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Latest PromarkerEso diagnostic test results presented at World Congress for Esophageal Diseases

- **Promarker®Eso is a first-in-class blood test that can detect early stages (I and II) of esophageal adenocarcinoma (EAC) with high accuracy**
- **Esophageal adenocarcinoma, the predominant form of esophageal cancer, is commonly caused by chronic acid reflux, a condition that impacts 10-20% of Western populations**
- **Results from 350-person study presented today at the 21st annual ISDE World Congress for Esophageal Diseases, Brisbane, Australia**
- **PromarkerEso test launched nationally and now available via a telehealth consultation or physician referral, and from over 2,100 blood collection sites across Australia**
- **Global health impact: currently 90% of EAC cases go undetected until late stage, leading to a median survival time of <1 year - surveillance of at-risk patients with PromarkerEso could enable earlier diagnosis of EAC and significantly improve health outcomes**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics is pleased to announce its latest results on its first-in-class blood test for esophageal adenocarcinoma (EAC), PromarkerEso, are being presented today at the 21st ISDE World Congress for Esophageal Diseases, in Brisbane, Australia, 18-20 September 2025.

The PromarkerEso diagnostic test has been shown in published studies to distinguish EAC from negative and healthy controls with high accuracy [ASX: 5 June], and recently published results showed the test had high sensitivity for early stages of EAC [ASX: 8 September].

The latest results from a 350-person study extend earlier findings demonstrating the test also has excellent discrimination (area under the curve (AUC)) for all stages of EAC, along with high levels of sensitivity, specificity, positive & negative predictive values for all stages of EAC, and acceptable performance for diagnosing the pre-malignant condition Barrett's Esophagus with high-grade dysplasia.

The five-year survival rate for EAC is less than 20% with a median survival time of less than one year[1], because the disease is frequently diagnosed too late for effective treatment. Men over 50 with a history of obesity face an elevated risk of EAC.

PromarkerEso is also being formally launched at the conference and is now available across Australia to patients through a telehealth consultation, and by physician referral. Both patients and physicians can gain access to the test via the www.myTEST.health website. Blood collection is available from over 2,100 collection sites across Australia facilitated by the Healius Pathology network.

[1] Nature Reviews Gastroenterology & Hepatology, 2021, doi.org/10.1038/s41575-021-00419-3

Proteomics International's Managing Director Dr Richard Lipscombe said, *"This is another major milestone for our growing diagnostics pipeline. We're proud to present these results to leading experts in the field from across the world - PromarkerEso is demonstrating excellent sensitivity and specificity for diagnosing all stages of esophageal adenocarcinoma. This conference is the perfect forum for launching our world-first blood test."*

Professor Hugh Barr, MD, a world-renowned expert in esophageal cancer and Consultant General & Gastrointestinal Surgeon, Gloucestershire Hospitals NHS Foundation Trust, UK said, *"The early, prompt detection and precise risk assessment of esophageal adenocarcinoma will enable curative treatment for this disease. Advanced diagnostics, in particular PromarkerEso, are proving to be an important and effective way to transform the outcomes for our patients."*

Esophageal adenocarcinoma, the predominant form of esophageal cancer, is commonly caused by chronic acid reflux, also known as gastroesophageal reflux disease (GERD), and is often asymptomatic in its early stages. It is estimated that 10-20% of Western populations have GERD [2].

Barrett's Esophagus (BE) is a pre-malignant condition that is the only known precursor to EAC, however, 95% of people with BE never develop EAC. Nonetheless, because of the risks, Barrett's Esophagus with high-grade dysplasia (BE-HGD) is often treated promptly and similarly to early stage EAC.

Current gold-standard screening for the disease requires a specialist endoscopy. These invasive procedures can be uncomfortable and costly for patients (US$2,750 in the US[3]) and despite this surveillance up to 90% of EAC cases continue to go undetected[4].

Esophageal cancer represents a critical global health challenge, ranking seventh in cancer-related mortality and eleventh in overall prevalence[5]. There is a growing incidence of EAC, potentially related to western diet, hence there is an urgent need for a more efficient, accurate, and patient-friendly diagnostic pathway.

Summary of Study

Presented at the International Society for Diseases of the Esophagus (ISDE) 21st World Congress 2025 [copy attached]

Presentation titled: *Clinical performance of the PromarkerEso blood test for diagnosing early stage esophageal adenocarcinoma and Barrett's Esophagus with high-grade dysplasia*

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Aim: To assess the performance of the PromarkerEso, a novel serum glycoprotein biomarker based diagnostic test, in patients with all stages of esophageal adenocarcinoma (EAC) and the pre-malignant condition Barrett's Esophagus**.**

Method: The PromarkerEso test measures the concentration of four glycoprotein biomarkers combined with a patient's age and BMI using a logistic regression approach. Glycoproteins are extracted from a standard blood sample using a lectin pull-down assay and their concentrations determined by mass spectrometry.

The study analysed 350 people across two independent cohorts: cohort A compared 89 healthy controls with esophageal adenocarcinoma (EAC) samples of known stage (stage I: n=16; stage II: n=23; stage III: n=16, stage IV: n=3); cohort B compared 40 negative controls with unstaged EAC (n=48), and 115 Barrett's Esophagus (BE) samples, comprising non-dysplastic (ND) (n=59), low-grade dysplasia (LGD) (n=29) and high-grade dysplasia (HGD) (n=27).

Results: PromarkerEso exhibited excellent diagnostic accuracy for all stages of EAC (see table). Results demonstrated the increasing severity of disease is significantly correlated with increasing PromarkerEso test scores ($p<0.0001$).

[2] www.yalemedicine.org/conditions/gerd-gastroesophageal-reflux-disease

[3] www.newchoicehealth.com/endoscopy/cost

[4] Diseases of the Esophagus, 2025, doi: 10.1093/dote/doaf038

[5] CA Cancer J Clin. 2024; doi: 10.3322/caac.21834

Promarker®Eso performance:	AUC	Sensitivity (Sn)(%)	Specificity (Sp)(%)	PPV	NPV
Stage I EAC	0.98	81	99	87	95
Stage II EAC	0.97	91	99	91	95
Stage III EAC	1.00	100	99	89	95
Stage IV EAC	1.00	100	99	60	95
BE-HGD	0.78	93	66	32	96
EAC + BE-HGD	0.77	96	66	58	94

Conclusions:

- The PromarkerEso blood test demonstrates strong performance in detecting early-stage EAC and BE-HGD.
- A low risk result (green zone) could help reduce unnecessary endoscopies, whilst a high risk result (red zone) could prioritise patients for targeted endoscopy.
- The test offers a minimally invasive diagnostic solution to assessing risk in chronic acid reflux and could readily be integrated with current standard of care in managing risk for EAC.

PromarkerEso is one of multiple assets in Proteomics International's pipeline of precision diagnostics and represents a substantial commercial opportunity in the public health market.

Glossary

Sensitivity (Sn) (true positive rate)	The ability of a test to correctly identify those with the disease. E.g. sensitivity of 80% means that for every 100 people with disease, the test correctly diagnosed 80 with the condition.
Specificity (Sp) (true negative rate)	The ability of the test to correctly identify those without the disease. E.g. specificity of 75% means that for every 100 people without disease, a test correctly identifies 75 as not having the condition.
Negative Predictive Value (NPV)	The probability that people who get a negative test result truly do not have the disease. Also known as 'rule-out' rate, it is the probability that a negative test result is accurate.
Positive Predictive Value (PPV)	The probability that a patient with a positive (abnormal) test result actually has the disease.
Probability (P)	The *P* value, or calculated *probability*, that an observation is true. Most authors refer to statistically significant as $P < 0.05$ and statistically highly significant as $P < 0.001$ (less than one in a thousand chance of being wrong).
AUC	"Area Under the ROC Curve". A receiver operating characteristic curve, or ROC curve, is a graphical plot that illustrates the performance of a classifier system.
Interpreting AUC values	Conventionally the clinical significance of AUC is: > 0.7 acceptable discrimination > 0.8 excellent discrimination > 0.9 outstanding discrimination

For comparison, the statistical performance of the Prostate-Specific Antigen (PSA) diagnostic test (blood test measuring the concentration of the PSA protein) for the diagnosis of prostate cancer is[6]:

- Prostate cancer versus no cancer: AUC 0.68
- PSA cut-off threshold 3ng/ml: Sensitivity 32%, Specificity 87%

Authorised by the Board of Proteomics International Laboratories Ltd (ASX: PIQ).

ENDS

[6] pubmed.ncbi.nlm.nih.gov/15998892/; JAMA. 2005 Jul 6;294(1):66-70; doi: 10.1001/jama.294.1.66

About Promarker®Eso

PromarkerEso is a first-in-class blood test that utilises biomarkers—'fingerprints' in the blood—to measure the risk of having EAC. The test combines four key serum glycoproteins (alpha-1-antitrypsin, alpha-1-antichymotrypsin, complement C9, and plasma kallikrein) with patient clinical factors age, sex, and body mass index (BMI). These are analysed through a proprietary algorithm to generate a clear and simple 'traffic light' risk score for EAC, classifying individuals as low-, moderate-, or high-risk for the disease. Patients identified as high risk of having EAC are recommended to consult a gastroenterologist. PromarkerEso has patents granted in Europe, China and Australia, with other territories pending.

Proteomics International recommends that patients concerned about chronic acid reflux or GERD seek advice from their doctors.

Further information on managing chronic reflux is available through the www.mytest.health web portal.

About Proteomics International Laboratories (PILL) (www.proteomicsinternational.com)

Proteomics International (Perth, Western Australia) is a wholly owned subsidiary and trading name of PILL (ASX: PIQ), a medical technology company at the forefront of precision diagnostics and bio-analytical services. The Company specialises in the area of proteomics – the industrial scale study of the structure and function of proteins. Proteomics International's mission is to improve the quality of lives by the creation and application of innovative tools that enable the improved treatment of disease.

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Clinical performance of the PromarkerEso blood test for diagnosing early-stage esophageal adenocarcinoma and Barrett's Esophagus with high-grade dysplasia

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ISDE
21st ISDE World Congress for Esophageal Diseases
September 18-20, 2025
Brisbane, Australia

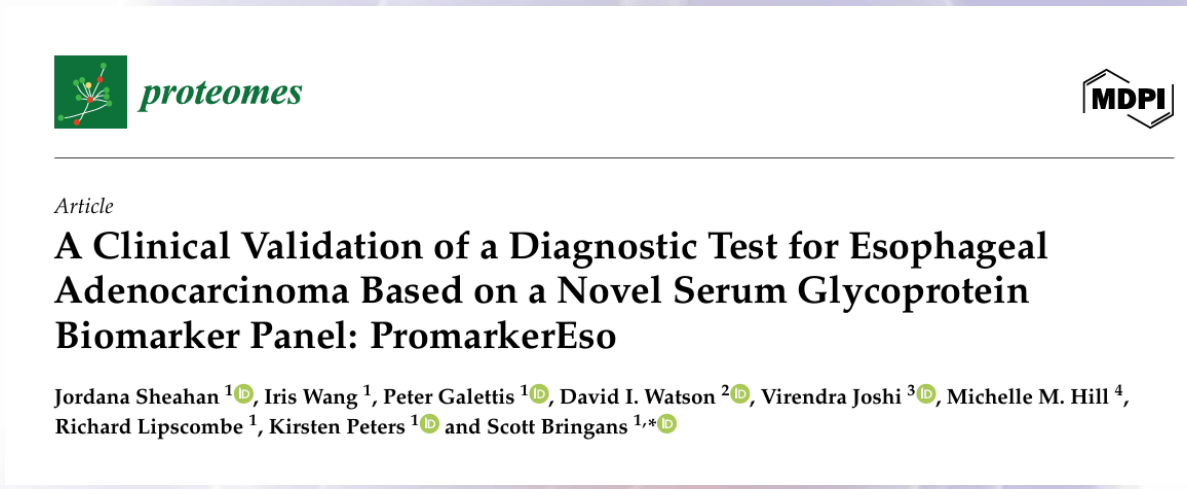
Disclosures

- The study was funded by Proteomics International
- Presenter disclosures: Jordana Sheahan is an employee of Proteomics International Laboratories Ltd, which is the license owner of a patent covering the use of the biomarkers, consequently, Jordana Sheahan may receive financial benefit from the commercial use of any test
- Co-author disclosures: Iris Wang, Peter Galettis, Scott Bringans, Kirsten Peters and Richard Lipscombe are employees and holders of shares of Proteomics International Laboratories Ltd, which is the license owner of a patent covering the use of the biomarkers, consequently, they may receive financial benefit from the commercial use of any test.

Esophageal Adenocarcinoma and Barrett's Esophagus

- Risk factors are gastroesophageal reflux (GERD) and Barrett's esophagous (BE)
- Gold standard endoscopy + biopsy
- Clinical guidelines recommend regular endoscopy surveillance BUT
  - BE frequently does not evolve to EAC (<0.3% progression)
- Endoscopies
  - Invasive
  - Hospital facilities required
  - Risk of misdiagnoses leading to under/over-treatment

- Need for non-invasive early detection method
- Previously validated PromarkerEso blood test



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Article

A Clinical Validation of a Diagnostic Test for Esophageal Adenocarcinoma Based on a Novel Serum Glycoprotein Biomarker Panel: PromarkerEso

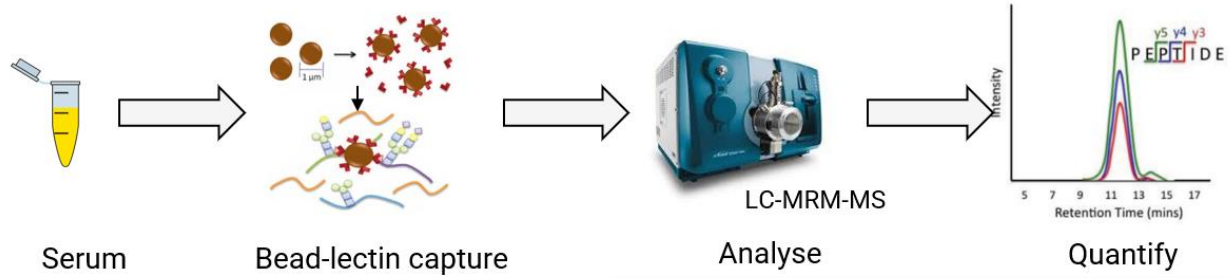
Jordana Sheahan [1], Iris Wang [1], Peter Galettis [1], David I. Watson [2], Virendra Joshi [3], Michelle M. Hill [4], Richard Lipscombe [1], Kirsten Peters [1] and Scott Bringans [1,*]

Proteomes 2025, 13, 23.
doi.org/10.3390/proteomes13020023

Objective: Validate PromarkerEso blood test for early EAC and BE-HGD detection

PromarkerEso – Novel Blood Test

- Glycoproteins (proteins with sugars attached) identified have known links to EAC
- Targeted mass spectrometry assay using lectin-based magnetic bead pulldown
- Previously developed & externally validated across 3 independent cohorts



- **4** glycoproteins + age + sex + BMI
  - Alpha-1-antitrypsin
  - Alpha-1-antichymotrypsin
  - Complement C9
  - Plasma kallikrein

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PromarkerEso previously demonstrated **sensitivity 91%, specificity 99%** to detect EAC

Combined in model for predicting probability of EAC

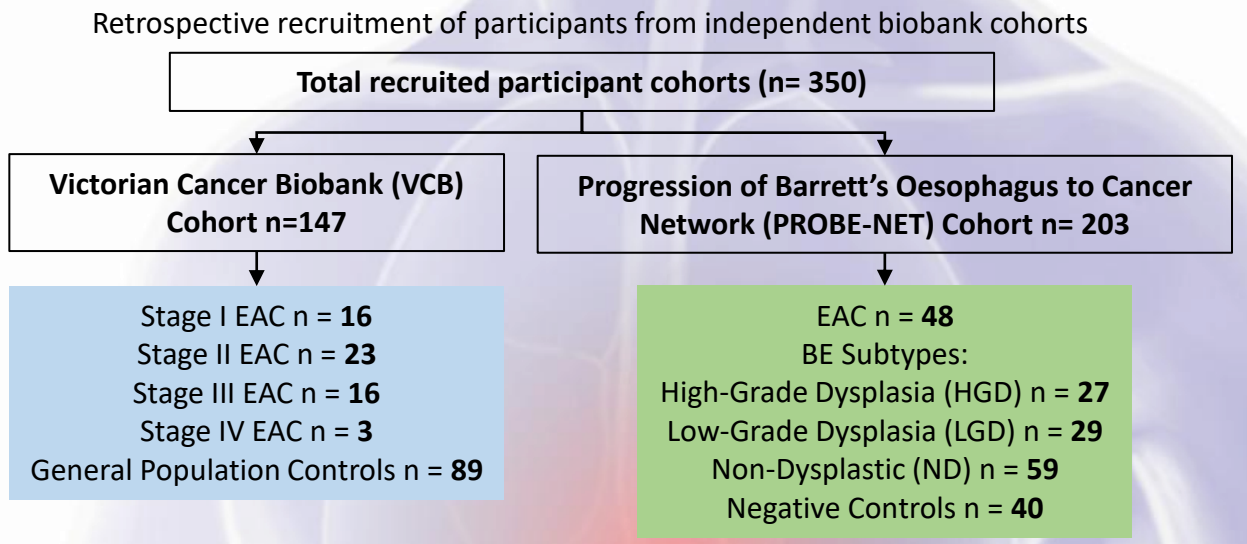
Methods

Cohorts:

- EAC, BE and Negative Control samples
  - Diagnoses confirmed by endoscopy with biopsy and histopathology
- General healthy population samples recruited with no diagnostic testing

Analysis:

- Performance: Area under curve (AUC), accuracy
- Compared:



Stage I EAC
Stage II EAC
Stage III EAC
Stage IV EAC

vs

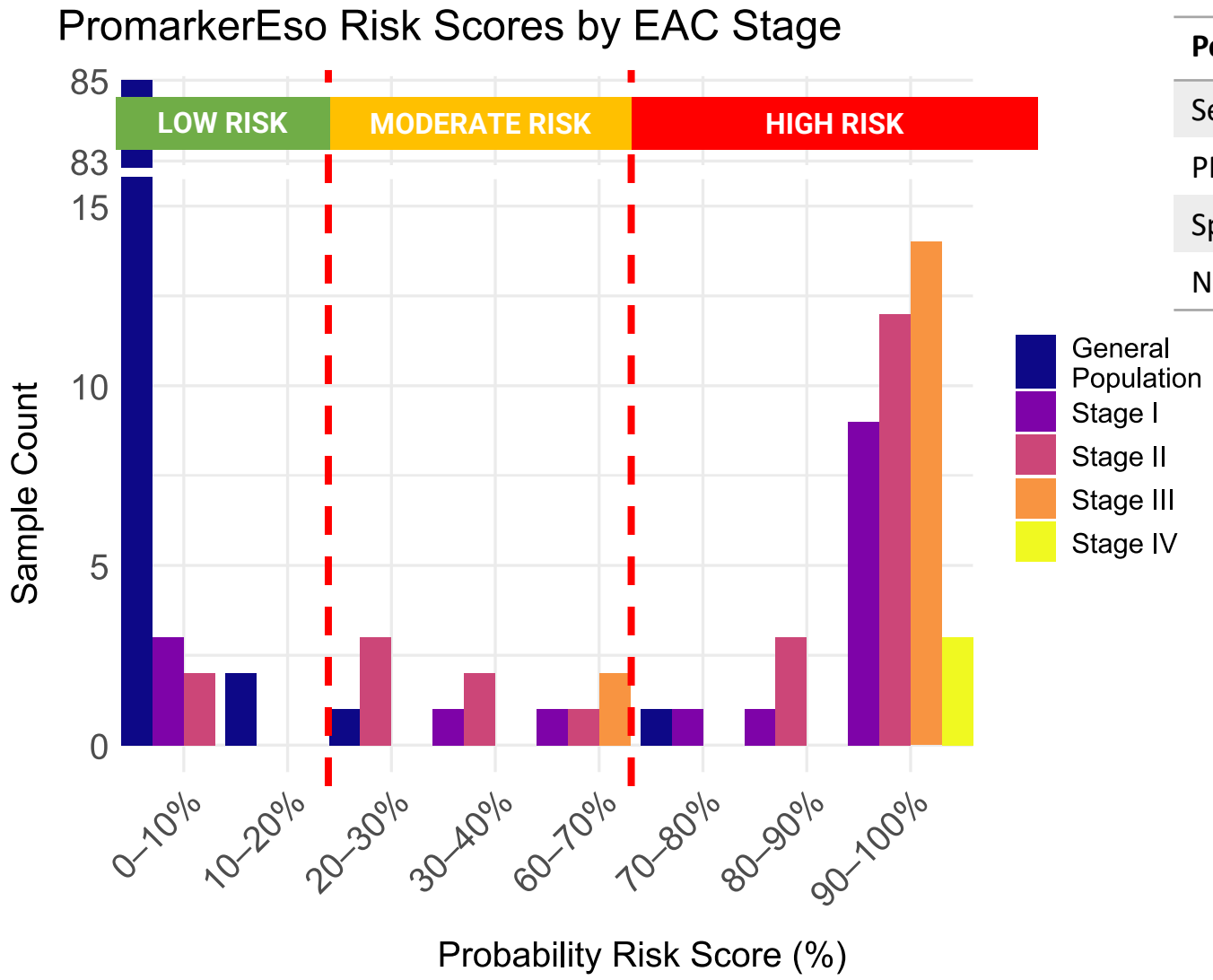
General Population Controls

BE-HGD
EAC + BE-HGD

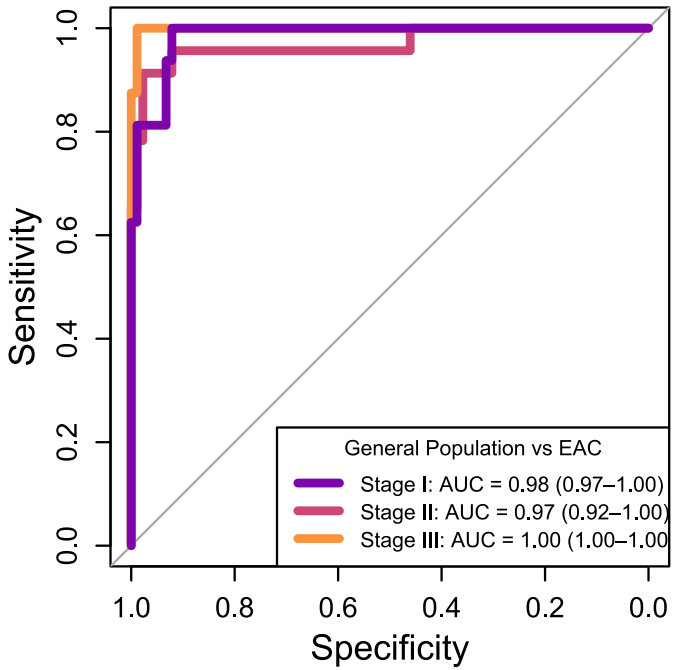
vs

BE-LGD + BE-ND + Negative Controls

PromarkerEso detects early EAC



Performance	EAC Stage I	EAC Stage II	EAC Stage III	EAC Stage IV
Sensitivity	81%	91%	100%	100%
PPV	87%	91%	89%	60%
Specificity	99%	99%	99%	99%
NPV	95%	95%	95%	95%



PromarkerEso detects BE-HGD as well as EAC

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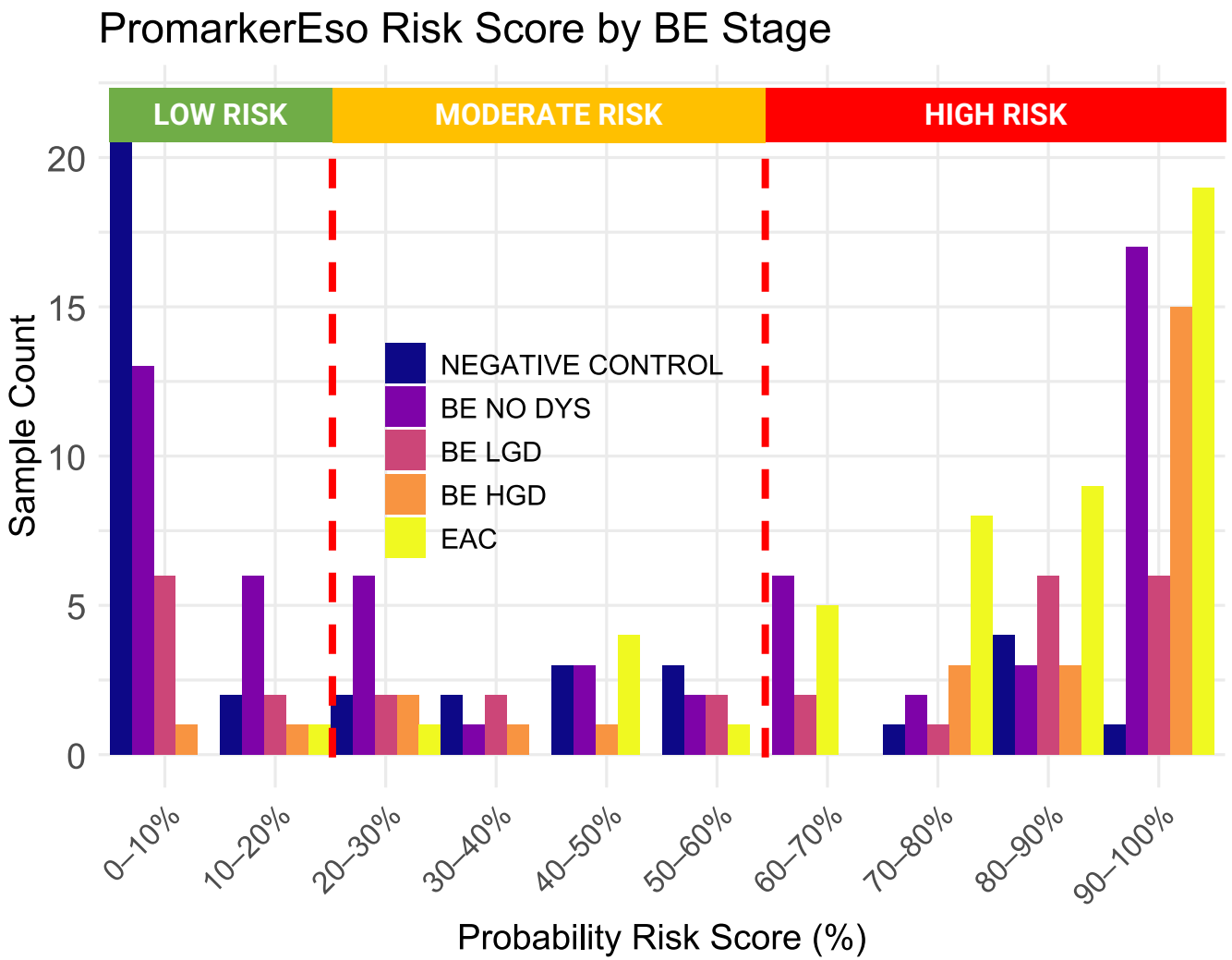

Performance	BE-HGD	EAC+BE-HGD
AUC (95%CI)	0.78 (0.68, 0.87)	0.77 (0.71, 0.84)
Sensitivity	93%	96%
Specificity	66%	66%
PPV	32%	58%
NPV	96%	94%

PromarkerEso detects BE-HGD as well as EAC

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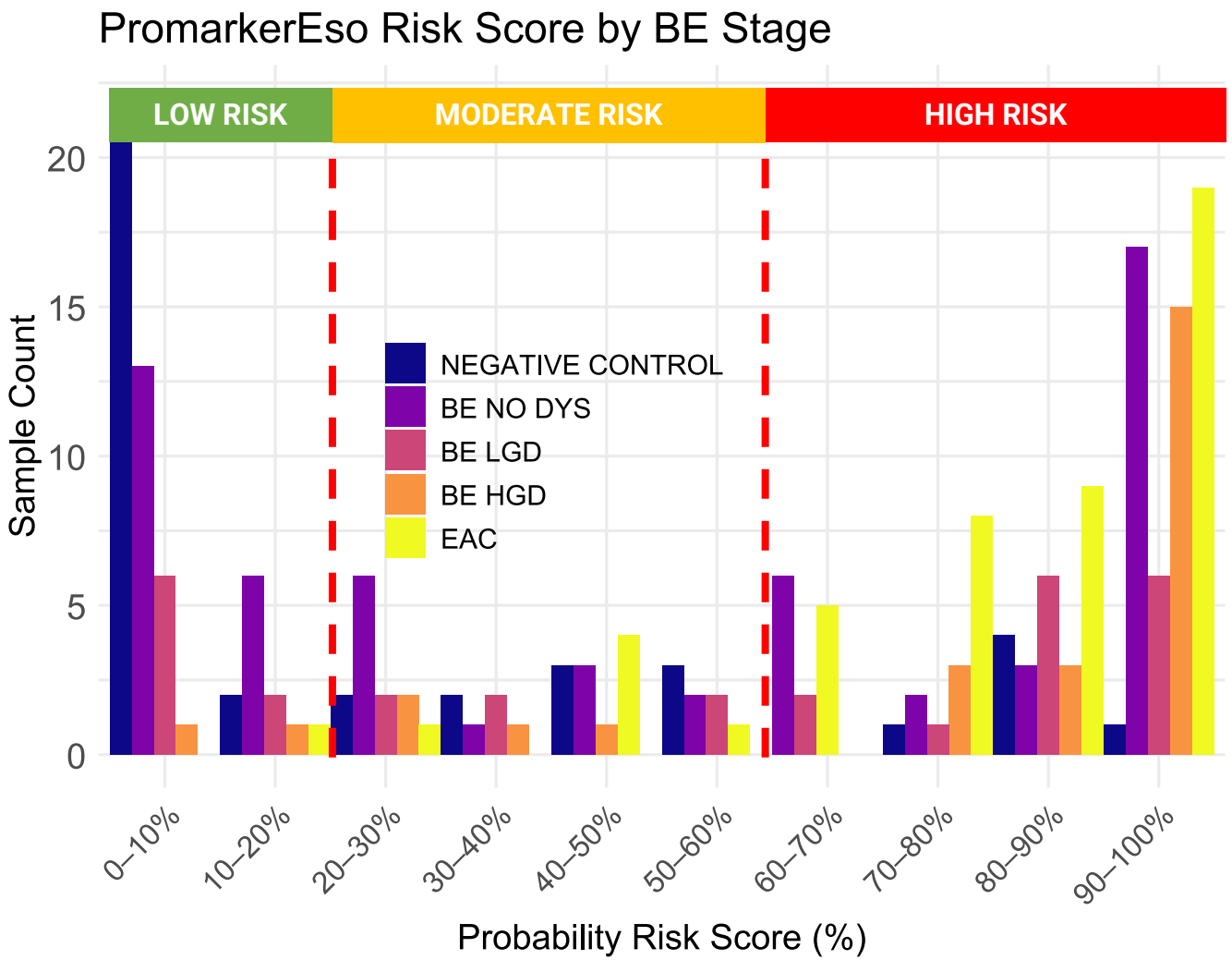
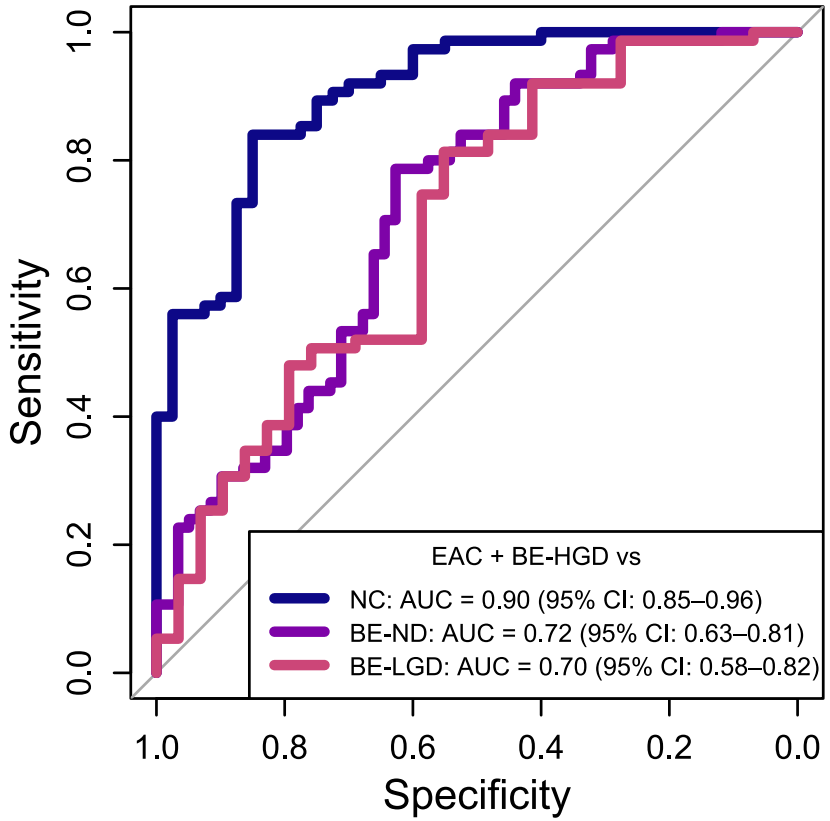
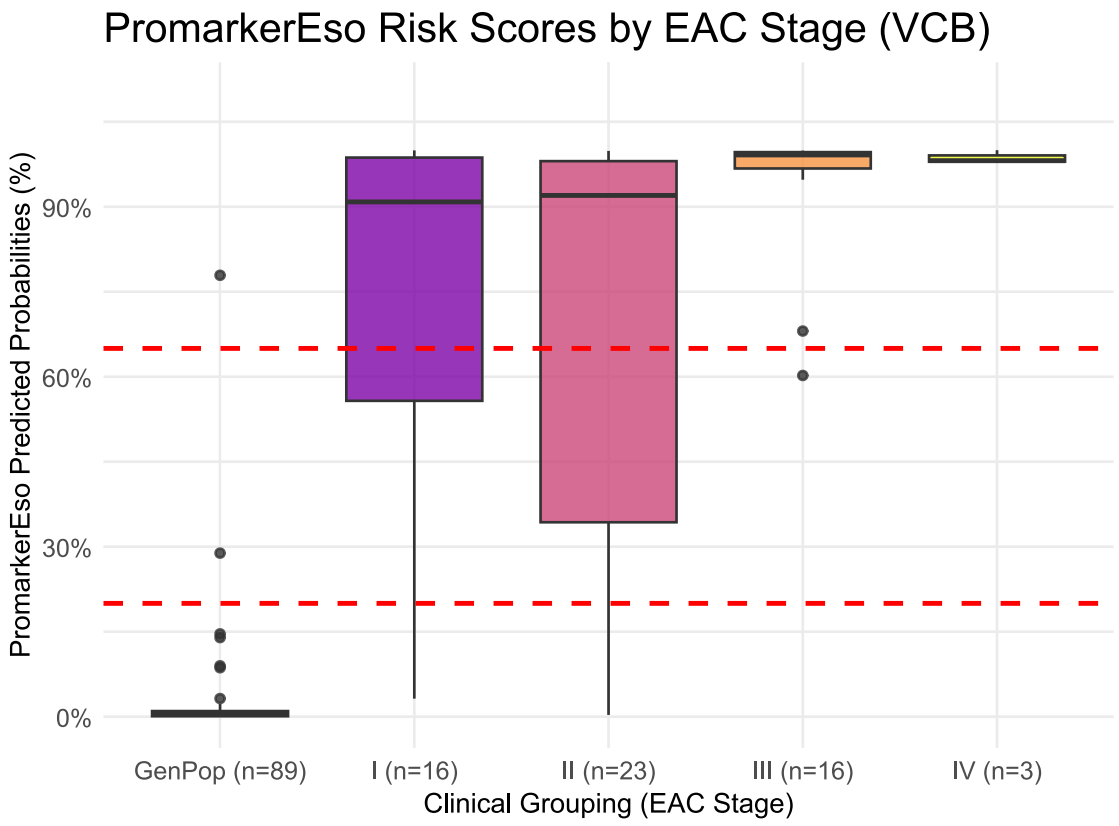


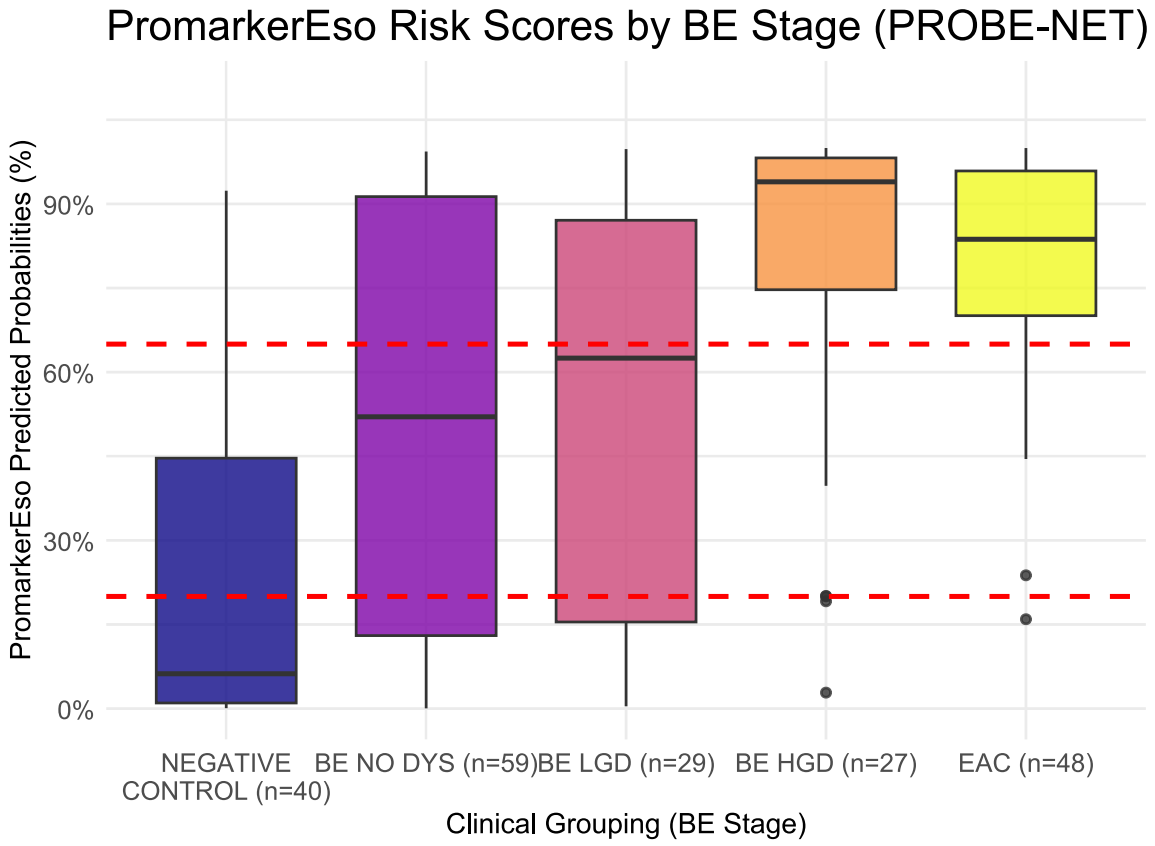
EAC+BE-HGD vs individual groups:



Test scores increase with increasing severity

↑ severity of disease significantly correlated with ↑ PromarkerEso test scores (P<0.0001)





Conclusion – Rule-out EAC and targeted interventions

- PromarkerEso has strong performance in **detection of early-stage EAC and BE-HGD**
- Minimally invasive and potential for integration with current standard of care
- Result interpretation:
  - **Low-risk: rule-out** likely healthy; reduce unnecessary endoscopies
  - **Moderate-risk: monitor** for change in symptoms
  - **High-risk: prioritise** for targeted endoscopy

- Next steps
  - PromarkerEso launched in Australia, other jurisdictions to follow
  - Test in broader demographic groups
  - Post-treatment surveillance studies in EAC patients

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Thank you

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For more information, come see us at Booth 6

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