Australian approval for Yourgene® DPYD Assay

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("Novacyt", the "Company" or the "Group")

Australian regulatory approval for Yourgene® Insight DPYD Assay

TGA approval extends commercial opportunity beyond research use to clinical diagnostic testing

Paris, France, and Manchester, UK – 11 November 2026 – Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international molecular diagnostics company with a growing portfolio of integrated technologies and services, announces Australian regulatory approval for its Yourgene® Insight DPYD assay. The approval enables Southern Cross Diagnostics Pty Ltd, part of the Novacyt Group, to market and supply the in vitro diagnostic assay for its approved clinical diagnostic use in Australia, extending its commercial opportunity beyond research use only to clinical diagnostic testing.

The Therapeutic Goods Administration (TGA) has approved the supply of the Yourgene® Insight DPYD assay in Australia. The assay, manufactured by Yourgene Health, is covered by an Australian Register of Therapeutic Goods (ARTG) inclusion for Class 3 pharmacogenetic in vitro diagnostic devices (IVDs), held by Southern Cross Diagnostics as the Australian sponsor. It is also certified under the European Union's In Vitro Diagnostic Regulation (IVDR).

The Yourgene® Insight DPYD assay detects 19 clinically relevant variants in the DPYD gene, supporting the identification of patients at increased risk of severe or potentially fatal toxicity in patients receiving 5-fluorouracil (5-FU) treatment. It provides laboratories and clinicians with information to support informed treatment decisions and improve patient management.

The Australian approval builds on the successful launch of the Yourgene® Insight DPYD assay as a Research Use Only (RUO) product in May 2026, followed by its certification under the IVDR in September 2026. TGA approval

represents a further step in the product's international regulatory expansion, enabling access to another highly regulated market.

The Yourgene® Insight DPYD assay is the first CE-marked DPYD assay certified under IVDR to incorporate all current Tier 1 and Tier 2 variants recommended by both the Association for Molecular Pathology (AMP) and the National Comprehensive Cancer Network (NCCN). Developed in close collaboration with leading clinicians and subject to extensive evaluation, the assay provides a comprehensive testing solution designed to meet the requirements of routine clinical laboratories.

TGA approval further extends the commercial reach of the Yourgene® Insight DPYD assay, building on its regulatory credentials in Europe and creating additional opportunities to supply laboratories in Australia. The Company estimates that the addressable market for DPYD testing in Australia is approximately 16,000 to 66,000 tests per year. Based on the current Australian Medicare reimbursement of approximately A$182 per test, this represents a total annual reimbursed testing value to laboratories of approximately A$3.0 million to A$12.0 million.

Lyn Rees, Chief Executive Officer of Novacyt, commented: “Australian approval expands the commercial opportunity for our Yourgene® Insight DPYD assay into routine clinical testing. Through Southern Cross Diagnostics, we can now offer Australian laboratories a registered diagnostic assay to support the identification of patients at increased risk of severe chemotherapy toxicity.

“Following IVDR certification in September, this approval advances our international expansion and demonstrates how our Australian distribution business can bring products from across the Group to clinical customers. We can bring our established pharmacogenomics testing solution to a wider international customer base and supports our strategy to grow our clinical genetics business and broaden access to pharmacogenomic testing.”

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About Novacyt Group (www.novacyt.com)

Novacyt is an international molecular diagnostics company providing a broad portfolio of integrated technologies and services, primarily focused on the delivery of genomic medicine. The Company develops, manufactures, and commercialises a range of molecular assays and instrumentation to deliver workflows and services that enable seamless end-to-end solutions from sample to result across multiple sectors including human health, animal health and environmental.

The Company is divided into three business segments:

Clinical	Broad portfolio of human clinical in vitro diagnostic products, workflows and services focused on three therapeutic areas: Reproductive Health: NIPT, Cystic Fibrosis and other rapid aneuploidy testsPrecision Medicine: DPYD genotyping assayInfectious Diseases: Winterplex, multiplex winter respiratory PCR panel

Instrumentation	Portfolio of next generation size selection DNA sample preparation platforms and rapid PCR machines, including: Ranger® Technology: automated DNA sample preparation and target enrichment technologygenesig q16 and q32 real-time quantitative PCR (qPCR) instruments
Research Use Only	Range of services for the life sciences industry: Design, manufacture, and supply of high-performance qPCR assays and workflows for use in human health, agriculture, veterinary and environmental, to support global health organisations and the research industryPharmaceutical research services: whole genome sequencing (WGS) / whole exome sequencing (WES)

Novacyt is headquartered in Le Vésinet in France with offices in the UK (Manchester), Singapore, the US and Canada and has a commercial presence in over 65 countries, including Australia, following the recent acquisition of Southern Cross Diagnostics in March 2026, which has opened new distribution channels to the life sciences and diagnostics industries in the territory and the wider Asia-Pacific region.

The Company is listed on the London Stock Exchange's AIM market ("NCYT") and on the Paris Stock Exchange Euronext Growth (“ALNOV”).

For more information, please refer to the website: www.novacyt.com

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