



ASX Announcement

26 October 2021

Atomo HIV Self-Test – improved supply and advertising conditions in Australia

SYDNEY Australia Tuesday, 26 October 2021 – Atomo Diagnostics Limited (ASX: AT1) (**Atomo**) is pleased to announce that the Therapeutic Goods Administration (**TGA**) has varied the conditions imposed on the entry of the Atomo HIV Self-Test in the Australian Register of Therapeutic Goods (**ARTG**) on 28 November 2018¹.

The TGA has broadened the organisations to whom the HIV Self-Test can be supplied. Atomo can now supply its HIV Self-Test to any business, organisation or institution (including a pharmacy) that employs or engages individuals who have received appropriate training. The varied conditions applicable to the Atomo HIV Self-Test also permit Atomo to supply the HIV Self-Test directly through pharmacy websites.

In addition, Atomo welcomes the TGA's recently updated advertising requirements in respect of HIV tests which became effective on 15 October 2021². These broad changes allow for advertisements regarding HIV tests in any form or media, and so allow Atomo to begin to market the Atomo HIV Self-Test in Australia. Prior to these advertising changes, Atomo was unable to advertise or promote its HIV Self-Test website or the HIV Self-Test product itself.

Commenting on these extensive changes by TGA, Atomo Co-founder and Managing Director, John Kelly said: "We are delighted that Atomo, and its partners, can now actively promote HIV Self-Testing, expand much needed awareness as to the availability of our TGA approved rapid HIV self-test and work with pharmacy groups to ensure that the HIV self-test is widely available in stores and online".

Mr. Kelly added. "As leaders in the design of easy-to-use rapid diagnostic test platforms, we are pleased to see the long-term resistance to rapid and home-based testing here in Australia

¹ https://search.tga.gov.au/s/search.html?collection=tga-artg&profile=record&meta_i=311989

² <https://www.tga.gov.au/advert-exempt/therapeutic-goods-prohibited-and-restricted-representations-hiv-self-tests-permission-2021>



across infectious disease applications such as HIV and COVID-19 softening and welcome the arrival of rapid testing to the Australian market.”

Atomo thanks the Australian Federation of Aids Organisation (AFAO) who were instrumental in their engagement with TGA, consistent with their goal of seeking to improve the rates of HIV testing in Australia by broadening access to HIV self-testing.

Atomo also acknowledges the participation of The Pharmacy Guild of Australia (PGA) who have worked with Atomo and the TGA to ensure that the pharmacy sector is ready and able to support the expansion of access to HIV Self-Testing through this important channel.

Atomo manufactures and supplies the only HIV Self-Test available in Australia.

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This announcement was authorised by the Board of Directors.

About Atomo

Atomo is an Australian medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market. Atomo's patented devices simplify testing procedures and enhance usability for professional users and untrained self-testers. The Company has supply agreements in place for tests targeting infectious diseases including COVID-19, HIV, viral vs bacterial differentiation and female health.

See more at www.atomodiagnostics.com.