Blood Test for Gastric Cancer

Phillip Munson, PhD
Medical Affairs Manager

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MiRXES

Our Purpose:
We deliver **early, actionable** and **personalised diagnoses** across the care continuum **to improve and save lives**.

Our Approach:
We **develop and curate miRNA centric and multi-omics technologies**
We partner with academic, clinical institutions and pharma to **discover novel biomarkers and develop in vitro diagnostic tests**

- Biomarker discovery and disease detection is key
- We have global reach: Singapore based with presence in USA, China, and Japan
Why miRNA?

- microRNA (miRNA): small, single-stranded, non-coding RNA molecules containing 21 to 23 nucleotides
- Circulating Biomarker
- Readily available in blood and biofluids
- Small sample size needed (under 200uL serum)
- MiRXES has novel miRNA qPCR technology
- Stable and measurable
GASTROClear™ by MiRXES

- Aid in detection of gastric cancer currently in use in Singapore
  - Not approved for use in the USA
- 12 serum miRNAs with differential abundance patterns
- Clinical need for detection!

5-year survival rates of gastric cancer by country:

- 69% Korea
- 60% Japan
- 36% China
- 33% USA
- 30% Singapore
GASTROClear™ Clinical Evidence

Discovery Phase
Singaporean Chinese Cohort (N=472)
236 Gastric Cancers and 236 Matched Healthy Controls
Asymptomatic controls - 81% Sensitivity, 90% Specificity

Verification Phase
Singaporean Chinese & Korean Cohorts (N=210)
94 Gastric Cancers and 116 Matched Healthy Controls
Asymptomatic controls - 82% Sensitivity, 88% Specificity

Prospective Validation Phase
Singaporean Cohort (N=4,566)
115 Gastric Cancers and 4,451 Non-cancer Findings
Symptomatic population - 87% Sensitivity, 68% Specificity
GASTROClear™ Regulatory Status

- Not approved in the USA

Regulatory approval obtained:
- 2017
- 2019

Regulatory submissions ongoing:
- Japan
- China

Approved for *in vitro* diagnostic (IVD) use in Singapore and CE-marked

Designed, developed and manufactured in Singapore
How it works

- Currently in clinical use in Singapore for certain risk groups
- Risk score and stratification
- Used in conjunction with endoscopy to detect gastric cancer


Regular screening at recommended intervals → Gastroscopy → Diagnosis

Gastroscopy

High risk group
Intermediate risk with other clinical evidence

Low risk group
Intermediate risk without other clinical evidence

Blood draw → 12-miRNAqPCR assay with algorithm to calculate risk score

Regular screening at recommended intervals
Summary and Future Outlook

• MiRXES has the first blood test for the detection of gastric cancer
• Bolster the ability to detect gastric cancer and save lives
• Aiming for introduction into US
• Working on preliminary pilot studies on research samples in the US
• Blood tests and liquid biopsies are a promising solution to finding cancer early
• Shift the paradigm on how and when gastric cancer is detected

Disclaimer: GASTROClear™ is an invitro diagnostic assay intended for use as an adjunctive test for the detection of gastric neoplasia associated miRNA biomarkers in human serum. GASTROClear™ is approved and listed with Health Sciences Authority (HSA) in Singapore and CE Mark under the EU IVD Directive 98/79/EC. GASTROClear™ has not been cleared or approved by the U.S. Food and Drug Administration. Caution: Federal law restricts this device sale or distribution in the United States and its territories.
Thank You

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