



Investor Presentation

A transformative and predictive
cancer diagnostics technology company

20 June 2023 [ASX:RHY](#)

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Introduction

- Rhythm's initial product, ColoSTAT® is a **simple, affordable** blood test for the early detection of colorectal cancer for **global mass-market** screening
- Developing alternative screening solutions for specific cancers via **patient friendly** blood tests is our primary focus
- IP protection for ColoSTAT® has been **secured** in all major international jurisdictions
- Focus our **commercialisation strategy** into international markets leveraging, specific country regulatory approvals in place for ColoSTAT®
- Commenced **platform technology** program for multiple / pan cancer targets

Company Overview

Capital Structure

ASX Code	RHY
Share Price (at 16 June 2023)	\$0.485
Shares on Issue	219.8 M
Unlisted Options	17.2 M
Market Capitalisation	\$115 M
Cash in bank (31 March 2023)	\$6.8M
Top 20 Shareholders	41%

Share Price Chart



Board and Management

Otto Buttula	Trevor Lockett	Lou Panaccio	Rachel David	Sue MacLeman
Executive Chairman	Executive – Technical Director	Non-Executive Director	Non-Executive Director	Non-Executive Director
<ul style="list-style-type: none"> Extensive financial, investment, IT and biotech experience. Co-Founder and CEO of IWL (ASX: IWL); Founder / former CEO of Investors Mutual. Formerly a Director of Imugene (ASX: IMU) and Chairman of Investorfirst, now HUB (ASX: HUB). Chairman of HITIQ (ASX: HIQ) and Oncosil Medical (ASX: OSL). 	<ul style="list-style-type: none"> Former Theme Leader Colorectal Cancer and Gut Health CSIRO. Leader – Personalised Health Group CSIRO. Inventor on seven commercially-licensed patent families. 	<ul style="list-style-type: none"> Chairman of Avita Medical (ASX: AVH). Non-executive Director of Sonic Healthcare (ASX: SHL). Chairman of NeuralDX. Non-executive Director of Adherium (ASX: ADR). Non-executive Director of Unison Housing. Former CEO Melb Pathology & Monash IVF. 	<ul style="list-style-type: none"> Currently the Chief Executive Officer (CEO) of Private Healthcare Australia (PHA). Previously: Senior Director Government Affairs, Policy and Market Access for Johnson & Johnson. Various senior roles with McKinsey, CSL and Pfizer (formally Wyeth). 	<ul style="list-style-type: none"> Non-executive member of Planet Innovation Holdings, ATSE and OMICO (Australian Genomic Cancer Medicines Ltd). Member of the NSW Innovation and Productivity Council. Fellow of the Australian Academy of Technology and Engineering (ATSE).

ColoSTAT® - “Our Market Opportunity”

Addressable market in the screening population – 481 million – currently low participation rates

A simple blood test as an alternative to current Colorectal Cancer (CRC) screening methods

Clinical trial performance at 81% Sensitivity. / 91% Specificity

International regulatory approved - CE Mark / CA Mark / Medsafe Approved (Europe, UK & NZ)

TGA ARTG listing application withdrawn, resubmission in planning

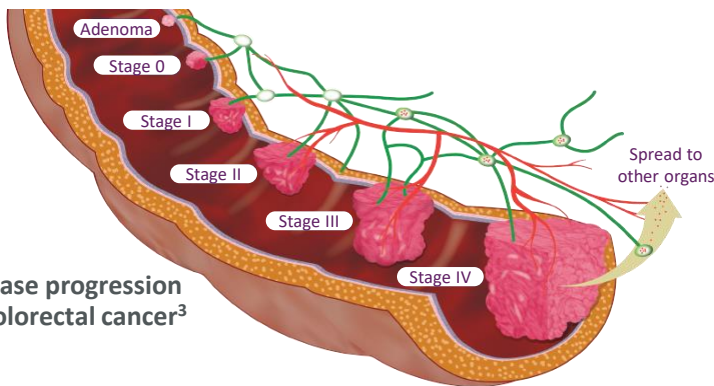
Increase production capacity with further international and local CMOs

Commercial partnership discussions ongoing

Commercial sales in FY'24

Colorectal cancer (CRC) is treatable and often curable, yet is the second leading cause of cancer death globally

CRC is a **progressive** disease in which epithelial cells in the colon or rectum grow out of control²



Disease progression of colorectal cancer³

- CRC is generally asymptomatic; in over 50% of cases it is diagnosed when already at an advanced stage⁴⁻⁶
- CRC grows slowly over many years and has the potential to be detected early⁷
- When localised to the bowel, CRC is highly treatable and often curable⁸

Global burden in 2020:

1.93 million new cases and ~940,000 deaths¹



CURRENT TESTING & SCREENING REGIME

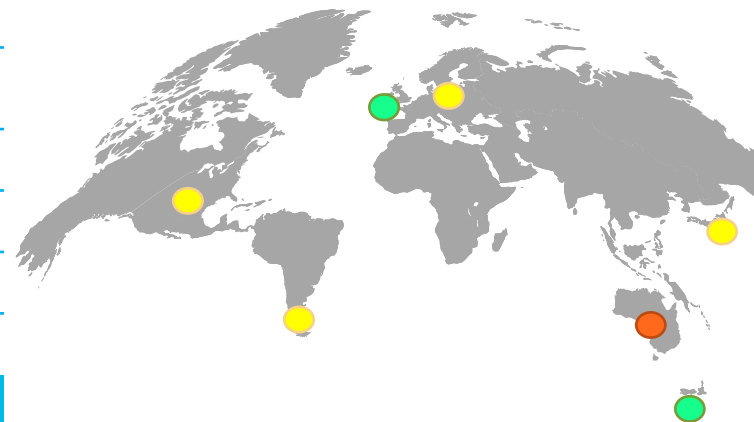
In most countries, screening is recommended for those aged between 50-74 years old, with the primary method being a faecal immunochemical test (FIT), which is designed to test only for blood in the stool.

CRC INCIDENCE IS ON THE RISE IN THE YOUNGER POPULATION

Data from major markets show that 11-15% of people diagnosed with CRC are below the age of 50,⁹ posing a tremendous public health challenge, premature death and increased healthcare costs.¹

Participation in CRC screening remains suboptimal despite national programmes being in place in many countries worldwide

Market	Population	Age – Screening Population	Screening Method	Screening Participation Rate	Unscreened Population/ Opportunity	Incidence of CRC	% of Total Addressable Markets
Europe (EU-27)	746.4 mill	231.0 mill (50 -74 yrs)	FIT, Colonoscopy [¶]	38%	143.0 mill	341,419	62%
UK (England, Scotland, Wales and Northern Ireland)	67.6 mill	10.6 mill (60 -74 yrs)	FIT	67%	3.5 mill	52,128	33%
USA	331.9 mill	161.5 mill (45 – 75+ yrs)	FIT, Colonoscopy, [¶] Cologuard	61%	62.9 mill	153,020	
Japan	125.7 mill	60.2 mill (> 40 yrs)	FIT	20% [‡]	48.2 mill	148,505	80%
South Africa	59.4 mill	9.3 mill (50 -74 yrs)	FIT	NA		8,671**	
Australia	25.7 mill	7.1 mill (50 – 74yrs)	FIT	43%	4.0 mill	15,713	56%
New Zealand	5.1 mill	1.1 mill (60 -74 yrs)	FIT	57% [*]	0.5 mill	> 3,000	
Total		480.8 mill			262.1 mill		



^{*}Based on pilot project, recent data not available - <https://www.health.govt.nz/our-work/preventative-health-wellness/screening/bowel-screening-pilot/bowel-screening-pilot-results>

^{**}https://journals.lww.com/ajg/Fulltext/2021/10001/S342_Evaluating_Trends_of_Colorectal_Cancer.342.aspx

[‡]Needs further investigation

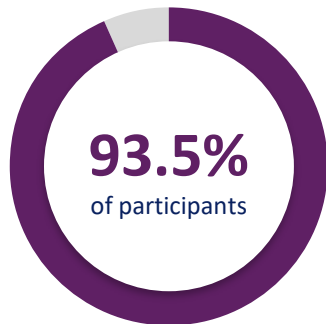
[¶]Every 10 years

FIT; faecal immunochemical test, NA; not available

Blood tests, such as ColoSTAT[®], are preferred by patients over FIT as they provide a more acceptable way to participate in testing

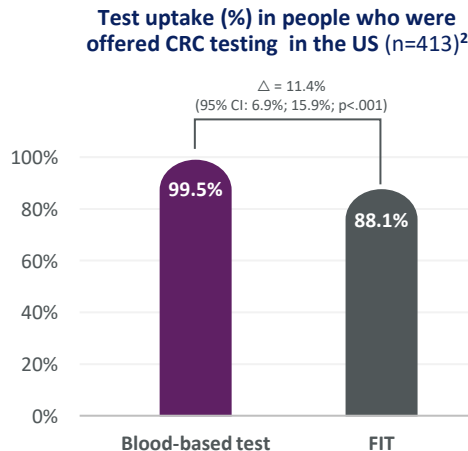
Blood-based tests are preferred over faecal tests (FIT) by 78–93% of people who are offered CRC testing¹⁻⁵, with ease and convenience being the main reasons for their preference³⁻⁴

In an observational study among 460 people in the US who were offered CRC testing¹:



Opted for a blood-based test[†] over FIT¹

In a randomized controlled trial, test uptake was significantly higher with a blood-based test[†] than with FIT ($p < 0.001$)²



Patient-reported reasons for preferring blood-based options³⁻⁴:

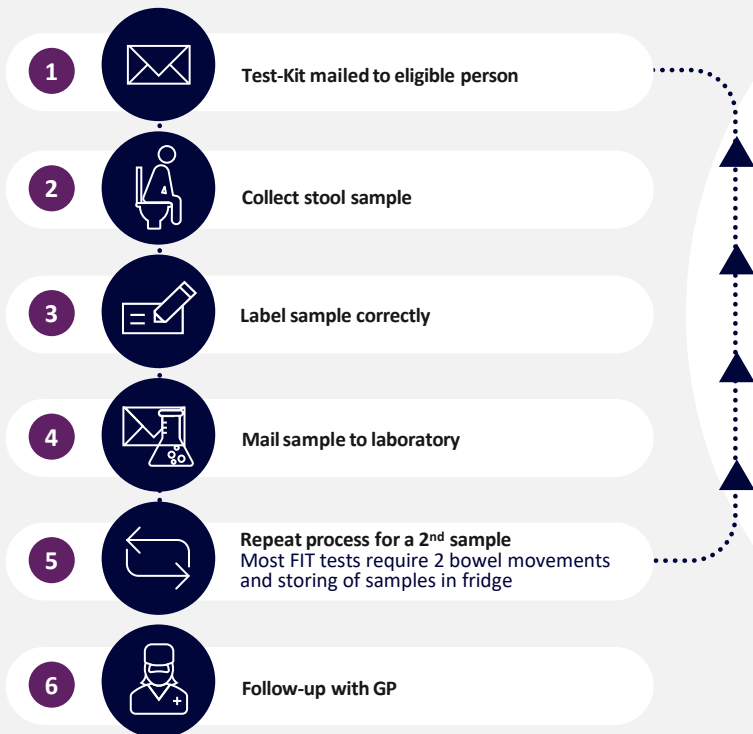
- Convenience of a blood draw in the physician's office (74%; 67/90 patients)
- Ease/comfort of a blood test (78%; 71/90 patients)
- Lower time requirement vs FIT (48%; 43/90 patients)

Abbreviations: CRC, colorectal cancer; FIT, faecal immunochemical test

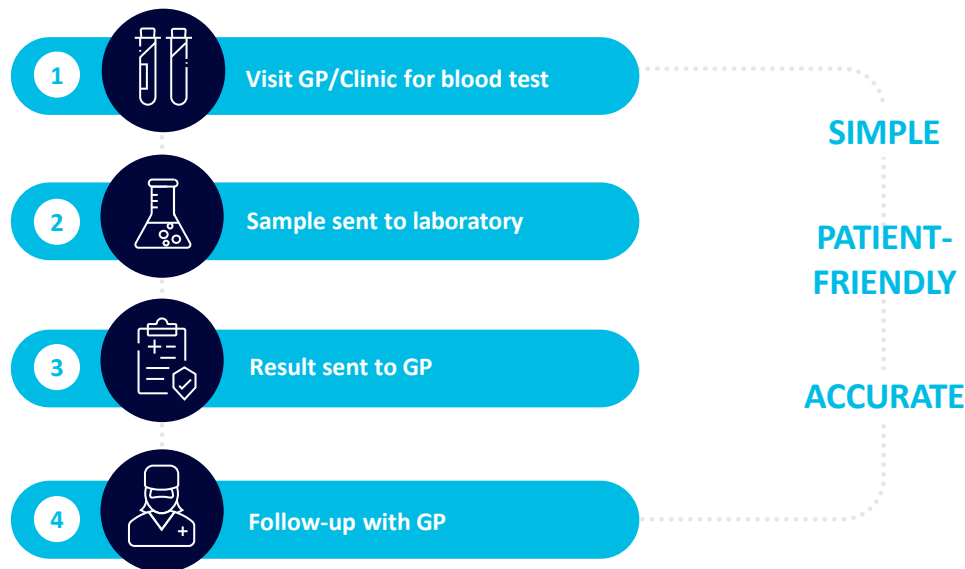
[†]Blood-based test offered was Septin9 DNA blood test (Epi proColon[®])

ColoSTAT[®] is a simple patient-friendly process compared with FIT

CURRENT MARKET SCREENING PROCESS Faecal Immunochemical Test (FIT)



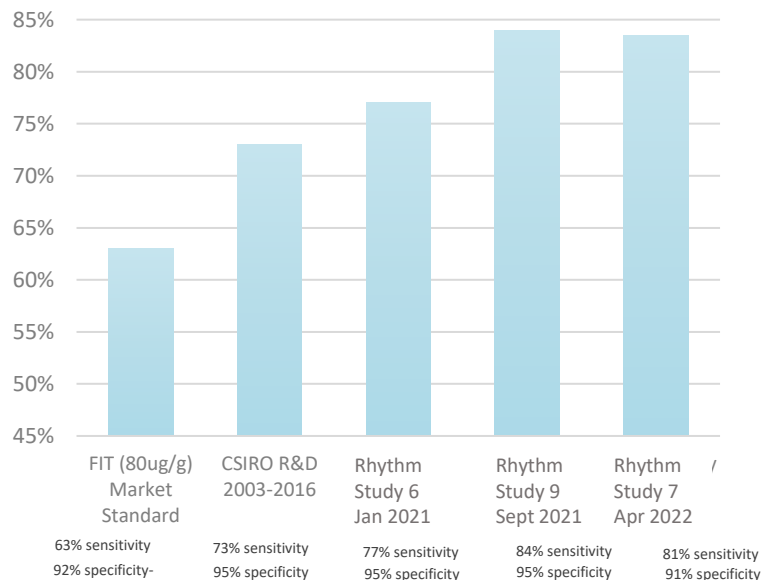
RHYTHM PROPOSED MARKET SCREEN PROCESS Rhythm ColoSTAT[®]



Abbreviations: CRC, colorectal cancer; FIT, faecal immunochemical test; GP, general practitioner

ColoSTAT® is expected to increase participation, leading to earlier detection and avoiding costly treatments

ColoSTAT® Sensitivity Performance Comparison



- **Accurate**
ColoSTAT® obtains a qualitative likelihood of CRC presence based on 5 protein biomarker levels in the blood, compared to FIT, which detects blood in the stool
- **Affordable and Simple**
Cost-efficient simple blood test that is suitable to global mass market screening programs
- **Preferred**
A blood test is preferred over FIT because of ease and convenience
- **Patient Friendly**
Convenient and can be part of routine health control / screening

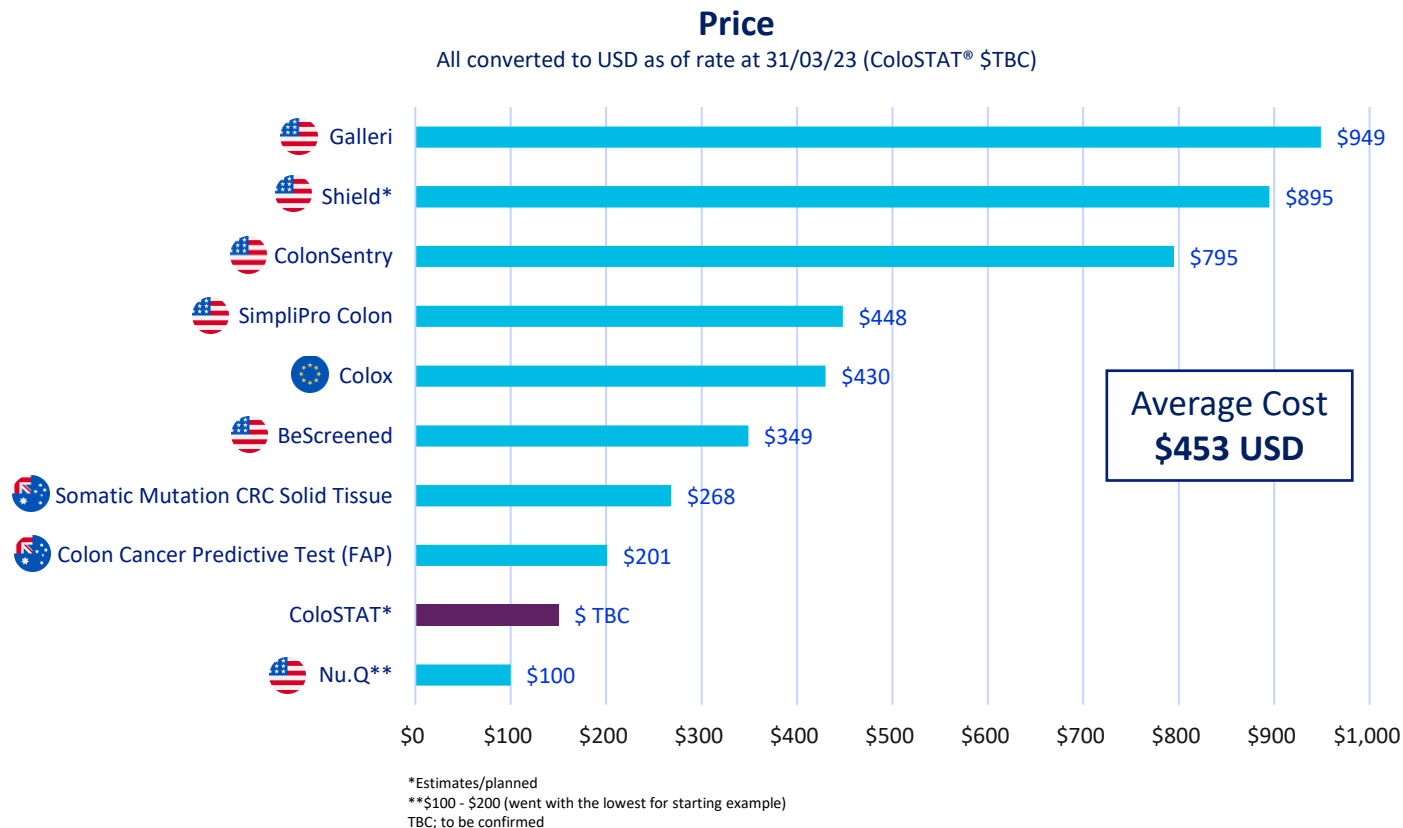
¹ 9. Osborne, J., Wilson, C., Moore, V., Gregory, T., Flight, I. and Young, G. (2012) Sample preference for colorectal cancer screening tests: Blood or stool? Open Journal of Preventive Medicine, 2, 326-331. doi: 10.4236/ojpm.2012.23047.
² Internal company data for Study 7.

Feedback about ColoSTAT®

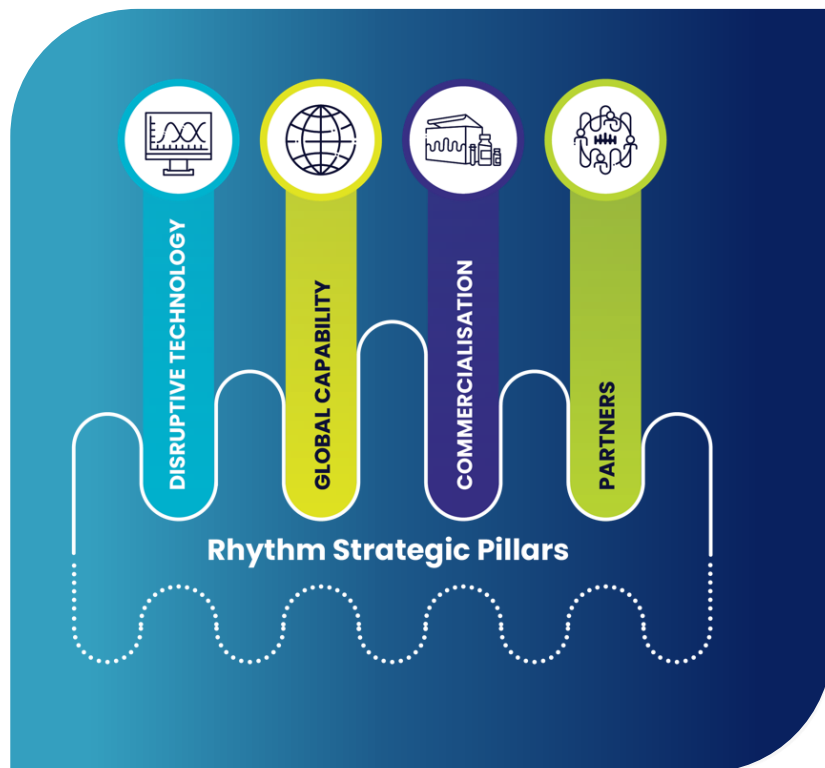
A recent Advisory Board with clinicians and payers from the UK and Australia agreed that:

- 1 ColoSTAT® can be used as an **alternative to the current screening methods**
- 2 ColoSTAT® will **increase screening participation rates**
- 3 ColoSTAT® may be able to **reduce the burden of colonoscopy** through targeting high risk CRC patients
- 4 ColoSTAT® can provide a **strong value proposition** compared to other blood-based diagnostic tests

Blood Based Test - Competitor Landscape



Strategic Pillars and Direction



DISRUPTIVE TECHNOLOGY

- ✓ Provides an alternative to current screening methods through a well-established ELISA based technology

GLOBAL CAPABILITY

- ✓ Manufacturing capability for our target markets
- ✓ Increase production capacity with further international and local CMOs

COMMERCIALISATION

- ✓ Commercial due diligence into international jurisdictions underway
- ✓ USA – commercialisation pathway:
 - Lab Developed Test (LDT) via a CLIA Lab
- ✓ Review additional regulatory requirements for IVDR and TGA submission
- ✓ Raise awareness among younger demographics as 11-15% of patients diagnosed with colorectal cancers are less than 50 years of age

PARTNERS

- ✓ Signed a collaborative UK partnership with LINK Medical Solutions
- ✓ Developing further strategic partnerships in international jurisdictions

Platform Technology Expansion

Leveraging Rhythm's own lead biomarker(s):

Cancer Type	Data base mining for candidate biomarkers	Literature cross check	~20 biomarkers selected	Preferred test provider for each biomarker and performance characterised	Serum samples obtained for 100 case/100 control clinical trial	CRO confirms preferred test performance reflects results obtained	CRO performs 100 case/100 control clinical trial	Rhythm identifies best performing biomarker combination, & algorithm
Breast (Agilex)								
Lung (Baker Institute)								
Stomach (Peter McCallum)								
Cervical (TBD)								
Pancreatic (TBD)								

Rhythm's 12 Month Focus

- ✓ FY'24 commercial sales – initially focused on addressable markets
- ✓ UK market launch:
 - Establishing KOLs
 - Developing partnerships with key labs for growth
 - Maximising sales revenue through the private market
- ✓ South African market strategy & entry:
 - Establishing a partnership with a key leading medical distributor
 - Market entry for ColoSTAT® in the private market
- ✓ New Zealand market strategy
 - Developing a partnership with potential market penetration into multifaceted jurisdictions

Rhythm's 12 Month Focus

- ✓ USA market launch and strategy
 - Finalise an approach to market via a CLIA lab pathway
 - Partner with leading pathology / medical institutions to provide ease of market entry

- ✓ Australian market entry:
 - Regulatory approval into Australia
 - Ensure that regulatory approval includes TGA requirements (including any changes) and IVDR expectations

- ✓ Development of other platform technology



Thank you and Questions

www.rhythmbio.com

Slide 6

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3. Kuipers EJ, Grady WM, Lieberman D, Seufferlein T, Sung JJ, Boelens PG, et al. Colorectal cancer. Nat Rev Dis Primers. 2015 Nov 5;1:15065.
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8. National Cancer Institute. Colorectal Cancer. Available at: [Colon Cancer Treatment \(PDQ®\)—Health Professional Version – NCI](#)
9. <https://www.cancer.net/cancer-types/colorectal-cancer/risk-factors-and-prevention#:~:text=About%2011%25%20of%20all%20colorectal,cancer%20in%20the%20United%20States>

Slide 7

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Slide 8

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3. Lamb YN, Dhillion S. Epi proColon((R)) 2.0 CE: A Blood-Based Screening Test for Colorectal Cancer. Mol Diagn Ther. 2017 Apr;21(2):225-32.
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