

HTG Molecular Diagnostics Achieves ISO 13485:2003 Certification

July 30, 2012 10:08 AM ET

Demonstrating Internationally Recognized Standards for Quality Management in Provision of Medical Devices and Related Services

TUCSON, Ariz. (July 30, 2012) – HTG Molecular Diagnostics, a privately-held company providing products for gene expression profiling, has achieved ISO 13485:2003 certification for the design, manufacture, and distribution of instruments, software, reagents and test kits used in the analysis of gene expression. The certification covers the design, development, production, and sale of the patented qNPA technology-based products and services in HTG Molecular Diagnostics' portfolio.

To earn this internationally recognized quality standard certification, an organization is required to demonstrate it has quality management systems in place to consistently meet customer and regulatory requirements for design and development of medical devices.

“The achievement of the ISO 13485:2003 certification demonstrates HTG Molecular Diagnostics' commitment to quality and attention to detail in the development and provision of qNPA technology-based products and services, laying a solid foundation for the future growth of HTG's clinical diagnostics business,” stated Sam Rua, Vice President of Regulatory Affairs and Quality Systems at HTG Molecular Diagnostics.