

## Ipsogen launches a new test to determine tumor HER2 status and guide Herceptin® prescription in breast cancer

**Ipsogen's HER2 test further strengthens the rapidly expanding MapQuant Dx™ platform, a microarray-based comprehensive solution designed to guide therapy decisions in breast cancer.**

**Marseille, Nov. 24, 2008** - IPSOGEN SA (Marseille, France and New Haven, CT, USA), a cancer profiler that markets molecular diagnostic assays for leukemia and breast cancer announced today the European launch of MapQuant Dx™ HER2 test. Developed on the MapQuant Dx™ microarray diagnostic platform, MapQuant Dx™ HER2 accurately measures a set of HER2-amplified genes that correlate with HER2 protein expression. This new HER2 test provides reliable, intelligible and decisive information for pathologists, oncologists and patients.

*"MapQuant™ Dx HER2 is the second test to be developed on our MapQuant Dx™ platform, after the Genomic Grade launched by Ipsogen earlier this year. Thanks to our experience in molecular diagnostics and to multiple research collaborations, we will keep delivering innovative tests at an accelerated pace."* says Dr. Jean-Marc Le Doussal, Director of the Breast Cancer Program at Ipsogen.

Commenting on its experience with Ipsogen, Pr. François Bertucci, Medical Oncologist at Institut Paoli Calmettes Cancer Center in Marseille adds: *"I was very pleased to collaborate with Ipsogen in rapidly and efficiently moving from our research findings to a market-ready diagnostic test. As a translational researcher, I believe that MapQuant Dx™ is a comprehensive "plug & play" solution, making research rapidly available to patients"*.

### About MapQuant Dx™ HER2

#### Clinical Rationale

The amplification of the HER2-region of chromosome 17 results in the constitutive overexpression of the HER2 oncogene protein and fuels uncontrolled tumor growth in approximately 15 to 30% of breast tumors. HER2 is considered today as a predictive marker for clinical benefit from trastuzumab, or Herceptin®, a monoclonal antibody directed against the HER2 protein, in both primary and metastatic tumors. However current testing methods are inaccurate for as much as 20% of cases and this may lead to missing the benefit of Herceptin® therapy for some patients or, on the contrary, to prescribing unnecessary therapy for others.

#### Testing solution

Currently, tumors are tested for HER2 with 2 main complementary technologies: immunohistochemistry (IHC) which identifies HER2 protein expressed in the tumor cells and *in situ* hybridization (ISH), which quantifies HER2 DNA copy number in the cell chromosomes. Some RT-PCR assays, that quantify the amount of HER2 mRNA, have also been developed more recently.

Ipsogen's MapQuant Dx™ HER2 test was designed to correlate with the expression of the HER2 protein at cell membrane level. The test, developed on a set of 152 tumors, was validated in 4 independent datasets totalling 269 tumors. The test correlates with the IHC method in 95% of the cases and it resolves IHC equivocal cases in 95 % of cases.



MapQuant Dx™ HER2 test is available for diagnostic use in Europe together with MapQuant Dx™ Genomic Grade test through MapQuant Dx™ platform. It includes :

- Easy and secured sample collection and shipment at room temperature using the CE-marked MapQuant Dx™ Path Kit.
- Sample testing performed using ISO-17025 MapQuant Dx™ Lab Services at DNAVision SA (Gosselies, Belgium) on Affymetrix GeneChip® Systems 3000Dx2 (GCS3000Dx2), ensuring highly reproducible sample processing.
- Data processing and result delivery with MapQuant Dx™ CE-compliant software , ensuring highly reliable quality controls.

MapQuant Dx™ solution is developed under the innovation support program of the French Health Products Safety Agency (Afssaps). Commercialization in the United States will depend upon FDA's (Food and Drug Administration) formal approval.

## About IPSOGEN

Ipsogen, Cancer Profiler, develops and markets molecular diagnostic tests designed to map diseases in order to guide patients and oncologists decisions along their complex therapeutic path.

With more than 60 tests already used routinely worldwide for the diagnosis, prognosis and follow-up of thousands of patients with leukemia, Ipsogen is now also targeting breast cancer. Its initial goal will be to provide diagnostic information that remained unavailable until now.

Strengthened by its first-rate scientific, clinical and technological partnerships, in addition to its highly skilled multidisciplinary team in France and the USA, Ipsogen is striving to become the leader in the molecular profiling of cancers. It is pursuing its development and promotion of diagnostic standards that have a significant impact on patients, medical professionals and society.

Ipsogen employed 41 people as of September 30, 2008. Its headquarters are located in Marseille, France. The company has also a subsidiary, Ipsogen Inc., in New Haven, CT, USA.

For more information, visit: [www.ipsogen.com](http://www.ipsogen.com)

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