RHYTHM BIOSCIENCES

COLOSTAT®

CLINICAL WHITE PAPER

ColoSTAT®: A Blood-Based Triage Test for Symptomatic Patients with Suspected Colorectal Cancer

*For primary care physicians and gastroenterologists: evidence-based guidance on integrating **ColoSTAT®** into the symptomatic colorectal cancer diagnostic pathway.*

IMPORTANT — INTENDED USE AND LIMITATIONS

ColoSTAT® is a decision support tool for use as an adjunct to clinical assessment in patients with symptoms suggestive of colorectal cancer. It is not a standalone diagnostic test and does not replace colonoscopy as the definitive diagnostic procedure. **ColoSTAT®** is not indicated for population-based screening, nor for surveillance in high-risk individuals. Results must always be interpreted in conjunction with clinical history, examination and other investigations. A negative **ColoSTAT®** result does not exclude colorectal cancer.

Developed by:
Rhythm Biosciences Limited (ASX: RHY) • Melbourne, Australia • **www.rhythmbio.com**
AU-WP-COLOSTAT-1-1 • April 2026 • Based on Nair et al., Journal of Gastrointestinal Cancer, 2026

How to Access ColoSTAT®

ColoSTAT® is now available to Australian clinicians through 4Cyte Pathology and specialist surgeons.

ColoSTAT® can be requested via standard pathology referral through 4Cyte Pathology, with blood collection available across a growing national network of sites in major Australian cities. Results are reported directly to the referring clinician with a binary risk classification (ColoSTAT® Positive / ColoSTAT® Negative) and are intended to guide colonoscopy referral decisions.

To refer a patient or locate your nearest collection centre:

- Visit: **www.rhythmbio.com/colostat**
- Email: **support@rhythmbio.com**
- Phone: **+61 3 8412 7000**
- Contact 4Cyte Pathology: **1300 522 178**

Regulatory and Accreditation Status

ColoSTAT® is currently offered as a laboratory-developed test through a NATA-accredited laboratory operating under ISO 15189. This pathway is consistent with Australian regulatory requirements for specialist diagnostic tests and has been accepted by the Therapeutic Goods Administration (TGA) for the current service model. Rhythm Biosciences continues to progress pathways for formal ARTG registration as an In Vitro Diagnostic Medical Device (IVD) to support broader distribution.

ColoSTAT® does not currently attract a Medicare Benefits Schedule (MBS) item number. Rhythm intends to pursue MBS listing in the future. Clinicians should advise patients of any applicable out-of-pocket costs at the time of referral.

When to Consider ColoSTAT®

ColoSTAT® is intended for use in patients aged 45–84 years presenting with symptoms suggestive of CRC, including:

- Unexplained change in bowel habit
- Rectal bleeding or blood in stool
- Iron deficiency anaemia without clear cause
- Unexplained weight loss or abdominal pain
- Elevated faecal immunochemical test (FIT) result with patient unwilling or unable to proceed to colonoscopy

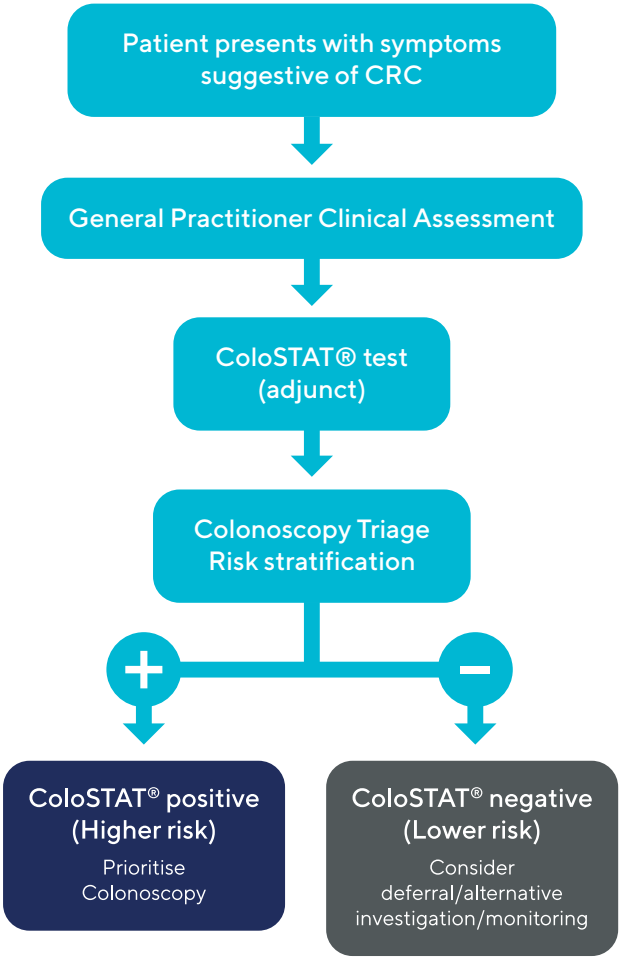

Figure 1. ColoSTAT® as an adjunctive triage tool in the symptomatic colorectal cancer diagnostic pathway. ColoSTAT does not replace current best practice clinical guidelines for CRC diagnosis.

ColoSTAT® is not indicated for patients who have already been referred for urgent colonoscopy on clinical grounds, for asymptomatic screening or for post-polypectomy surveillance.

1. Executive Summary

ColoSTAT® is a novel, multiplexed, serum-based, enzyme-linked immunosorbent assay (ELISA) that simultaneously quantifies five cancer-associated protein biomarkers. Developed by Rhythm Biosciences Limited, the test uses a proprietary machine-learning algorithm to generate a binary colorectal cancer (CRC) likelihood score from a single blood sample, classifying patients as ColoSTAT® Positive / ColoSTAT® Negative for CRC.

This white paper presents the analytical validation, clinical performance data and healthcare utility of ColoSTAT®, as published in Nair et al. (Journal of Gastrointestinal Cancer, 2026).[1] In an independent validation cohort of 300 patient samples, ColoSTAT® achieved the following results:

Key Clinical Takeaways:

- **Detects ~9 in 10 colorectal cancers** from a single blood draw (90.3% sensitivity)
- **>99% negative predictive value** supports ruling out cancer with high confidence in patients with cancer
- **Consistent performance across all stages**, including early-stage disease (Stage I/II: 90.7%)
- **Detects 58% of advanced adenomas**, exceeding FIT (18–44%) and ctDNA tests (6–13%)

Performance Metric	Result	Clinical Significance
Sensitivity — all-stage CRC (ages 45–84)	90.3%	Detects 9 in 10 cancers from a blood draw
Negative Predictive Value (NPV)	>99.0%	ColoSTAT® Negative result gives high confidence that a negative result means the patient is unlikely to have disease*
Early-stage sensitivity (Stage I/II)	90.7%	Equivalent performance at early, treatable stages
Late-stage sensitivity (Stage III/IV)	89.4%	Consistent detection regardless of stage
Advanced adenoma detection	58.0%	Substantially higher than FIT (18–44%) or ctDNA (6–13%)

These results establish ColoSTAT® as a clinically meaningful triage tool, with the potential to reduce unnecessary urgent colonoscopy referrals by up to 50%, addressing a critical capacity crisis in gastrointestinal diagnostic services across Australia and globally.

** Clinical followup, based on best practice guidelines are still recommended for all low-risk ColoSTAT® results, especially for persistent symptoms.*

2. Background and Unmet Clinical Need

The Burden of Colorectal Cancer in Australia

Colorectal cancer (CRC) is the third most commonly diagnosed cancer globally and the second leading cause of cancer-related death, with approximately 1.9 million new cases and 935,000 deaths annually.[1] Australia and New Zealand have among the highest incidence rates worldwide. In Australia, CRC is the fourth most common cancer diagnosis and second leading cause of cancer death, with over 15,000 cases diagnosed each year, at an estimated total healthcare cost exceeding AUD $1 billion annually.[2, 3, 4]

Colonoscopy remains the gold standard diagnostic procedure, with over 900,000 procedures performed annually in Australia.[5] However, fewer than 4% of colonoscopies performed in the symptomatic pathway yield a CRC diagnosis, meaning the vast majority of urgent referrals are ultimately unnecessary.[6] An anticipated 7–10% annual increase in colonoscopy demand through 2030 threatens to further overwhelm endoscopy services.[7]

Only 1 in 25 (~4%) colonoscopies in the symptomatic pathway yield a CRC diagnosis.

The clinical challenge in plain terms.

A GP sees a patient with rectal bleeding and a change in bowel habit. Clinical guidelines indicate urgent colonoscopy referral. But only 1 in 25 such patients will have CRC. The remaining 24 face a procedure with bowel prep, sedation, time off work and a small, but signficant risk of perforation. ColoSTAT® can help identify which patients genuinely need urgent investigation and which can be safely deferred.

ColoSTAT® is an adjunctive blood-based triage tool used between initial clinical assessment and colonoscopy referral in symptomatic patients aged 45–84 years. It does not replace urgent referral or colonoscopy, but supports clinicians in prioritising higher-risk patients while identifying those suitable for deferral or alternative management based on clinical judgement.

Limitations of Current Triage Approaches

The majority of CRCs in Australia are diagnosed after symptomatic presentation to primary care. Only 10–15% of cases are detected through the National Bowel Cancer Screening Programme (NBCSP).[2] The overlapping symptom profile of CRC and benign gastrointestinal conditions makes confident triage extremely challenging, leading to broad referral to colonoscopy.

The Faecal Immunochemical Test (FIT/FOBT) is widely used in both screening and symptomatic settings.[10] Importantly FIT/FOBT sensitivity for advanced adenoma (AA) — the pre-cancerous lesion most likely to progress to cancer — ranges from just 18–44%.[14] ctDNA-based blood tests offer AA sensitivity of only 6–13%.[14]

There is strong evidence that patients show greater willingness to participate in blood-based testing compared with faecal tests, driving increasing clinical interest in serum-based CRC detection technologies.[11, 13]

The case for a blood-based proteomic triage test

ColoSTAT® addresses this clinical gap by offering a rapid, reproducible, high-throughput proteomic blood test that can be integrated into routine primary care workflows. Unlike ctDNA platforms, which require expensive sequencing infrastructure, ColoSTAT® uses a cost-scalable ELISA format. It provides an additional decision support tool for GPs to identify and prioritise patients with suspected CRC for urgent colonoscopy or conversely to safely defer lower-risk patients.

3. About ColoSTAT® — Simple, Sensitive, Patient Friendly

How ColoSTAT® Works

ColoSTAT® measures five specific protein biomarkers in a standard serum blood sample. The concentrations of these proteins are processed by a validated machine-learning algorithm that generates a CRC probability score. This is reported as a binary ColoSTAT® Positive or ColoSTAT® Negative, which is reported to the clinician.

The five biomarkers were originally identified and validated in a discovery programme published by Fung et al. (PLoS One, 2015)[16] and further characterised by including findings from Brierley et al. (Cancer Biomark, 2013).[19] The ELISA format is cost-scalable and uses instrumentation already standard in pathology laboratory environments, avoiding the need for expensive genomic sequencing infrastructure.

ColoSTAT® supports two complementary clinical use cases; first an urgent referral pathway: identify high-risk patients most likely to have CRC for prioritised colonoscopy. Second, safe deferral: confidently exclude CRC in low-risk patients, reducing unnecessary colonoscopy burden with a >99% NPV*.

Patient Journey

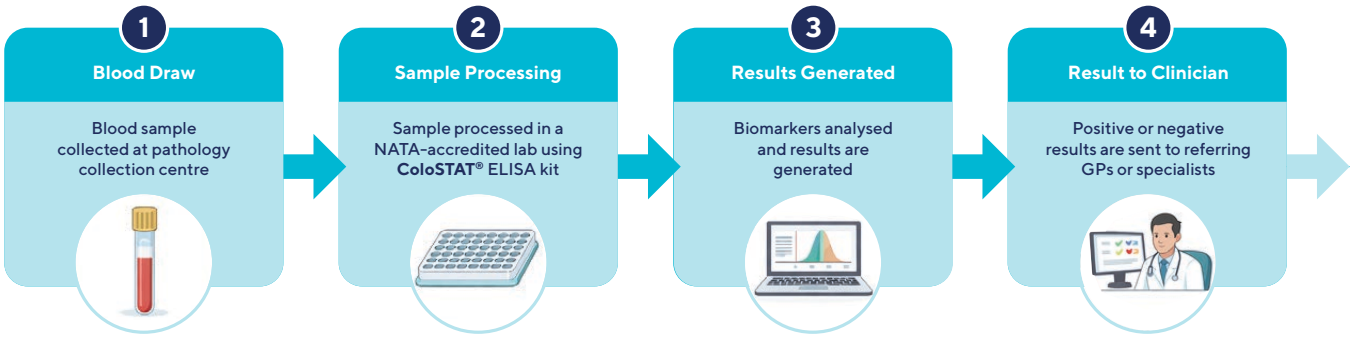

Figure 2. From test collection to clinical result reporting within 5-7 days

Key Product Attributes

Attribute	Detail
Simple	Standard blood draw — no bowel prep, no stool sample handling, no special patient preparation
Accurate	90.3% sensitivity and >99% NPV — means few cancers are missed, and that provides high confidence that a negative ColoSTAT® test is truly negative*
Patient Sensitive	Higher patient acceptance than FIT; more accessible for patients unable or unwilling to complete faecal testing
Scalable	High-throughput ELISA format compatible with standard pathology lab infrastructure
Clinically Validated	Independent validation cohort of 300 patient samples; results published in peer-reviewed literature

** Clinical followup, based on best practice guidelines are still recommended for all low-risk ColoSTAT® results, especially for persistent symptoms.*

4. Clinical Study Design and Methods

Study Overview

Patient samples were drawn from two prospective cross-sectional studies and a retrospective biobank, as described by He et al. (Journal of Gastrointestinal Cancer, 2026).[1] All patients were undergoing colonoscopy with clinical suspicion of CRC. CRC diagnoses were histologically confirmed; non-cancer diagnoses were confirmed by colonoscopy findings. Samples were stored at −80°C prior to analysis.

Model Development (Training Cohort)

In the training cohort (n=300), the five-biomarker logistic regression model achieved an Area Under the Curve (AUC) of 0.83. Cross-validated performance showed a sensitivity of 85% and specificity of 62%. Stage-stratified training performance showed 88.2% sensitivity for Stage I/II disease and 81.0% sensitivity for Stage III/IV disease.

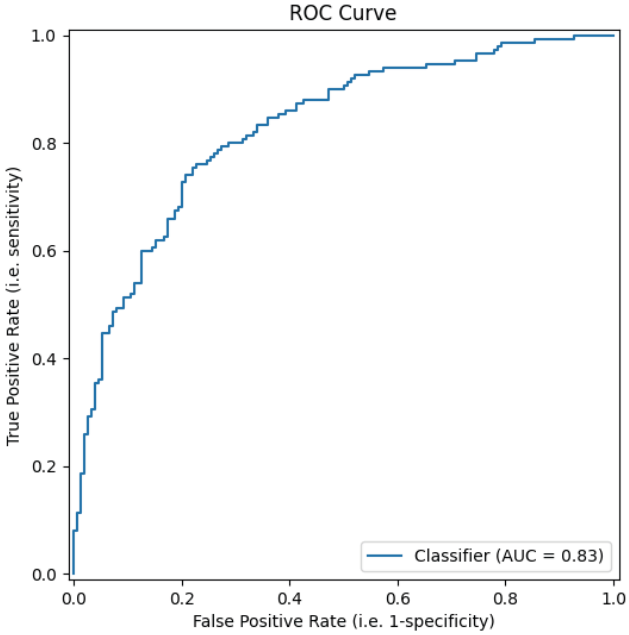

Figure 3. Receiver Operating Characteristic (ROC) curve for the ColoSTAT® diagnostic model in the training cohort. AUC = 0.83.

Statistical Methods

Sample size was determined to achieve a minimum sensitivity of 85% with 90% power, requiring a minimum of 98 samples. Performance metrics (sensitivity, specificity, NPV, PPV) were calculated against histopathological and colonoscopic confirmation as the reference standard. Stage-specific sensitivity comparisons used the binomial test. Gender subgroup comparisons used Fisher's exact test. Age subgroup analysis was restricted to patients aged 45–84 years due to limited sample numbers outside this range.

Training Cohort (n=300)

Characteristic	CRC (n=150)	Non-Cancer (n=150)
Male (%)	59.3%	54.6%
Median age (years)	61.4	61.4
Age range (years)	28–91	28–91
Stage I	20%	—
Stage II	27%	—
Stage III	32%	—
Stage IV	21%	—

Table 1. Training cohort demographic and clinicopathological summary. Cohort was matched for age, sex and clinical diagnosis.

Validation Cohort (n=300)

Characteristic	CRC (n=100)	Non-Cancer (n=100)	Adv. Adenoma (n=100)
Male (%)	55%	54%	50%
Median age (years)	62.5	62.5	63.7
Age range (years)	32–87	32–87	44–84

Table 2. Validation cohort patient characteristics. The advanced adenoma (AA) cohort was added as a supplementary validation set.

5. Clinical Performance Results

Validation Cohort Performance (Ages 45–84)

ColoSTAT® was validated in an independent cohort of 300 patient samples. Restricting analysis to the clinically relevant age window of 45–84 years, ColoSTAT® demonstrated the performance shown below.

Performance Metric	Value	Notes
Sensitivity — all-stage CRC	90.3%	Age-restricted analysis (45–84 years)
Specificity	54.3%	Age-restricted analysis (45–84 years)
Negative Predictive Value (NPV)	>99%	Strong rule-out performance; supports deferral of colonoscopy*
Advanced Adenoma Sensitivity	58.2%	Incidental finding; algorithm trained on CRC only

Table 3. ColoSTAT® validation performance in samples from patients aged 45–84 years (n=300). Note: 95% confidence intervals for sensitivity and specificity are not yet reported in the primary publication; clinicians should consider these point estimates in the context of the full validation study (He et al., 2026).[1]

Stage-Specific Sensitivity

A critical concern for any early detection test is whether sensitivity is maintained across cancer stages, particularly Stage I and II disease where surgical intervention is most likely to be curative. ColoSTAT® demonstrated equivalent sensitivity across all CRC stages, with no statistically significant difference between early and late-stage disease (binomial test p=0.7).

Stage I	Stage II	Stage III	Stage IV	Advanced Adenoma
85.0%	95.7%	84.4%	100.0%	58.2%

Table 4. ColoSTAT® detection sensitivity per stage in the validation cohort (n=100 CRC; n=100 AA). Early-stage composite (I/II): 90.7%. Late-stage composite (III/IV): 89.4%. No statistically significant difference (binomial test p=0.7).

Why stage-equivalent sensitivity matters clinically.

Many diagnostic tests perform well on late-stage disease but miss early cancers when they are most treatable. ColoSTAT® achieves 90.7% sensitivity for Stage I/II disease — equivalent to its performance on Stage III/IV disease. This means that a high-risk ColoSTAT® result is as likely to reflect early, curable cancer as it is advanced disease.

Gender and Age Subgroup Analyses

Age-stratified analysis confirmed stable assay performance across 10-year age bands within the 45–84 year range. Sensitivity increased marginally when analysis was restricted to this clinically defined window (90.3% vs. 89.0% in all-ages analysis), consistent with the test's intended use population.

** Clinical followup, based on best practice guidelines are still recommended for all low-risk ColoSTAT® results, especially for persistent symptoms.*

Advanced Adenoma Detection

ColoSTAT® detected 58% of patients with advanced adenoma (AA) — a clinically important pre-cancerous lesion. This result is particularly noteworthy, given that the diagnostic algorithm was trained exclusively on adenocarcinoma samples; no AA-specific model was developed.

Test	Advanced Adenoma Sensitivity	Sample Type
ColoSTAT®	58.2%	Blood (serum)
FIT	18–44%	Stool
ctDNA blood tests (e.g. Shield/Guardant)	6–13%	Blood (plasma)

Table 5. ColoSTAT® advanced adenoma detection compared with available alternatives. ColoSTAT® data from Nair et al. 2026.[1] FIT and ctDNA figures from published literature.[14,15]

Clinical Utility and Health Economic Impact

Reducing Colonoscopy Demand

With a specificity of 54.3%, ColoSTAT® used as a triage test in the symptomatic pathway has the potential to substantially reduce urgent colonoscopy referrals by up to approximately 50%, while retaining high sensitivity and NPV to ensure that few clinically significant lesions are missed. Applied to the Australian healthcare system, this could translate to savings of approximately AUD $500 million per year in diagnostic colonoscopy costs from the current estimated AUD $1 billion annual expenditure.[4]

Preliminary analysis in a subset of patients (n=40) with concurrent FIT data suggests that a combined ColoSTAT®-negative/FIT-negative result may allow approximately 68% of colonoscopies to be deferred while maintaining high sensitivity for significant neoplasia. Larger studies are required to confirm this finding.

Supporting Colonoscopies Non-Adherence

Up to 20% of adults with a positive faecal occult blood test (FOBT) result do not proceed to colonoscopy follow-up.[12] ColoSTAT® could provide an additional risk stratification layer for this population — motivating prioritised colonoscopy follow-up for those who test high-risk, while providing evidence-based reassurance and deferral for those who test low-risk.

Patient Quality of Life

Colonoscopy requires bowel preparation, procedural sedation, recovery time, and carries a small but real risk of perforation and bleeding. For the 96% of symptomatic patients who are ultimately found not to have CRC, avoiding this procedure eliminates unnecessary anxiety, discomfort, and disruption to work and daily life. Blood-based testing aligns with reported patient preferences and is anticipated to improve compliance across both screening and diagnostic pathways.[11, 13]

7. Competitive Landscape

The following table summarises the performance characteristics of available non-invasive CRC detection technologies. ColoSTAT® occupies a distinct differentiated position: the only blood-based test offering both high CRC sensitivity across disease stages and substantially superior advanced adenoma detection.

Test	CRC Sensitivity	AA Sensitivity	Sample	Key Limitation
ColoSTAT® (Rhythm)	90.3%	58.2%	Blood (serum)	Specificity 54.3%; RCT validation in progress
FIT	~79%	18–44%	Stool	Low participation; stool-handling aversion
Shield / ctDNA (Guardant)	83%	13%	Blood (plasma)	High cost; low AA sensitivity
Cologuard 2.0 (Exact Sciences)	93%	~43%	Stool + DNA	Complex stool collection; cost
Galleri MCED (GRAIL)	~67%*	N/A	Blood (plasma)	*CRC-specific sensitivity lower; multi-cancer design

Table 6. Indicative comparison of non-invasive CRC detection technologies. Figures represent published or publicly reported performance data for comparable patient populations. ColoSTAT® data from Nair et al. 2026.[1] All other figures from peer-reviewed literature.[14, 15]

8. Conclusions

ColoSTAT® represents a clinically validated, minimally invasive blood test with strong potential as a decision support tool in the symptomatic CRC diagnostic pathway. Its key differentiators include:

- **Clinically meaningful**: Stage-independent sensitivity, enabling early CRC detection with equivalent performance across all disease stages
- **Clinically meaningful:** Superior advanced adenoma detection compared with FIT and all available ctDNA blood tests
- **Clinically meaningful**: High NPV (>99%) providing high confidence that negative result can rule out the presence of cancer*
- **Clinically meaningful**: Simple blood-based format with strong patient acceptance and high-throughput laboratory scalability

As healthcare systems grapple with rising CRC incidence, colonoscopy capacity constraints and the need for cost-effective triage, ColoSTAT® offers an evidence-based approach to improving patient outcomes, optimising resource allocation and reducing the economic burden of colorectal cancer diagnosis. ColoSTAT® is now available to Australian clinicians through 4Cyte Pathology. For referral information visit **www.rhythmbio.com/colostat**.

** Clinical followup, based on best practice guidelines are still recommended for all low-risk ColoSTAT® results, especially for persistent symptoms.*

Declarations

Sponsorship and Funding

This white paper was produced by Rhythm Biosciences Limited. Clinical study funding and publication support were provided by Rhythm Biosciences. The primary clinical validation study (He et al., 2026; Nair et al., 2026) was conducted independently and published in peer-reviewed literature.

Conflicts of Interest

This document has been prepared by Rhythm Biosciences Limited, the developer and commercial sponsor of ColoSTAT®. Clinicians should consider this context when evaluating the data presented. All primary efficacy data is sourced from independently published peer-reviewed studies; full references are provided below.

Regulatory Disclaimer

ColoSTAT® is not approved as a standalone diagnostic device. It is offered as a laboratory-developed test under NATA accreditation (ISO 15189). Results must be interpreted in conjunction with clinical judgement. ColoSTAT® does not replace colonoscopy as the definitive diagnostic procedure for colorectal cancer.

Glossary of Key Terms

Term	Definition
Advanced Adenoma (AA)	A pre-cancerous polyp in the bowel that has a significant risk of progressing to colorectal cancer, if untreated
AUC (Area Under the Curve)	A measure of a diagnostic test's overall ability to distinguish between people with and without disease. A score of 1.0 is perfect; 0.5 is no better than chance. ColoSTAT® achieved AUC = 0.83
ctDNA	Circulating tumour DNA — fragments of cancer cell DNA found in the blood. Used in some blood-based cancer tests (e.g. Shield, Galleri)
ELISA	Enzyme-Linked Immunosorbent Assay — a standard laboratory technique to detect and quantify proteins. ColoSTAT® uses a multiplex ELISA to measure five biomarkers simultaneously
FIT (Faecal Immunochemical Test)	A stool-based test that detects hidden blood in the faeces. Used in both screening and symptomatic settings, but requires patient to handle and return a stool sample
FOBT (Faecal Occult Blood Test)	A broader category of stool-based tests including FIT; used to detect blood that is not visible to the naked eye
Logistic Regression Algorithm	A type of mathematical model used to classify patients into categories (e.g. high risk / low risk) based on multiple input values (in this case, five biomarker concentrations)
MBS (Medicare Benefits Schedule)	The Australian government's list of subsidised health services. ColoSTAT® does not currently have an MBS item number; MSAC engagement is in progress
NATA	National Association of Testing Authorities — the Australian accreditation body for laboratories. ColoSTAT® is processed in a NATA-accredited laboratory
Negative Predictive Value (NPV)	The probability that a patient who tests negative does not have the disease. A ColoSTAT® NPV of >99% means fewer than 1 in 100 patients with a ColoSTAT® negative result will have CRC*
Sensitivity	The proportion of patients with the disease who test positive. A sensitivity of 90.3% means ColoSTAT® correctly identifies ~9 in 10 patients who have CRC
Specificity	The proportion of patients without the disease who test negative. A specificity of 54.3% means approximately half of non-cancer patients will still receive a high-risk result and require colonoscopy
TGA	Therapeutic Goods Administration — Australia's regulator for therapeutic goods including in vitro diagnostic devices

** Clinical followup, based on best practice guidelines are still recommended for all low-risk ColoSTAT® results, especially for persistent symptoms.*

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