

CELLMID 

GENERAL MEETING

21 May 2020

ASX: CDY

CELLMID

Forward looking statements

This presentation contains forward-looking statements that are subject to risks and uncertainties. Such statements involve known and unknown risks that may cause the actual results, performance or achievements of Cellmid to be materially different from the statements in this presentation. Actual results could differ materially depending on factors such as the availability of resources, regulatory environment, the results of advertising, sales activities and competition.



AGENDA

Section 1: Cellmid operations: consumer health and biotech

- Advangen (consumer health): Resilient during pandemic
- Lynamid (biotech): Expansion of diagnostics to boost assets

Section 2: Overview of COVID-19 diagnostics landscape

- COVID-19: What we know about the pandemic
- Three different testing approaches
- Analysis of PCR and antibody testing
- Why antibody testing is important

Section 3: Upcoming Milestones



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SECTION 1:
CELLMID OPERATIONS

Cellmid operations

ADVANGEN (Consumer Health)

évolis®

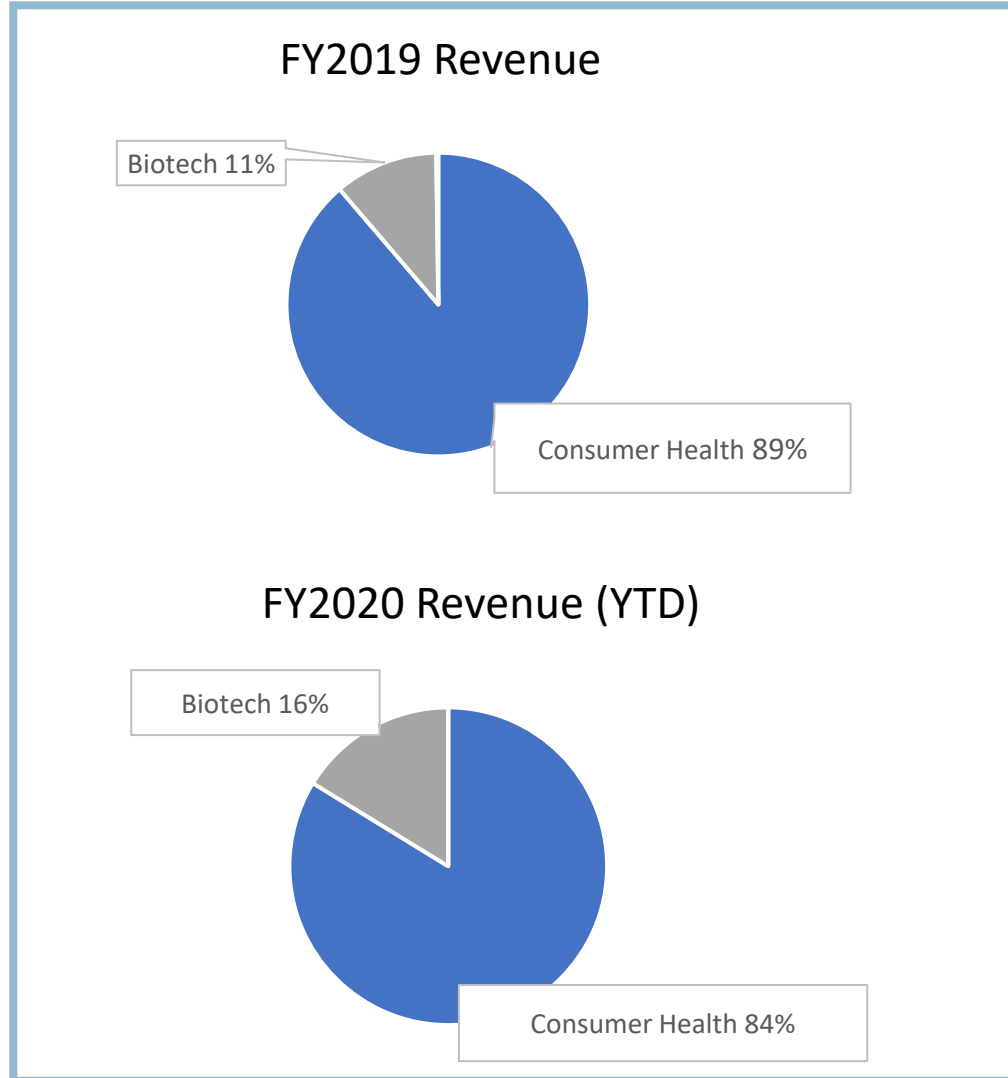
- First in class/best in class anti-aging hair care products
- Operations in Japan, Australia and USA
- Sales in Japan, China, Australia, USA and Europe



LYRAMID (Biotech)

- Largest patent portfolio globally around the novel target midkine
- Midkine is implicated in a number of inflammatory diseases and cancer and Cellmid's antibodies have shown early efficacy
- Diagnostic patent licensed (CxBladder), MK-ELISA
- New product line: Wondfo antibody test

Consumer health has been the major driver of revenue



- The consumer health division accounted for 89% of total \$8.35M Cellmid revenue in FY2019
- Year to Date (YTD) to 31 March 2020, the consumer health division accounted for 84% of total Cellmid revenue
- Staff is allocated to the consumer health and biotech segments in roughly the same proportion as the revenue split between the divisions with several shared functions

Consumer health: resilient during pandemic

The Consumer Health division has been resilient during the pandemic with several new sales channels active and slowly improving trading conditions in China, Japan and Australia.

- **JAPAN:** Japan remains on target to be profitable in FY2020 despite domestic salon sales ending lower and export sales to China delayed.
- **AUSTRALIA:** Australia is currently showing 40% revenue growth YTD from last year. This is a strong result in light of the delay in the evolis Professional product launch in Priceline stores. The growth is the result of higher retail sales during the second quarter, increasing online sales and successful television shopping campaigns.
- **USA:** The USA revenue is up 50% YTD from last year, however, it will be difficult to maintain momentum in the short term due to Neiman Marcus, our biggest customer, entering Chapter 11 proceedings.

Overall, we expect the Consumer Health division to report FY2020 results similar to FY2019*

*Revenue numbers and percentages are unaudited and may change during the remainder of the financial year.



New product line: SARS-CoV-2 antibody test

- **Supply Agreement:** Cellmid signed an agreement with Australia Applications Pty Ltd on 22 March for the supply of the Wondfo SARS-CoV-2 antibody rapid diagnostic tests
- **Strong demand:** The Company received a large number of expressions of interests from industry and government organisations since 27 March 2020
- **Tests received:** First shipment of 12,000 tests received on 14 April 2020, some sold to customers others have been reserved for testing, collaborations and future sales
- **Independent testing:** Cellmid provided 500 tests to the TGA for testing at the Doherty Institute
- **In-house testing:** Cellmid commenced its inhouse 'ATLAS' study with participants including recovered COVID-19 patients and healthy volunteers:
 - To demonstrate the Wondfo test performance
 - To generate data on long term antibody status for those recovered from COVID-19
- **Key Hires:** Boosted capabilities by adding new senior business development manager
- **New products and markets:** Assessing other SARS-CoV-2 tests with the view to build a portfolio of complementary diagnostic products including IgM/IgG split antibody and rapid PCR tests plus pursue new geographies





SECTION 2:
OVERVIEW OF COVID-19 AND
DIAGNOSTICS LANDSCAPE

COVID-19: What we know about the pandemic

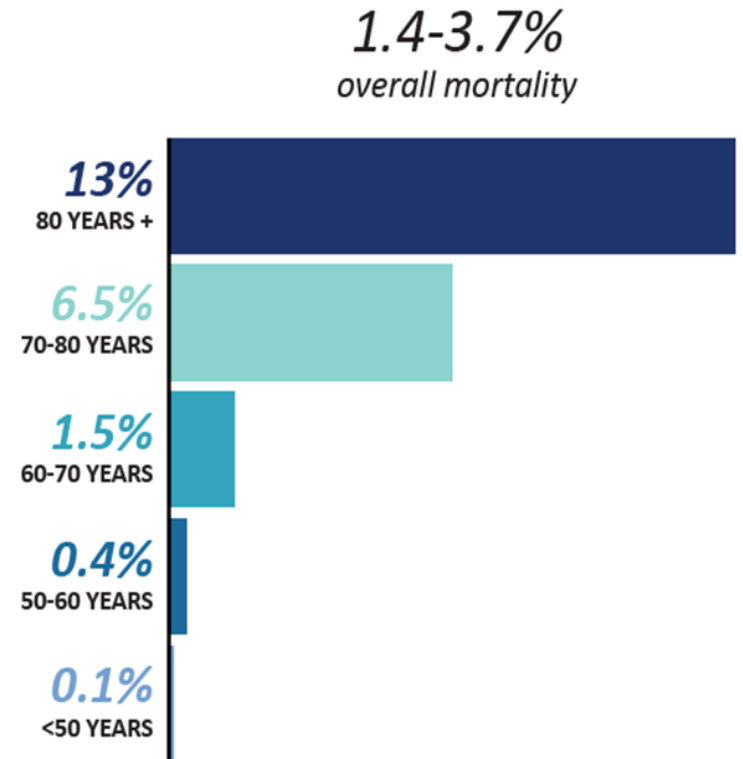
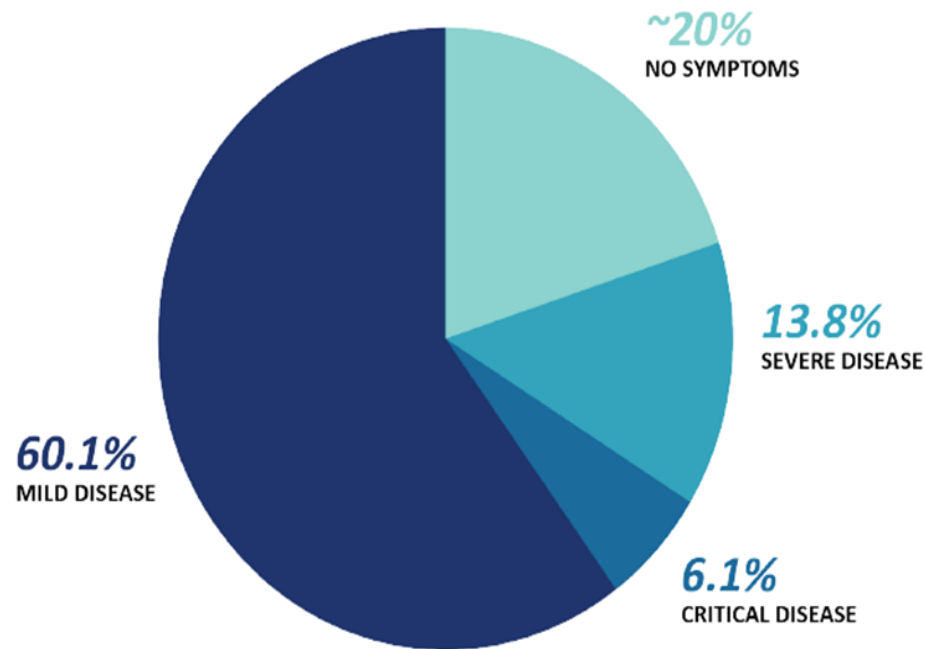
Quick facts COVID-19

EXPOSURE TO ONSET:
Average 5.2 days up to 3 weeks

ONSET TO FIRST CLINIC VISIT:
4.6 days

ONSET TO ICU:
7-12 days

ONSET TO RECOVERY / DEATH:
24.7 / 17.8 days



- Mortality rates vary, depending on population dynamics and extent of testing. Very few governments have tested widely so mortality rates are inflated
- Data sourced from: Li et al., NEJM (2020), Park et al., JCM (2020), Verity et al., Lancet 2020, Phua et al., Lancet Resp Med., (2020), among others

COVID-19: Three different diagnostic approaches – no perfect test

1. Look for the virus

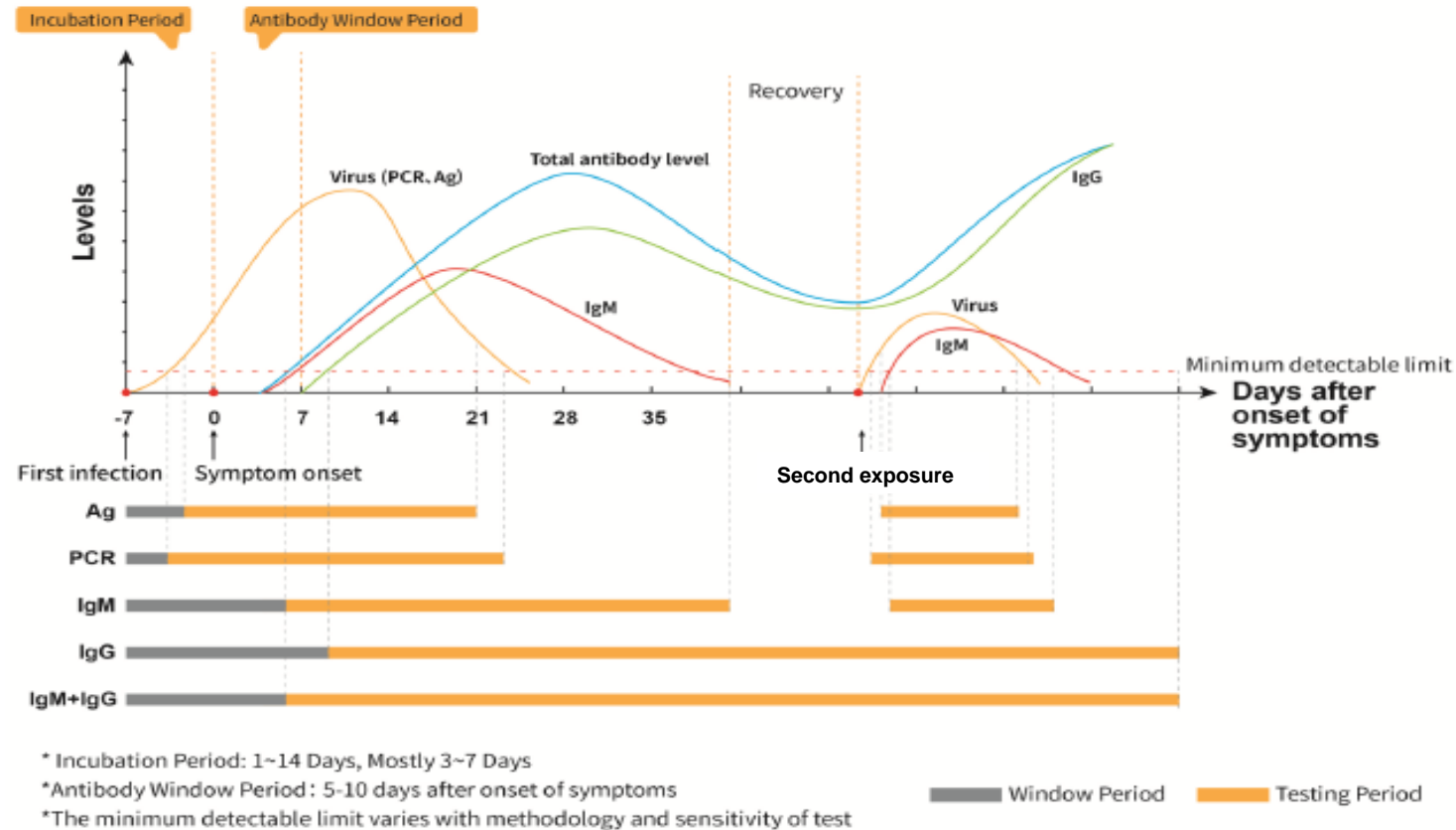
- Evidence of infection
- Viral RNA in respiratory tract can be detected by polymerase chain reaction testing (**PCR**)

2. Look for the body's response to the virus

- Evidence of exposure to the virus
- SARS-CoV-2 specific **antibody tests** (IgA, IgG, IgM)

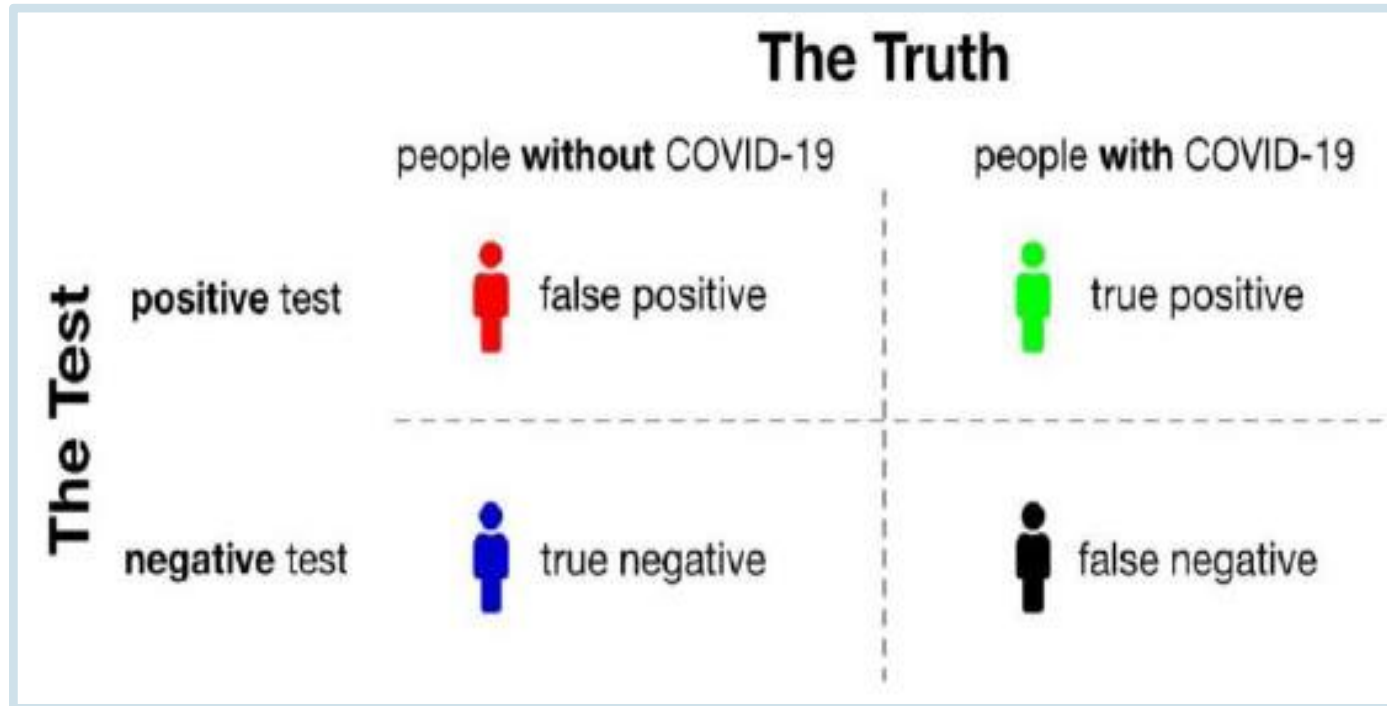
3. Look for distinct clinical evidence of disease

- Patient history, symptoms such as loss of smell/taste, respiratory distress, CT lung imaging



Graph by Wondfo

Different tests are most useful in different phases of the infection.



The accuracy of evaluation is strongly dependent on a well-defined test population. The tests should be assessed in terms of how well they perform for their intended use.

Sensitivity

Measures the accuracy of the test in identifying true positives which is important in acute diagnosis

Specificity

Measures the accuracy of the test in identifying true negatives, which is important in determining prevalence, long term treatment and monitoring

Negative Predictive Value

Probability of true negatives and false negatives

Positive Predictive Value

Probability of true positives and false positives

Polymerase Chain Reaction (PCR) based testing

Polymerase chain reaction (PCR) –why use it?

- PCR is used to detect viral nucleotide (DNA or RNA)
- PCR is very good at amplifying small amounts of virus from a sample, as little as 5-10 virus particles
- Highly specific depending on probe choice

PCR – challenges

- Requires several steps that introduce variability before the test is done – sampling, storage, extraction, PCR
 - **False negatives** from wrong sampling site or processing error
 - **False positives** from cross contamination
- Can detect dead virus – impacts clinical utility
- Narrow window of use
- Some reported “reinfections” have been shown to be incorrect PCR results
- PCR accuracy was recorded as low as 63% in nasal swabs and 32% in throat swabs in COVID-19 patients.*

Table. Detection Results of Clinical Specimens by Real-Time Reverse Transcriptase-Polymerase Chain Reaction

Specimens and values	Bronchoalveolar lavage fluid (n = 15)	Fibrobronchoscope brush biopsy (n = 13)	Sputum (n = 104)	Nasal swabs (n = 8)	Pharyngeal swabs (n = 398)	Feces (n = 153)	Blood (n = 307)	Urine (n = 72)
Positive test result, No. (%)	14 (93)	6 (46)	75 (72)	5 (63)	126 (32)	44 (29)	3 (1)	0

*Wang et al JAMA 2020



SARS-CoV-2 antibody testing – an overview

Background

Originally developed in February 2020 to assist in acute testing in China and S Korea due to shortage of PCR capability, needed rapid deployment of highly specific tests to triage population and overcome false negative issues with PCR.

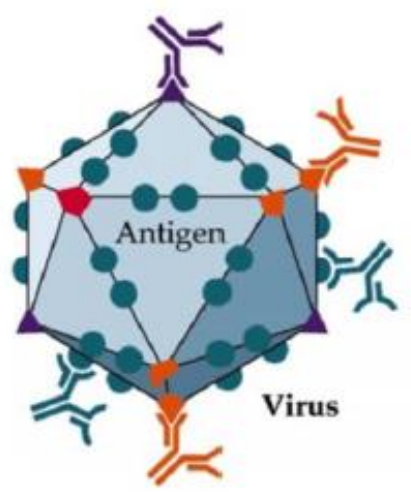
Serology – Detection of antibodies specific to SARS-CoV-2

- Specific to virus
- Fast and easy to implement
- Large window of detection
- Can determine past infection
- Can determine if the body has developed an immune response

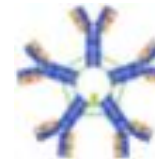
Serology – challenges

- Does not tell if you have an active infection
- Window period before antibodies rise are variable patient to patient, so not a standalone acute diagnostic tool
- Depends on the individual's immune response – a very small number may not produce the right kind of response (current data suggest this is less than 1% of convalescent patients*)

*Wajnberg et.al, Icahn School of Medicine at Mount Sinai, New York, NY




The diagram shows a blue, spherical virus particle with a central core labeled 'Antigen'. The surface of the virus is covered with green dots representing antigens. Several Y-shaped antibodies are shown binding to these antigens. One antibody is purple, one is orange, and one is blue. The word 'Virus' is written at the bottom right of the diagram.



The diagram shows a single IgM antibody molecule, which is a large, multi-subunit protein with five antigen-binding sites. It is depicted as a blue and orange Y-shaped structure with five arms extending from a central point.

IgM is the EARLIEST antibody produced by human body after infection



The diagram shows a single IgG antibody molecule, which is a monomeric protein with two antigen-binding sites. It is depicted as a blue and orange Y-shaped structure with two arms extending from a central point.

IgG is the most abundant antibody (75%~80%) and persists for a long time.

Three reasons why antibody tests are misunderstood

1. Antibody tests are often compared to PCR, an imperfect standard

- PCR is evaluated against other PCR tests – inherent false positives and negatives are undetected
- The inaccuracies of PCR are misclassified as incorrect results in serology

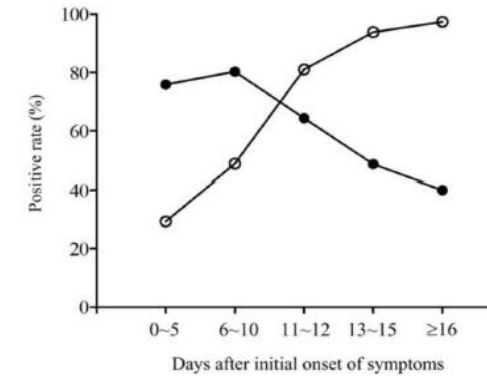
2. Intended use is not as a stand alone for acute diagnosis

- Evaluation at timepoints outside of relevant usage window skews results
(day 2 of symptoms \longrightarrow No antibodies \longrightarrow Negative antibody test in COVID-19 patient)

3. New disease = unknowns: the only way to learn is by testing

- At early stages of the pandemic, the rate of antibody response and development of immunity was unknown
- Latest evidence shows the vast majority of patients (>99%) develop specific antibody and memory immune responses*

*Wajnberg et.al, Icahn School of Medicine at Mount Sinai, New York, NY



○ Ab
● PCR

Antibody testing and PCR have opposite dynamics

Liu, Lei, et al. "A preliminary study on serological assay for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in 238 admitted hospital patients." medRxiv (2020).

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Title Page

Type of article: Correspondence

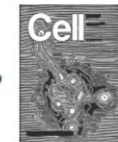
Title

False-negative of RT-PCR and prolonged nucleic acid conversion in COVID-19: Rather than recurrence

(which was not certified by peer review) is the author/funder, who has granted medRxiv a license to display the preprint in perpetuity. It is made available under a CC-BY-NC-ND 4.0 International license.

- 1 Humoral immune response and prolonged PCR positivity in a cohort of 1343
- 2 SARS-CoV 2 patients in the New York City region
- 3 Authors: Ania Wajnberg MD, Mayce Mansour, MD, Emily Leven, MD, Nicole M. Bouvier,

Journal Pre-proof



Targets of T cell responses to SARS-CoV-2 coronavirus in humans with COVID-19 disease and unexposed individuals

Alba Grifoni, Daniela Weiskopf, Sydney I. Ramirez, Jose Mateus, Jennifer M. Dan, Carolyn Rydyznski Moderbacher, Stephen A. Rawlings, Aaron Sutherland, Lakshmanane Premkumar, Ramesh S. Jodi, Daniel Marrama, Aravinda M. de Silva, April Frazier, Aaron Carlin, Jason A. Greenbaum, Bjoern Peters, Florian Krammer, Davey M. Smith, Shane Crotty, Alessandro Sette

PII: S0092-8674(20)30610-3

DOI: <https://doi.org/10.1016/j.cell.2020.05.015>

Why use antibody tests?

Combining PCR and serology improves detection

- To improve the accuracy of detection by using in conjunction with other diagnostics*

Post recovery surveillance

- To determine whether the body has developed an immune response and how long it lasts

Population screening

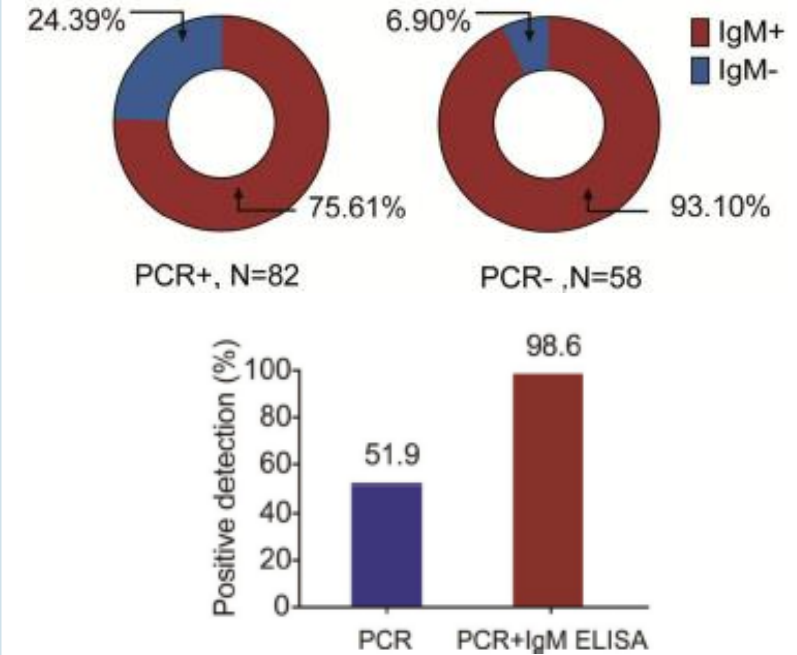
- To determine the actual exposure rate in the population and how many are potentially at higher risk if the virus re-emerges

Risk management in combination with social distancing, face masks and/or hygiene

- To assist in return to work scenarios, particularly with high contact and mobile workforce

Vaccine development

- 159 vaccine candidates under development
- Very large and long term trials will be needed
- All studies will require monitoring of both antibodies and cell mediated immunity



Guo, Li, et al. "Profiling early humoral response to diagnose novel coronavirus disease (COVID-19)." *Clinical Infectious Diseases* (2020).

Combining PCR and antibody detection significantly improved overall accuracy from 51.9% (PCR alone) to 98.6% (PCR and antibody test)



* p<0.001 Zhang et al., (Emerging Microbes & Infections 2020)

Wondfo SARS-CoV-2 Antibody test (lateral flow method)

- An Australian sponsor of the Wondfo SARS-CoV-2 Antibody test. Wondfo test information:
 - **Experience:** Wondfo has been manufacturing POCT for >25 years, e.g. AIDS, pregnancy, hepatitis tests
 - **Highest quality:** Internationally certified facility (MDSAP, ISO13485, ISO9001)
 - **High capacity:** 1.5M tests strips per day
 - **Regulatory approvals:** NMPA approved for export, CE marked, ARTG
 - **Independent evaluation:** Sensitivity > 80% (11+ days from symptoms), specificity > 98% (11+ days from symptoms)*
 - **Supply agreement** until 30 June 2020, may be extended subject to approval by Wondfo.

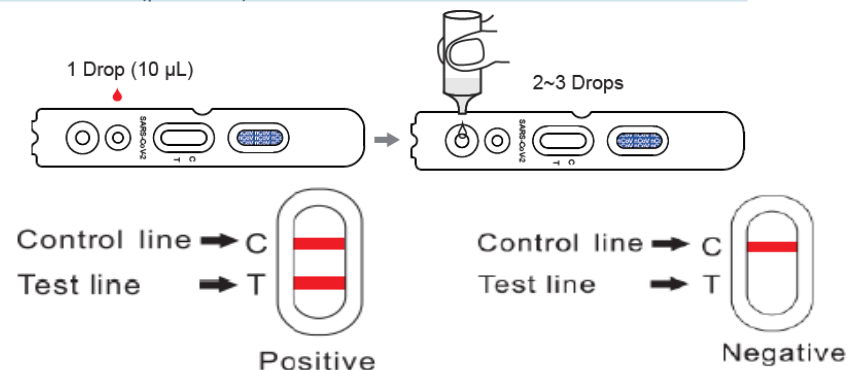
*Whitman et al, University of California, San Francisco (published)

Doherty Institute Testing

- The COVID-19 pandemic led to the fast track emergency registration of many devices with the TGA
- Post market review applies to all medical devices (for SARS-CoV-2 Antibody devices it is Doherty Institute testing)

What do we consider to be a very good testing result for Wondfo?

- Consistent with manufacturer's claims and user instructions
- Specificity 97% +
- Sensitivity at early onset, days 0-7 of symptoms, of between 25-40%
- Sensitivity from days 8-14 of 70%
- Sensitivity for days 15+ of 80%+





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SECTION 3:
UPCOMING MILESTONES

UPCOMING MILESTONES

Consumer health

- Continue to expand e-commerce in key markets
- Grow Chinese distribution of heritage brands
- Opening new sales channels
- Increase sales into existing channels

Diagnostics

- Results of the TGA testing by the Doherty Institute
- Results of the ATLAS study
- Broaden diagnostic portfolio and geographic rights
- Antibody test sales and commercial partnerships

