

2nd Generation, ColoSTAT® Multiplex *Alpha* Kit Outperforms Original Kit Results

Highlights

- ✓ **Completion of ColoSTAT® Multiplex *Alpha* Kit Performance Evaluation exhibits superior analytical results to original ColoSTAT® Kits; and**
- ✓ **Provides positive backdrop as Rhythm advances towards *Beta* Kit assay production and final validation.**

Transformative, predictive cancer diagnostics technology company, Rhythm Biosciences Ltd (ASX: **RHY**) (**Rhythm** or the **Company**) advised on 28 August 2024 that it had received the first batch of the *Alpha* version of the multiplex antibody detection kits developed and manufactured by the Company's CMO, Quansys Biosciences (Quansys), in the USA.

The Company is pleased to report that completion of its preliminary testing results (including a novel custom algorithm) reveals **superior analytical results from the ColoSTAT® 2nd generation (multiplexed) Kits**, compared to those previously reported for the first-generation product. The tests were conducted upon 200 previously collected patient serum samples (100 from cancer patients and 100 controls) to generate new assay data using the *Alpha* kits. A subset of this data was used to create a new prototype algorithm designed to separate cancer from non-cancer samples.

The table below summarises the data with the two key observations being:

- ✓ The generation of an effective algorithm on these initial samples has resulted in a **statistically significant** classification of samples as either cancer or non-cancer.
- ✓ The performance of the new, 2nd generation ColoSTAT® kit meets the goal of not only being equivalent to the first-generation kit but has a >70% probability of having **superior performance** characteristics.

ColoSTAT® Kit Version	Performance Value (Area under the curve)	Probability of performance value occurring by chance
2 nd Generation ColoSTAT® Alpha	0.805	p<0.0001
1 st Generation ColoSTAT®	0.784	P<0.0001

Commenting on the primary analysis, Rhythm CEO and MD, Dr David Atkins said:

"The second generation ColoSTAT® multiplex assay kits combine five (5) separate antibody-based assays that previously constituted the original ColoSTAT® assay into a single reaction for each patient blood sample.

Directors

Otto Buttula
Sue MacLeman
Trevor Lockett
Louis Panaccio
David Atkins

Non-Executive Chairman
Non-Executive Deputy Chair
Non-Executive Director
Non-Executive Director
CEO / Managing Director

It is well known that combining multiple antibodies into a single reaction vessel could generate unexpected results and the evaluation of the Alpha kit has always been an important milestone for the Company to achieve. The goal was to successfully re-engineer the assay to increase quality and make the assay easier to use and more reproducible while maintaining at least the performance of our first generation ColoSTAT® assay.

This represents an important step forward and reduces a significant portion of development risk from the pathway to eventual commercialisation.”

Further information regarding primary testing:

The testing method utilised by Rhythm is more stringent than that used previously. Further, the Company justifiably expects **performance to continue to improve as the assay is optimised** and further data becomes available for **algorithm development**.

The prototype algorithm was tested multiple times, and a performance value was established. In parallel, these results were compared to historical data obtained from the same samples using the original ColoSTAT® kit and algorithm.

Next Steps:

To work with our CMO, Quansys, over the coming weeks to generate the *Beta* version of the assay that will then be used for starting the development of the commercial version of the algorithm and further verification and validation. In parallel, the Company is finalising the plans for assay validation using entirely independent clinical samples and will announce clinical partners in the near future.

- ENDS -

Authorised for release by the Board.

For further information contact us via investor@rhythmbio.com:

Dr. David Atkins Chief Executive Officer and Managing Director	Mr. Guy Carisbrooke Financial Controller
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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 is curable.

The ColoSTAT[®] Test-Kit is Rhythm Bioscience's simple blood test for the detection of CRC. It measures five specific protein biomarkers that indicate the likelihood presence of CRC. The test can be used as an alternative for individuals who are unable or unwilling to participate in current screening programs.

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.