ColoSTAT® Commercial Rollout Update: TGA In-House IVD Notification Accepted; MedicalDirector Ordering Live; Collection Network Expands

Highlights

- ✓ **ColoSTAT® has been included in Rhythm's in-house IVD notification to the TGA, completing the notification step applicable to in-house IVDs used within Rhythm's NATA-accredited laboratory and marking a further regulatory and compliance milestone supporting the Australian commercial rollout of ColoSTAT®**
- ✓ **ColoSTAT® ordering has been integrated into MedicalDirector — one of Australia's leading general practitioner clinical software platforms — with ordering live from 1 August 2026, reducing a key practical barrier to routine GP ordering**
- ✓ **ColoSTAT® collection-site coverage has continued to expand across New South Wales, Victoria and Queensland through July, with more than 100 collection sites now live across the eastern states**
- ✓ **These milestones build on Rhythm's previously announced commercialisation activities and progressively expand the infrastructure through which GPs can order, and patients can access, ColoSTAT®**

Melbourne, Australia, 20th August 2026: Rhythm Biosciences Ltd (ASX: RHY) is pleased to provide a further update on the commercial rollout of ColoSTAT®, its blood-based colorectal cancer triage test. The developments outlined below build on the Company's previously announced commencement of ColoSTAT® commercialisation and subsequent expansion of its clinician and collection-site network, and represent further progress in establishing the regulatory, ordering and patient-access infrastructure required to support broader adoption of ColoSTAT® in Australia.

The Company has received confirmation that its TGA in-house IVD notification for ColoSTAT® has been accepted into the TGA In-House IVD Notification Database. In addition, ColoSTAT® ordering is now live in MedicalDirector, one of the leading general practitioner (GP) clinical software platforms in Australia, and ColoSTAT® collection-site coverage continues to expand across Australia's eastern states.

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TGA In-House IVD Notification Accepted for ColoSTAT®

This milestone follows Rhythm's previously announced progression of ColoSTAT® through assay validation, NATA assessment and inclusion within the scope of the Company's ISO 15189 NATA-accredited laboratory services. Rhythm has received confirmation that ColoSTAT® has been accepted into the TGA In-House IVD Notification Database as an in-house in vitro diagnostic (IVD) test. This completes the notification applicable to in-house IVDs developed and used within a laboratory accredited by the National Association of Testing Authorities (NATA). This is the established compliance pathway for Class 1–3 laboratory-developed IVDs used within an accredited laboratory under the applicable NPAAC/NATA framework.

ColoSTAT® is performed within Rhythm's ISO 15189 NATA-accredited laboratory in Parkville, Melbourne. The notification complements that accreditation and forms part of the compliance infrastructure underpinning ColoSTAT®'s deployment in Australia and completes the final administrative step in the regulatory and compliance pathway supporting its domestic commercialisation.

MedicalDirector Integration Now Live

Rhythm has integrated the ColoSTAT® test request form — the electronic order form a GP completes to refer a patient for a test — into MedicalDirector. From 1 August 2026, GPs using MedicalDirector can order ColoSTAT® within their existing clinical workflow rather than downloading and manually filling in the form details.

Integration into commonly used GP clinical software is an important component of Rhythm's commercial rollout strategy, reducing administrative steps required for clinicians to order ColoSTAT® and supporting its incorporation into routine clinical workflows. Rhythm is now progressing equivalent integration with other platforms with the objective of progressively broadening electronic ordering access across Australian GPs.

Collection Site Network Expanding

ColoSTAT® can be ordered where a nearby collection centre is available to take the patient's sample, so each new site directly widens patient access. As previously announced, Rhythm had activated 78 commercial collection sites by the end of March 2026, more than doubling the 38 sites announced earlier that month. The network has continued to expand and now comprises more than 100 collection sites across Australia's eastern states.

Working with 4Cyte, Rhythm has prioritised regional hubs serving wide catchments and areas of high potential demand. Recent activations spanned New South Wales (Central Coast and Hunter — Toukley, Woy Woy, Dora Creek, Singleton), regional Victoria (Hamilton, Shepparton, Ballarat, Sale) and South-East Queensland (Tweed Heads, Toowoomba, Caloundra). Further activations have been completed during August across Victorian, NSW/ACT and Queensland catchments, each selected to reach a defined potential patient population.

Commercial Rollout

Rhythm will continue to expand the infrastructure supporting the commercial rollout of ColoSTAT®, including further GP ordering-system integrations and collection-network coverage. Together with the regulatory and laboratory milestones previously achieved, these initiatives are progressively addressing the key practical requirements for broader commercial adoption: an accredited and compliant testing pathway, accessible clinician ordering and convenient patient sample collection.

The Company's focus is now on leveraging this infrastructure to support increased clinician engagement, patient access and utilisation of ColoSTAT® in the Australian market.

CEO Commentary

Rhythm Biosciences CEO & Managing Director, Dr David Atkins, said: "Over the past year we have progressively moved ColoSTAT® from final assay validation through laboratory accreditation and initial commercialisation, and we are now building the practical infrastructure required to make the test increasingly accessible to clinicians and patients. Acceptance of the in-house IVD notification confirms that we are operating within the applicable compliance requirements for laboratory-developed tests in Australia, while integration with MedicalDirector and expansion beyond 100 collection sites makes ColoSTAT® easier for GPs to order and more accessible for patients.

"These are practical but important milestones in the commercial rollout. Our focus is increasingly shifting from establishing the infrastructure required to deliver ColoSTAT® towards driving clinician engagement, patient access and test utilisation."

– 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™

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.