



ASX Announcement

29th October 2026

Atomo Signs Agreement with Innovation Scientific to Develop a Generation 4 HIV Assay

- In partnership with Innovation Scientific, Atomo formally launches a development program for Gen 4 HIV in its Galileo cassette
- Innovation Scientific will complete the development, analytical and clinical studies
- Atomo will be the manufacturer of record with plans to seek regulatory approval from TGA and for IVDR

SYDNEY, Australia, 29th October 2026 - Atomo Diagnostics Limited (ASX:AT1 or Atomo) is pleased to announce a Memorandum of Understanding (MOU) with Innovation Scientific related to a Generation 4 HIV rapid test in Atomo's Galileo cassette. Following the recent completion of feasibility studies, Innovation Scientific will conduct additional development, analytical and clinical studies. Within the next four months, the Parties agree to negotiate license, development and supply agreements where Atomo will commercialise the rapid Generation 4 HIV assay on a global basis.

Atomo will be the legal manufacturer of the assay and plans to register the product under IVDR and with the TGA over the next 18 months. By the end of 3Q27, the Parties expect to execute a detailed supply agreement whereby Innovation Scientific will incorporate Atomo's Galileo sub-assemblies with the Innovation Scientific test strip and buffer, delivering a final packaged product. Atomo expects to launch the product commercially within 24 months.

Fourth-generation HIV tests are designed to detect both HIV-1/2 antibodies and the HIV-1 p24 antigen. The addition of p24 antigen detection can enable earlier identification of infections compared with antibody-only third-generation tests, depending on the test's performance, specimen type and stage of infection. Gen 4 rapid tests use lateral-flow technology to detect these biomarkers in a blood sample, delivering results at the point of care without conventional laboratory equipment.



The Gen 4 HIV test will expand Atomo's global franchise in HIV testing, strategically complementing Atomo's existing Gen 3 HIV and Active Syphilis portfolio, broadening its offering across HIV screening, earlier infection detection and sexually transmitted infection (STI) testing. Together, the expanded portfolio is intended to strengthen Atomo's position with healthcare providers, self-test markets, professional markets, public-health programs, and distribution partners seeking integrated HIV/STI screening solutions in decentralised testing locations. The growing product portfolio provides commercial synergies as Atomo scales its business by introducing revenue from its own new product pipeline beginning in late FY2028.

Key Agreement Terms

- **Counterparty:** Innovation Scientific Pty Ltd, an Australian-based diagnostic company.
- **Term:** The term covers the period of time of development, clinical trials, and IVDR registration for the Gen 4 HIV product.
- **Intellectual Property:** IP for the strip component of the assay remains with Innovation Scientific, with Atomo licensed to commercialise globally. The IP for the Galileo cassette remains with Atomo.
- **Financial Terms:** Both Parties cover their costs; other commercial and financial terms to be finalised in supply, license and development agreements.
- **Materiality:** The Board considers this agreement to be strategically significant to Atomo having regard to its current revenue base and the expected contribution of the Gen 4 HIV product in FY28 and beyond.

Atomo's CEO Cheri Walker said, "We are pleased to be immediately fulfilling our promise of adding new products to Atomo's own product development pipeline on an accelerated timeline through our partnership with Innovation Scientific. The partnership allows Atomo to rapidly complete the development and studies necessary to pursue the appropriate regulatory filings required for commercial launch of the product. We expect the commercial launch of both Gen 4 and Active Syphilis products within the next 24 months, establishing new revenue streams and supporting Atomo's next phase of growth.

Atomo is committed to growing its franchise of commercialised rapid point of care devices targeted to the professional and self-test markets, where its technologies bring better performance and ease of use to blood-based rapid testing. Alongside our Active Syphilis program, the Gen 4 HIV initiative represents an opportunity to build a broader portfolio of rapid diagnostic solutions for professional healthcare and self-testing markets. Our focus is on translating our technology and product development capabilities into commercially viable products that can support more accessible testing in decentralised settings and contribute to Atomo's future growth."



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This announcement was authorised by the Managing Director & CEO on behalf of the Board.

About Atomo

Atomo is an Australian headquartered medical device company supplying unique, integrated rapid diagnostic test (RDT) devices to the global diagnostic market.

Atomo's unique patented devices simplify testing procedures, enhance usability and improve reliability across rapid point-of-care (POC) and at-home testing applications. The Company has successfully commercialised a number of products across international markets and has license, development and supply agreements in place for testing applications targeting infectious diseases including HIV, active syphilis, ALT liver test, early detection of pregnancy, ferritin, and stroke.

See more at www.atomodiagnostics.com

About Innovation Scientific

Founded in 2014 in Sydney, Innovation Scientific is an ISO 13485 certified, and in 2025 is now a Medical Device Single Audit Program (MDSAP) certified, TGA approved, Australian manufacturing and marketing company of in-vitro diagnostic (IVD) reagents, kits and instruments for national and international markets. Their testing technology helps revolutionise access to healthcare solutions and deliver improved healthcare outcomes. They are focused on rapid testing solutions that put the user in the centre of the testing experience and specialise in infectious disease testing, including 4:1 COVID/RSV/FluA/FluB and drugs of abuse assays.