Australian Government

Department of Health and Aged Care

## Therapeutic Goods Administration

## MEDIA RELEASE

# TGA confirms the performance of Australian approved Rapid Antigen Tests with COVID-19 Variants

**1 Feb 2023**

The Therapeutic Goods Administration (TGA) is aware of recent media reports that are critical of the performance of several COVID-19 rapid antigen tests on the Australian market and quoting a James Cook University academic as stating "We need to have a clean up of the RAT tests that are currently available" and "The RAT tests that are available were not cross compared independently because they were released in an Emergency Act".

The TGA disagrees with these assertions. Firstly, all COVID-19 RAT tests on the Australian market have been through the normal stringent processes of full TGA approval – they were not "released in an Emergency Act". Secondly, in addition to in depth evaluation of submitted data by TGA scientists, independent assessment of approved RATs in collaboration with the Peter Doherty Institute for Infection and Immunity and the National (Serology) Reference Laboratory confirmed that RATs approved for use in Australia met global standards for sensitivity as set by the World Health Organisation (WHO) guidelines.

Studies on 91 tests showed that only three RATs did not comply with the minimum requirements and these tests have been removed from supply in the Australian market. Results from the comprehensive validation testing, as they are finalised, are made public on the TGA's website.

This means consumers can be assured that if used correctly, RATs continue to be an important part of detecting and managing COVID-19 infections. Members of the public are encouraged to refer to the TGA for accurate information about therapeutic goods approved for supply in Australia.

Suspected non-compliance with regulatory requirements or issues experienced by consumers with performance can be reported online to the TGA.

Contact for members of the media:


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