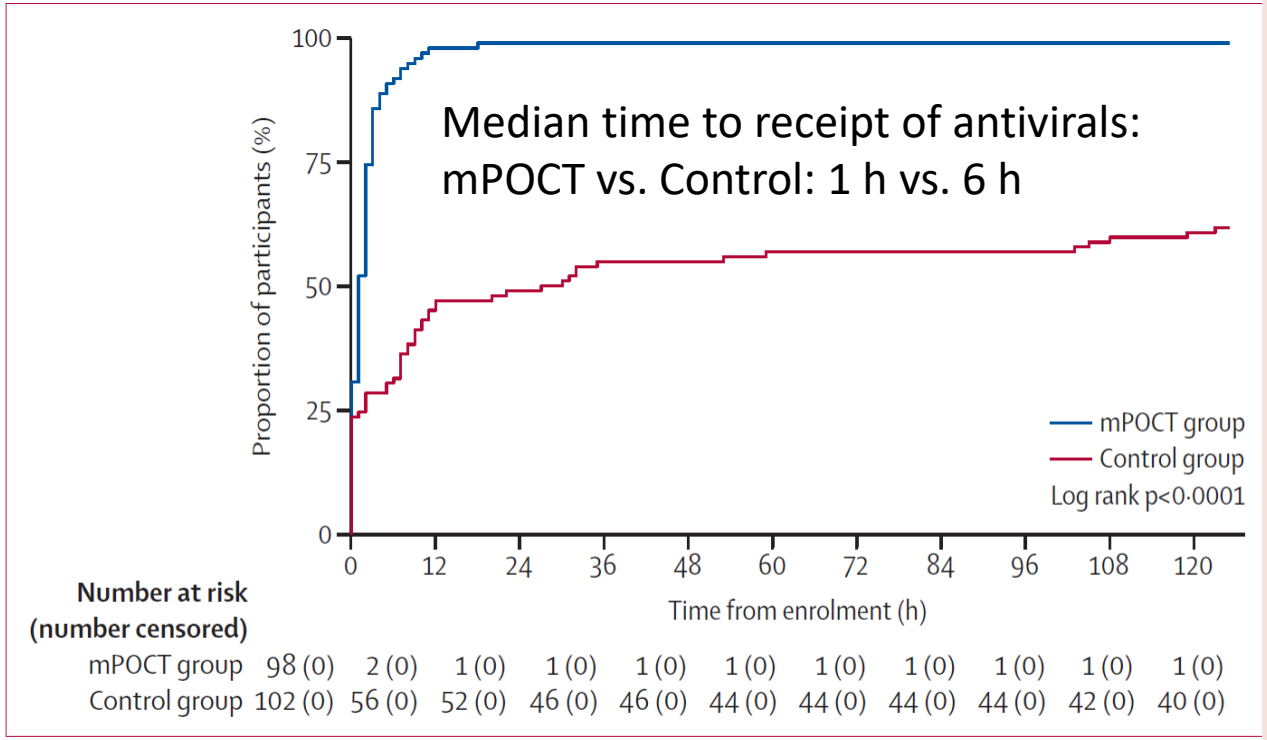
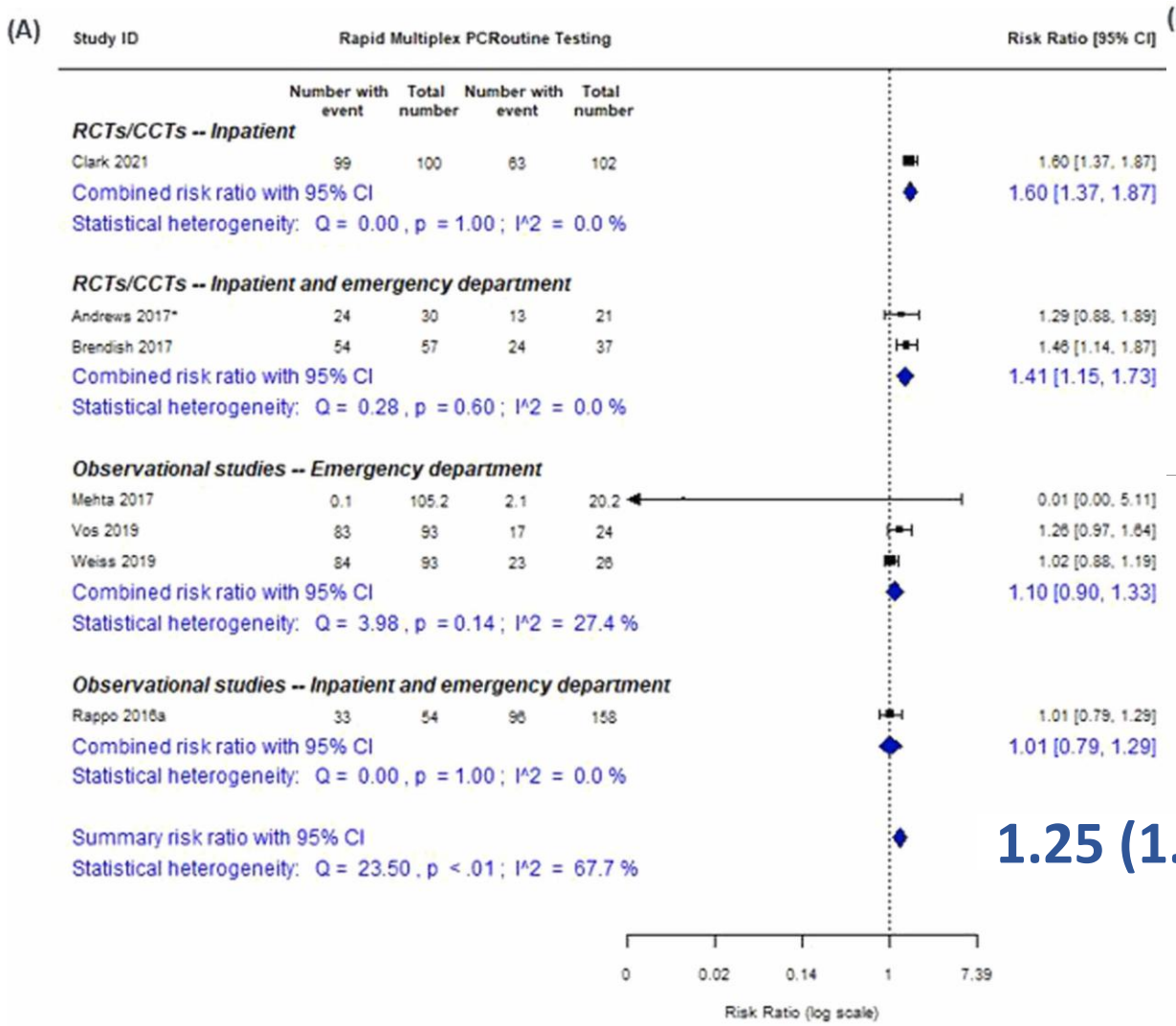


Figure 2: **Antiviral use over time in patients with influenza (ITT influenza-infected population)**
ITT=intention-to-treat. mPOCT=molecular point-of-care test.

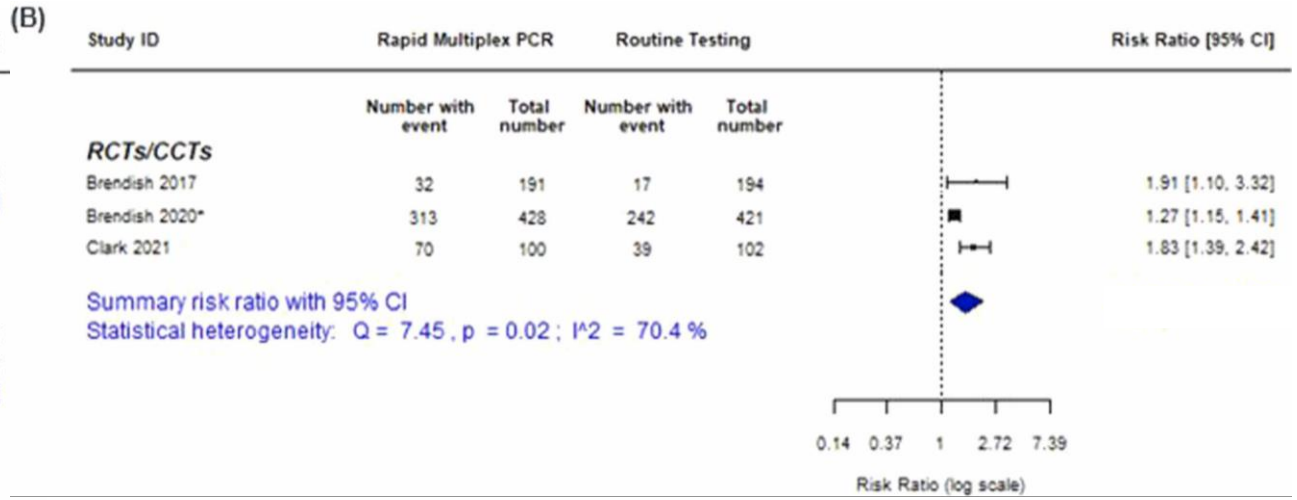
	mPOCT group (n=100)	Control group (n=102)	Difference or relative risk (95% CI)	p value
(Continued from previous page)				
Clinical outcome measures				
Length of hospital stay, days	2·7 (1·1 to 4·2)	2·7 (1·1 to 5·4)	0·0 (–0·4 to 0·9)	0·37
Discharged within 24 h	23 (23%)	18 (18%)	0·9 (0·8 to 1·1)	0·34
Duration of supplementary oxygen, h	32·0 (15·0 to 59·0)	33·0 (14·0 to 81·0)	1·0 (–8·0 to 18·0)	0·48
Time to clinical improvement, h‖	8·8 (3·2 to 23·9)	13·9 (5·1 to 42·5)	5·1 (–0·3 to 9·9)	0·077
Hospital recovery score at day 7 after admission‖				
1 Home	90 (90%)	82 (80%)	NA	0·045
2 Hospital ward not requiring oxygen	8 (8%)	12 (12%)	NA	..
3 Hospital ward requiring oxygen	2 (2%)	5 (5%)	NA	..
4 ICU, not ventilated	0	1 (1%)	NA	..
5 ICU, ventilated	0	1 (1%)	NA	..
6 Death	0	1 (1%)	NA	..

Clark TW, et al. Lancet Respir Med. 2021

Appropriate NAI use and appropriate infection prevention control



1.25 (1.06, 1.48)



1.55 (1.16, 2.07)

NAIs=Neuraminidase inhibitors

Clark TW, et al. J Infect. 2023

秋冬挑戰 Respiratory syncytial virus (RSV）

- **致病原**

  單股負鏈 RNA 病毒，屬副黏液病毒科（ paramyxoviridae ）
- **感染途徑**

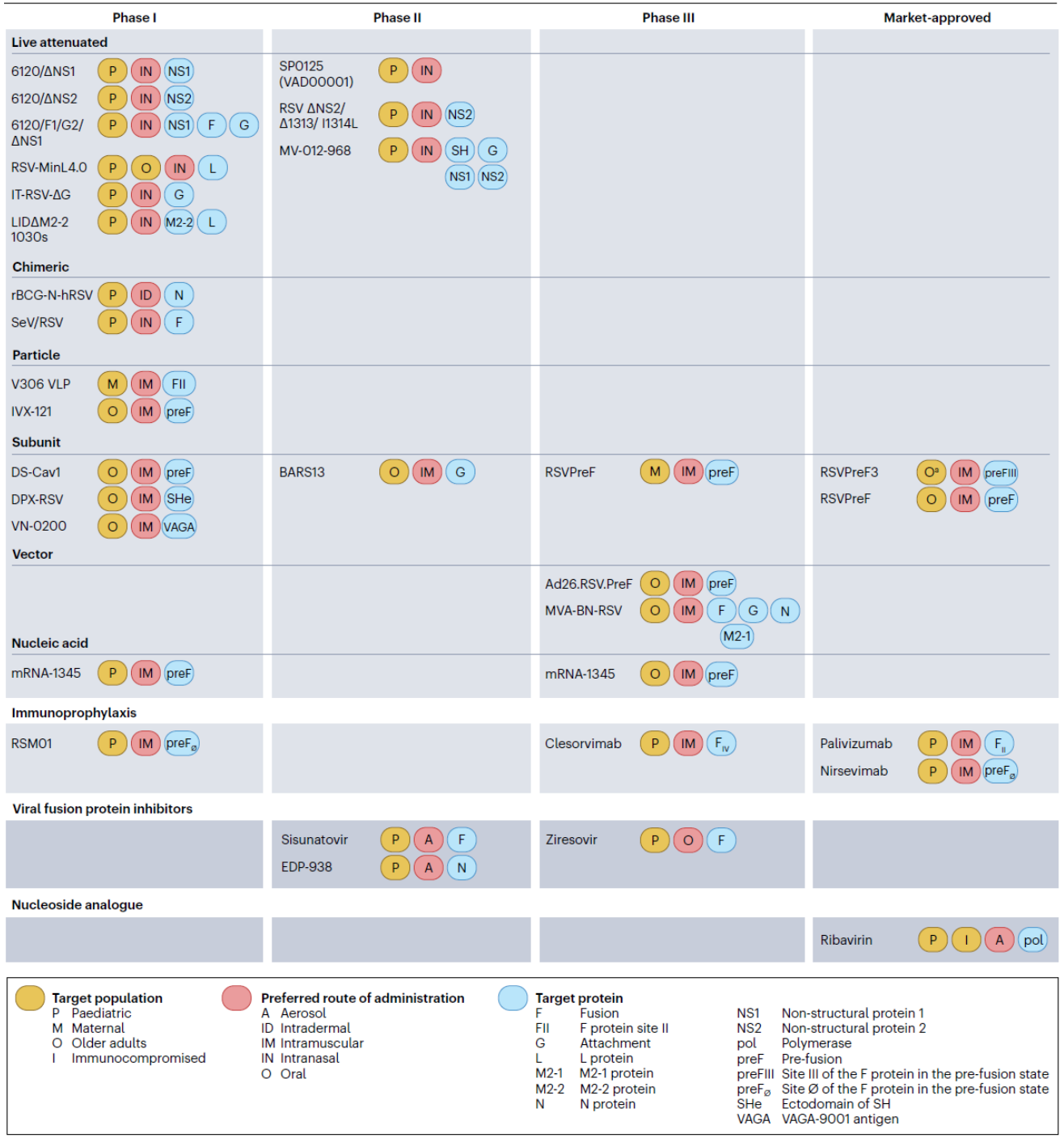
  以飛沫傳染和接觸傳染為主
- **潛伏期**

  RSV 潛伏期為 2 至 8 天，以 4 至 6 天最常見
- **臨床症狀**

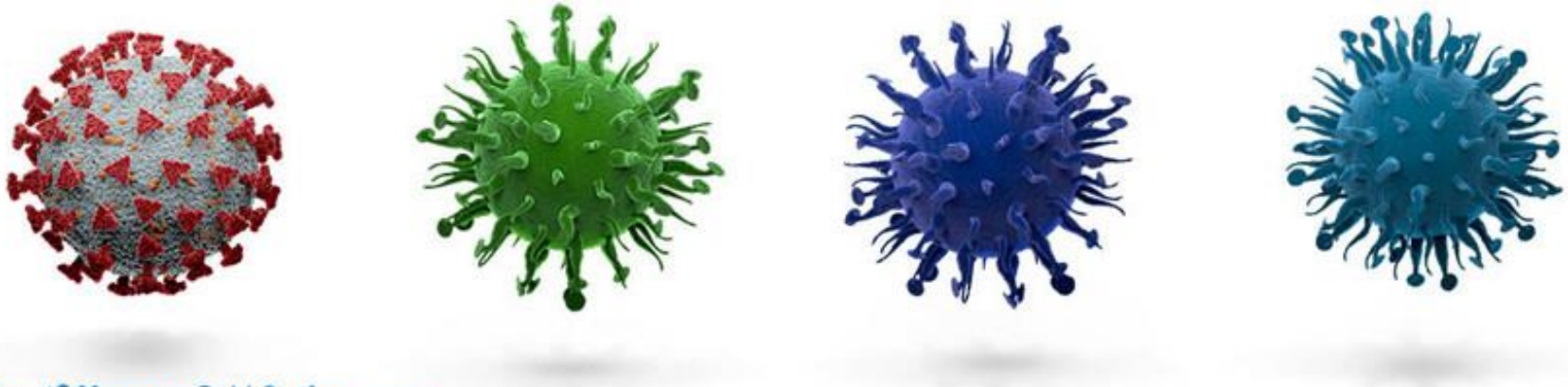
  感染後症狀通常不嚴重，容易產生嚴重症狀的高危險群為：早產兒、小於 2 歲併有先天性心臟病或慢性肺病的孩童、65 歲以上的老年人、免疫力低下者及心肺疾病患 者等。

Preventive and therapeutic pipeline for the treatment of RSV infections

- The world's first vaccines and first monoclonal antibody to prevent RSV among older adults and all infants, respectively, have recently been approved.
- Large-scale introduction of RSV prophylactics emphasizes the need for active surveillance to understand the global impact of these interventions over time and to timely identify viral mutants that are able to escape novel prophylactics.



Langedijk AC, et al. Nat Rev Microbiol. 2023.



Xpert® **Xpress** CoV-2 ***plus***

Xpert® **Xpress** CoV-2/Flu/RSV ***plus***

Gene Targets

SARS-CoV-2	Flu A	Flu B	RSV
RdRP RNA-dependent RNA polymerase gene	**M** Matrix gene	**M** Matrix gene	**RSV A** Nucleocapsid gene
E Envelope protein gene	**PB2** polymerase basic protein 2 gene	**NS** non-structural protein gene	**RSV B** Nucleocapsid gene
N2 Nucleocapsid gene	**PA** polymerase acidic protein gene		

Home / Tests / Critical Infectious Diseases / Xpert Xpress CoV-2/Flu/RSV plus

Xpert® Xpress CoV-2/Flu/RSV *plus*

Actionable, rapid respiratory results to meet the challenges of the ongoing pandemic

Product Resources | Ordering Info

https://www.newswire.ca/news-releases/cepheid-receives-health-canada-licence-for-xpert-r-xpress-cov-2-plus-803130897.html

THE BIOFIRE RESPIRATORY 2.1 PANEL MENU

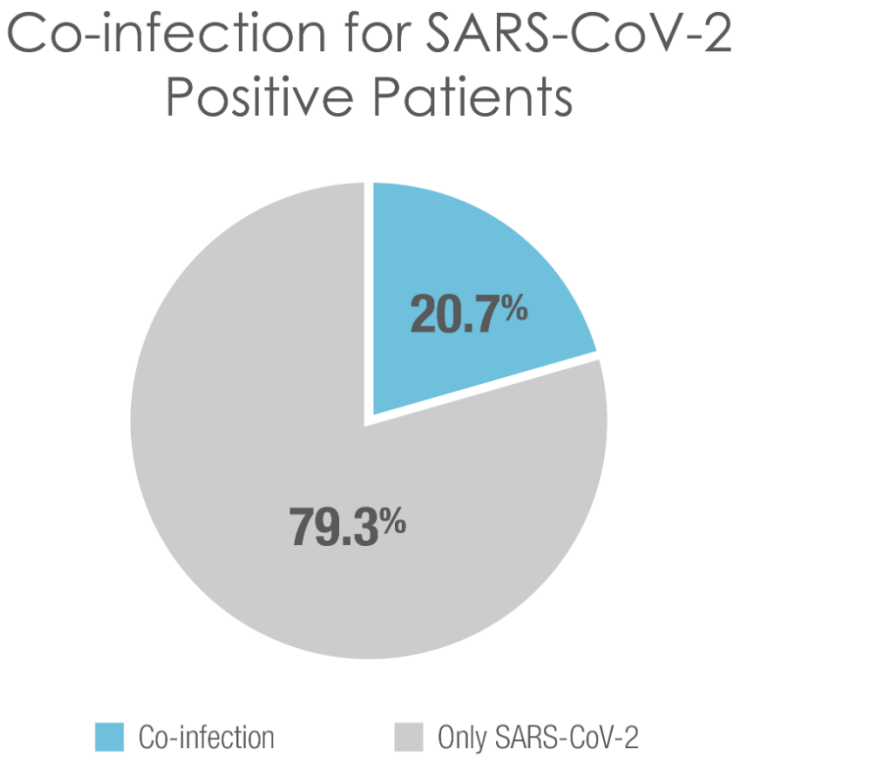
Overall 97.1% sensitivity and 99.3% specificity [1]
SARS-CoV-2 98.4% PPA and 98.9% NPA[2]

VIRUSES:

- Adenovirus
- Coronavirus 229E
- Coronavirus HKU1
- Coronavirus NL63
- Coronavirus OC43
- **Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)**
- Human Metapneumovirus
- Human Rhinovirus/Enterovirus
- Influenza A virus
- Influenza A virus A/H1
- Influenza A virus A/H3
- Influenza A virus A/H1-2009
- Influenza B virus
- Parainfluenza virus 1
- Parainfluenza virus 2
- Parainfluenza virus 3
- Parainfluenza virus 4
- Respiratory syncytial virus

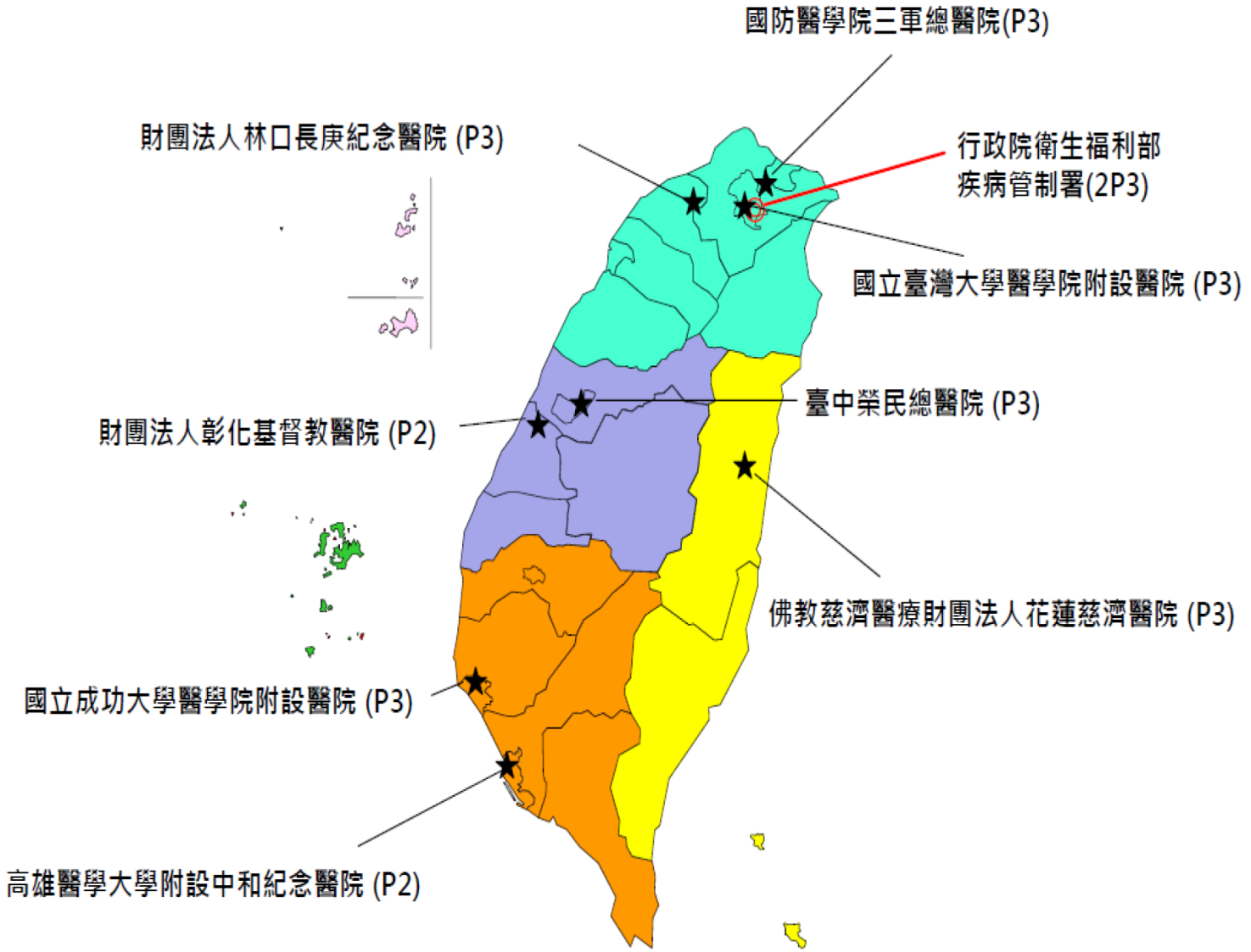
BACTERIA:

- *Bordetella parapertussis*
- *Bordetella pertussis*
- *Chlamydia pneumoniae*
- *Mycoplasma pneumoniae*

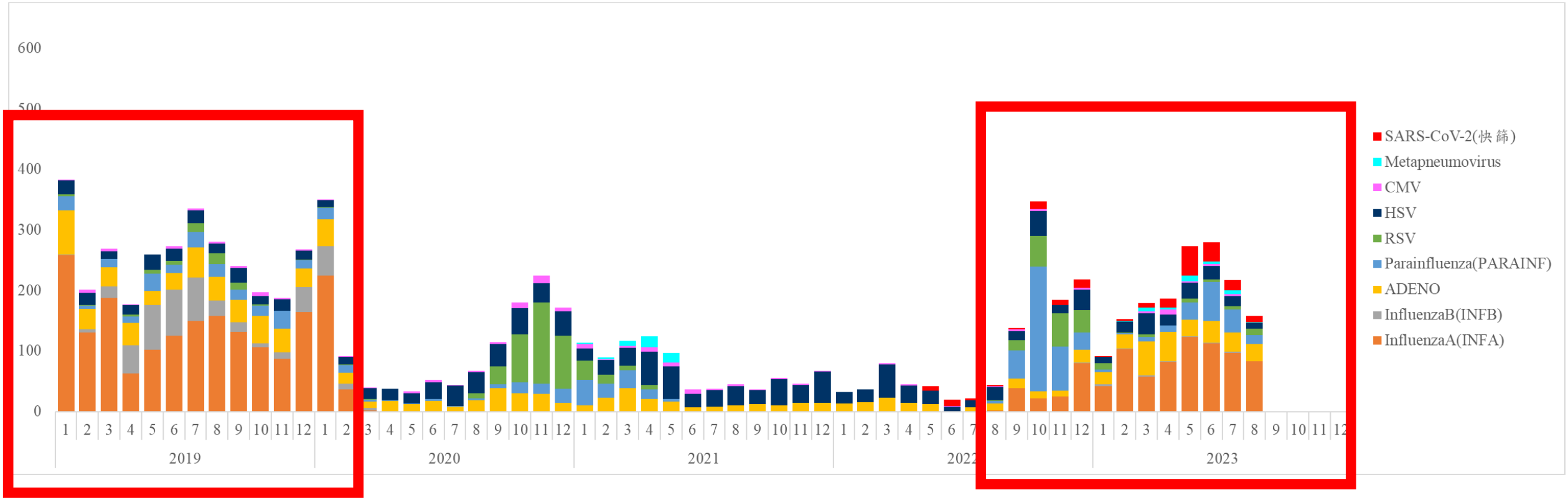


1.Based on the prospective portion of the clinical study for the BioFire® FilmArray® Respiratory 2 Panel
2.Overall performance based on prospective SARS-COV-2 clinical study for the BioFire® Respiratory 2.1 Panel in comparison to 3 EUA tests, Data on file, BioFire Diagnostics.
3.Martinez R, et al. Clinical Virology Symposium, Poster #C-368, May 2016.

病毒合約實驗室：社區監測

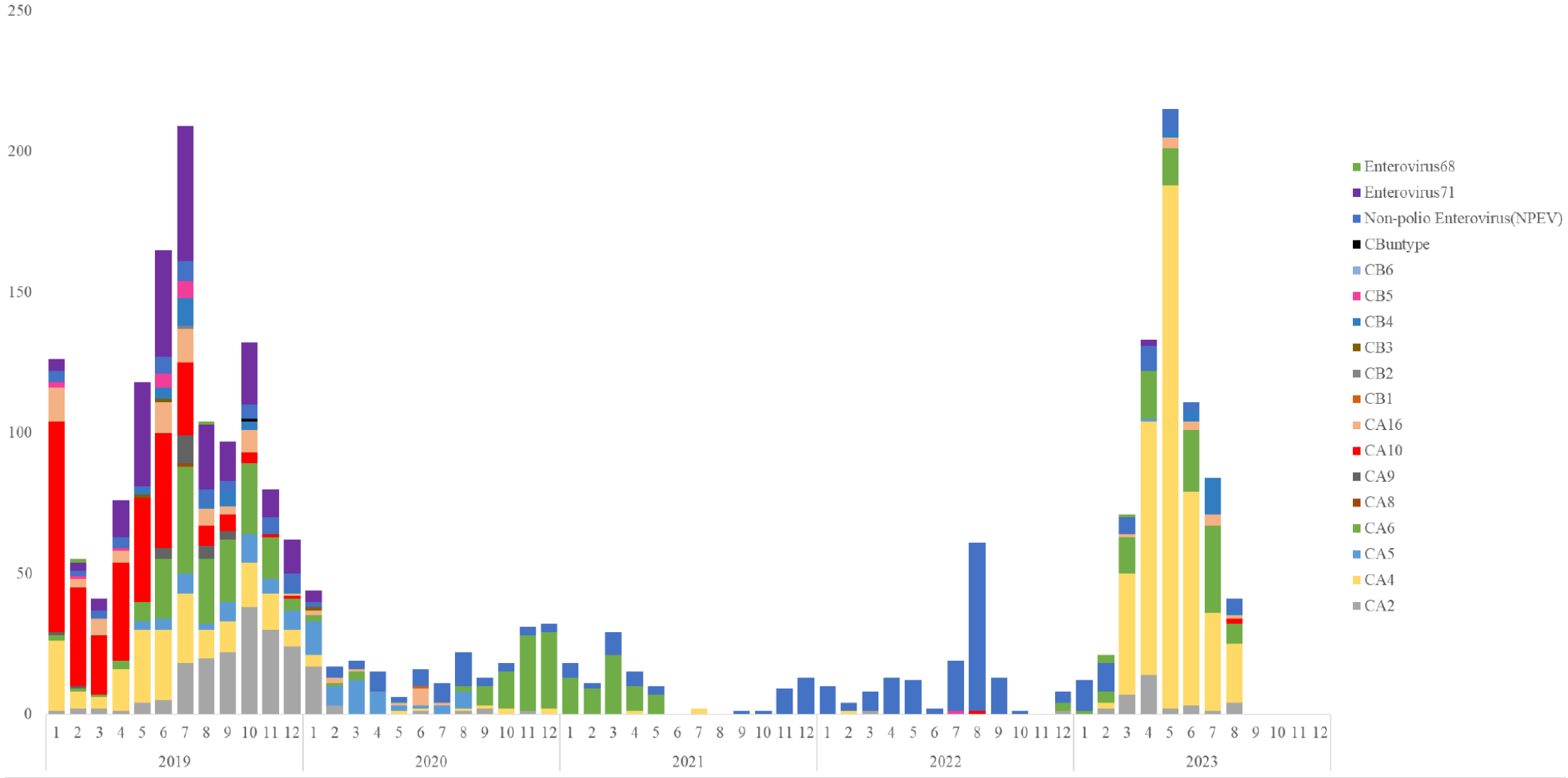


2019-2023 年呼吸道病毒株及其病毒亞型分離情形



疾病管制屬病毒合約實驗室週報 2023.08.25

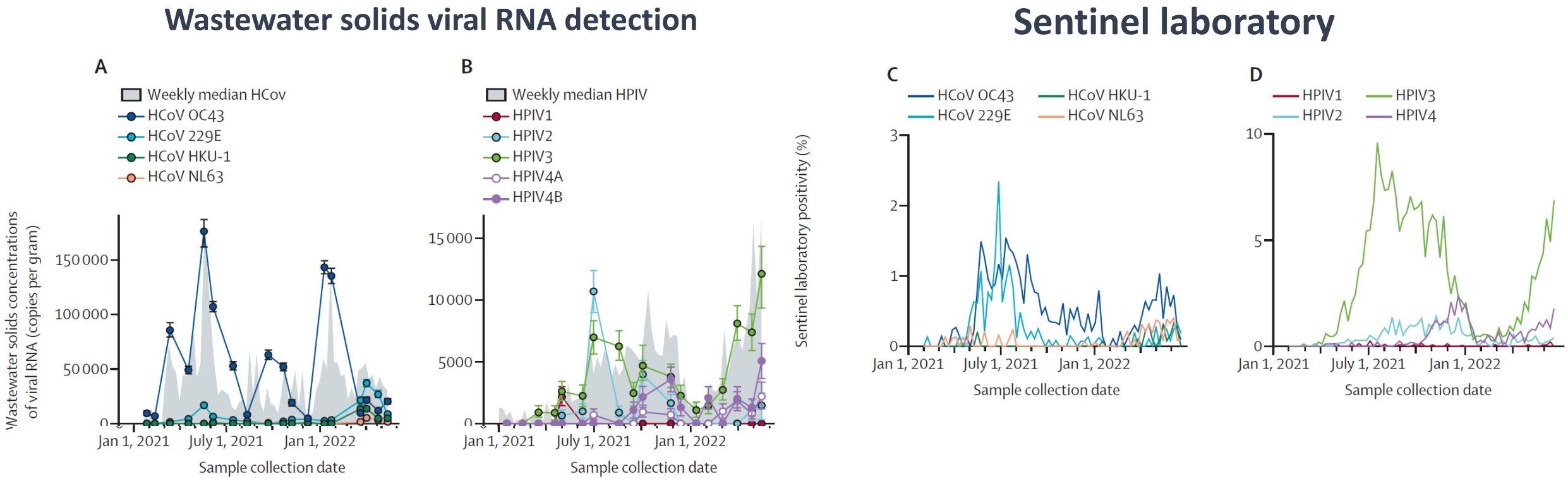
2019-2023 年腸病毒型別(細類)流行分析圖



疾病管制屬病毒合約實驗室週報 2023.08.25

廢水監測系統用於呼吸道病毒檢測

Concentrations of viral RNA in wastewater solids and comparison to sentinel laboratory percent positivity data



HCoV=human coronavirus. HPIV=human parainfluenza virus

Boehm AB, et al. Lancet Microbe. 2023

總結

- 呼吸道症狀仍建議進行新型冠狀病毒檢驗，及早用藥(高風險族群)及適當隔離
- PCR及抗原快篩比較；目前抗原快篩仍是主要的診斷工具
- 不建議無症狀篩檢，除非有其他考量(ex, 易感受族群、長照機構)
- 醫療機構無症狀新冠篩檢的考量
- 呼吸道病毒監測系統的重要性
- 呼吸道病毒的檢測(流感與呼吸道融合病毒)與監測