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Agilent receives approval for GenetiSure Dx Postnatal Assay in Japan

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Agilent Technologies has obtained clearance from the Ministry of Health, Labour and Welfare (MHLW) in Japan for the GenetiSure Dx Postnatal Assay, a microarray-based assay for diagnostic use.

This assay enables clinical geneticists to detect genetic aberrations associated with developmental delay, intellectual disabilities, congenital anomalies, and unexplained dysmorphic features.

The company also announced that it has registered its microarray scanner, SureScan Dx Scanner, as a Class I medical device in Japan, intended for use with the assay.

Based on Agilent's proprietary microarray for comparative genomic hybridization (CGH), the GenetiSure Dx Postnatal Assay is a qualitative assay for the postnatal diagnosis of copy-number alterations (CNVs) and copy-neutral loss of heterozygosity (cnLOH) from genomic DNA (gDNA), obtained from the peripheral whole blood in patients who have been referred for chromosomal testing based on clinical presentation.

The GenetiSure Dx Postnatal Assay is the result of a clinical validation utilizing 900 samples and brings CGH technology into a diagnostic setting in Japan. Available since 2017 as an in vitro diagnostic assay (IVD) in Europe and the United States, Japanese clinical geneticists can now have access to this assay to help identify a definitive genetic diagnosis for their patients.