

## Press Release

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### Vivacta's Quality Management System certified to ISO 13485:2003



Vivacta has taken an important step towards the successful commercialisation of its ultrasensitive Point-of-Care immunochemistry system by achieving compliance with ISO13485.

This clears the way for the company to partner with larger in vitro diagnostic companies, which place major demands on compliance with global regulatory requirements.

Commenting on the certification, Vivacta's Director of Quality, Sonja Johnston, stated "Following 18 months of Quality System development, the company now has a very robust system, designed around our processes and operating procedures. This was confirmed in the audit carried out by LRQA, as it revealed no major, or minor non-conformities."

Johnston added, "Vivacta decided very early in the development of its Quality Management System to adopt modern processes, including electronic document control, even though these brought with them issues with regard to the use of appropriately validated systems. This is particularly relevant for the US market, where Part 11 compliance is required."

By adopting a system that embraces these requirements, Vivacta now has a documentation system that is readily accessible by all employees using computers in their working environment.

Neil Butler, CEO Vivacta, added, "As the establishment of fruitful partnerships with the larger diagnostics companies is key to our long-term development, it was essential that we could meet all the demands with respect to quality compliance."

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Issued on behalf of Vivacta by De Facto Communications

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