

Ipsogen launches a new test to guide hormone therapy prescription in breast cancer

The Genomic HR test will help pathologists to identify endocrine-responsive tumors that should benefit from hormone therapy

Marseille, May 7, 2009 - IPSOGEN SA (Alternext - FR0010626028 - ALIPS), a molecular diagnostic company specialized in the development, manufacturing and commercialization of diagnostic assays for breast cancer and leukemia, today announces the European launch of the MapQuant Dx™ HR test. Running on an Affymetrix microarray diagnostic platform, this new genomic test will improve the identification of endocrine-responsive tumors by measuring the expression of genes related to oestrogen and progesterone biology in breast cancer.

Current issues with endocrine-responsiveness determination in breast cancer

Determining endocrine-responsiveness of breast cancer is essential as it guides the use of hormone therapy, based primarily on tamoxifen and aromatase inhibitors such as letrozole and anastrozole. Currently, endocrine-responsiveness is routinely assessed by immunohistochemistry (IHC), a semi-quantitative method measuring the expression of hormone receptors (HR) for estrogen (ER) and progesterone (PR) on tissue sections. However, and despite constant efforts toward technical standardisation, IHC reproducibility and accuracy is not satisfactory, with as much as 15% of cases reported as equivocal. This may lead to inappropriate treatment decisions.

Beyond the technical and standardisation issues, two biological problems are unsolved: (i) do ER-/PR+ tumors exist, or should they be considered as technical artifacts? (ii) how to define the threshold for receptor positivity (which is different in US and EU pathology practices)?

MapQuant Dx™ Genomic HR

The Genomic HR test measures the hormone receptor status of invasive breast tumors. It has been developed on a training set of 137 tumors with unequivocal receptor expression by IHC. It was validated in 7 independent datasets totalling 691 tumors. It measures, by microarray technology, the expression profile of genes selected to best discriminate tumors expressing ER and/or PR proteins. These genes, selected on a statistical rationale, are known to be related to the estrogen and progesterone biology, adding a strong pathological rationale to the selection process.

Through this micro-array technique, an objective and biologically-relevant cutoff for receptor positivity could be identified. Over 97% of tumors could be given an unequivocal result. Moreover, no tumor expressing PR but not ER could be identified, supporting the current hypothesis that such PR+/ER- tumors could be artifacts of the IHC technique.

Multi-testing with MapQuant Dx™

Together with the Genomic Grade test and the Genomic HER2 test, the Genomic HR test provides a complete genomic testing panel for breast cancer that will help pathologists to better determine tumor grade, HR and HER2 status, and, ultimately, allow a more individualised treatment decision in breast cancer patients.



The Genomic HR test is made available for diagnostic use in Europe through an ISO-17025/CLIA Lab Service performed by DNAVision SA (Gosselies, Belgium). It can also be performed directly by cancer care centers equipped with the CE-marked, FDA-cleared Affymetrix GeneChip® 3000Dx2 (GCS3000Dx2) system.

The MapQuant Dx™ testing solution for routine micro-array profiling of breast tumors also includes: a Path Kit, CE-marked, ensuring easy sampling, RNA-preservation and sample shipping at ambient temperature; and CE-compliant software, ensuring highly reliable quality controls, data processing and genomic test computation.

MapQuant Dx™ testing solution is developed under the Innovation Support Programme of the French Health Products Safety Agency (Afssaps).

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 70 references 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 was not available until now. Ipsogen is also a partner of choice for biopharmaceutical companies committed to the development of 'companion diagnostic' tests.

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 molecular profiling of cancers. It continues its efforts to identify, develop and commercialise diagnostic tests that will become standard references and will have a significant impact on patients, medical professionals and society.

Ipsogen employed 51 people as of March 31, 2009. Its headquarters are located in Marseille, France. The company also has a subsidiary, Ipsogen Inc., in New Haven, CT, USA.

For more information, visit: www.ipsogen.com

Contacts

IPSOGEN

Vincent Fert

President and CEO

Tel: + 33 (0)4 9129 3090

fert@ipsogen.com

Hélène Peyro-Saint-Paul

CMO

Tel: + 33 (0)4 9129 3090

peyro-saint-paul@ipsogen.com

ATCG Press

Corporate and Product Information

Marielle Bricman

Tel: + 33 (0)4 9125 0785

ipsogen@atcg-partners.com

NewCap

Financial Communication and Investor Relations

Axelle Vuillermet & Pierre Laurent

Tel: + 33 (0)1 44 71 94 93

ipsogen@newcap.fr