CLARITY IN ONE BLOOD DRAW

GASTROClear™

- World's first molecular blood test for early detection of gastric cancer to be used in conjunction with gastroscopy.
- Clinically 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), the National University Hospital, Tan Tock Seng Hospital, and MiRXES.
- CE marked and Health Sciences Authority approved.

Why is gastric cancer early detection important?

In 2020 within Asia alone, there were 819,944 new gastric cancer cases and 575,206 deaths due to gastric cancer[2].

Gastric cancer can be cured if detected earlier but around 60% of gastric cancers in Singapore are diagnosed late (in stages III-IV)[3].

Who is GASTROClear 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 GASTROClear help medical professionals detect patients with gastric cancer earlier?

1. Intended use 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. GASTROClear detects all stages of gastric cancer with up to 86% sensitivity and up to 89% specificity verified in an asymptomatic, average-risk population[1].

GASTROClear test results and interpretation

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

Risk Score	Risk Score Interpretation	Recommended Action
0 to <40	Low Risk	Individual is recommended to repeat blood test after 1 year or at an interval recommended by a physician.
40 - 50	Intermediate Risk	Individual is recommended to repeat blood test at an interval recommended by a physician. Decision to recommend follow-up with gastroscopy should be made together with other clinical evidence by the physician.
> 50 to 100	High Risk	Individual is recommended to visit a gastroenterologist (specialist) and consider a follow-up gastroscopy

For medical professionals only.

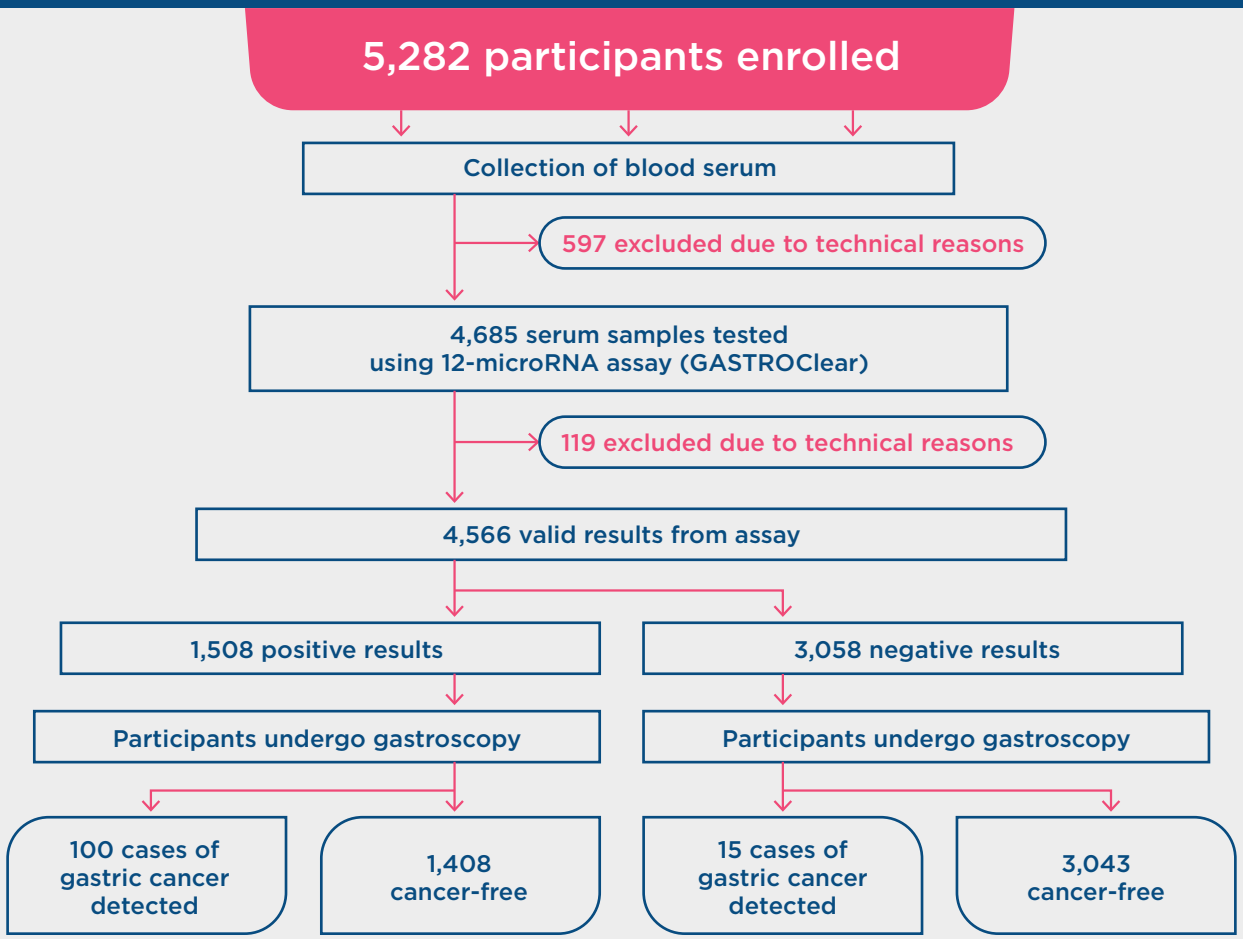


Figure 1. Flowchart of prospective validation study design[1]

GASTROClear Clinical 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.

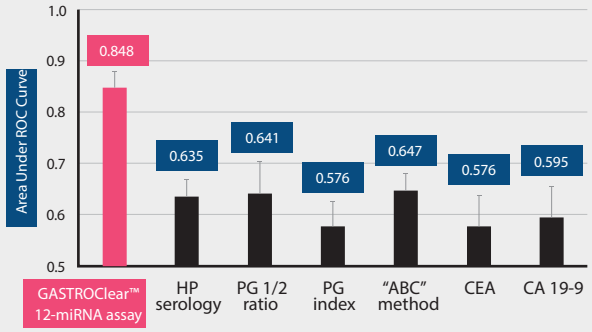
Clinical performance of GASTROClear was evaluated against the clinical gold standard of gastroscopy and pathohistological examination. Performance was also compared against conventional blood-based biomarkers CEA, CA19-9, pepsinogen (PG) 1/2 ratio, PG index, H. pylori serology, and the "ABC" method that 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	The GASTROClear, an in-vitro diagnostic medical device (IVD), is intended for use as an adjunctive test for the detection of gastric neoplasia associated miRNA biomarkers in human serum. GASTROClear is NOT intended as a replacement for gastroscopy; it should be used in conjunction with gastroscopy and other test methods in accordance with recognized clinical guidelines. It is thus an adjunctive tool to aid in the detection of gastric cancer. As such, only patients who met certain criteria are tested using GASTROClear. The result obtained from the test may indicate the presence of gastric cancer and the patient then goes for gastroscopy and biopsy as required. The output of GASTROClear test is a risk score where a high score may indicate the presence of gastric cancer and should be followed up by gastroscopy. This test is intended for adults of either sex, 40 years or older at average risk of having gastric cancer.
Sample Requirement	5-6 mL blood sample in SST tube. No fasting required prior to blood collection.
Lab Procedure	Uses RT-qPCR to detect multiple microRNA biomarkers associated with gastric cancer.

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 2021; doi: 10.1136/gutjnl-2020-322065

2. Ferlay J, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2020). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: https://gco.iarc.fr/today, accessed [19 Jan 2021].

3. Singapore Cancer Registry 50th Anniversary Monograph (1968 - 2017). National Registry of Diseases Office.

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TO KNOW. TO ACT.

Visit our GASTROClear website to find out more.

https://gastroclear.mirxes.com/

GASTROClear™ test is available through our clinical diagnostic laboratory partners. Email us to enquire.

gastroclear@mirxes.com

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About the Company

mirxes
TO KNOW. TO ACT.

MiRXES is a Singapore-headquartered biotechnology company focused on saving and improving lives with RNA-powered early detecton tests for diseases, and has operations in China, Japan and the United States, as well as commercial activities in over 45 countries globally.

In 2019, MiRXES launched GASTROClear, the world's first microRNA blood test for early detection of gastric cancer, which was developed and validated through a large-scale clinical study of over 5,000 patients in Singapore and Korea prior to regulatory approval and commercial launch in Singapore.

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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