



MiRXES Japan Co., Ltd.

Project to develop and validate a novel non-invasive cancer biomarker screening test service in Japan

Purpose of the Project

■ Cancer incidence and its mortality rate are rapidly increasing worldwide. To reduce the mortality rate, it is necessary to detect cancer at an early stage by minimally invasive and frequent tests. The availability of liquid biopsy is expected to lower the hurdle to undergoing testing, which would then lead to early detection of cancer and an increase in the number of people undergoing testing. Our Singapore HQ, MiRXES Pte. Ltd., has already provided a gastric cancer risk screening test service, GASTROClear™, using PCR for miRNAs based on our proprietary patent, and has obtained IVD certification from the Singapore government. However, to take the test in Japan, specimens after blood collection need to be pre-processed at each medical institution and shipped to Singapore for the test. Therefore, the goal of this project was set to establish the same testing system at Nagawa Pharmaceutical's registered clinical laboratory in Japan to reduce risks and costs associated with specimen transportation and to enable prompt reporting of test results.



Details of Demonstration

■ This project was carried out in cooperation with three companies: our Chinese branch, Hangzhou Mi Yin Biotechnology Co., Ltd., [Hangzhou], which provided training on laboratory operations, manufactured and exported testing reagents, and supported testing system validation; Nagawa Pharmaceutical Co., Ltd. [Nagawa], which built the testing facilities, validated the testing system, and delivered reports; and our company, MiRXES Japan, which managed and coordinated the entire project.

■ The list of equipment, protocols, and test plans required for the following three steps of our gastric cancer miRNA assay were shared with Nagawa: 1) RNA Isolation from Serum, 2) cDNA Synthesis, and 3) Real-time qPCR. Then, the equipment was prepared on time. At the same time, test reagents and kits were imported from Hangzhou. After Hangzhou provided training to Nagawa on these procedures, six tests were performed: 1) Positive Control Test, 2) Negative Control Test, 3) LOB Test, 4) LOD Test, 5) Precision Test, 6) Linearity Test. The results were summarized in a performance verification report. As a result, the performance of the miRNA PCR test installed at Nagawa passed all the tests, meeting both the manufacturer's and Nagawa's requirements. The laboratory staff training required to launch this test service was also completed.

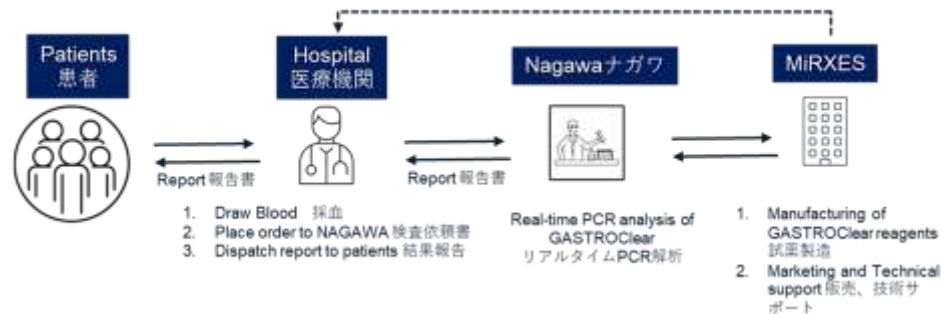


MiRXES Japan Co., Ltd.

Project to develop and validate a novel non-invasive cancer biomarker screening test service in Japan

Project Outcome

■ In this project, we successfully conducted technology transfer and local set up of a Singapore-developed and operated gastric cancer microRNA screening test. We were able to set up a work flow that allows fast turnaround time and reasonable logistics costs for GASTROClear™ test in Japan.



■ The test will first be conducted in Tokyo, with a short turnaround time and reasonable pricing. GASTROClear™ will become more widely adopted by health check-up centers and hospitals in Japan, which could offer a new option for non-invasive gastric cancer screening. This should increase the gastric cancer screening rate, especially among people who are reluctant or find it difficult to access endoscopic examinations, thereby contributing to the early detection of gastric cancer and ultimately reducing the mortality rate of gastric cancer.

Challenges and Solutions

■ The preparation period and the marketing activities were the challenges for us to overcome. Regarding the preparation period, negotiations among partner companies would have been conducted more smoothly if we had had more time to prepare before the start of the project. As for marketing activities, one example is participation in exhibitions: Since the applications for participation are usually required to submit 6 months in advance, it was before the start of this project and could not be included in the project. In order to solve such challenges and increase recognition of GASTROClear™ in Japan, we plan to collaborate with Nagawa on marketing activities in the future.

Future Plans

■ Since the cost of international transportation of specimens has been cut, more accessible test price will be set.

■ Lung cancer is another type of cancer that has a much higher five-year survival rate with early detection. When the diagnosis is made at an advanced stage, the cost of long-term drug administration is high, chest X-rays are less sensitive, and low-dose computed tomography (LDCT) is available only for high-risk patients. We also plan to introduce our lung cancer risk screening test (LUNGClear™), which is a liquid biopsy using microRNA, to Japan market as a next step.