

Agena, DaRui Biotechnology announces China FDA clearance of MassArray Technology

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Commercially branded in China as DR MassARRAY by DaRui, the approval of the MALDI-TOF based system for targeted genetic analysis is the successful culmination of the commercial partnership that was initiated in 2016 between the two companies.



Agena Bioscience (Agena), a San-Diego-based develops, manufactures, and supplies genetic analysis systems and reagents, including the MassARRAY System and DaRui Biotechnology (DaRui), a Guangzhou-based company specialized in diagnostic test development, manufacturing, distribution, technical service and consulting services for the clinical laboratory market in China and has long focused on screening of birth defects, inherited disease, oncology screening and diagnosis, and also the development of advanced immunodiagnosics has announced that the MassARRAY System has formally passed the registration application of Guangdong Food and Drug Administration, becoming the first CFDA approved MALDI-TOF mass spectrometry system to directly detect nucleic acids for *in vitro* diagnostics in China. Commercially branded in China as DR MassARRAY by DaRui, the approval of the MALDI-TOF based system for targeted genetic analysis is the successful culmination of the commercial partnership that was initiated in 2016 between the two companies.

"The CFDA approval is a major milestone and demonstrates that the performance, accuracy, and safety of the MassARRAY System meets these stringent regulatory requirements," said Dr. Ming Li, Chairman of DaRui. "The rapid turn-around time and low per test cost will enable broader adoption of genetic tests, and ultimately benefit more patients in China."

"We are thrilled with this achievement and look forward with our partnership to introducing a new era of multi-gene, high-throughput and low-cost routine diagnostic testing in Chinese hospitals and independent laboratories," said Peter Dansky, Chief Executive Officer of Agena.