

# COVID-19 antibody tests and the UK Rapid Testing Consortium

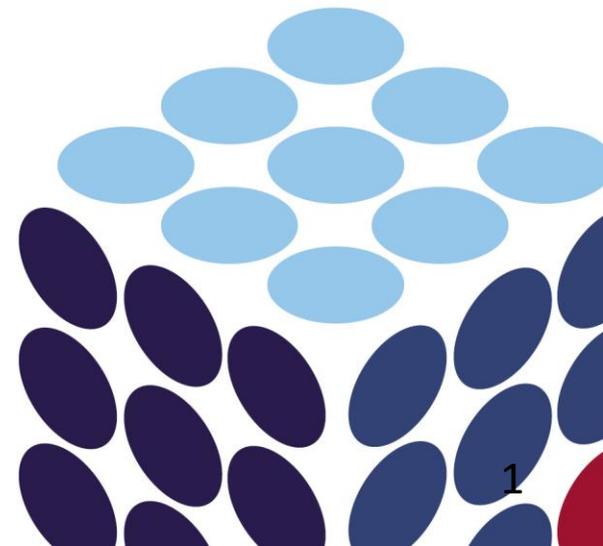
June 18, 2020

Jonathan Allis, D.Phil.

CEO Blue Earth Diagnostics

Chairman Polarean Imaging plc.

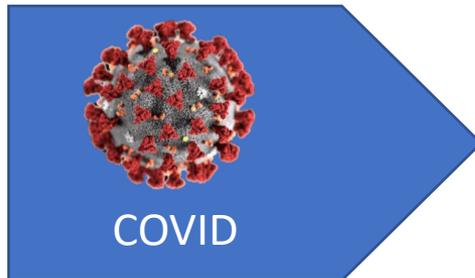
Chairman UK Rapid Test Consortium



# And now for something completely different ..

- Blue Earth Diagnostics\*
  - Robust portfolio of approved and investigational PET diagnostic/therapeutic compounds for prostate cancer and brain metastases
- Polarean Imaging\*
  - Hyperpolarized gas MRI imaging of lungs

My normal job



Professor Sir John Bell (Oxford)  
“Your Country Needs You”!

\*Blue Earth Diagnostics and Polarean Imaging are not connected to the UK Rapid Test Consortium

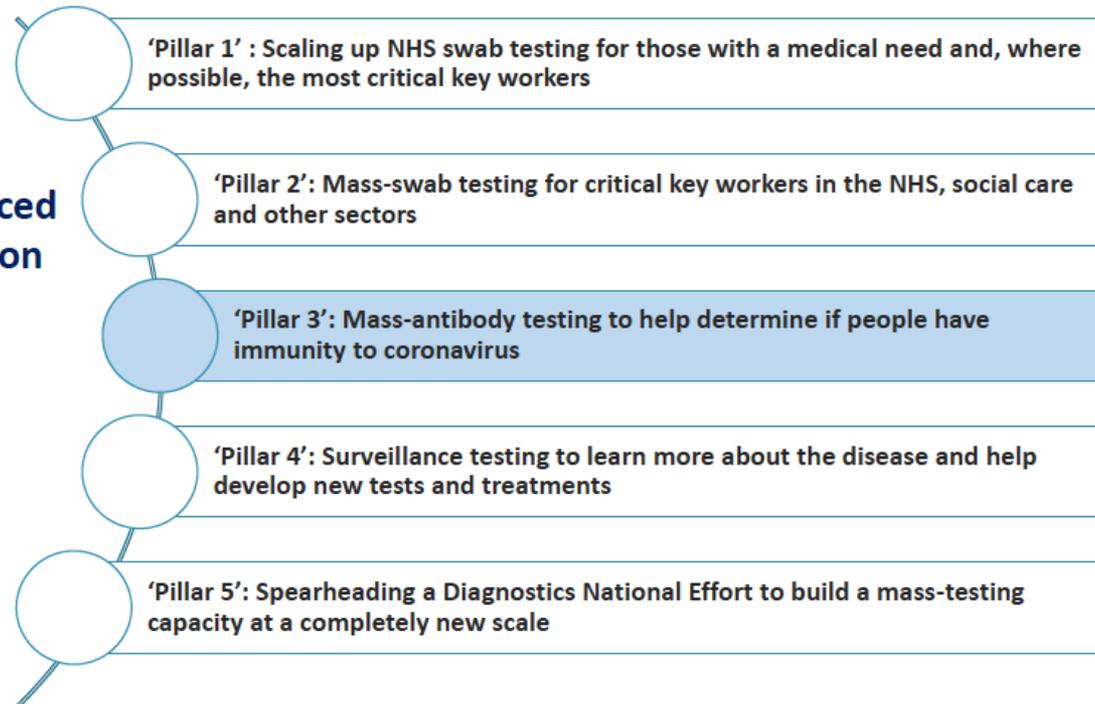
# UK government 5 pillar plan for COVID-19 testing



## Our National Testing Strategy

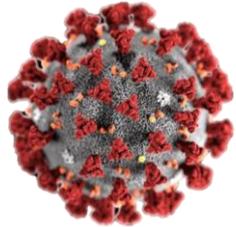
The strategy was announced by the Secretary of State on 2<sup>nd</sup> April and has 5 key strands

The webinar today will focus on Pillar 3: Antibody testing



Pillars 1,2: Antigen tests for virus; Pillar 3: Antibody (to SARS-CoV-2) testing

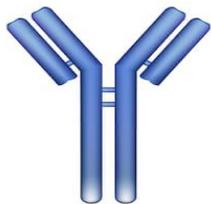
# COVID-19 testing



## Antigen testing

- Detecting SARS-CoV-2 viral RNA in nasal swabs, etc..
- RT PCR  
(Reverse Transcription Polymerase Chain Reaction)

Do you have  
COVID now?



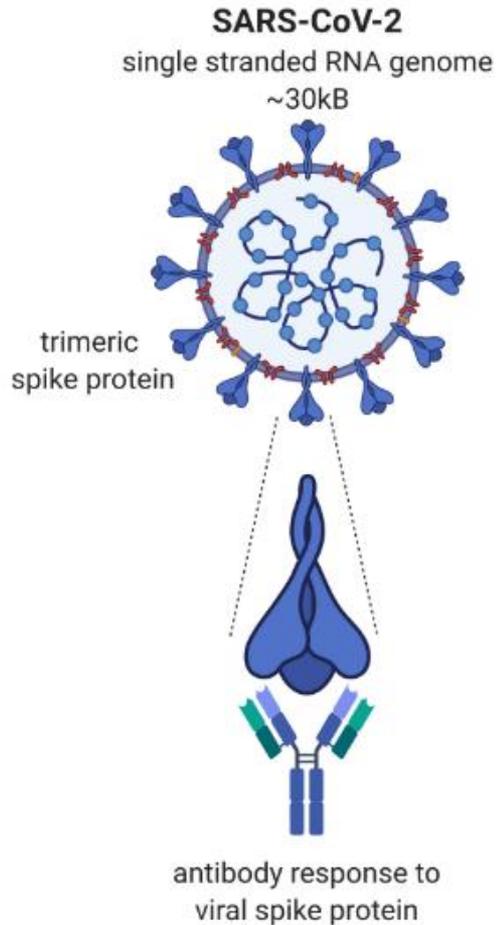
## Antibody testing

- Detecting antibodies to SARS-CoV-2 in blood
- ELISA and other Lab-based tests
- Lateral Flow Tests (decentralized & home use)

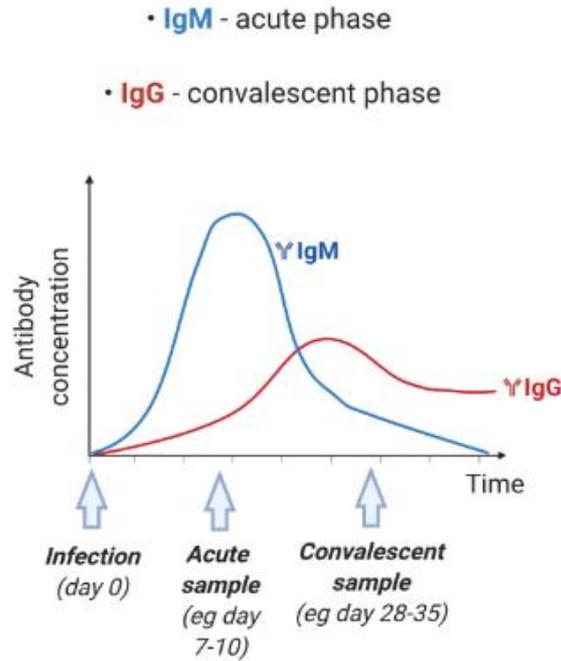
Have you had  
COVID?

# Immune response to SARS-CoV-2 infection

## A: viral infection

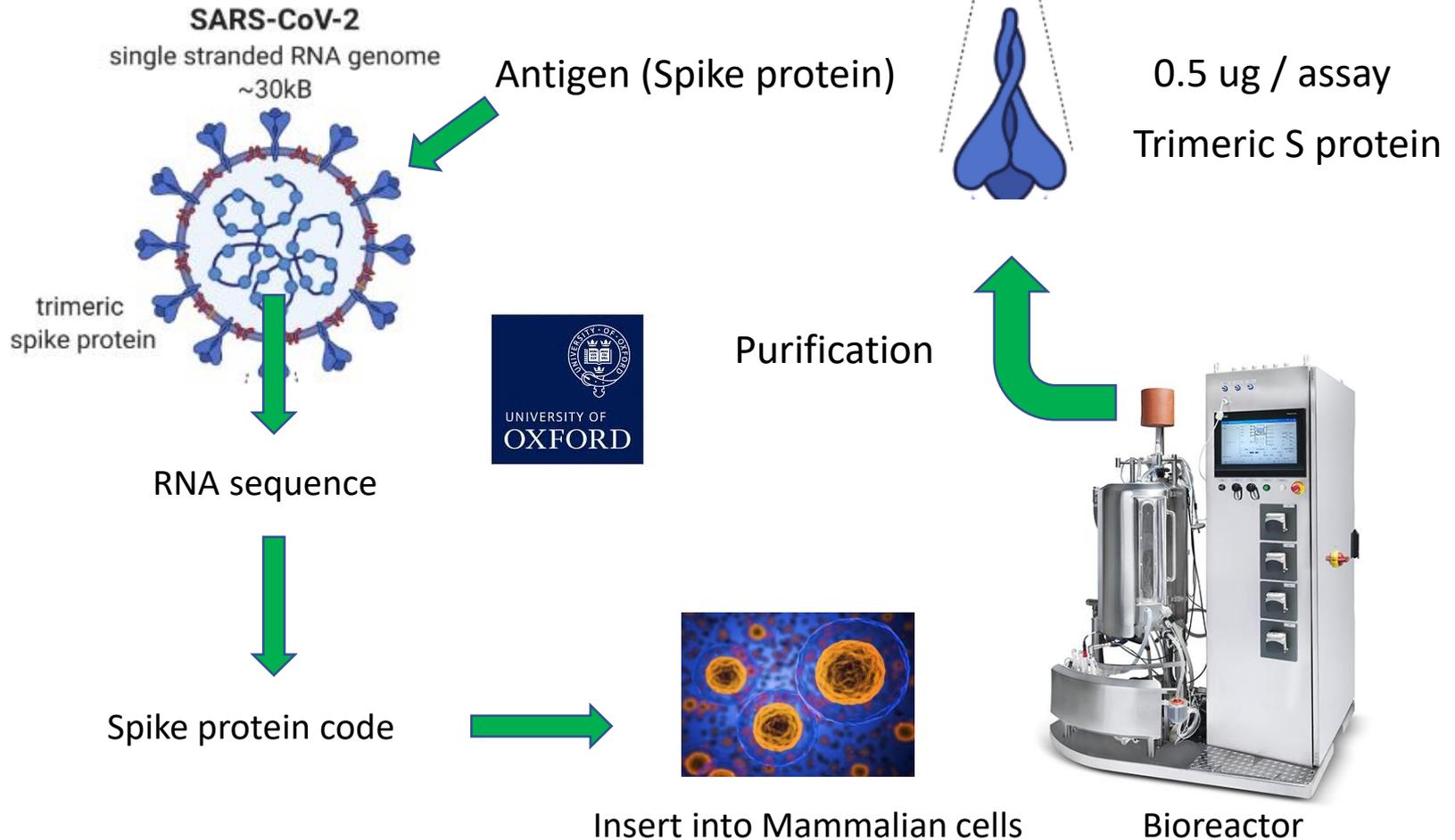


## B: antibody response



Long(er) term immunity?

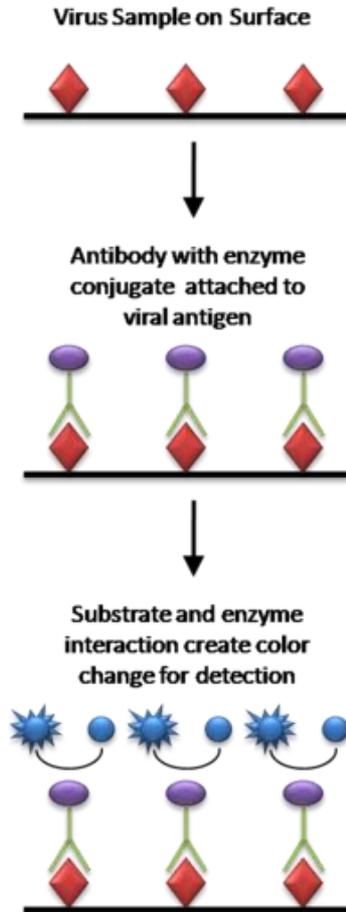
# Antibody tests need a good Antigen



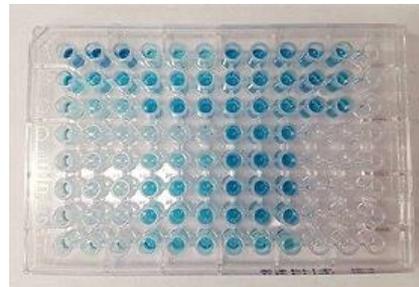
An alternative antigen used in some Antibody tests is the Nucleocapsid (N) protein

# ELISA

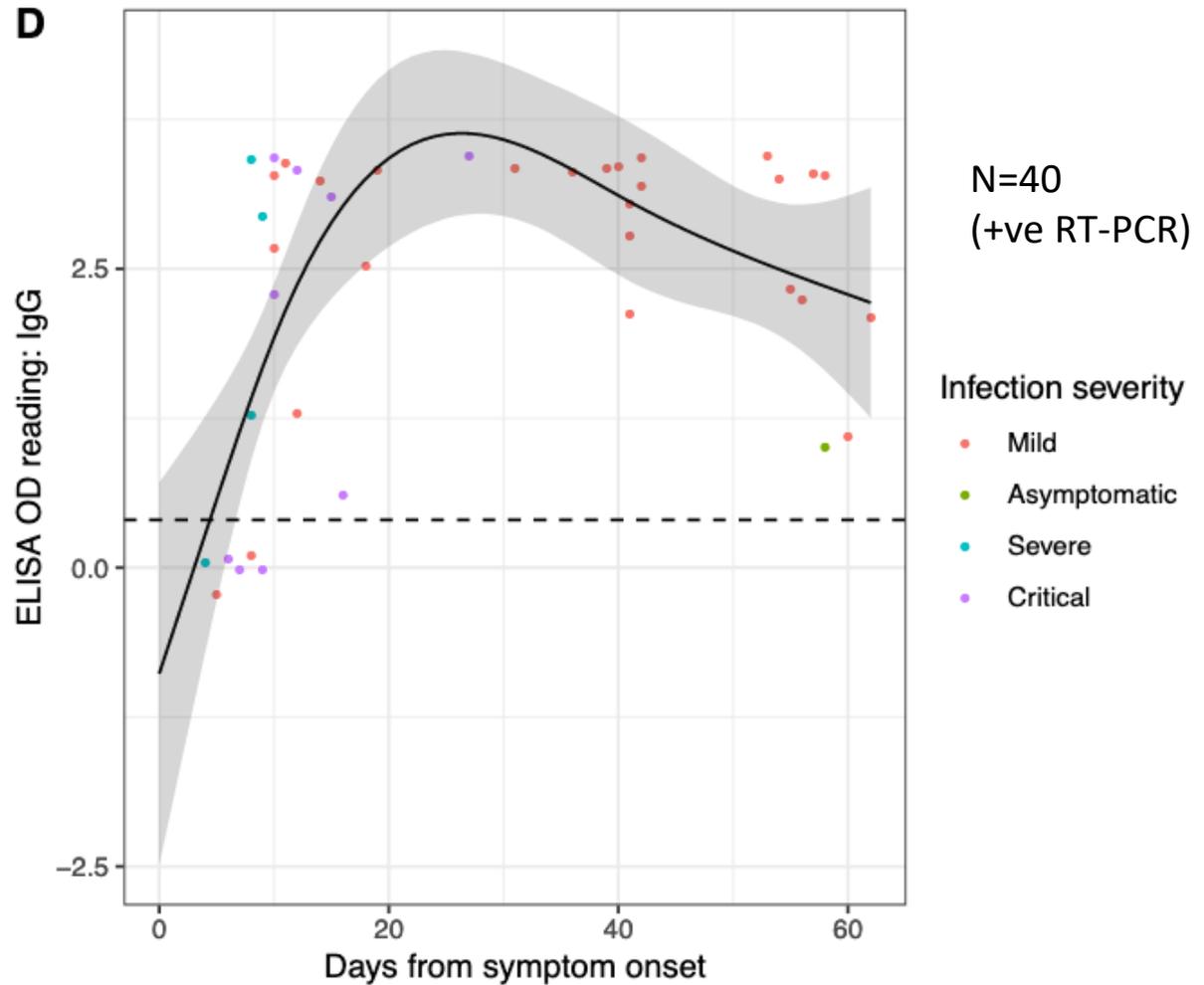
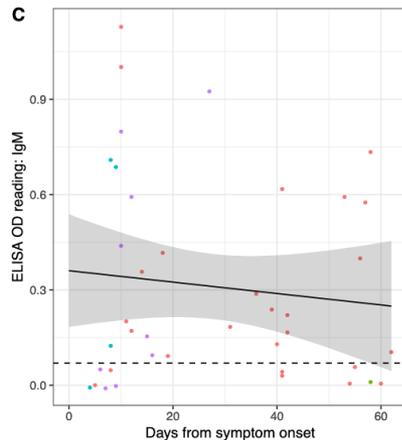
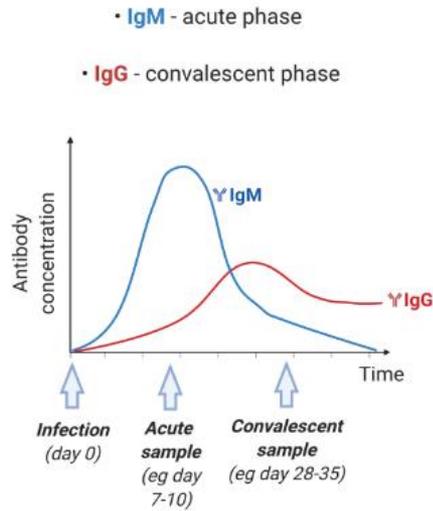
## Enzyme-linked Immunosorbent Assay



- Once you have a good antigen, you can use it to detect the Neutralizing Antibodies to the antigen in a sample
- The “Gold Standard” method employs the ELISA technique
- There are multiple ELISA techniques for COVID IgG
- The Oxford ELISA seems to be a very good one



# Evolution of IgG over time (Oxford ELISA)

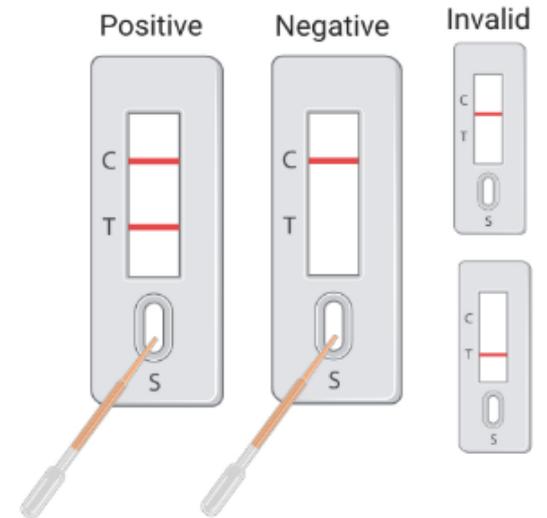
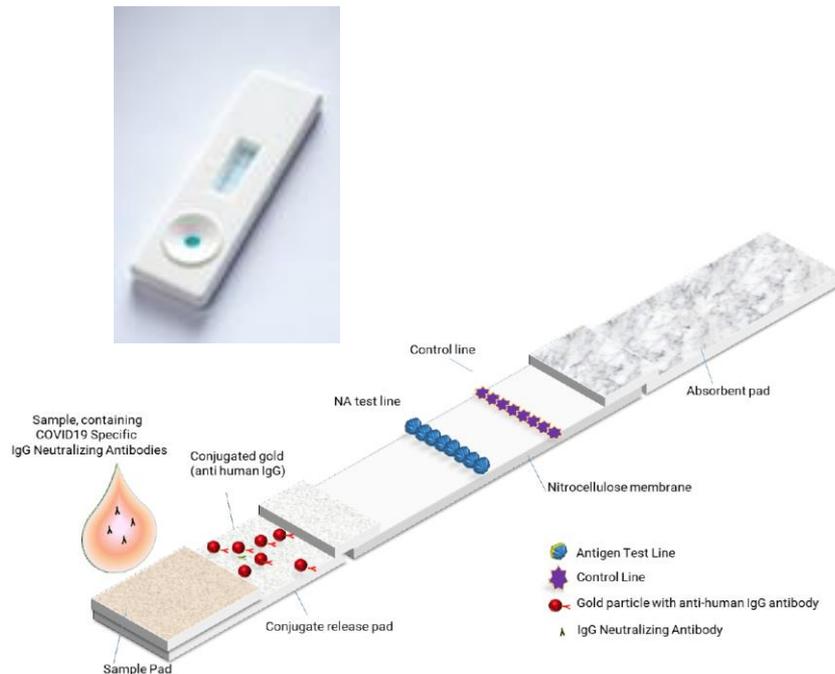


# Lateral Flow Tests (LFTs)

- Point of care / Home use
- Fast ~ 20 minutes
- Cheap ~ \$10-20
- Essential .. UK lacks extensive testing lab infrastructure

## Lateral flow device

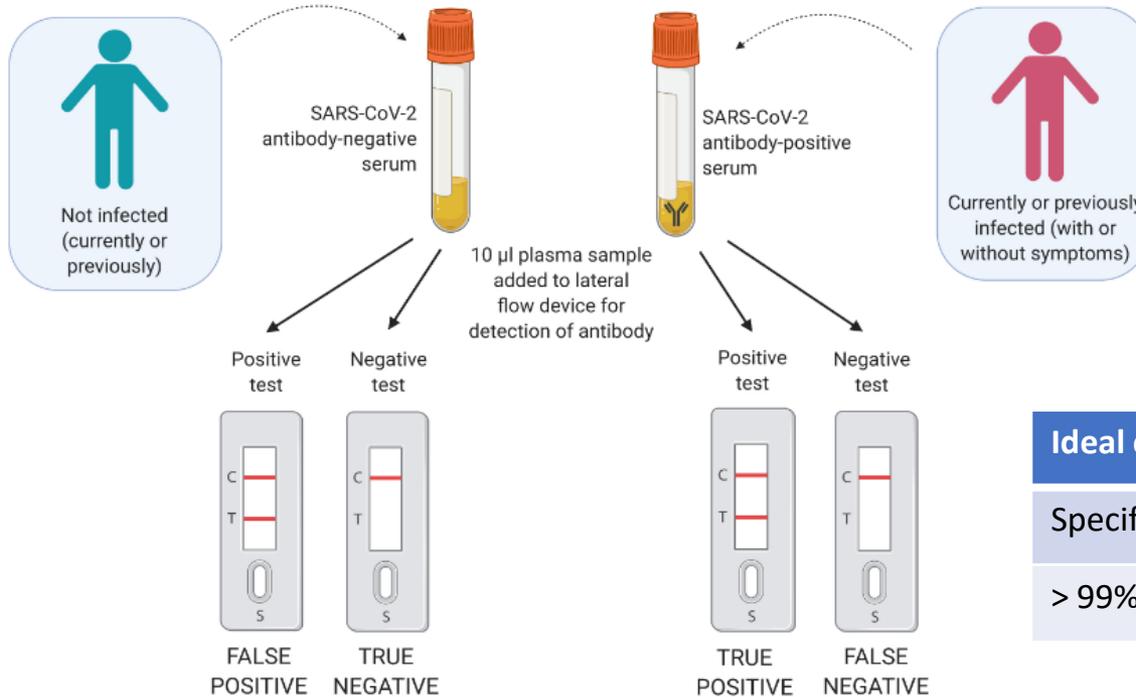
For detection of IgG



1 5 uL whole blood ; add buffer and incubate at room temperature according to manufacturer's instructions

# Optimal characteristics for any COVID Antibody test (including LFT)

## D: outcomes of lateral flow assays



### Ideal characteristics

Specificity

> 99%

Sensitivity

> 95%

**Specificity**

**Sensitivity**

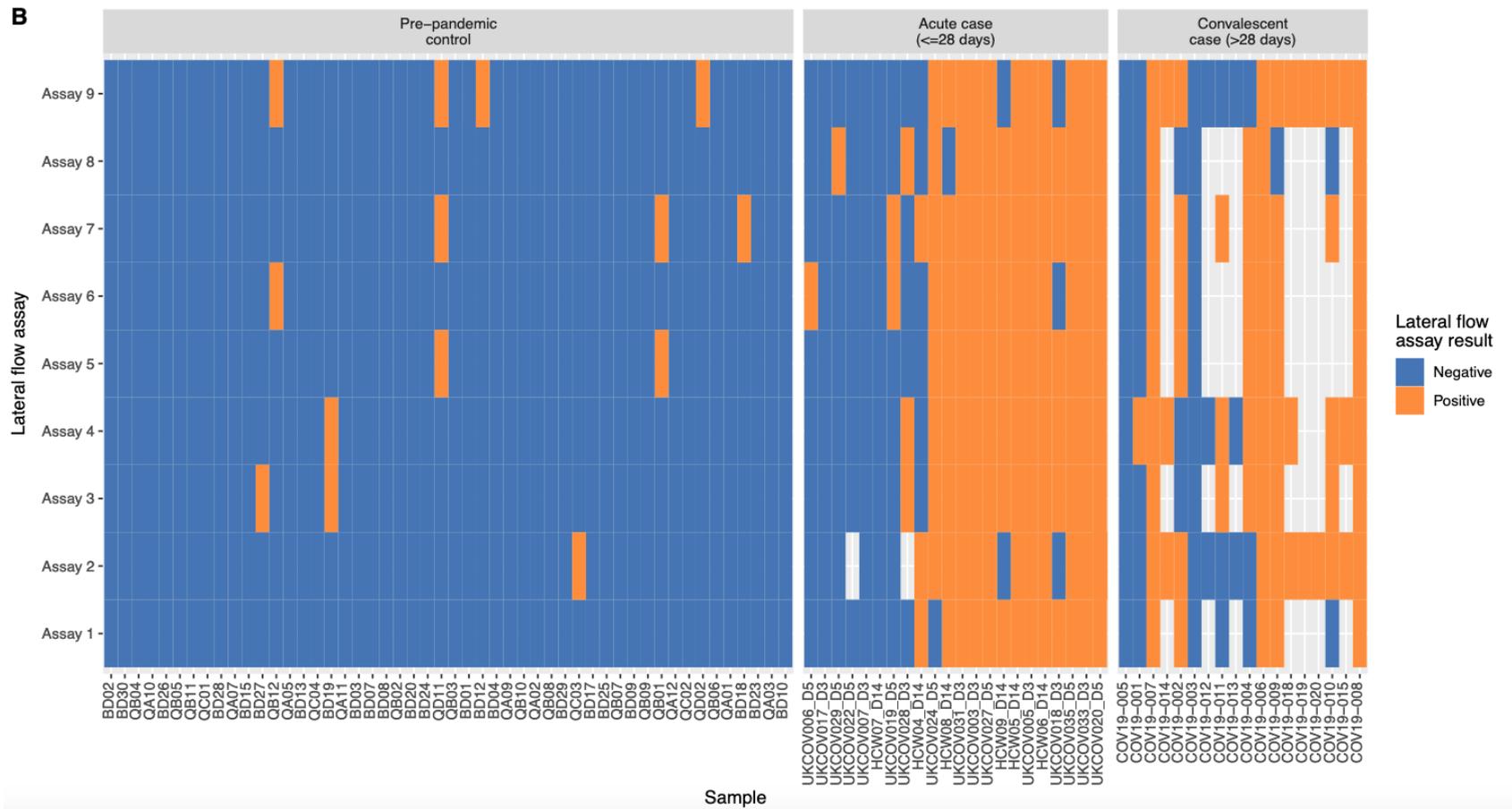
- Need very high Specificity
- Don't want False Positives

- Need high Sensitivity
- False negatives less risky, but not helpful

# 9 LFTs tested against Oxford ELISA



- 9 Commercially available LFTs were compared to Oxford ELSIA



# Performance of 9 COVID-19 LFTs in detail

Assay	RT-PCR positive		Pre-pandemic control		Sensitivity (95% CI)	Specificity (95% CI)
	True positive	False negative	True negative	False positive		
ELISA	34	6	50	0	85 (70,94)	100 (93,100)
1	18	15	60	0	55 (36,72)	100 (94,100)
2	23	15	90	1	61 (43,76)	99 (94,>99)
3	21	12	58	2	64 (45,80)	97 (88,>99)
4	25	13	59	1	66 (49,80)	98 (91,>99)
5	19	12	58	2	61 (42,78)	97 (91,>99)
6	20	11	59	1	65 (45,81)	98 (91,>99)
7	23	10	57	3	70 (51,84)	95 (86,>99)
8	18	14	60	0	56 (38,74)	100 (94,100)
9	22	18	138	4	55 (38,74)	97 (93,>99)

## 9 LFTs performance characteristics

Specificity	Sensitivity
93%-100% (point 98%)	65-85% (ideal ~ 90+%)

# Most COVID -19 Lateral Flow Antibody Tests don't work that well



[Our Research](#) / Coronavirus Research

Oxford University Blog

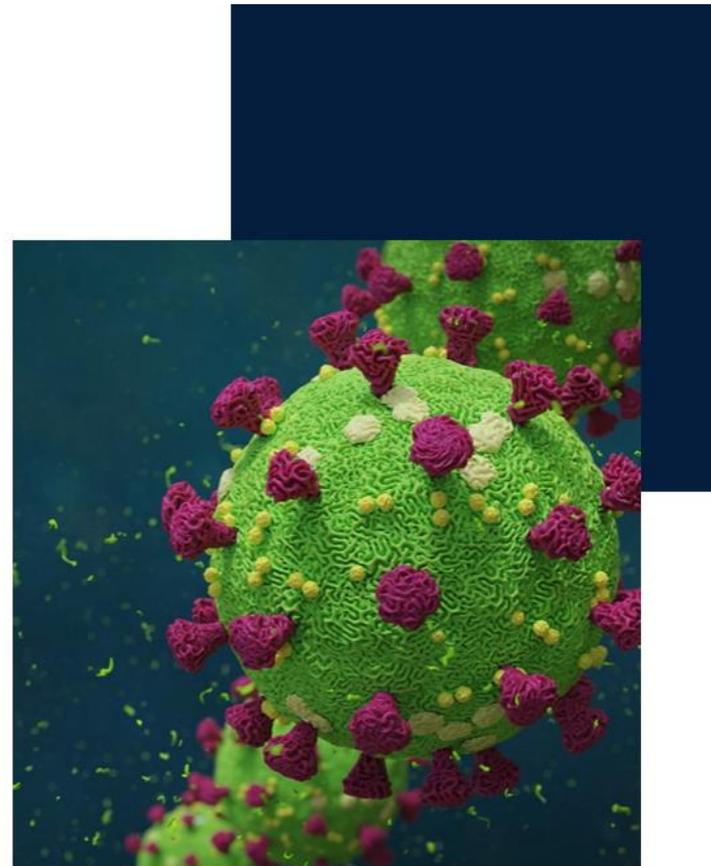
## Trouble in testing land

5TH APR 2020

CORONAVIRUS

DIAGNOSTIC TOOLS

SHARE THIS:



# Everyone wanted COVID LFTs ..

- Lots of tests approved on very small (carefully chosen) data sets
- Need to be very careful if you use/buy them ..

## *U.K. Paid \$20 Million for New Coronavirus Tests. They Didn't Work.*

Facing a global scramble for materials, British officials bought millions of unproven kits from China in a gamble that became an embarrassment.



Parliament in London. Britain is aiming to conduct 100,000 coronavirus tests a day by May, but as of this week was still doing less than 20,000 a day. Andrew Testa for The New York Times

FINANCIAL TIMES

myFT Daily Digest



Health sector

Delay and confusion about finding a reliable antibody test in the UK

JUNE 16, 2020

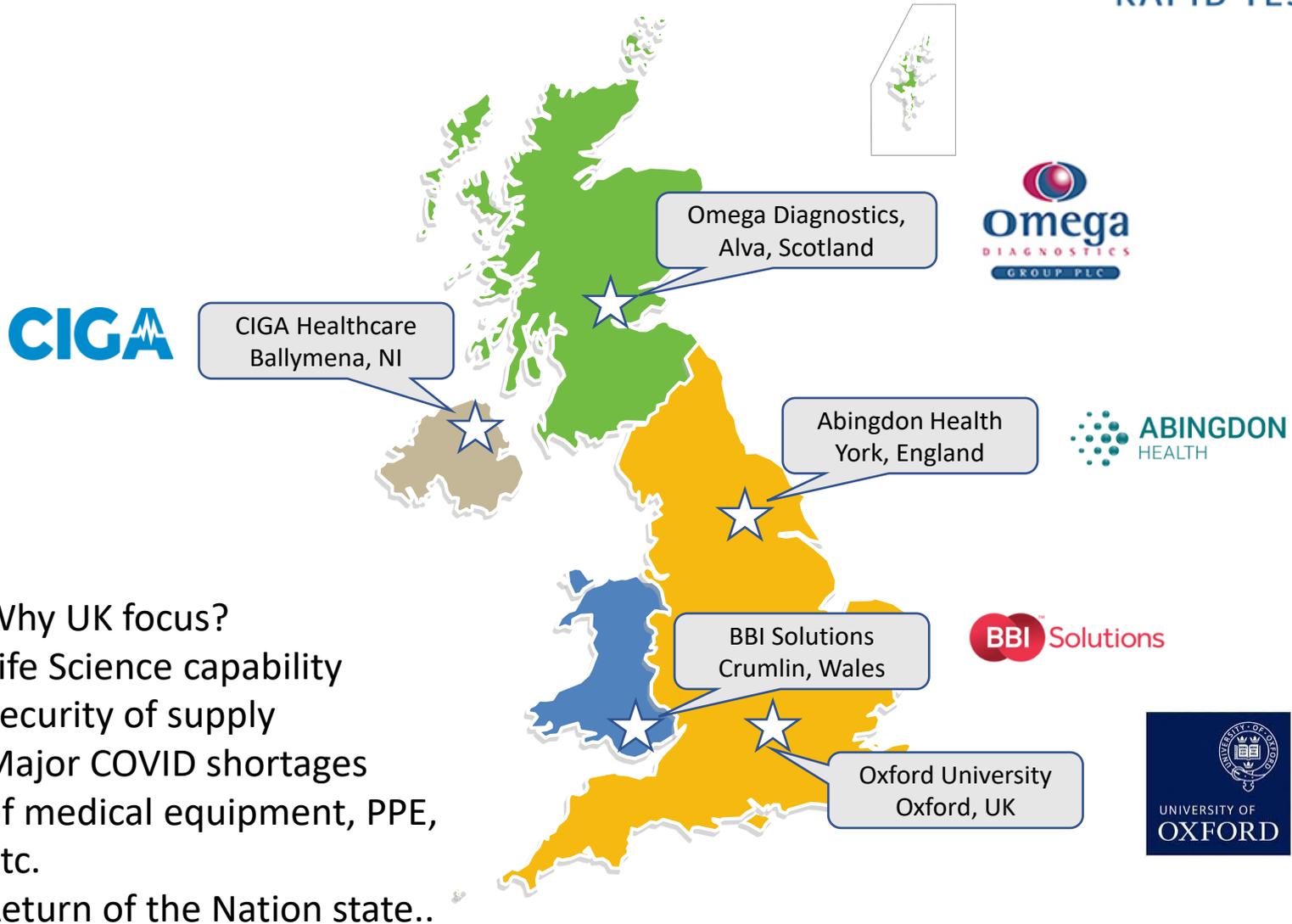
MedTech

## FDA names 28 antibody tests to be taken off the market

by Conor Hale | May 22, 2020 10:40am

# Can we make a better LFT for COVID?

## Formation of UK Rapid Test Consortium (RTC)



- Why UK focus?
- Life Science capability
- Security of supply
- Major COVID shortages of medical equipment, PPE, etc.
- Return of the Nation state..

# RTC objectives

## My role as Chairman

### RTC objectives:

- Perform an 8-month development project in 25% of the time
- Develop Phone App to read test
- Scale up to manufacture later in 2020



## My role as Chairman

- Wikipedia “research” on LFTs
- Independent of the companies involved
- Promote trust and cooperation
- Provide moral support when working with UK Department of Health & Social Care, NHS, UK Treasury
- Forming, Norming, Storming, Performing in real time

# RTC challenges

## Macro

- COVID-19 is a new disease, not fully understood
- Government strategy being developed at pace
- The situation changed on a weekly / daily basis
- Interfacing between 4 small companies and DHSC / Treasury

## Micro

- Supply of key materials (antigen, lancets, nitrocellulose, ...)
- Finding enough blood samples with appropriate ethics for testing
- Developing user instructions that work for the whole population
  
- Everyone I know wants a free test

# Almost there ... !



- LFT developed and optimized
- Modification of existing Phone App to work with new test and interface to NHSx (Digital)
- Development of Regulatory strategy and collaboration with MHRA
- Transition to large scale manufacture for more widespread evaluation & distribution

ELISA negative  
Specificity  
**Close to optimal**

ELISA positive  
Sensitivity  
**Close to optimal**



# How's it different to PET radiopharmaceuticals?

- Very rapid development!
  - Not a lot of IP hurdles
  - You can do a clinical trial with 100s of samples in a day!
  - Simpler Regulatory environment
  - Very low cost
  - Very high volume
- 
- I need to come back to PET for a rest



# Thank you!

