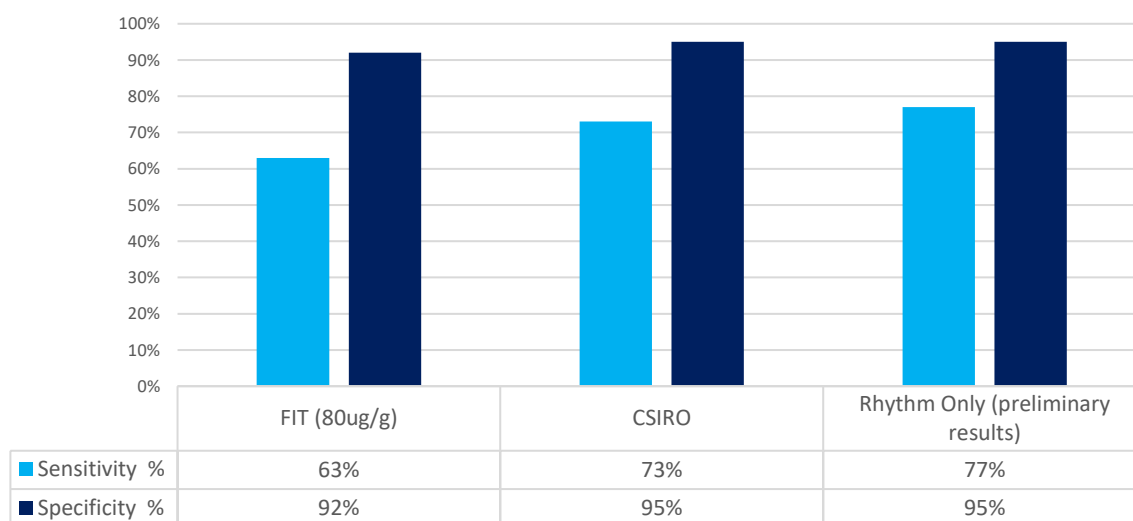


## ColoSTAT® Prototype Test-Kit Outperforms Current Market Standard, Faecal Test

- ✓ **ColoSTAT® Prototype test-kit successfully completed;**
- ✓ **Performance testing indicates high accuracy, outperforming the current market standard faecal test and prior CSIRO testing; and**
- ✓ **Successful ongoing differentiation between cancerous and healthy blood samples.**

**12 November 2020, Melbourne:** Rhythm Biosciences Limited (ASX: RHY) is pleased to confirm that the ColoSTAT® prototype test-kit has been successfully completed. Preliminary test results demonstrate superior performance to both:

- i) the globally accepted and market standard faecal immunochemical test (FIT); and
- ii) to previous testing data generated by CSIRO on commercially sourced individual biomarker test kits.



**Summary of ColoSTAT® prototype test-kit performance vs the current market standard faecal immunochemical test (FIT) and previous CSIRO test work.**

<sup>1</sup> **Sensitivity** is the ability of the test to correctly identify those patients with colorectal cancer, that is, the percentage of people with colorectal cancer who are correctly identified as having illness.

<sup>2</sup> **Specificity** is the ability of the test to correctly identify people who do not have colorectal cancer, that is, the percentage of people without colorectal cancer who are correctly identified as not having cancer.

#### Rhythm Biosciences

ASX: RHY  
 ACN: 619 459 335

#### Issued Capital

201,495,811 Shares  
 6,650,000 Options

#### Australian Registered Office

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#### Directors

Otto Buttula – Chairman of the Board  
 Trevor John Lockett – Executive Director  
 Louis James Panaccio – Non-Executive Director  
 David John White – Non-Executive Director  
 Eduardo Vom – Non-Executive Director

This significant milestone underpins the global mass market commercial potential of ColoSTAT® as an effective screening test beneficial to patients, physicians, and national healthcare systems alike.

Rhythm CEO, Mr Glenn Gilbert commented, “these preliminary results demonstrate the high accuracy and specificity of the ColoSTAT® prototype test-kit which clearly distinguishes between cancerous and healthy blood samples. This is a significant step forward for the Company as we take steps to commercialise our world leading, transformative diagnostic test that will save lives”.

### **About the ColoSTAT® prototype test**

Rhythm recently completed a study on 200 blood samples (n=200) made up of 100 known cancerous and 100 known healthy samples. The preliminary results demonstrate that the ColoSTAT® prototype test-kit not only outperforms the previous reported faecal test results, but also outperforms previous studies conducted by both CSIRO and earlier internal Rhythm results.

The ColoSTAT® prototype test-kit encompasses five individual biomarker tests that have been technically validated. Results for each biomarker are fed into Rhythm’s proprietary algorithm, which are then combined and processed with all relevant data to deliver a final performance result.

The study concluded that the ColoSTAT® prototype test-kit shows a high accuracy for the detection of colorectal cancer, across all genders, and could accurately distinguish between cancerous and healthy blood samples at a specificity of 95%. A graphical and tabular summary of the results and comparison against the current market standard faecal immunochemical test (FIT) and prior CSIRO studies is shown on the prior page.

The faecal immunochemical test (FIT) is widely used as a colorectal cancer detection test in Australia and elsewhere globally. Unfortunately, this test only detects blood in the stool and experiences sub-optimal compliance on a global level, with only 40% of high-risk patients completing the test here in Australia. One of the significant benefits of ColoSTAT® is that we expect to increase the compliance rate whilst having the potential to widen the patient pool outside of the standard 50 to 74-year-old bracket. This is particularly important as colorectal cancer is the most common cause of cancer deaths for those aged between 25-29 in Australia.

The performance results for the ColoSTAT® prototype test-kit is largely attributable to the success of Rhythm’s development program. Since the beginning of the year, the Company has delivered a number of key milestones that have culminated in the successful production of the ColoSTAT® prototype test-kit:

- maintaining ISO certification of the Company’s quality management system;
- the successful, reproducible and stable technical validation of the complete individual biomarker antibody tests; and
- ongoing development of Rhythm’s proprietary algorithm.

This development program will play out further as we move toward product registration and market authorisation.

The Company will now move to design transfer the technology and initiate scale-up activities to a high-volume manufacturer to produce further test-kits that Rhythm will conduct additional testing upon. Some of the additional testing relating to further cancerous and healthy samples on the third-party kits will form Study 6 that is expected to be completed by Q3FY'21.

"ColoSTAT® addresses the significant global unmet need for a simple, accurate, reliable and affordable blood test to detect colorectal cancer within a mass-screening environment and we are excited to be at the forefront of this transformative development" Mr. Gilbert said.

With the authority of the Board.

For further information, please contact:

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#### **About Rhythm Biosciences**

Rhythm Biosciences (ASX: RHY) is a transformative, predictive diagnostics company, specialising in early cancer detection. Rhythm's initial business pursuit is centred upon technology originally developed by the CSIRO and involves the development and commercialisation of a screening and diagnostic test for the early detection of colorectal cancer, the third biggest cause of cancer-related deaths globally.

Rhythm's lead product, ColoSTAT®, is intended to be a simple, affordable, minimally invasive and effective blood test for the early detection of bowel cancer for the global mass market. It is expected to be comparable to, if not better than, the current standard of care, the faecal immunochemical test (FIT), at a lower cost. ColoSTAT® also provides an alternative for those who choose not to, or are unable to, be assessed using standard screening programs.

ColoSTAT® is designed to be used easily by laboratories without the need for additional operator training or additional infrastructure. ColoSTAT® has the potential to play an important role in reducing the morbidity and mortality rates and healthcare costs associated with colorectal cancer via increasing current screening rates.

Globally, over 850,000 people die from colorectal cancer each year. Colorectal cancer is typically diagnosed at a later stage when there is a poor prognosis for long-term survival. Annual estimated unscreened 50-74-year old's is estimated at +130m for the US, EU and AU alone, with this market potential being more than \$6.5b.