COVID-19 Government Response enquiry submission.

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Dear Ms Kruk, Professor Bennett, and Dr Jackson,

Thank you for the opportunity to make a submission to the COVID-19 Government Response enquiry.

I am submitting under the term of reference:

- Support for industry and businesses (for example responding to supply chain and transport issues, addressing labour shortages, and support for specific industries).

Background:
I am the Senior Principal Research Scientist for the Australian clinical diagnostics company Genetic Signatures Ltd (ASX: GSS). We manufacture clinical diagnostic kits in Sydney, for sale to public and private pathology laboratories in Australia and overseas. These kits are based on the polymerase chain reaction (PCR) detection of pathogen DNA/RNA in clinical samples. Accordingly, we developed a PCR kit for SARS-CoV-2 detection very early in the pandemic, and I was personally heavily involved in the R&D, validation and production of these kits, and hand-delivered the first batch of PCR kits on 05 March 2020 to one of our customers (public pathology lab) in Sydney. In the following years our company made a mammoth effort to keep up with demand for these kits, and also continually improve their performance and ensure they gave sensitive and accurate detection of all the SARS-CoV-2 variants as they arose. I am proud to say that we never let our pathology lab customers down during the whole period of COVID-19 PCR testing in Australia, both in terms of supply of kits, and kit performance. However, it was a hard period for the following reasons:

(1) Supply issues getting raw materials into Australia. PCR relies on synthetic DNA molecules (we call primers and probes). Sadly, Australia lost the ability to manufacture these at scale on-shore several years before COVID-19. Demand went up dramatically world-wide for PCR reagents, and most companies favoured their own local clients, at the expense of places like Australia. Thus Australia must have the capability to manufacture synthetic DNA primers and probes on-shore. Further, this capability needs to be able to be rapidly scaled up as required. This will avoid delays with both the manufacture of such materials, as well as delays in freight to Australia when international flights greatly diminish when borders close. I understand that the National Measurement Institute (NMI) has been tasked with investigating this capability, but it must be rapidly put in place.

(2) We had great difficulty importing standard materials (ie the inactivated SARS-CoV-2 virus itself) into Australia due to quarantine/AQIS/DAFF import permit regulations. Such material is essential to both develop a molecular diagnostic test, and determine performance specifications/quality control for the said test. While import restrictions are a critical part of Australia's quarantine system, there must be some flexibility under conditions such as the COVID-19 pandemic, whereby such material can be both safely imported, and then rapidly disseminated to relevant parties; companies such as ourselves, and also pathology laboratories, to use as an in-house standard material. Inactivation of pathogens (such as the SARS-CoV-2 virus) is a routine procedure, and such inactivated material can be safely imported from reputed suppliers, such as the American Type Culture Collection (ATCC). Alternatively, such standards can be developed on-shore, which the NMI eventually did, but such material needs to be made available in a more timely manner, to allow rapid development of urgently needed diagnostic kits.

(3) We are a small Australian company, and had to invest heavily into large amounts of primers and probes (and other items required for PCR such as enzyme mixes and the reagents to purify the nucleic acids). The Department of Health had on many occasions suggested a repayable grant would be made available to allow our company to buy these reagents at scale with confidence. This grant never materialised, even though the COVID-19 taskforce told us it had been approved. There was a great risk that the reagents we purchased would be wasted if SARS-CoV-2 was a short-lived outbreak, such as its predecessor SARS-CoV-1, and our company would have been placed under considerable financial pressure. Our company has the skillset and ability to pivot and respond quickly, however some form of repayable grant would significantly de-risk this process for our company. Similarly, with support, our company could have made many more tests, rather than importing them as the government supported Minderoo to do.

I would be happy to provide more specifics if required.

Yours sincerely,

Rohan Baker, PhD.