

## Completion of ColoSTAT® Assay Validation and Submission of Request to NATA for Inclusion in ISO15189 Accreditation Scope

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### Highlights

- ✓ Rhythm completed the final full system validation of ColoSTAT® for the kits, algorithm and instrumentation using an extensive range of clinical samples.
  - ✓ Validation data shows that ColoSTAT® performance will meet the needs for the intended initial clinical indication.
  - ✓ A request was submitted to NATA for the addition of ColoSTAT® to Rhythm ISO15189 laboratory accreditation to support commercialisation.
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**Melbourne, Australia, 26th August 2025:** Rhythm Biosciences Ltd ('RHY', the 'Company' or the 'Group') (ASX:RHY), a transformative, predictive cancer diagnostics technology company, is pleased to announce completion of the Final ColoSTAT® process validation and regulatory submission to NATA for the addition of ColoSTAT® to the scope of the Rhythm Biosciences ISO15189 accreditation to enable commercialisation of the clinical assay.

Rhythm have completed the in-house laboratory validation of the final, highest quality ColoSTAT® kits produced by a manufacturing partner, Quansys Biosciences, using a scalable manufacturing process. ColoSTAT® has shown to be a highly robust and reproducible test following analytical testing in over 450 sample replicates across different analytical conditions.

In addition to the robust analytical performance of the kit, it has strong clinical performance. We are pleased to share that following analysis of over 300 clinical samples, ColoSTAT® achieved a sensitivity of 91% for the identification of colorectal cancer in those individuals considered at higher risk of colorectal cancer (> 45 years of age. <https://www.cancer.org.au/clinical-guidelines/bowel-cancer/colorectal-cancer>). Furthermore, the high Negative Predictive Value (98%) means that ColoSTAT® has the performance characteristics required to be used for the safe triage of patients with symptoms of bowel cancer. In addition, ColoSTAT® could be used as a safe and effective alternative for those symptomatic individuals who prefer not to do stool-based testing to support a decision regarding use of colonoscopy.

The laboratory validation data has now been submitted to National Association of Testing Authorities (NATA) in order to add ColoSTAT® to Rhythms existing ISO15189 test portfolio in advance of commercialisation.

#### Directors

Otto Buttula  
Sue MacLeman  
Gavin Fox-Smith  
David Atkins

Non-Executive Chairman  
Non-Executive Director  
Non-Executive Director  
CEO & Managing Director

**Rhythm Managing Director and Chief Executive Officer, Dr David Atkins** commented “We are delighted to have achieved these critical validation milestones and to report promising performance that reinforces the potential of ColoSTAT® to improve the early detection of colorectal cancer. Our focus now turns to commercial pathways to bring this much-needed diagnostic to market. Furthermore, we recognise the need to continue to add new data to our existing evidence base and look forward to announcing important clinical partnerships in the near future. ”

The Company remains committed to driving ColoSTAT® toward regulatory approval and commercial roll-out, with further updates to be provided as progress is made.

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

**For further information contact us via [investors@rhythmbio.com](mailto: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](http://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 is curable.

The ColoSTAT® Test-Kit 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. The test is an alternative for individuals who are unable or unwilling to participate in current screening programs. It is being updated to meet relevant regulatory standards.

The ColoSTAT® Test-Kit 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™**

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](http://www.genetype.com).