Sharing Experiences in POCT for Respiratory viruses

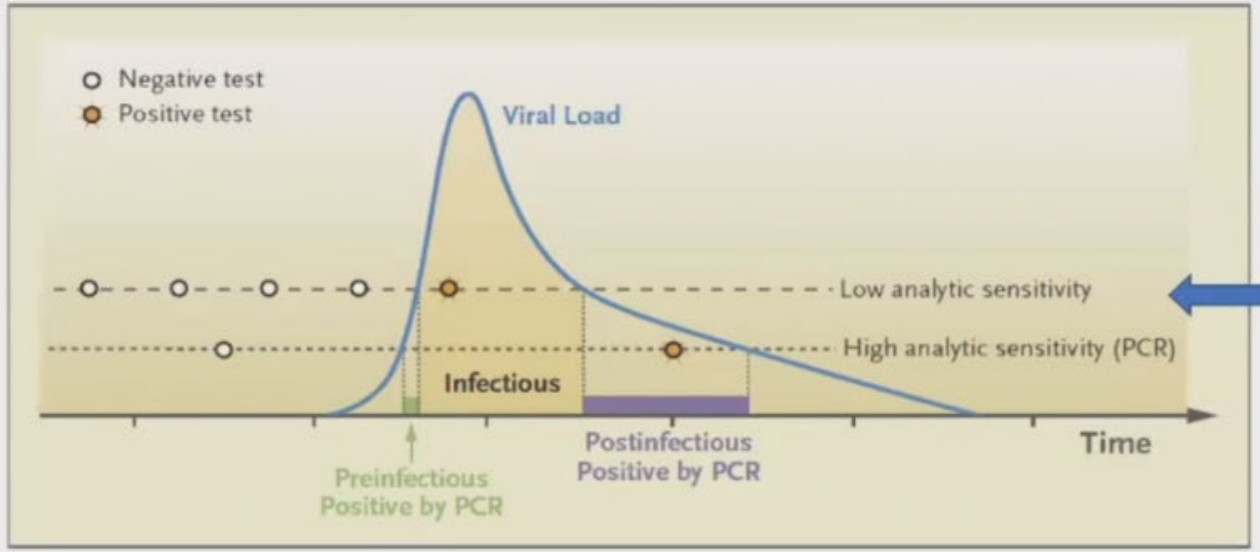
- รุ่งเรือง จารุมโนกุล

- 22-7-2568

MARIO PLEBANI

Rethinking Covid-19 Test Sensitivity — A Strat for Containment

Michael J. Mina, M.D., Ph.D., Roy Parker, Ph.D., and Daniel B. Larremore, Ph.D.



N Engl J Med 2020

Rapid Antigen

High-Frequency Testing with Low Analytic Sensitivity versus Low-Frequency Testing with High Analytic Sensitivity.

อะไรคือ ข้อดี ข้อเสีย ข้อจำกัด

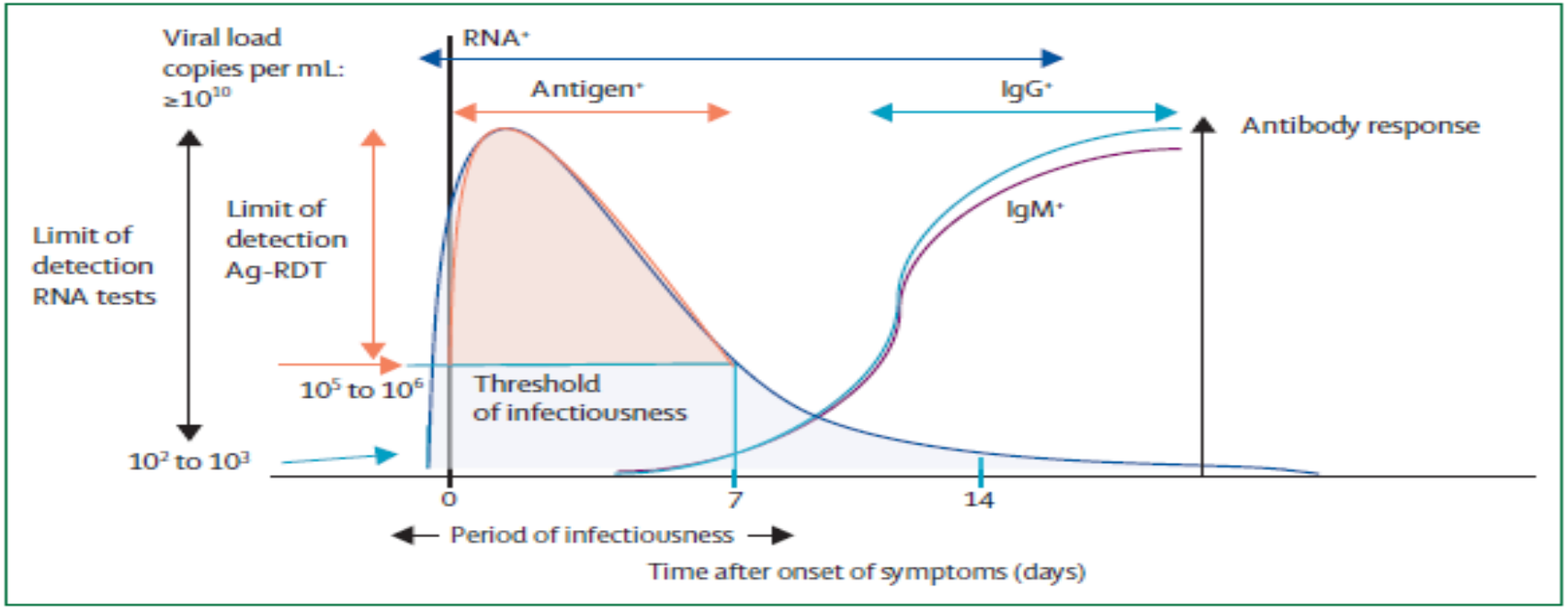


Figure 1: **Timelines for optimal use of different diagnostic tests for COVID-19 detection and host response**
The optimal timeframe during which molecular and antigen tests can be used for confirming the clinical diagnosis in a patient infected with SARS-CoV-2, based on the lower limits of virus detection for these tests, the dynamics of viral shedding, and the period of infectiousness over the course of infection as reported in the peer-reviewed literature.[16–24] Serology tests to detect host response to infection are usually used 7 days or more after symptom onset to determine exposure or past or recent infection and are primarily used for surveillance. Ag-RDT=antigen rapid detection test.

Table 2: Most reported perceived benefits or challenges of offering COVID-19 self-testing among respondents with experience implementing

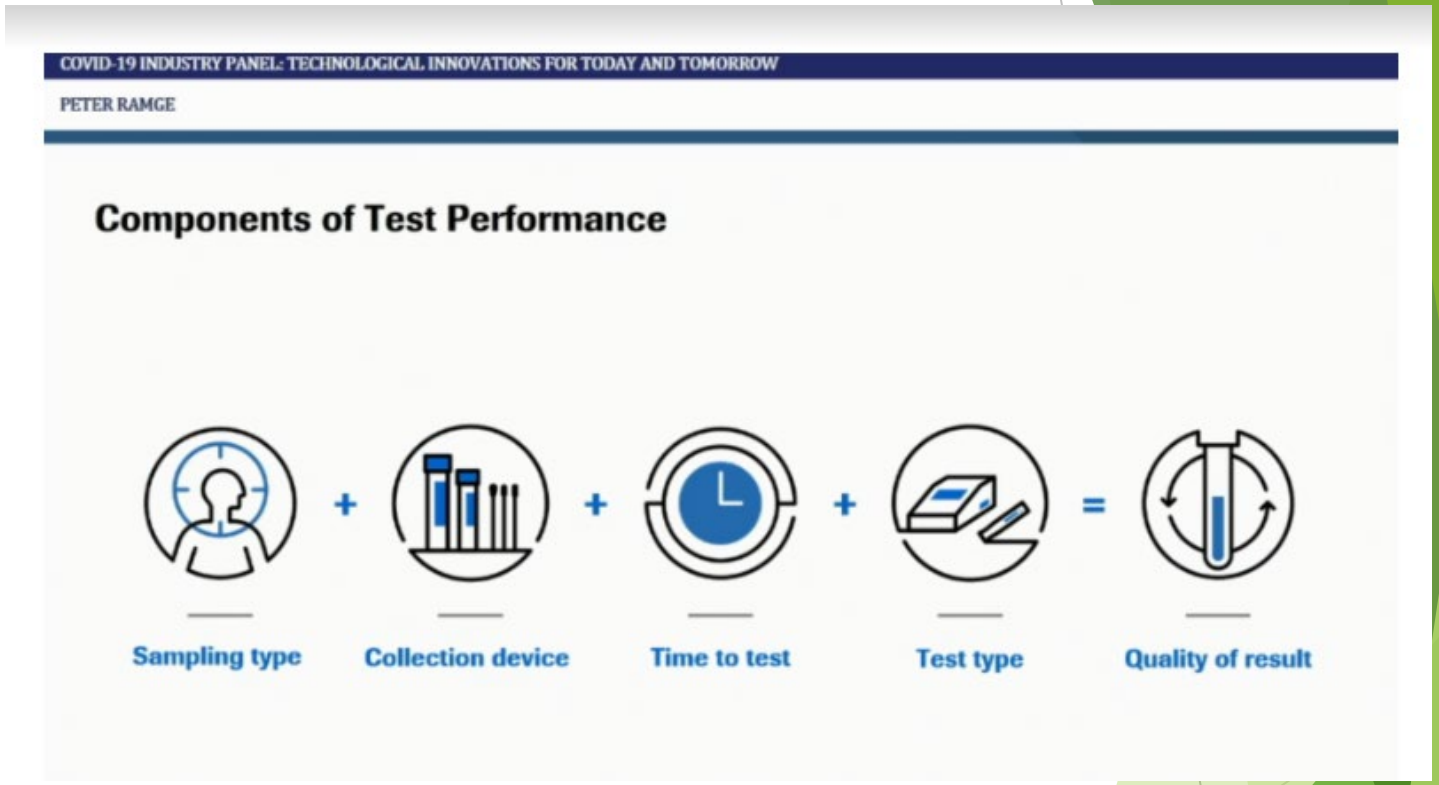
Benefits	Challenges
• More timely diagnosis and self-isolation • Increased access and uptake of testing in the targeted populations • Increased frequency of testing in the targeted population • Increased adherence to public health and social measures • Decreased transmission • Increased ability for the country to resume more "normal" activities	• People unable to perform self-tests or interpret results correctly • False positive result with the self-tests • False negative results with the self-tests • People being forced to self-test • People failing to report positive results • People failing to present for confirmatory testing • People failing to report negative results

From : **Web Annex D.** Global survey on COVID-19 self-testing using SARS-CoV-2 Ag-RDTs

Titus Divala, Melody Sakala, James Chirombo, Rachel Baggaley, Jilian A. Sacks, Cheryl Johnson

ปัจจัยที่มีผลกระทบ

- 1. ปริมาณ Protien Antigen **<u>แปรผันตามช่วงเวลาที่เก็บตัวอย่าง</u>**
- 2. คุณภาพตัวอย่างที่เก็บ
- 3. วิธีทดสอบที่ถูกต้อง
- 4. ชุดตรวจที่เลือกใช้
- 5. การจัดเก็บ/ขนส่งชุดตรวจอย่างเหมาะสม



Note: Cycle threshold (Ct) between 21.1 (around 2.3 10^7 copies/mL) and 23.3 (around 6.8 10^6 copies/mL).

Sample collection : Inactivate VTM???

cobas® SARS-CoV-2 & Influenza A/B Nucleic Acid Test

Expanded specimen collection device for better testing flexibility

Compatible specimen collection device	P/N
Nasopharyngeal Swab Kits	
Flexible minitip FLOQSwab™ with Universal Transport Media™ (UTM) from Copan Diagnostics	305C
BD™ Universal Viral Transport (UVT) 3-mL collection kit with a flocked flexible minitip swab	220531
Nasal Swab Collection Kits	
FLOQSwab™ with Universal Transport Media™ (UTM) from Copan Diagnostics	306C
BD™ Universal Viral Transport (UVT) 3-mL collection kit with a flocked regular swab	220528
Thermo Fisher™ Scientific Remel™ M4RT	R12565, R12566, R12567
Thermo Fisher™ Scientific Remel™ M4	R12550
Thermo Fisher™ Scientific Remel™ M5	R12555
Thermo Fisher™ Scientific Remel™ M6	R12563, R12568, R12569

Please note: saline claim is still in development and expected post launch. Status will be communicated in due course

cobas® SARS-CoV-2 & Influenza A/B for use on the **cobas®** Liat® System is in development.
Design goals are reflected and are for informational purposes only

Sample preparation: Verified method too

วิธีทดสอบ/การแปลผล/ข้อจำกัด : มี Pre-Amplification???

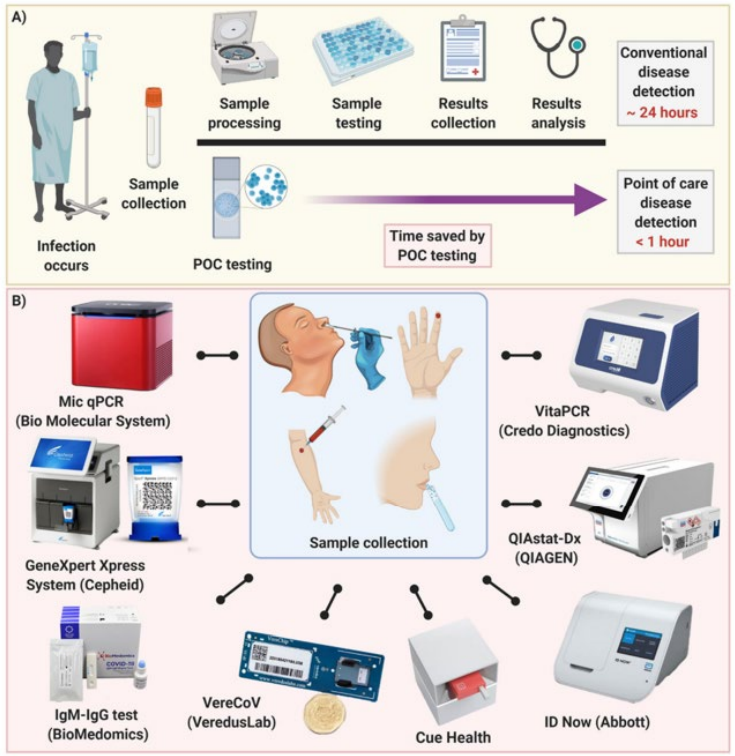


Figure 3. (**A**) Schematic illustration of disease detection using conventional methods relied on centralized laboratories and POC testing approaches. POC devices can drastically reduce the amount of time needed to detect disease. (**B**) Current rapid commercially available POC devices that possess FDA approval for COVID-19. After sample collection and processing, these devices are capable of testing the sample in a time frame of mostly less than 30 min.

at the
ient

Fast, 20 minutes

Suitable for STAT testing
Immediate treatment decisions

Lab quality performance

Reliable results
Immediate actionable results

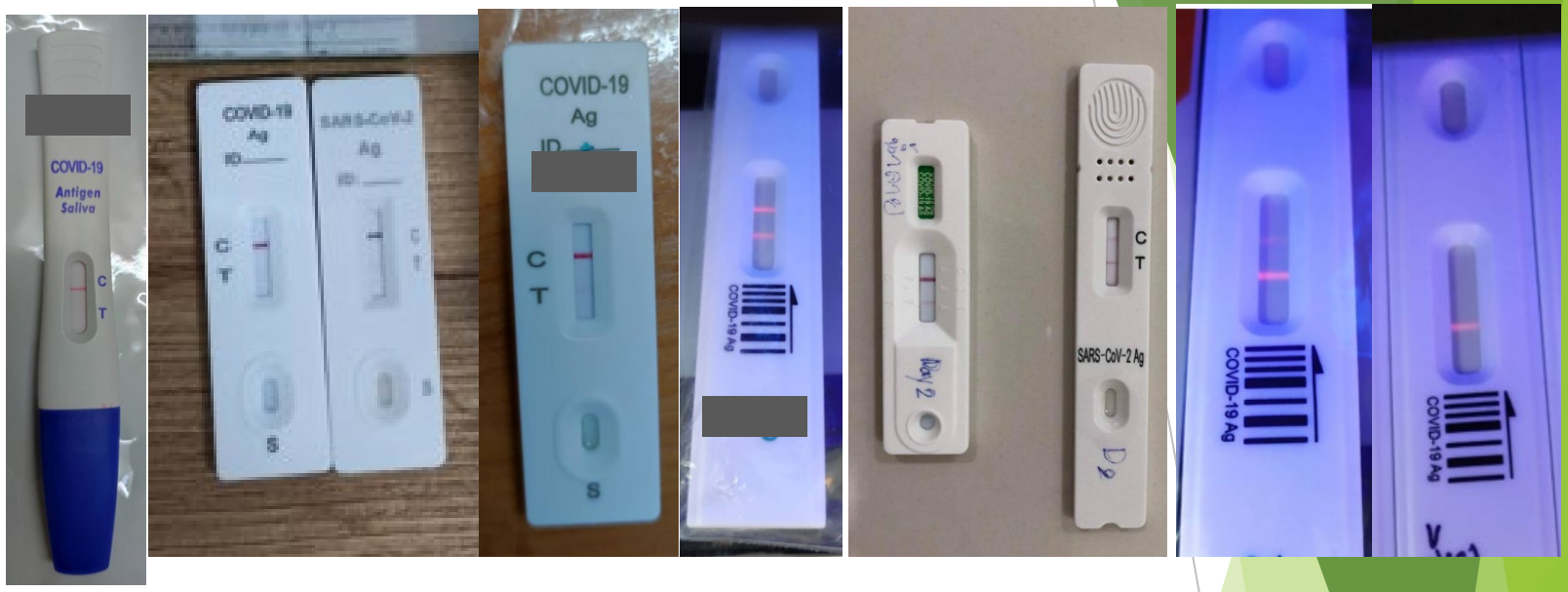
uenza A/B & RSV ~20 min
ial

CONFIDENTIAL DO NOT DISTRIBUTE

cobas Liat
Lab in a tube

ขั้นตอนการตรวจที่ควรเน้น

- ช่วงเวลาที่ตรวจ : **day3- day5**
- การเก็บตัวอย่างให้ได้ตัวอย่างที่ดี: ถูกต้อง
- วิธีทดสอบ: ตามคู่มือชุดตรวจนั้น- เวลาอ่านผล, บัฟเฟอร์
- การอ่านผลและแปลผล: กลุ่มเสี่ยง



Cycle threshold (Ct) between 21.1 (around 2.3 10^7 copies/mL) and 23.3 (around 6.8 10^6 copies/mL).

ปัญหาที่ผู้ใช้อาจพบได้

- Case 1. การจัดเก็บสินค้าคงคลัง/การขนส่งสินค้า มีผลต่อความคงทน(stability)

85	LY-1	66.67	100	16/2/2022
122	LY-2	75	100	5/4/2022
171	LY-3	93.33	100	1/7/2022
154	Wr NS	61.67	97	25/5/2022
155	Wr saliva	55	99	25/5/2022

- Case 2. ประสิทธิภาพของชุดตรวจที่ใช้

94	Ai-2 -saliva	98.33	100	
89	Ai 1-nasal	63.33	100	27/2/2022
90	Ai1-saliva	71.67	100	22/2/2022

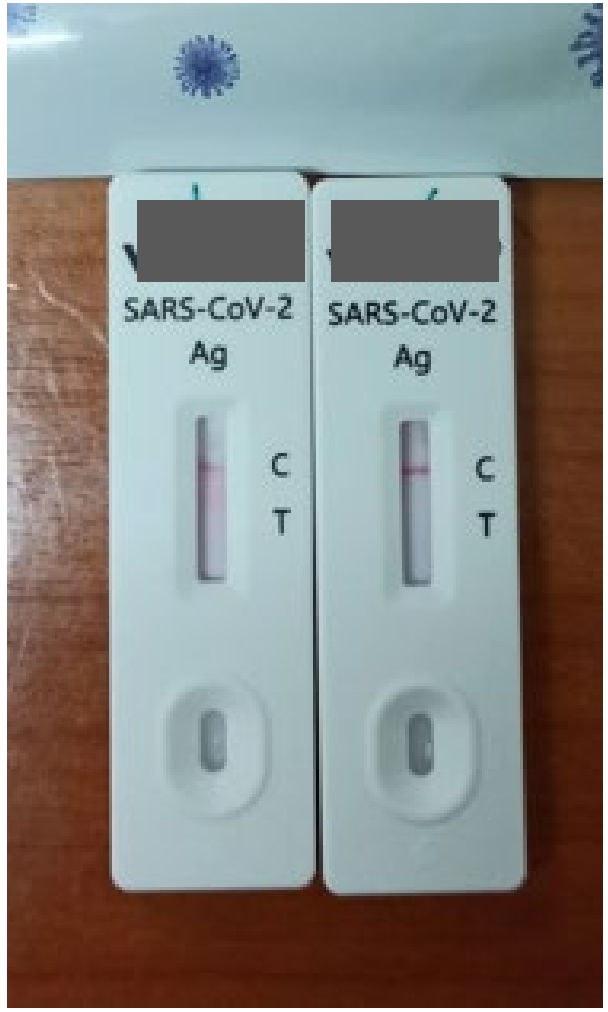
Case 4. ช่วงเวลาที่ตรวจผลตรวจ ATK After Day 5

1.ส่วนใหญ่ ตรวจไม่พบ

2. น้ำลาย มักให้ผลลบก่อน nasal swab

3. จะตรวจ เพื่อจะทำอะไรต่อมั้ย- เลือกชุดตรวจให้เหมาะกับงาน

ปัญหาที่ผู้ใช้อาจพบได้ case 3. วิธีทดสอบ

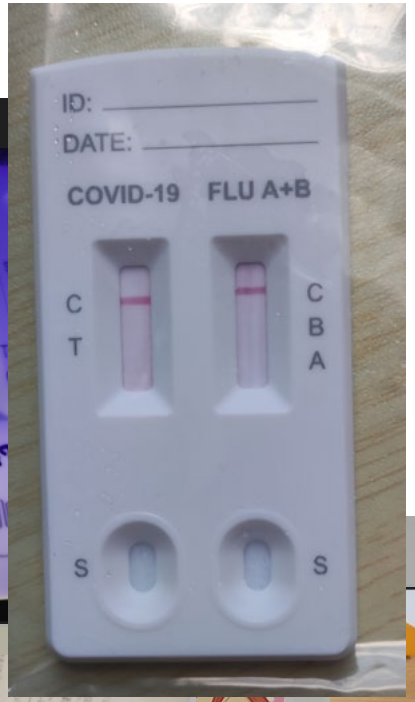


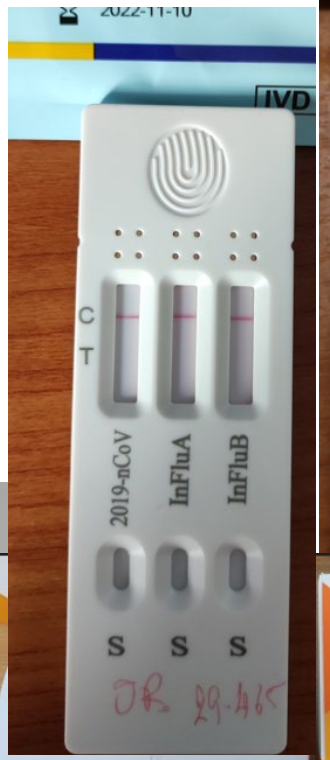
ปัญหาที่พบได้

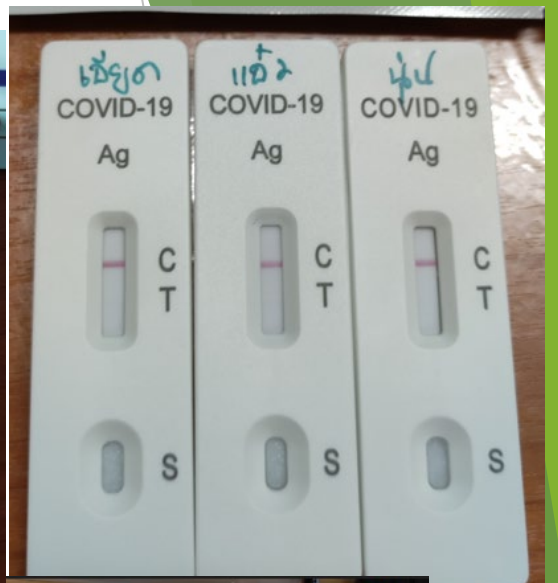
Case 5. รายไหน ให้ผลบวกบ้าง (การอ่านผลตรวจ)


DEEPBLUE
COVID-19
Ag
COVID-19 Ag
COVID-19
Antigen
COVID-19
Antigen
Saliva
C
T
S


SARS-CoV-2
Ag
T
C
P43
P44
P45
P46


ID:
DATE:
COVID-19
FLU A+B
C
T
C
B
A
S
S


2022-11-10
IVD
C
T
2019-nCoV
InFluA
InFluB
S
S
S


เชียงา
COVID-19
Ag
แอ๋ว
COVID-19
Ag
นุ่น
COVID-19
Ag
C
T
S


COVID-19
Ag
C
T


BioWin
COVID-19
CE
TEERAKAN
นึกนัก
11:55
F-TEST


11b NS
CITEST
Fluorescence
Immunoassay Test Kit
Swab Specimen Extraction Procedure Card


LEPU MEDICAL
136-NS
Negative