

## Consultation with Major Diagnostic Laboratories Underway - IVD Kit Development Update

### Highlights

- IVD kit development continues on schedule
- Rhythm highlights key milestones in IVD kit development
- Consultation with major diagnostic laboratories underway

Rhythm Biosciences ("Rhythm", ASX:RHY), developer of the ColoSTAT™ antibody-based blood test targeting the accurate and early detection of colorectal cancer, is pleased to advise its expected development pathway of the IVD kit required for ColoSTAT™, continues to progress according to plan. Its reagent development program, the initial focus for the company, will pave the way for the next phase - IVD kit development and technology transfer - that will enable commercial-scale production.

Upon completion of laboratory scale reagent production and purification, lab protocols will be translated into a set of standard operating procedures to support the scalable production of the reagents by a contract manufacturer.

Once the new reagents are established, Rhythm will then develop and refine specifications for an enzyme-linked immunosorbent assay (ELISA), the basis of the new testing kit.

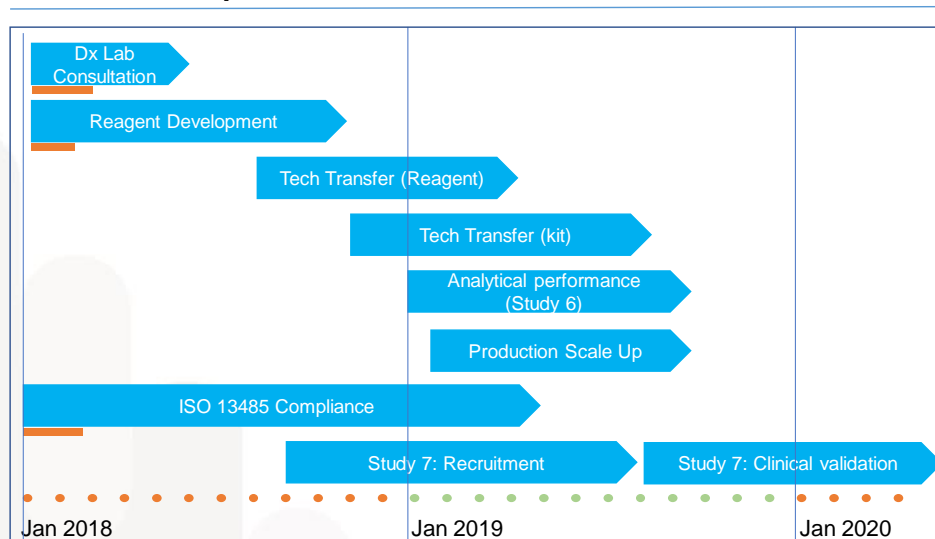
The performance of this new kit, in combination with the algorithm that converts protein biomarker concentrations to a colorectal cancer risk score, will be qualified using real patient samples while also being compared head to head with the equivalent commercial kits. Kit qualification will be a critical stepping stone towards validation of ColoSTAT™ in the subsequent major prospective clinical trial (Study 7) that will form a key component of cases for EU and Australian regulatory approvals.

Also as part of the development and regulatory pathway, Rhythm has commenced the development of its quality management systems. Complete implementation should see the company's operations fully compliant with the ISO 13485 standard.

Currently Rhythm is in consultation with a number of diagnostic laboratories, both public and private, to help define key test parameters and features that would facilitate the easy adaptation of ColoSTAT™ into the existing workflows of major diagnostics companies and other service providers.

The following outlines the next technical steps required in the IVD kit development for Rhythm's ColoSTAT™ test:

### IVD Kit Development



**For further information, please contact:**

**TREVOR LOCKETT**  
MANAGING DIRECTOR  
0418 647 490

**SHANE TANNER**  
CHAIRMAN  
0411 107 099

### **About Rhythm Biosciences**

Rhythm Biosciences is developing and commercialising Australian medical diagnostics technology for sale across national and international markets.

Rhythm's lead product, ColoSTAT™, is intended to provide the accurate and early detection of colorectal cancer, acting as either a 'first-step' screening test or within the triage of persons with a positive faecal immunochemical test (FIT) or colonoscopy. As well as being of value to those with risk factors associated with colorectal cancer, ColoSTAT™ provides an alternative for those who choose not to or are unable to be assessed using standard screening programs.

Being developed to be an affordable and effective diagnostic, ColoSTAT™ has the potential to play an important role in reducing morbidity, mortality and healthcare costs associated with colorectal cancer.