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PromarkerEso blood test detects early stages of Esophageal Adenocarcinoma with high accuracy

- **Promarker®Eso is a first-in-class blood test clinically validated to diagnose esophageal adenocarcinoma, the predominant form of esophageal cancer**
- **Esophageal adenocarcinoma is commonly caused by chronic acid reflux or GERD, a condition that is estimated to impact 10-20% of Western populations**
- **New results show Proteomics International's novel blood test can also detect early stages (I and II) of esophageal adenocarcinoma with high accuracy, potentially offering an improved screening pathway for a cancer that currently has a median survival time of less than one year**
- **Results from 350 participant study published online ahead of presentation at the 21st annual ISDE World Congress for Esophageal Diseases, Brisbane, Australia**
- **Global health impact: currently 90% of esophageal adenocarcinoma cases go undetected - improved surveillance of at-risk patients using PromarkerEso could enable earlier diagnosis and significantly improve health outcomes**

Proteomics International Laboratories Ltd (Proteomics International; ASX: PIQ), a pioneer in precision diagnostics is pleased to announce new results showing its first-in-class PromarkerEso blood test can diagnose the early stages of esophageal adenocarcinoma (EAC) with high accuracy.

The five-year survival rate for EAC is less than 20% with median survival time 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 elevated risk of EAC. PromarkerEso is a novel serum glycoprotein biomarker based diagnostic test previously shown in published studies to distinguish EAC from negative and healthy controls with high accuracy [ASX: 5 June 2025].

Proteomics International Managing Director Dr Richard Lipscombe said, "*These new results have enormous significance, because if EAC can be detected early it can be more readily treated, whereas late-stage EAC has a very poor prognosis. With the increasing numbers of people living with chronic acid reflux, PromarkerEso has the potential to revolutionise how doctors manage the risk of esophageal cancer - offering a standard blood test that could reduce reliance on invasive procedures and improve early detection rates.*"

Esophageal adenocarcinoma (EAC), 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. In Australia, the Royal Australian College of General Practitioners (RACGP) has reported that 11% of all GP clinic visits were for the management of gastric reflux[2] and it is estimated that 10-20% of Western populations have GERD[3].

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

[2] www.racgp.org.au/afp/2015/october/gastro-oesophageal-reflux-disease-gord-in-australia

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

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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. In the United States 6.1 million upper endoscopies are performed annually[4], however, these invasive procedures can be uncomfortable and costly for patients (US$2,750 in the US[5]) and despite this surveillance up to 90% of EAC cases continue to go undetected[6].

Esophageal cancer represents a critical global health challenge, ranking seventh in cancer-related mortality and eleventh in overall prevalence[7]. 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.

A summary of the results has been published online[8] in the journal *Diseases of the Esophagus*, the official journal of The International Society for Diseases of the Esophagus (ISDE). The study has also been selected for an oral presentation at the forthcoming 21st ISDE World Congress for Esophageal Diseases, in Brisbane, Australia, to be held 18-20 September 2025.

Summary of Study[8]

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 Barrett's Esophagus (BE) (n=115) samples.

PromarkerEso exhibited excellent diagnostic accuracy for all stages of EAC with a minimum area under the curve (AUC) of 0.97. The test also exhibited high sensitivity for EAC in all stages (I: 81%, II: 91%, III: 100%; IV: 100%) and also for BE-HGD (93%). Results demonstrated the increasing severity of disease is significantly correlated with increasing PromarkerEso test scores ($p<0.0001$).

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.
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

[4] Gastroenterology, 2019; doi: 10.1053/j.gastro.2018.08.063

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

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

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

[8] Diseases of the Esophagus, 2025; academic.oup.com/dote/issue/38/Supplement_1: Abstract 148, "*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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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[9]:

- 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

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 for an endoscopy. PromarkerEso has patents granted in Europe, China and Australia, with other territories pending.

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