

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Inquiry into Australian Government's response to the COVID-19 pandemic

Written Question on Notice, 6 August 2021

PDR Number: IQ21-000191

Rollout and use of Rapid COVID Antigen tests

Written

Senator: Katy Gallagher

Question:

Rapid tests:

1. Noting the release of the National COVID Vaccine Campaign Plan, what preparation has the Department made for the potential rollout and use of Rapid COVID Antigen tests in Australia?

Answer:

As the COVID-19 pandemic evolves, the Department of Health continues to monitor and explore alternative testing technology and strategies to ensure Australia can sustain response activities and achieve maximal public health benefit, especially during outbreaks and in the context of the National Plan to transition Australia's National COVID-19 Response. With the global circulation of more infectious variants of SARS-CoV-2 this consideration has never been more critical.

In certain settings, rapid antigen testing may be useful for public health investigation or screening. While not recommended for definitive diagnosis of COVID-19 (because of false positive and false negative results), rapid antigen tests are intended for use at the point-of-care (or near person care) to detect the presence of viral protein from SARS-CoV-2. Importantly, rapid antigen test use would complement rather than replace PCR, and any positive result on a rapid antigen test would be confirmed by a follow-up PCR test in a laboratory.

On 1 October 2021, the Therapeutic Goods Administration (TGA) made a new regulation (The Therapeutic Goods (Medical Devices—Excluded Purposes) Amendment (COVID-19 Rapid Antigen IVD Medical Devices for Self-Testing) Specification 2021) to allow companies to formally apply for TGA regulatory approval to legally supply self-tests for use at home in Australia from 1 November 2021. As at 15 October 2021, the TGA has approved five rapid antigen self-tests.

As of 18 October 2021, a total of **1,797,700 rapid antigen tests** have been delivered from the National Medical Stockpile (NMS) to 355 residential aged care facilities located in NSW (1,299,225 tests) and 109 residential aged care facilities located in Victoria (498,475), so they can regularly screen workers and visitors (not residents), on a voluntary basis. RAT tests may be used to screen residents in some circumstances, such as the initial response to outbreaks in residential care settings, as required.