CLARITY IN ONE BLOOD DRAW

GASTROClear™

- Blood-based biomarker test for early detection of gastric cancer 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), 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 gastritits and intestinal metaplasia[1].
3. GASTROClear™ detects all stages of gastric cancer with 81-82% sensitivity and 88-90% 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

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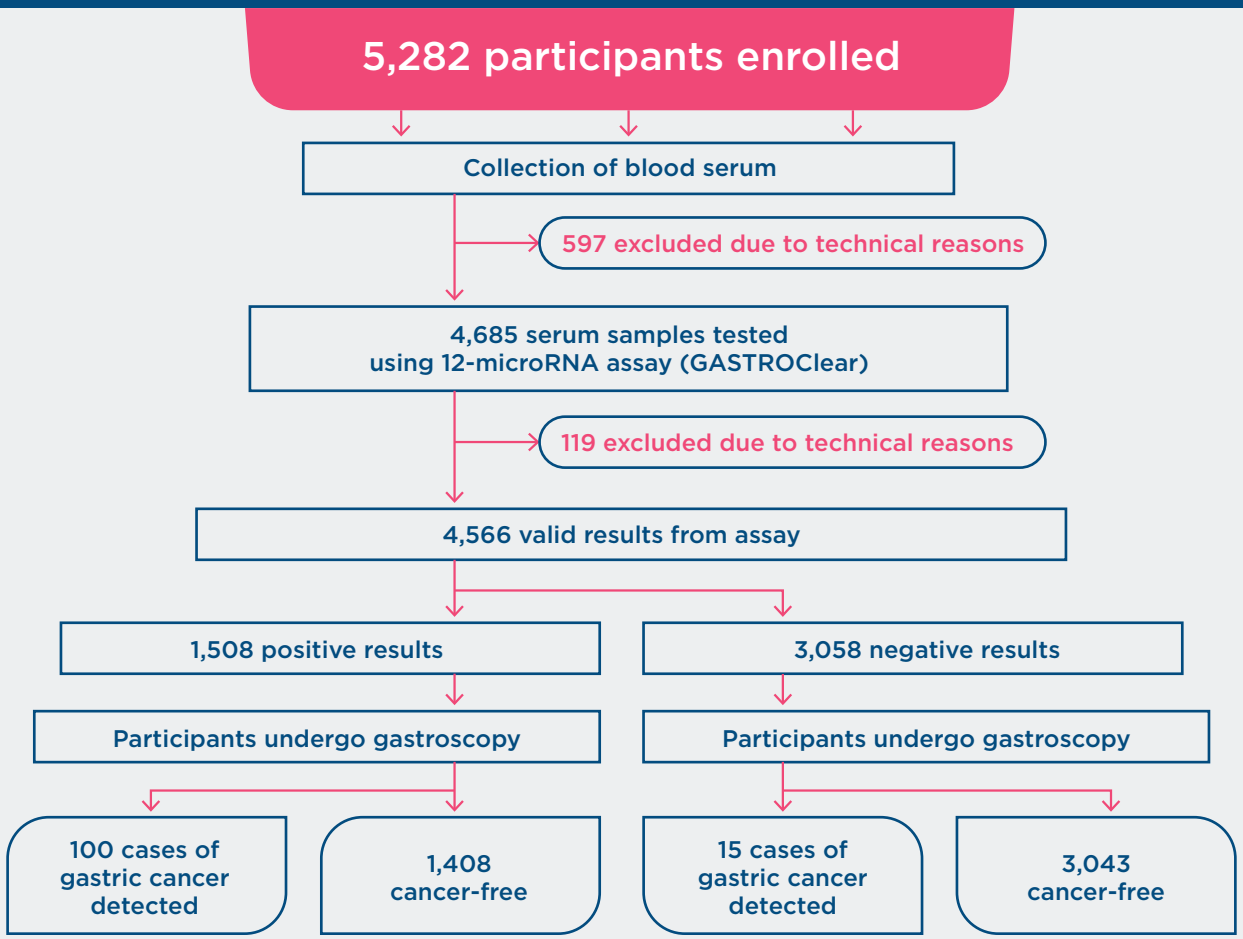


GASTROClear™ Clinical Validation

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.

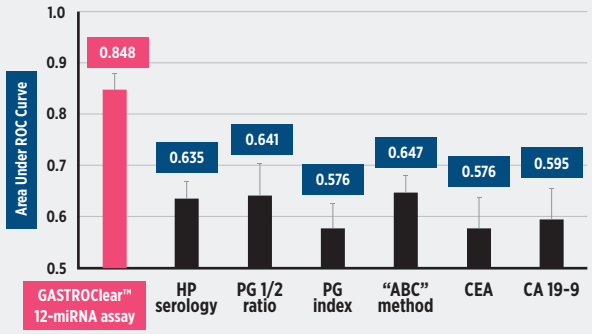
Clinical performance of GASTROClear™ was evaluated against the clinical gold standard of gastroscopy and pathohistological examination. Performance was also compared against conventional blood-based biomarkers CEA, CA19-9, pepsinogen (PG) 1/2 ratio, PG index, H. pylori serology, and the "ABC" method 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	GASTROClear™, an in vitro diagnostic test, 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.
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 2020; 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. PDQ® Adult Treatment Editorial Board. PDQ Gastric Cancer Treatment. Bethesda, MD: National Cancer Institute. Updated 14 Jan 2021. Available at: https://www.cancer.gov/types/stomach/hp/stomach-treatment-pdq. Accessed 19 Jan 2021. [PMID: 26389209]
4. Singapore Cancer Registry 50th Anniversary Monograph (1968 - 2017). National Registry of Diseases Office.

MiRXES
TO KNOW IS TO ACT

GASTROClear test is available through our clinical diagnostic laboratory partners. For enquiries, contact MiRXES via email: **gastro@mirxes.com**.

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