

UNDER EMBARGO
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FIRST HAND-HELD, COVID-19 PCR SELF-TEST KIT TO BE AVAILABLE FOR AUSTRALIANS BY END OF YEAR

- New technology introduced to market amid concerns of new waves to hit shores over Summer
- PCR test detects all Covid variants within an hour, offering more reliable testing to RATs

17 August, 2022, Brisbane: Elamaan Health, today launched the first portable PCR self-test kit into the Australian market, as waves of the Covid-19 virus continues to permeate Australian society. The EasyNAT Covid-19 RNA self-test kit was ARTG listed for over-the-counter sale in June 2022, and is expected to be widely available for consumer purchase in November this year.

The EasyNAT Covid-19 RNA self-test kit is Australia's first personalised self-testing PCR unit, providing detection of all strains of Covid-19 including Alpha, Beta, Delta, Kappa, Gamma, Mu, Lambda, and Omicron as well as future variants expected over the coming years. The self-test delivers results in at least 55 mins and is 99% accurate, significantly quicker and more convenient than a laboratory test.

Until now, Australians have only had access to the Rapid Antigen Tests (RATs) for self-use, which have been receiving increasing criticism throughout the current wave of Omicron BA.4 and BA5. RATs are designed to detect antigens found on the surface of the virus, and do not detect all variants of the SARS-CoV-2, whereas PCR tests detect the presence of viral genetic material (RNA) in the molecular genome irrespective of the varying antigen.

Dr Roy Hardman, a researcher at Swinburne University of Technology, a recognised external agent to the TGA, and a consultant to Elamaan Health, commented: "RNA or PCR tests are widely accepted to be more accurate than RAT technology, but to date they have been extremely expensive requiring resource from testing centres, clinicians and pathologists. During the Covid Beta wave, lab-based PCR results were taking between 12 and 36 hours. During the current Omicron variant wave, we're seeing significant spread and lack of reporting of results which may, in part, be attributed to an over-reliance on RAT tests — which appear to have accuracy limitations. The need for accurate, fast results is paramount to limiting the spread of future waves of the virus."

"I've reviewed the results of both the clinical studies of the EasyNAT Covid-19 RNA self-test kit, along with the Usability Study conducted earlier this year in the Netherlands, as these were submitted to the TGA for inclusion of the device on the register and am pleased that the tests have high levels of accuracy against multiple comparators". This data was accepted by the TGA for the device inclusion.

With the caseloads from the current Omicron variants expected to diminish in the coming months, a sense of apathy towards covid is increasing among Australians, as well as government bodies and even some healthcare workers. However, leading Australian epidemiologists warn that the risk of future variants is imminent, citing the coming summer season as high risk.

At the National Cabinet Meeting, held on 4th August, Chief Medical Officer Paul Kelly warned Australian people not to become complacent, "This is not the last wave, this is coming towards the end of this (Omicron B.A.4) wave. We will continue to have to plan for that, be ready and know when that is happening and respond to that accordingly."

Professor Adrian Esterman, a renowned epidemiologist and the current Chairperson of biostatistics at the University of South Australia's department of Clinical & Health Sciences agrees that the risk of future variants is a real possibility.

"The challenge we face is that new variants have greater transmissibility than the initial strains of Covid. This may be because the strains replicate faster, combine more readily with the human H2 receptor or escape immunity through genetic mutation. It is likely that any future variants may continue to be more transmissible which will lead to greater spread.

"We've removed almost all Covid restrictions nationally and we are reducing testing protocols which could prove extremely problematic if future Covid variants are more aggressive than the current BA.4 and BA.5. While we can't predict the intensity or timing of future waves, it is likely we will see more variants in Australia in the near future.

Prof Esterman continued, "We have seen reported actual case numbers be lower through this current wave which may be, in part, due to a general sense of Covid fatigue, along with the use of RAT tests. To mitigate against future waves, we need accurate testing and more robust reporting to ensure the public takes the necessary measures to prevent the spread of the virus and the resultant impact on Australian society and the economy."

The EasyNAT Covid-19 RNA self-test kit is a self-administered nasal swab with results processed through a battery powered processing unit that fits into the hand. The units are stored in refrigerated conditions and are simple to use anytime, anywhere.

Elamaan Health is currently in discussions with several Government organisations along with private companies and retailers to ensure the product is available for retail purchase in major Australian cities by November 2022, in readiness for summer vacations, increases in international travel and Christmas and New Year celebrations — potential contributors for new waves of Covid 19.

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About Elamaan Health

Elamaan Health is an Australian medical device company committed to providing real solutions for today's most pressing health problems. Elamaan Health is working with UStar Biotechnologies (Hangzhou) Ltd to introduce the EasyNAT Covid-19 RNA self-test kit to the Australian market, offering the fastest, convenient, and most reliable PCR self-test for all known variants of Covid-19.