

NATA ISO15189 Certification - Genetype Laboratory Operations

Highlights

- ✓ **Successful transition of geneType™ Laboratory to ISO 15189:2022 secures updated accreditation**
- ✓ **Harmonisation of laboratory services and market access for all Company products.**
- ✓ **Positions Rhythm to progress ColoSTAT® as an in-house IVD**

Melbourne, Australia, 2nd December 2025: Rhythm Biosciences Ltd ('RHY', the 'Company' or the 'Group') (ASX:RHY), a transformative, predictive cancer diagnostics technology company, is pleased to announce the successful completion of our NATA reassessment audit for transition to ISO 15189:2022. The audit confirmed that the Rhythm geneType™ laboratory's quality and operational systems fully comply with the updated international standard, ensuring the Company's accreditation under the new requirements.

With accreditation now aligned to the ISO 15189:2022 standard, Rhythm continues to deliver its accredited geneType™ risk assessment clinical testing service. This outcome also establishes the foundation for the Company to commercialise ColoSTAT® as an in-house IVD, subject to completion of a variation assessment by NATA to add ColoSTAT® as an accredited service. In addition, it will enable Rhythm to optimise operational costs by revoking the now redundant ISO13485 status.

Dr. David Atkins, CEO and MD: " Our transition to ISO 15189:2022 demonstrates the strength and maturity of our laboratory systems. Focussing on a single laboratory service and unified commercial strategy for all our products is the next step in our ongoing efforts to capture synergies between ColoSTAT® and Genetype in both operational and market access activities".

- ENDS -

This announcement was authorised by the Board of Directors of Rhythm Biosciences Limited.

For further information contact us via investors@rhythmbio.com.

About Rhythm Biosciences

Rhythm Biosciences Ltd (ASX: RHY) is an Australian innovative, medical diagnostics company aimed at delivering simple, affordable blood tests for accurate and early detection of cancers. Rhythm is focused on improving patient outcomes through detection at the earliest possible stage, reducing the global burden of cancer, and saving lives. Rhythm Biosciences is committed to working with likeminded global partners to achieve commercialisation and distribution of these simple solutions. The company was founded in 2017 and is headquartered in Melbourne, Australia. For more information, visit rhythmbio.com and follow the company on LinkedIn and X.

About ColoSTAT®

Colorectal cancer (CRC), also referred to as bowel cancer, is the second leading cause of cancer deaths globally. If diagnosed early, colorectal cancer can be curable. The ColoSTAT® Test is Rhythm Bioscience's simple blood-based test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood of CRC. It is intended for individuals with symptoms associated with Colorectal Cancer (CRC). The ColoSTAT® Test is based on research from Australia's CSIRO and is patent protected internationally. It has the potential to play a key role in reducing the mortality rate and healthcare costs associated with colorectal cancer.

About geneType™

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geneType™ is a sophisticated genetic risk assessment testing platform that combines clinical, family history and genetic data to provide comprehensive risk assessments for various diseases. The platform leverages polygenic risk scores and clinical risk factors to generate personalized health insights, helping individuals and healthcare providers make more informed medical decisions. The technology allows for risk assessment across multiple conditions including breast cancer, cardiovascular disease, diabetes, colorectal cancer, prostate cancer, and melanoma. The tests are delivered through healthcare providers and genetic counsellors, ensuring appropriate clinical oversight and support for patients receiving their results. The platform's multi-disease assessment capabilities and clinical utility position it well to capture growing demand in the preventative healthcare and precision medicine markets. For more information, please visit www.genetype.com.