



Australian medical device design and manufacturing company targets major international markets with backing from big name healthcare investors

Atomo Diagnostics is transforming rapid diagnostic testing with innovative, all-in-one test devices that offer best-in-class performance and excellent usability.

This medical device innovator, headquartered in Sydney, Australia, is emerging as a global leader in the field of rapid diagnostic tests (RDTs). Its refreshing, user-centered approach to design and willingness to reimagine what has gone before has led it to produce devices that are simpler to use and so help to prevent user errors common with standard multi-component test kits.

Atomo's all-in-one devices put the end user first and make it easy to test for a range of infectious diseases and screen for various chronic conditions. Its products simplify test procedures and include features that are interlocked to ensure each user step is performed in the correct sequence. The built-in safety lancet activates automatically on contact with the skin and retracts cleanly and safely after use to prevent needlestick injuries and the risk of cross-infection.

Global recognition

Atomo's RDT solutions are recognised by a growing number of frontline healthcare and medical professionals worldwide for the contribution they make to improving test accuracy and encouraging early diagnosis.

The test platforms developed by Atomo can be adapted to suit a variety of blood-based rapid diagnostic test assays and are, therefore, appropriate for a range of applications including detection of infectious diseases, measurement of key biological markers and hormone levels, as well as screening for chronic conditions such as cardiovascular disease.

Commitment to quality

Atomo and its operations are fully compliant to international medical device standards and certified to ISO 13485 and ISO 9001 for the design, development and manufacture of rapid diagnostic test platforms.

The company's integrated HIV test, AtomoRapid™ HIV (1&2), was launched in southern Africa in 2014, where it has demonstrated overwhelming user preference and

garnered support from frontline healthcare professionals for its ease of use and reliability. AtomoRapid HIV has since been granted the CE Mark to support commercial rollout in countries of the European Union and beyond.

Clinical studies for AtomoRapid HIV have demonstrated 99.8% sensitivity and 100% specificity in laboratory tests conducted by the Institute of Tropical Medicine, Belgium and the German Red Cross.

Designed for simplicity

Point-of-care rapid diagnostic test kits are intended to be used away from laboratory settings, such as in doctors' rooms, pharmacies, community clinics, etc.

Atomo RDT products have been designed specifically to meet the needs of such settings and include functionality to address specific in-field challenges. This commitment to usability and simplicity in design means that Atomo's test devices are simple to learn and teach and so can be deployed quickly and easily in the field.



As well as commercialising test applications under its own brand, Atomo also makes its unique RDT technologies available to diagnostic and healthcare companies worldwide. Atomo provides OEM device options for companies wanting to launch new test assays or to upgrade and enhance their existing product offerings.

Atomo's suite of test platforms are modular solutions with features and functionality to suit all in-market needs, whether deployed as professional use, self test or OTC applications.

Valued partners

Atomo gratefully acknowledges the support it has received from a number of established global healthcare investors including the Global Health Investment Fund (GHIF) structured by JPMorgan Chase & Co. and the Bill & Melinda Gates Foundation, with founding support from Grand Challenges Canada, the German government-owned development bank KfW and the Swedish International Development Cooperation Agency (SIDA).

Other stakeholders include high net worth Australian investors, such as property investor Lang Walker. Both the Australian Federal and NSW State Governments have provided funding to support the company to achieve its impact goals.

Atomo Diagnostics Pty Ltd key facts (as at May 2016)

Established: 2010
Number of employees: 25

Locations:
Atomo Diagnostics is headquartered in Sydney, Australia, with corporate offices in South Africa and the United Kingdom

Capital raised to date: AU\$7.25 million
Other funding: AU\$4.8 million

Executive Board:
John Keith, Non-Executive Chairman;
John Kelly, Founder & CEO;
George Sidis, Non-Executive Director

Global Health Advisory Board:
Professor Linda-Gail Bekker, Deputy Director of the Desmond Tutu HIV Centre at the Institute of Infectious Disease and Molecular Medicine (IDM), UCT and Chief Operating Officer of the Desmond Tutu HIV Foundation, and President-Elect of the International AIDS Society;

Ian Boulton, Managing Director of TropMed Pharma Consulting and member of the Board of Trustees of Malaria Consortium;

Professor Alex Doodoo, Associate Professor at the University of Ghana Medical School;

Anna Wang, Director of Global Health for Atomo Diagnostics

AtomoRapid Branded Products:
Lateral flow rapid blood tests using an Atomo proprietary test platform. Current test applications include HIV and Malaria.

Medical Device Design & Development Services:
OEM services for design and manufacture of device platforms for in vitro diagnostic (IVD) rapid tests for capillary blood samples.

Example test applications suitable for deployment on Atomo's device platforms:

Dengue virus
Chikungunya virus
Ebola virus
Troponin
Cholesterol
Hepatitis C virus (HCV)

QA and Regulatory Certifications:
The company and its operations are fully compliant to international medical device standards and certified to ISO 13485 and ISO 9001 for the design, development and manufacture of rapid diagnostic test platforms.

Awards:
Medical Design Excellence Awards 2014, Best in Show
Medical Design Excellence Awards 2014, Gold Winner in IVD category
Johnson & Johnson Innovation 2014, Emerging Australian Company of the Year
Bradfield Prize, Engineering Excellence Australia, 2014
#1 Anthill Smart 100 Most Innovative Product in Australia, 2014
NSW Innovation in Export Award from the Export Council of Australia, 2015

Vision:
To ensure people get accurate results by creating affordable and best-in-class rapid diagnostic test devices designed to take account of their needs.

Website:
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