

# IVDR accreditation for Yourgene QST\*R Base assay

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

## IVDR accreditation for Yourgene® QST\*R Base assay

**Paris, France, and Manchester, UK - 20 February 2025** - Novacyt (EURONEXT GROWTH: ALNOV; AIM: NCYT), an international molecular diagnostics company with a broad portfolio of integrated technologies and services, announces that it has received accreditation under the new EU requirements of the In Vitro Diagnostic Regulation ("IVDR") for the Yourgene® QST\*R Base assay. The Yourgene® QST\*R Base is a Class C *in vitro* medical device under IVDR and is intended for use by healthcare professionals within a molecular laboratory environment.

Yourgene® QST\*R Base is a highly multiplexed, single tube assay containing 22 markers for rapid diagnosis of the common autosomal and sex chromosome aneuploidies during pregnancy. For those women identified as being at high risk of carrying a fetus with one of these conditions, chorionic villus sampling (10-12 weeks) or amniocentesis (14-18 weeks) is offered and QST\*R Base would then be used by the laboratory. Autosomal markers are used to detect the three most common viable autosomal trisomies: trisomy 21 (Down's syndrome), trisomy 18 (Edwards' syndrome) and trisomy 13 (Patau's syndrome). The chosen markers are highly informative with results obtained in >99% of samples.

IVDR ensures that the Yourgene® QST\*R Base assay, which is manufactured for sale in the EU, is assessed against stringent quality, safety and performance requirements. Manufacturers must provide considerable evidence of scientific validity, as well as data demonstrating analytical and clinical performance of the tests. The Yourgene® QST\*R Base assay was assessed by British Standards Institution (BSI), an independent conformity assessment body, and was shown to conform to the new regulations.

**Lyn Rees, CEO of Novacyt, commented:** *"This is the third IVDR accreditation for Novacyt which further demonstrates the high quality and accuracy of our products, and our team's ability to navigate the stringent new regulatory environment for in vitro diagnostic tests. Novacyt has a range of tests for the reproductive health lifecycle and the QST\*R Base test is complementary to our NIPT tests providing a follow-on confirmatory test after a high risk NIPT result. We are very proud to have developed an assay that provides accurate and reliable results*

*during a stressful time in the pregnancy for expecting parents."*

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## About Novacyt Group ([www.novacyt.com](http://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:

<b>Clinical</b>	<p>Broad portfolio of human clinical <i>in vitro</i> diagnostic products, workflows and services focused on three therapeutic areas:</p> <ul style="list-style-type: none"> <li>· Reproductive Health: NIPT, Cystic Fibrosis and other rapid aneuploidy tests</li> <li>· Precision Medicine: DPYD genotyping assay</li> <li>· Infectious Diseases: Winterplex, multiplex winter respiratory PCR panel</li> </ul>
<b>Instrumentation</b>	<p>Portfolio of next generation size selection DNA sample preparation platforms and rapid PCR machines, including:</p> <ul style="list-style-type: none"> <li>· Ranger® Technology: automated DNA sample preparation and target enrichment technology</li> <li>· genesig q16 and q32 real-time quantitative PCR (qPCR) instruments</li> </ul>
<b>Research Use Only</b>	<p>Range of services for the life sciences industry:</p> <ul style="list-style-type: none"> <li>· 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 industry</li> <li>· Pharmaceutical research services: whole genome sequencing (WGS) / whole exome sequencing (WES)</li> </ul>

Novacyt is headquartered in Le Vésinet in France with offices in the Manchester, UK, Singapore, the US and Canada and has a commercial presence in over 65 countries. 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](http://www.novacyt.com)

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