

Press release

Study Validates Performance of MiRXES qPCR Platform for microRNA Biomarker Development

Cross-platform evaluation study shows that MiRXES ID3EAL qPCR microRNA (miRNA) profiling platform has superior reproducibility and detection rate compared to other commercial miRNA profiling platforms when used for discovery and validation of blood-based miRNA biomarkers.

SINGAPORE – 11 March 2021 – A cross-platform evaluation study has validated the performance of the MiRXES ID3EAL microRNA (miRNA) quantitative polymerase chain reaction (qPCR) technology, showing that the MiRXES platform has superior reproducibility and detection rate for miRNA profiling compared to other commercial miRNA profiling platforms. The study, performed in collaboration with researchers from MSD (known as Merck & Co. Inc., Kenilworth NJ in the US and Canada), provides important data to help researchers select appropriate tools for discovery and validation of blood-based miRNA biomarkers that can be developed into diagnostic tests for early disease detection and precision medicine.

Since their discovery in human blood in 2008, circulating miRNAs in various biofluids have been proposed as promising biomarkers for various diseases. Today, diagnostic tests based on circulating miRNA expression, such as MiRXES' GASTROClear blood test for early detection of gastric cancer, are beginning to enter routine clinical practice. However, it remains technically challenging to quantify miRNAs in biofluids due to their low abundance, the small size of miRNA molecules, and the high degree of similarity between miRNA family members. Although many platforms, including MiRXES' ID3EAL qPCR assay, have been developed for quantifying miRNA expression, their relative performance in quantifying miRNA in human biofluids like serum and plasma is unclear.

“Profiling of miRNA expression in serum and plasma has the potential to allow further identification of miRNA biomarkers that are informative for early disease diagnosis and to predict response to therapy,” said Dr Lihan Zhou, Co-founder and CEO of MiRXES, and a co-author of the study published on 24 February 2021 in *Scientific Reports*, an online multidisciplinary journal by Nature Research.

The researchers systematically evaluated four different qPCR platforms, a hybridization-based platform, and a miRNA sequencing (miRNA-Seq) platform for their performance in quantifying miRNA from a common set of reference samples, including Reference Serum (Ref. Serum), a large stock of pooled human serum. The six platforms were compared based on performance parameters such as reproducibility and detection rate.

The reproducibility of each platform was assessed by performing at least three independent runs on Ref. Serum to obtain miRNA expression profiles. The results showed that the MiRXES ID3EAL qPCR assay and miRNA-Seq had the best reproducibility with almost perfect concordance in results between runs while the other three qPCR platforms had moderate inter-run concordance.

In terms of detection rate, the MiRXES ID3EAL qPCR assay reliably detected the highest number of miRNAs (438 miRNAs) among all the platforms compared. In comparison, miRNA-Seq detected 372 miRNAs reliably while the other qPCR platforms detected less than half the number of miRNAs detected by the MiRXES platform with low variability in replicate measurements. The study also showed that the MiRXES platform also had good inter-platform overlap with the miRNA-Seq platform, with 243 miRNAs detected reliably by both platforms and a good correlation in the expression profiles of these miRNAs.

Overall, the researchers showed that the MiRXES qPCR platform had the highest sensitivity among all the platforms evaluated in detecting miRNA in Ref. Serum. However, they observed that even though miRNA-Seq had a slightly lower detection rate, the platform offers several advantages such as lower cost and faster turn-around time compared to qPCR-based platforms. Balancing the strengths and weaknesses of each platform, the researchers proposed that a rational strategy for miRNA biomarker development is to use miRNA-Seq for discovery and targeted qPCR for subsequent validation of the biomarkers.

The full text of the paper can be accessed at the following link:

<https://www.nature.com/articles/s41598-021-83365-z>

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About MiRXES

Founded in 2014 as a spin-off from Singapore's Agency for Science, Technology, and Research (A*STAR) and National University of Singapore (NUS), MiRXES is the world's leading developer of microRNA centric molecular diagnostic tests, with strong pipelines in cancer, cardiovascular, and infectious diseases. MiRXES has physical presence in Singapore, USA, China and Japan with sales in over 40 countries globally. In 2019, MiRXES launched GASTROClear, the world's first microRNA blood test for early detection of gastric cancer. In response to the COVID-19 pandemic, MiRXES worked with Singapore government agencies to launch Fortitude Kit, Singapore's first authorized COVID-19 RT-PCR test. Since February 2020, millions of Fortitude tests have been deployed globally.

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Forward-Looking Statements

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MiRXES media contacts:

Yew Chung Tang

yewchungtang@mirxes.com