CLARITY IN ONE BLOOD DRAW

GASTROClear™

- Blood-based biomarker test for early detection of gastric cancer in conjunction with gastroscopy.
- Validated to detect 87.5% of stage 1 gastric cancers and 89.5% of stage 2 gastric cancers[1].
- Jointly developed in Singapore by Agency for Science, Technology, and Research (A*STAR), National University Hospital, Tan Tock Seng Hospital, and Mirxes.

Why is gastric cancer early detection important?

In Singapore[2]:

1. Gastric cancer is one of the highest incidence cancers (8th in males, 10th in females).
2. It is also one of the leading causes of cancer mortality (6th in males, 7th in females).
3. About 60% of gastric cancers are diagnosed late (in stages 3 & 4).

Who is the GASTROClear™ test intended for?

Adults of either sex, aged 40 years or older, at average risk of having gastric cancer with one of the following risk factors:

- Medical history:
  - Family history of gastric cancer.
  - History of Helicobacter pylori (H. pylori) infection.
  - Previous history of stomach lymphoma and stomach polyps.
  - Long-term stomach inflammation (chronic gastritis).
- Lifestyle habits:
  - Diets containing large amounts of fried food, smoked foods, salted fish, processed meat, and pickled foods.
  - Diet low in fruits and vegetables.
  - Smoking

How does the GASTROClear™ test help medical professionals detect patients with gastric cancer earlier?

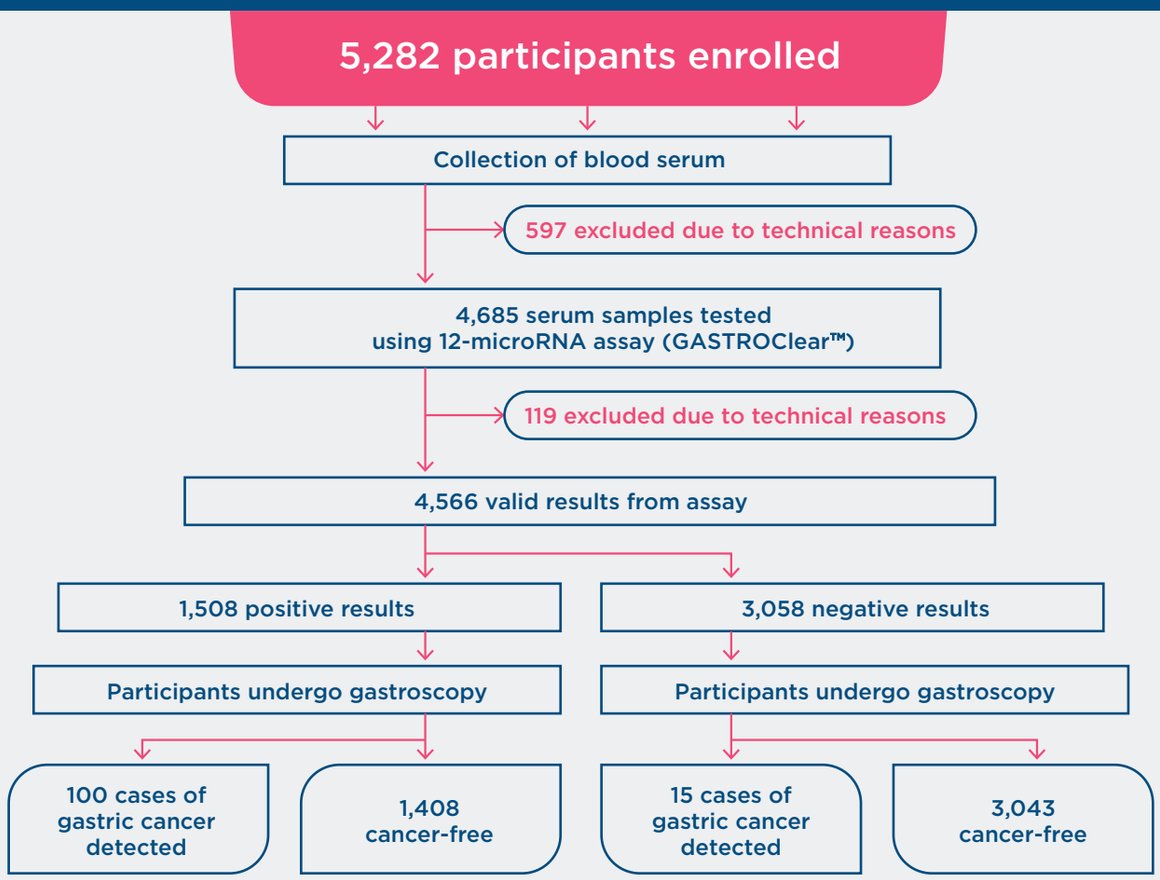
1. Intended to be used as an adjunctive test to identify high-risk patients who should undergo gastroscopy for more detailed examination to detect gastric cancer.
2. An option for high-risk patients who are not keen on first-line gastroscopic screening as the test can differentiate between patients with gastric cancer and those with gastric conditions like gastritis and intestinal metaplasia[1].
3. The test detects all stages of gastric cancer with up to 86% sensitivity and up to 89% specificity[1].

GASTROClear™ test results and interpretation

The test report gives a quantitative risk score calculated based on the expression levels of 12 selected microRNA biomarkers.

Risk Score	Risk Category	Interpretation
0 to 39.9	Low Risk	Likelihood of gastric cancer is not elevated.
40.0 to 50.0	Intermediate Risk	Likelihood of gastric cancer is slightly elevated. Further medical evaluation and/or repeat testing may be appropriate.
50.1 to 100	High Risk	Likelihood of gastric cancer is elevated. Specialist medical consultation is advised for further evaluation.

For medical professionals only.



GASTROClear™ validation

Clinical validation of GASTROClear was performed with a total of 4,566 subjects from a prospective study which enrolled 5,282 symptomatic high-risk patients referred to gastroscopy at two Singapore hospitals[1]. There were 115 gastric cancer subjects confirmed with biopsy and 10 subjects with high-grade dysplasia.

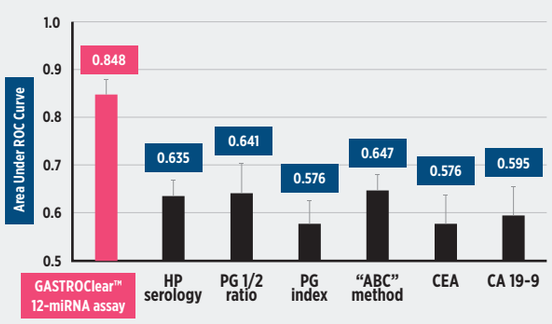
Clinical performance of GASTROClear was evaluated against the clinical gold standard of gastroscopy and pathohistological examination. Performance was also compared against conventional blood-based biomarkers CEA, CA19-9, pepsinogen (PG) 1/2 ratio, PG index, H. pylori serology, and the "ABC" method that combines H. pylori serology and PG 1/2 ratio.

The assay, which measures 12 miRNA biomarkers, detected gastric cancer with >80% sensitivity regardless of cancer stage, gender, ethnicity, age and had minimal cross-reactivity with other common cancers including those of the gastrointestinal tract.

Tumor subtypes and pre-cancerous lesions detected by GASTROClear™ in prospective clinical validation study:

- ☑ High-grade dysplasia
- ☑ Gastric cancer
  - › All cancer stages (1-4)
  - › All subtypes (intestinal, diffuse
  - › mixed) Regardless of gender, age, and ethnicity (Singaporean population)

GASTROClear™ performance comparison[1]



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GASTROClear™ Test Specifications

Intended Use	GASTROClear is a lab developed test (LDT) which utilizes a proprietary RT-qPCR technology to evaluate the expression of multiple circulating human microRNAs associated with gastric cancer. The test measures multiple cancer-associated microRNA biomarkers and detects signatures that are often present in the blood of persons with gastric cancer. These are combined to create a risk score to reflect the likelihood of gastric cancer being present at the time of testing, based on scores from a cohort of patients with and without gastric cancer.
Sample Requirement	5 mL blood sample in SST or red top blood tube. No fasting required prior to blood collection.
Lab Procedure	Uses RT-qPCR to detect multiple microRNA biomarkers associated with gastric cancer.

This test is not intended to provide a definitive diagnosis of gastric cancer and is not a substitute for gastroscopy. The test result is intended solely for use by a medical professional and does not constitute medical advice by Mirxes and related parties.

References:

1. So JBY et al. Development and validation of a serum microRNA biomarker panel for detecting gastric cancer in a high-risk population. Gut 2020; doi: 10.1136/gutjnl-2020-322065
2. Singapore Cancer Registry Annual Report 2021.

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TO KNOW. TO ACT.

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About the Company

mirxes
TO KNOW. TO ACT.

Our mission is to save and improve lives through early, actionable, and personalized diagnoses across the care continuum.

Mirxes At A Glance

1. Global leader in microRNA focused molecular diagnostics.
2. Focused in the delivery of early and actionable cancer diagnoses using proprietary RNA-powered blood tests.
3. Strong pipeline in Oncology, Infectious and Cardiovascular Diseases.
4. End-to-end Capabilities in R&D, Manufacturing & Clinical Diagnostic Services.

Visit our website for more information.

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