# IVDR certification for DPYD genotyping assay

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Novacyt S.A.

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

IVDR certification achieved for DPYD genotyping assay

One of the first products of its kind to conform with new IVDR requirements

Paris, France, and Eastleigh and Manchester, UK - 7 November 2023 - Novacyt S.A. (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international specialist in clinical diagnostics, confirms IVDR accreditation under the new EU requirements of the In Vitro Diagnostic Regulation ("IVDR") for its DPYD genotyping assay, which supports the identification of cancer patients at risk of suffering a severe, and potentially life-threatening, reaction to common chemotherapy.

The Yourgene® DPYD assay is used to identify patients with Dihydropyrimidine Dehydrogenase (DPD) deficiency, through the rapid detection of six clinically relevant variants in the DPD enzyme. Patients with a DPD deficiency have a high risk of severe, and sometimes lethal, side effects following the administration of 5-Fluorouracil (5-FU), a widely used chemotherapy agent used in the treatment of many cancers including colorectal, head and neck, breast, pancreatic and stomach cancer.

An estimated two million people globally are treated with fluoropyrimidines (including 5-FU) each year1, with between 10-30% of these patients suffering severe side effects associated with DPD deficiency2. DPYD genotyping for 5-FU toxicity has been adopted in many countries internationally with screening introduced into cancer care clinical pathways following government reimbursement in England, Wales, Germany, Spain, Belgium and the Ontario province of Canada. The screening enables clinicians to reduce the risk of increased toxicity from 5-FU exposure in these patients by treatment with a lower dose, or with an alternate drug therapy where indicated.

The Yourgene® DPYD assay is a Class C in vitro medical device under IVDR and is intended for use by healthcare professionals within a molecular or oncology laboratory environment.

The new IVDR ensures that in vitro diagnostic devices manufactured for sale in the EU are assessed against stringent quality, safety and performance requirements. Manufacturers must provide, among other things, considerable evidence of scientific validity, as well as data demonstrating analytical and clinical performance of the devices. The DPYD assay was assessed by BSI, an independent conformity assessment body (the "Notified Body") and was shown to conform to the new regulations.

The DPYD assay is the first product within the now enlarged Novacyt product portfolio to conform to the new EU IVDR and is one of the first pharmacogenomics tests in the market, and the only assay for the rapid detection of the six clinically relevant variants in the DPD enzyme, as defined by the CPIC* guidelines, to conform to IVDR. The Directors of Novacyt believe that conformity with IVDR provides clinicians and patients with additional confidence in the high-quality and accuracy of this test, which is increasingly becoming an essential screening requirement ahead of cancer patient treatment.

Commenting James McCarthy, Acting Chief Executive Officer, said: "We are delighted to announce the first conformity of one of our products to the new EU regulations for in vitro diagnostic products. This success reflects the high-quality of the product in terms of both performance and safety, and follows a rigorous review by our Notified Body. It is a clear market advantage to have our product as the first assay to detect DPD deficiency to conform to IVDR, particularly as more and more countries in Europe and elsewhere are adopting this form of screening as their recommended procedure ahead of chemotherapy treatment."

Sources

1 D. Meulendijks et al./Cancer Treatment Reviews 50 (2016) 23-34

2 Cancer Research UK https://bit.ly/2kLn1uT

*CPIC Guidelines (Clinical Pharmacogenetics Implementation Consortium) provides clinical dosing recommendations based on DPYD genotype for patients
https://cpicpgx.org/guidelines/guideline-for-fluoropyrimidines-and-dpyd/

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About DPYD

https://yourgenehealth.com/our-products/assays-and-applications/precision-medicine/dpyd-genotyping/

About Novacyt Group (www.novacyt.com)

Novacyt is an international diagnostics business delivering a broad portfolio of in vitro and molecular diagnostic tests for a wide range of infectious diseases, enabling faster, more accurate, accessible testing to improve healthcare outcomes. The Company provides customers with a seamless sample-to-result workflow using its integrated and scalable instrumentation/solutions. The Company specialises in the design, manufacture, and supply of real-time PCR kits, reagents and a full range of laboratory and qPCR instrumentation for molecular biology research and clinical use. Novacyt offers one of the world's most varied and comprehensive range of qPCR assays, covering human, veterinary, biodefence, environmental, agriculture and food testing.

The acquisition of Yourgene in September 2023 added a complementary international genomics technology and services business, focussed on delivering accurate molecular diagnostic and screening solutions, across reproductive health and precision medicine. Yourgene's portfolio of in vitro diagnostic products includes non-invasive prenatal tests (NIPT) for Down's Syndrome and other genetic disorders, Cystic Fibrosis screening tests, invasive rapid aneuploidy tests and DPYD genotyping assays. Yourgene also works in partnership with global leaders in DNA technology to allow its Ranger® Technology to deliver dynamic target enrichment.

Novacyt is headquartered in Vélizy in France with offices in the UK in Stokesley, Eastleigh and Manchester. The Company also has offices in Taipei (divestment pending), Singapore, the US and Canada and is listed on the London Stock Exchange's AIM market ("NCYT") and on the Paris Stock Exchange Euronext Growth ("ALNOV").

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