



## **Agendia Receives Fifth FDA Clearance for Industry Leading MammaPrint® Assay**

**IRVINE, CA, and AMSTERDAM, THE NETHERLANDS, February 22, 2011** – Agendia, a world leader in molecular cancer diagnostics, today announced that the company has received its fifth U.S. Food and Drug Administration (FDA) clearance for MammaPrint®, its widely used breast cancer recurrence assay. The new clearance is comprised of two additional Agilent Microarray scanners and two Agilent Bioanalyzers, expanding laboratory capacity to handle the increasing number of MammaPrint, TargetPrint® and Blueprint® test requests. The company said that the presence of FDA cleared equipment in both of its locations will further mitigate risk posed by a potential interruption to its business in the event of an equipment breakdown at either location. MammaPrint previously received several FDA clearances for clinical use in the U.S. and remains the first FDA cleared IVDMIA (In Vitro Diagnostic Multivariate Index Assay) on the market and the only FDA cleared breast cancer recurrence test

“Agendia continues to lead by example in the genomic testing industry by ensuring that our products and equipment are in full compliance with the most recent FDA standards, despite the fact that such oversight is not mandatory,” said Dr. Bernhard Sixt, Agendia’s CEO and founder.

MammaPrint was previously defined by the FDA as a qualitative in vitro diagnostic test service, performed only in Agendia’s Irvine labs. The latest FDA clearance defines a new “intended use” which allows for the test to be performed in a central laboratory. This empowers Agendia to legally perform tests for the U.S. market in both the Irvine and Amsterdam CLIA and CAP accredited facilities, and also additional future central labs under Agendia control.

### **About Agendia**

[Agendia](#) is at the forefront of the personalized medicine revolution, striving to bring more effective, individualized treatments within reach of patients. Building on a cutting-edge genomics platform for tumor gene expression profiling, the company's tests help physicians more accurately tailor cancer treatments. Agendia markets four products, with several new genomic tests under development. In addition, Agendia collaborates with pharmaceutical companies to develop highly effective personalized drugs in the area of oncology. Agendia is based in Irvine, California, and in Amsterdam, the Netherlands.

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