3529 **Poster Session**

A prospective, cross-sectional, multicentre study to evaluate the clinical performance of the ColoSTAT in vitro diagnostic for the detection of biomarkers associated with colorectal cancer.

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Background: Colorectal cancer (CRC) survival rates could be improved if more cancers were detected early. The ColoSTAT blood test and algorithm combines concentrations of 5 protein biomarkers with age and sex to provide an alternative to current CRC screening methods like the faecal immunochemical test (FIT). We compared the performance of ColoSTAT to colonoscopy in detecting CRC. **Methods:** Patients in this Australian study were either recently diagnosed with CRC using colonoscopy and progressing to surgery or neoadjuvant treatment (Cohort 1) or had no CRC history and were scheduled for colonoscopy (Cohort 2). Due to COVID-19 pandemic-related recruitment delays, the samples from Cohort 1 were supplemented with bio-banked blood samples (BBS) from patients with clinically confirmed CRC. Patients provided a 17 mL blood sample and were followed until start of cancer treatment or colonoscopy. All blood samples were de-identified prior to testing by an independent laboratory. The primary endpoints were ColoSTAT sensitivity of ≥73% (lower 95% confidence limit [LCL] > 60%), and specificity ≥90% (LCL > 80%). Sensitivity by TNM stage was an exploratory endpoint (ACTRN12619000301167). **Results:** Cohort 1 enrolled 29 patients, Cohort 2 enrolled 768 patients and 192 BBS were included. Patient demographic characteristics were similar in Cohorts 1, 2 and BBS. Overall, the median age of the patients (n = 989) was 64 years (range 40 to 88) and 53.4% were female. Definitive ColoSTAT results were obtained for 22 patients in Cohort 1, 554 in Cohort 2 and 81 in BBS. Overall, the estimated sensitivity of ColoSTAT for detection of CRC compared with colonoscopy was 81.3% (95%CL 73.0%-87.4%) and estimated specificity 91.0% (95%CL 87.7%-93.5%) (Table). **Conclusions:** The ColoSTAT test met the primary endpoints of performance based on sensitivity and specificity in detecting CRC compared to colonoscopy. ColoSTAT sensitivity and specificity for CRC were comparable with published performance parameters for FIT which range from 74-93% (sensitivity) and 85-96% (specificity).[1] Clinical trial information: ACTRN12619000301167. Research Sponsor: This study was solely funded by Vision Tech Bio Pty Ltd (subsidiary of Rhythm Biosciences Limited). S. Gibb, WriteSource Medical Pty Ltd provided medical writing services funded by Rhythm Biosciences.

Sensitivity and specificity of ColoSTAT vs colonoscopy.

	All participants/BBS (N = 989)
Definitive ColoSTAT result (indeterminant, invalid, no test)	657 (97, 208, 27)
Colonoscopy result available (no colonoscopy)	911 (78)
Definitive ColoSTAT and colonoscopy	603
ColoSTAT True +ve (A), False +ve (B), False -ve (C), True -ve (D)	91, 35*, 21, 354*,
Sensitivity (95%CI) (A/[A+C])	81.3% (73.0%-87.4%)
Specificity (95%CI) (D/[B+D])	91.0% (87.7%-93.5%)
ColoSTAT sensitivity by CRC stage (I, II, III, IV)# (95%CI)	I: 87.5% (64.0%-96.5%), II: 91.3% (73.2%-97.6%), III: 92.3% (66.7%-98.6%), IV: 100% (87.9%-100%)

*Specificity calculated using the prospective cohorts #Exploratory endpoint; staging data available for BBS only [1]Switalski J et al, Cancers 2022, 14, 4391.