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Press Release

DUTCH MEDICAL CENTRE ACHIEVES ACCREDITATION FOR CLINICAL USE OF MICROARRAYS

University Medical Centre Utrecht select BlueGnome CytoChip™ for ISO registration

The Dutch Council for Accreditation (RvA) has accredited the Array facility of the Genome Diagnostic section of the University Medical Centre Utrecht with NEN-EN-ISO 15189. This is the first such accreditation, and is of particular importance to the cytogenetics community, as it is the first to include the clinical use of microarrays for arrayCGH.

ArrayCGH uses microarrays to measure genomic copy number imbalance. Until recently it was reserved for those patients left undiagnosed by traditional approaches such as karyotyping and fluorescent in-situ hybridization (FISH). Increasingly however arrayCGH is used, in combination with karyotyping, as a primary screen in order to deliver high resolution genetic information around which further investigations may be planned.

The quality system for genetic diagnostics at the University Medical Centre has been developed to meet NEN-EN-ISO 15189, the ISO standard for quality and competence in medical laboratories. The accreditation with the RvA describes the methods, equipment and reporting required for clinical arrayCGH.

In order to achieve the accreditation the BlueGnome CytoChip™ was selected to replace the academic microarray used to establish the service. Marcel Nelen, Clinical Molecular Geneticist responsible explained, 'Comparing the first 300 patients investigated using the CytoChip™ with the last 300 processed using our academic microarray we have increased our diagnostic yield while reducing false positives and failed investigations. This translates into a service for our patients that is faster, more cost effective and more clinically informative'.

Dr Nick Haan, CEO of BlueGnome confirmed, 'Clinical applications demand levels of quality and repeatability which are difficult to obtain with a research platform. A more rigorous regulatory framework for clinical applications is to be expected and is something that we plan to support with the CE marking of the CytoChip as an in vitro medical device'.

About BlueGnome

BlueGnome (www.cambridgebluegnome.com) is a specialist developer of software and consumables for the clinical application of arrayCGH. BlueGnome's CytoChip, a high quality BAC microarray, has been developed in collaboration with leading laboratories of the UK NHS to support the investigation of 74 known genetic conditions and screening of the genome at a 1Mb resolution in a single, dye swap experiment. For more information see www.cytochip.com.

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Cambridge, UK, 30th April 2007