



Press release

TcLand Expression in compliance with the ISO 13485:2003 for its *in vitro* medical diagnostics

Nantes (France), April 15, 2010 - TcLand Expression, a global leader in the field of gene expression biomarkers and companion diagnostics in immunology, today announced that it had achieved ISO 13485:2003 compliance of its quality management system and renewal of its existing ISO 17025:2005 accreditation.

One year after the company's ISO 17025:2005 accreditation for the performance of gene expression assays, TcLand Expression has reaffirmed its sector leadership and its commitment to the most rigorous international standards by ensuring compliance with ISO 13485:2003 for the quality management of its *in vitro* diagnostic (IVD) medical devices.

Renewal of ISO 17025: 2005 accreditation thus confirms the skill of the company's staff and the validity of the analytical methods that TcLand Expression is applying. Compliance with ISO 13485:2005 constitutes an additional guarantee of the quality of TcLand Expression's procedures for IVD design, production environment control, traceability and risk analysis. It also represents a milestone on the road to CE marking for TcLand's products.

"By fulfilling the criteria for ISO 13485:2003 accreditation, we have shown that our IVD design, development and manufacturing processes meet objective quality standards. Now that we have reached this milestone, we can continue to proactively deploy our ambitious development plans in France and internationally. We have decided to make our quality management system compliant with the USA's 21 CFR part 820 federal regulations ("Medical Devices – Quality System Regulation"), emphasized Hasnae Niang-Picot, Quality Assurance Manager at TcLand Expression.

TcLand Expression

TcLand Expression is an acknowledged pioneer in the discovery, the development and the validation of gene expression biomarkers for unmet medical needs in transplantation and auto-immune disease. The company benefits from an exceptional scientific and clinical environment.

For more information, please visit our website: <http://www.tcland-expression.com/>

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