ASX Announcement **27 October 2020**

Atomo receives TGA approval for its COVID-19 rapid antigen test[1]

Highlights:

- **Therapeutic Goods Administration (TGA) has approved the Atomo COVID-19 rapid antigen test for inclusion on the Australian Register of Therapeutic Goods (ARTG)**
- **Agreement secured with Health Solutions Group Australia to provide professional test services deployment for Atomo's rapid antigen and antibody tests for detection of Sars-Cov-2, the virus that causes COVID-19**
- **Atomo believes the combined rapid antigen / antibody testing at the point of care has the potential to be significant in the diagnosis and treatment of COVID-19**

SYDNEY Australia Tuesday, 27 October 2020: Atomo Diagnostics Limited (ASX: AT1) (Atomo) is pleased to announce that the Therapeutic Goods Administration (TGA) has approved its rapid SARS-CoV-2 antigen blood test for use by medical professionals in Australia. The product has been added to Atomo's existing Australian Register of Therapeutic Goods (ARTG) listing, alongside the Atomo HIV Self-Test and the AtomoRapid™ COVID-19 (IgG/IgM) rapid antibody test.

Now that the product is listed on the ARTG, Atomo can commence supply of the test to departments of health, laboratories, medical practitioners and health care professionals in aged care facilities in Australia. The TGA requires all approved distributors to provide it with additional evidence to demonstrate ongoing safety and performance within 12 months of approval. The Peter Doherty Institute for Infection and Immunity (Doherty Institute) has been engaged the Department of Health to assist with the post-market validation of new COVID-19 rapid tests to inform their best use.

The Atomo COVID-19 rapid antigen test is a nasopharyngeal swab test designed to screen for antigens produced in response to COVID-19 infections at the point of testing and a positive

[1] The Atomo COVID-19 rapid antigen test detects SARS-COV-2, the virus that causes COVID-19

result implies current viral infection[2]. For further information on the Atomo rapid antigen test, refer to Atomo's announcement on 29 September 2020.

Unlike the general nasal swab testing in Australia which typically uses molecular PCR assays to test for the presence of the virus and must go to a central laboratory for processing, the Atomo COVID-19 antigen test is processed at the point of care and results are available after 10 minutes. As such, antigen testing may have benefits for early identification and the control of outbreaks in some situations, as compared to PCR tests in settings with prolonged turnaround times.[3] Based on a third party clinical evaluation the antigen test demonstrated Sensitivity of 88.4% and Specificity of 100%. Please refer to Atomo's release dated 29 September 2020.

The rapid antigen test has the potential to complement Atomo's TGA approved AtomoRapid™ COVID-19 rapid antibody test, which identifies whether a patient has developed antibodies in response to the virus and is most accurate around 15 days from exposure. In comparison, the Atomo COVID-19 Antigen Test is most accurate immediately after the onset of symptoms. By running the two tests in parallel, patients would understand after 15 minutes with a high degree of accuracy, whether they currently have COVID-19, or whether they may have had it previously. Studies of the COVID-19 antibody test conducted in Atomo's Pascal device by Hopital Bicêtre and the Pasteur Institute, France found that "Sensitivity and Specificity were 97.0% and 100% respectively, 15 days after the onset of symptoms[4]. Please refer to Atomo's release dated 10 August 2020.

Atomo Diagnostics co-founder and Managing Director John Kelly said "*Atomo can now offer, in a single 15 minute window, rapid testing for both COVID-19 antigen and antibody responses. This comprehensive rapid screen will help determine acute active infection and also indicate those patients who may have had prior exposure to the virus and built up an antibody response".*

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[2] Centre for Disease Control (2020), *Interim Guidance for Rapid Antigen Testing for SARS-CoV-2,* https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html (last accessed on 28 September 2020).

[3] Centre for Disease Control (2020), Interim Guidance for Rapid Antigen Testing for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html (last accessed on 28 September 2020).

[4] Pasteur Institute Report - Performance evaluation for the detection of SARS-CoV-2 antibodies, National Reference Center for Respiratory Infection Viruses (including influenza), Paris, France (Unpublished).

Mr Kelly added *"Up to 20% of infections are asymptomatic[5] and this has led to many countries now establishing regular, proactive testing regimes. Antigen tests have been proven to provide good detection of COVID-19 infection in the early stages of exposure, We believe this makes them useful both for people showing onset of symptoms or for broad scale screening of at-risk communities and frontline workers. Furthermore, Atomo believes that when combined with our rapid antibody test that detects virus exposure over a longer period, they should offer excellent performance where reliable testing is most convenient and needed – outside of the laboratory."*

To ensure the professional delivery of rapid testing services to organisations where there is a need, Atomo has engaged Health Solutions Group Australia, a leading provider of professional healthcare workers in Australia, to provide the professional testing services to Atomo customers. Health Solutions' professional team of Registered Nurses and specialist healthcare professionals visit workplaces via customised pop-up style clinics, providing a range of point of care services, making it an ideal partner to support the launch and delivery of Atomo's rapid antigen and antibody tests to corporate and age care clients.

Mr Kelly added, "We are delighted to be partnering with Health Solutions for the provision of COVID-19 screening services to our clients. Having a large national service provider with experience in professional testing to help rollout this service is very important".

For more information, please contact:

Jane Lowe
IR Department
jane.lowe@irdepartment.com.au
Phone: +61 411 117 774

John Kelly
Atomo Diagnostics Limited
john.kelly@atomodiagnostics.com
Phone: +61 401 922 279

This announcement was authorised by John Kelly, Managing Director.

[5] Plos One, Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: A living systematic review and meta-analysis https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003346 (last accessed on 26 October 2020)

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 and viral vs bacterial differentiation.

See more at www.atomodiagnostics.com.