

COVID-19 antibody tests and the UK Rapid Testing Consortium

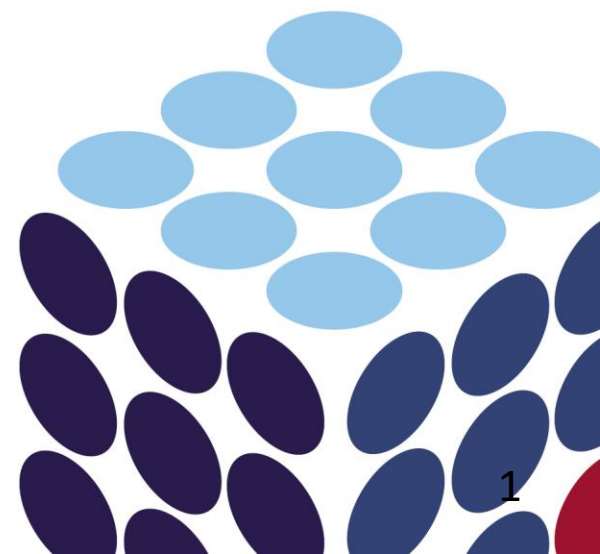
June 18, 2020

Jonathan Allis, D.Phil.

CEO Blue Earth Diagnostics

Chairman Polarean Imaging plc.

Chairman UK Rapid Test Consortium

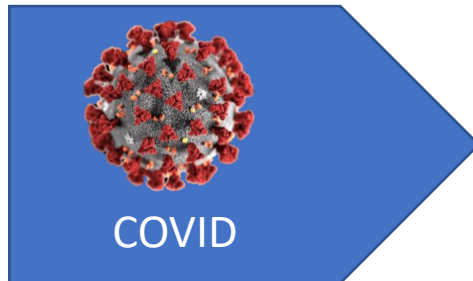


And now for something completely different ..



- 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

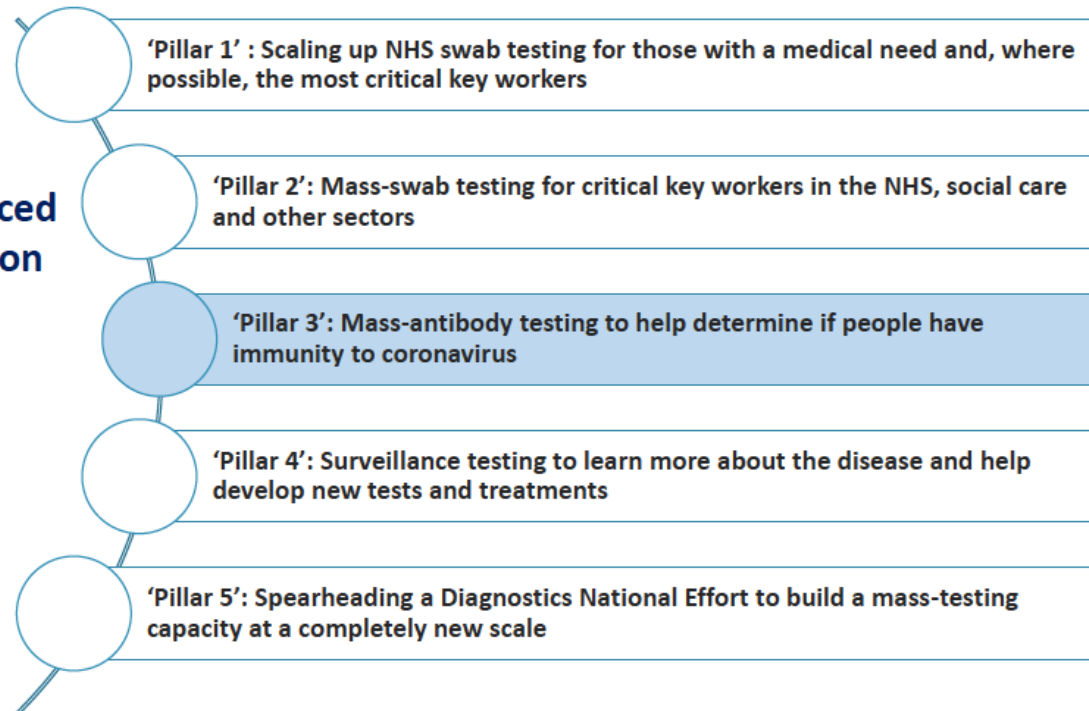
UK government 5 pillar plan for COVID-19 testing



Our National Testing Strategy

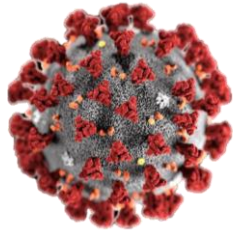
The strategy was announced by the Secretary of State on 2nd April and has 5 key strands

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

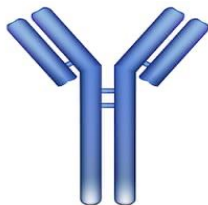
COVID-19 testing



Antigen testing

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

Do you have
COVID now?



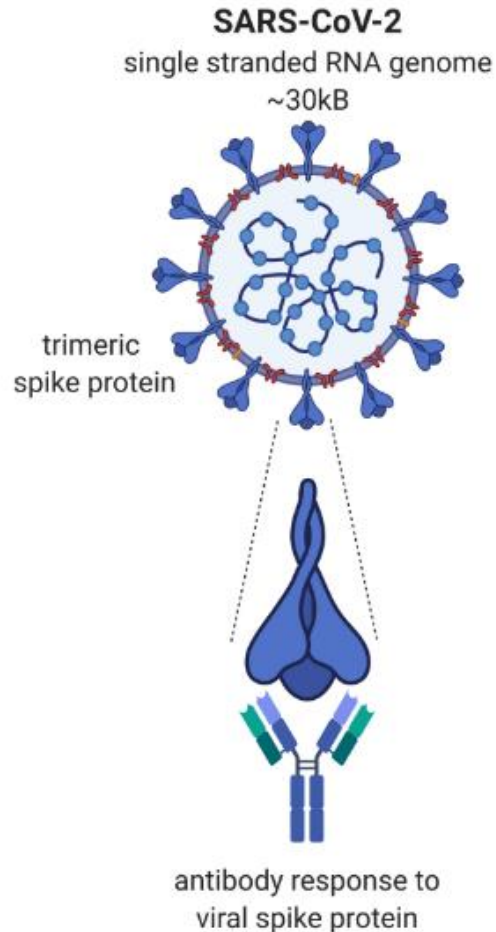
Antibody testing

- 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

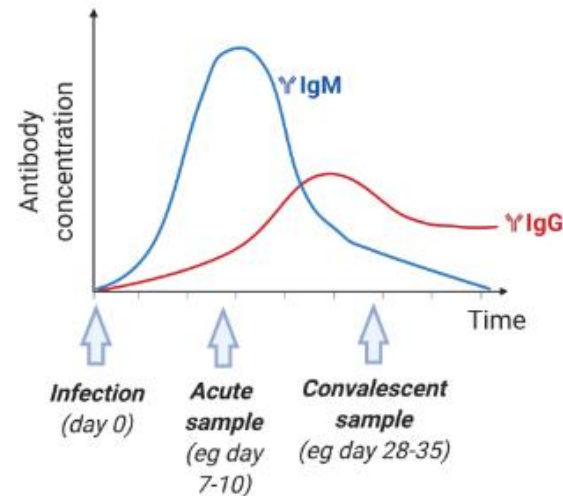
A: viral infection



B: antibody response

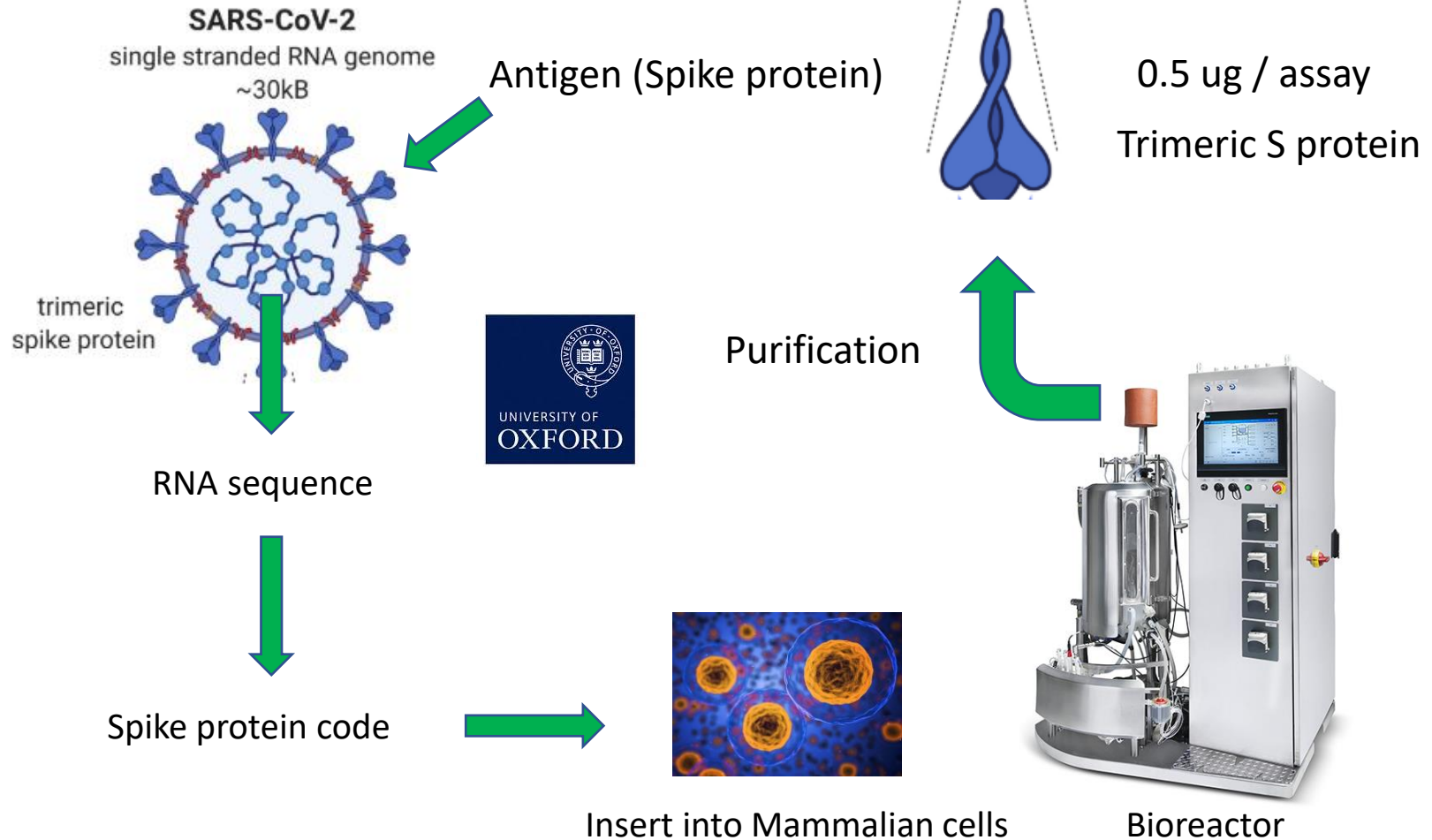
• **IgM** - acute phase

• **IgG** - convalescent phase



Long(er) term immunity?

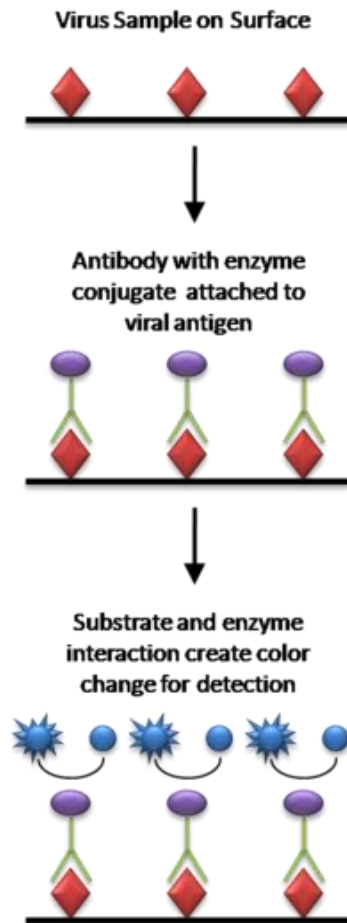
Antibody tests need a good Antigen



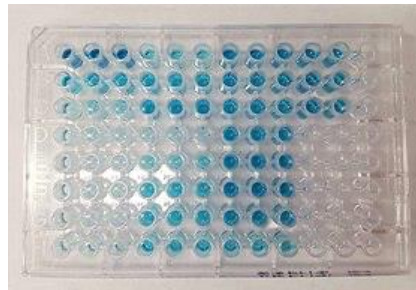
An alternative antigen used in some Antibody tests is the Nucleocapsid (N) protein

ELISA

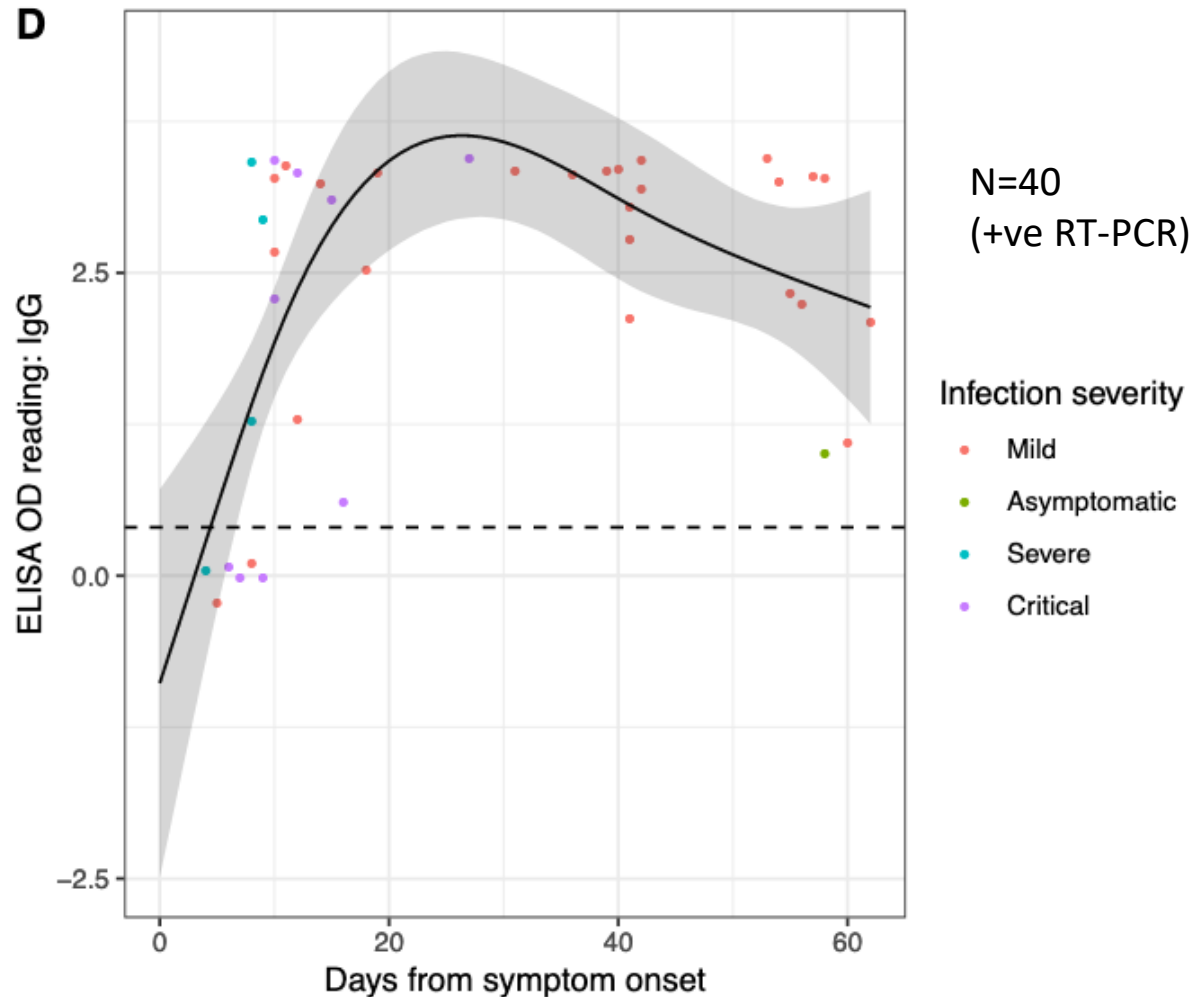
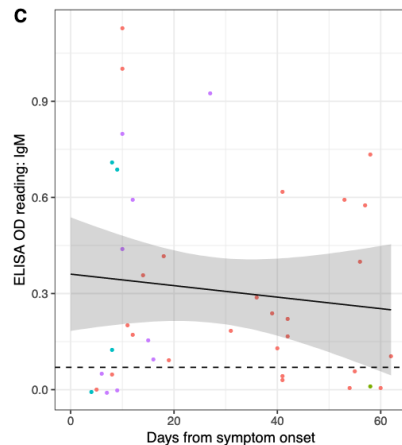
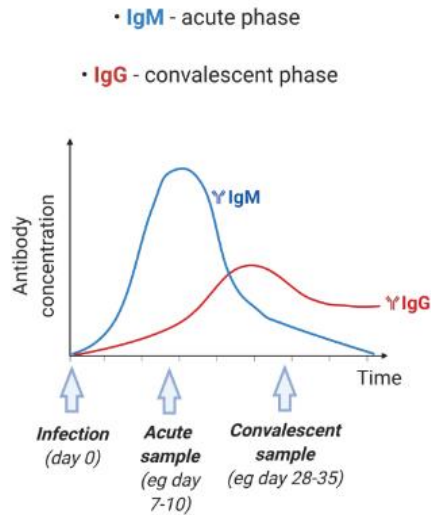
Enzyme-linked Immunosorbent Assay



- 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

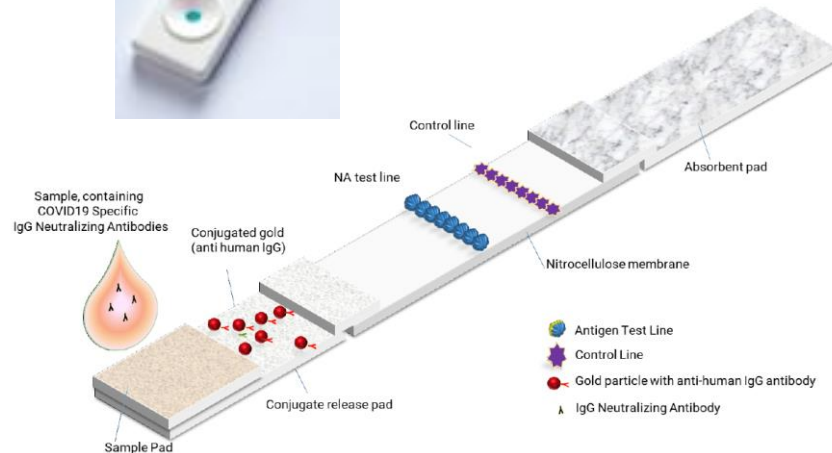


Evolution of IgG over time (Oxford ELISA)



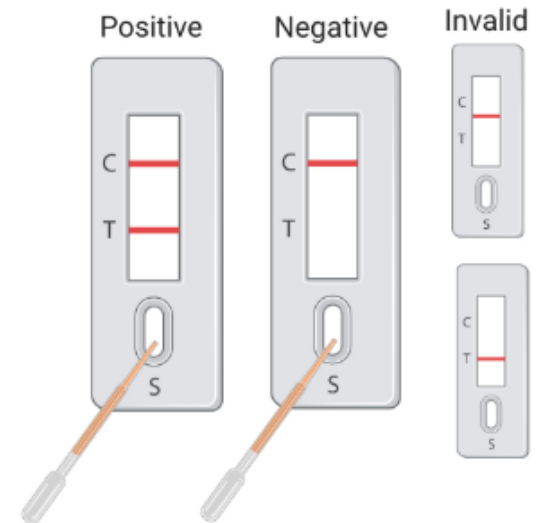
Lateral Flow Tests (LFTs)

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



Lateral flow device

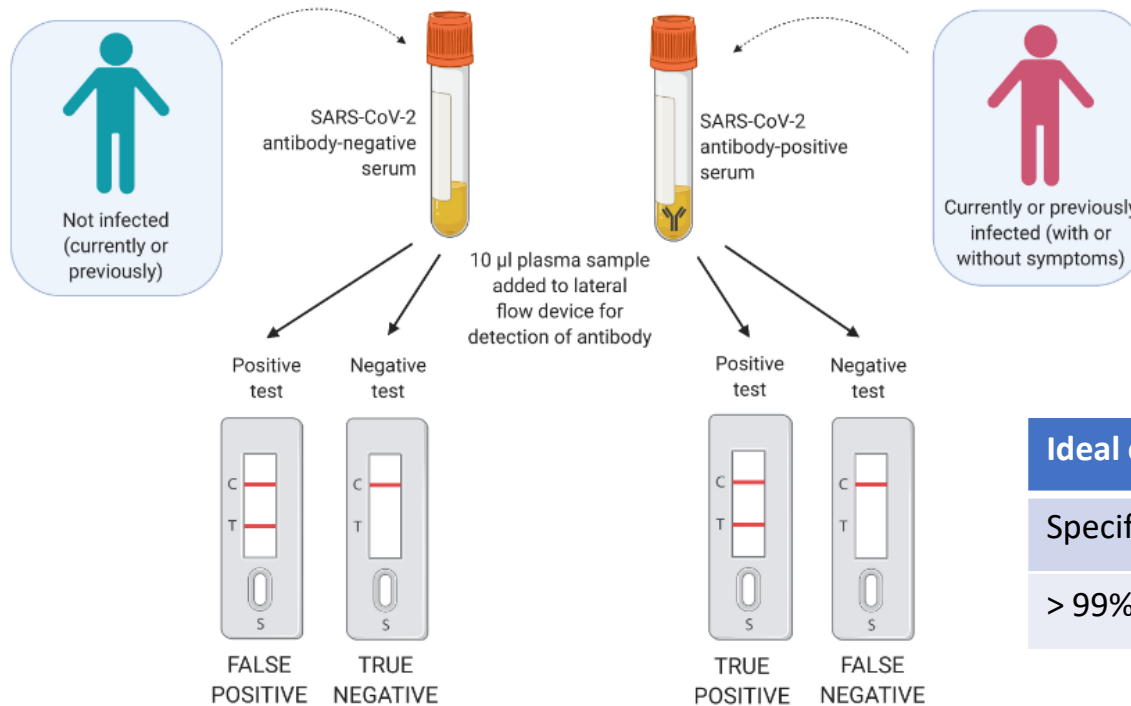
For detection of IgG



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

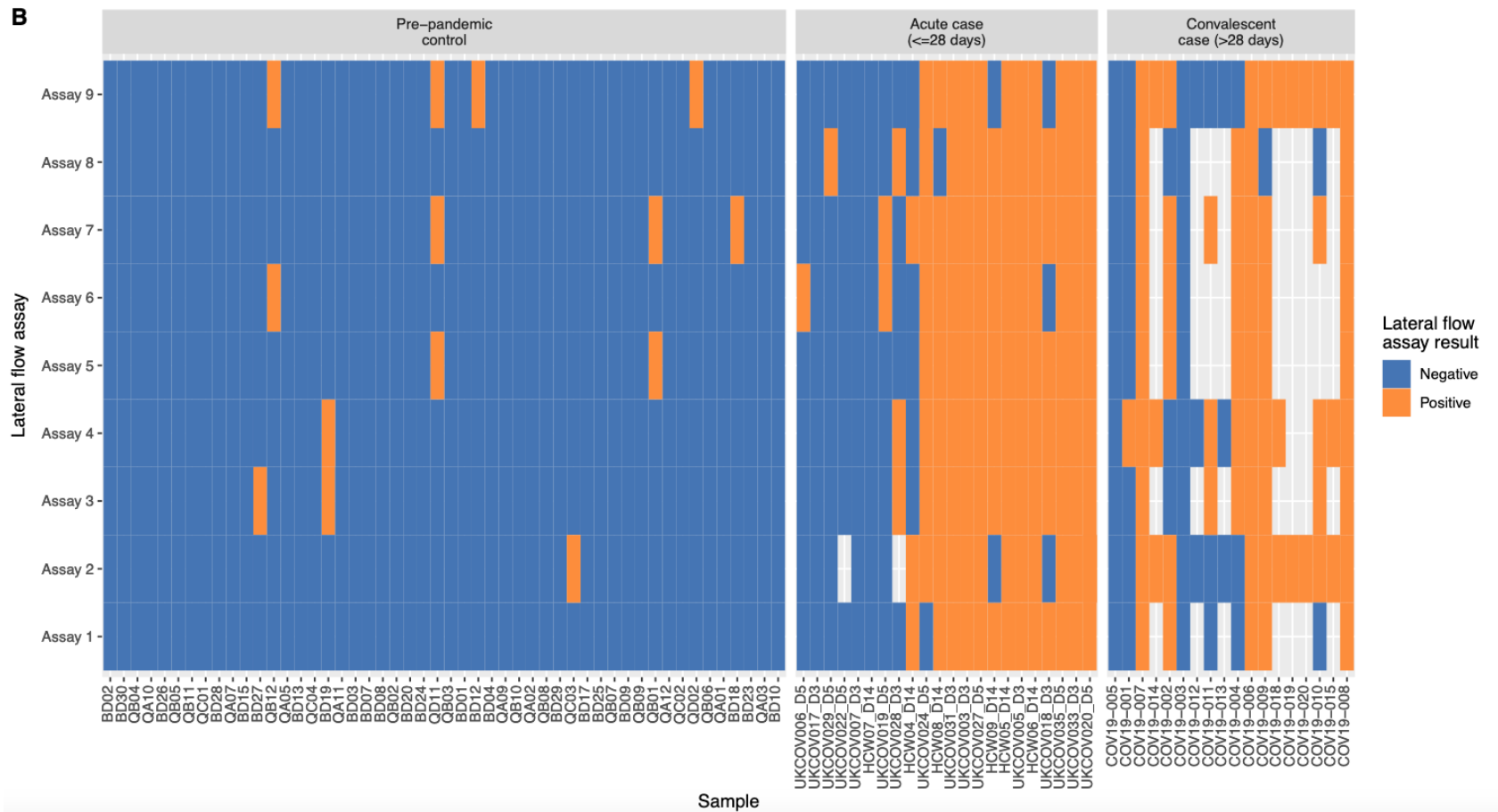
Sensitivity

- 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

93%-100%
(point 98%)

Sensitivity

65-85%
(ideal ~ 90+%)

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



[Our Research](#) / Coronavirus Research

Oxford University Blog

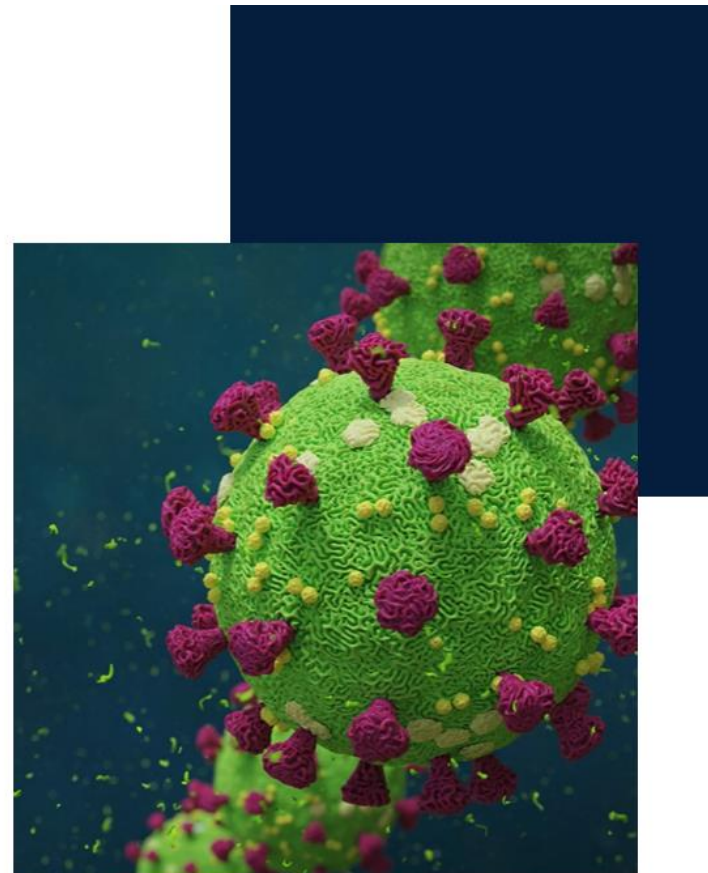
Trouble in testing land

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

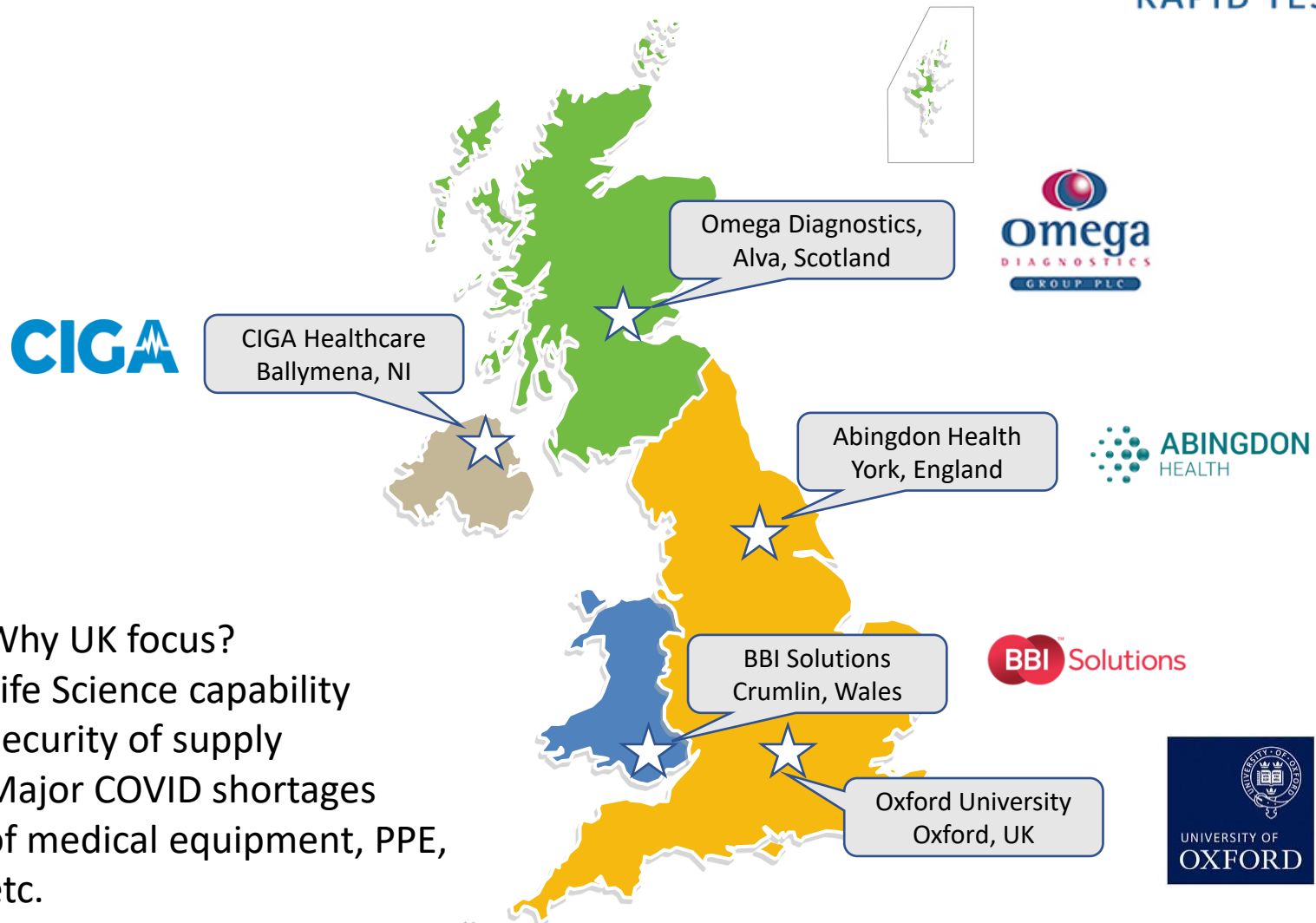
MedTech

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!

