

IVDR accreditation for Yourgene QST*R Base assay

RNS Number : 7690X

Novacyt S.A.

20 February 2025

NOVACYT

Novacyt S.A.

("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."

Contacts

Novacyt SA	https://novacyt.com/investors
Lyn Rees, Chief Executive Officer	Via Walbrook PR
Steve Gibson, Chief Financial Officer	
SP Angel Corporate Finance LLP (Nominated Adviser and Broker)	+44 (0)20 3470 0470
Matthew Johnson / Charlie Bouverat (Corporate Finance) Vadim Alexandre / Rob Rees (Corporate Broking)	
Deutsche Numis (Joint Broker)	+44 (0)20 7260 1000
Freddie Barnfield / Duncan Monteith / Michael Palser	
Allegra Finance (French Listing Sponsor) Rémi Durgetto / Yannick Petit	+33 (1) 42 22 10 10 r.durgetto@allegrafinance.com / y.petit@allegrafinance.com
Walbrook PR (Financial PR & IR) Paul McManus / Lianne Applegarth Phillip Marriage / Alice Woodings	+44 (0)20 7933 8780 or novacyt@walbrookpr.com +44 (0)7980 541 893 / +44 (0)7584 391 303 +44 (0)7867 984 082 / +44 (0)7407 804 654

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

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

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@lseg.com or visit www.rns.com. RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

MSCTLMPTMTTBPA