



## GENOMARK CHIP

AN EASY-TO-USE RTqPCR ARRAY

PROVIDING HUMAN-BASED MECHANISTIC INFORMATION FOR  
DE-RISKING POTENTIAL GENOTOXICITY OF COMPOUNDS

### Background

Genotoxicity is a key endpoint in the hazard assessment of any sort of chemical as damage to the genetic material might lead to detrimental effects on human health. To assess the potential of chemicals to induce genotoxicity, several *in vitro* and *in vivo* tests have been developed. Regulatory bodies worldwide recommend a battery of *in vitro* tests to cover the three important genotoxicity endpoints i.e. mutagenicity, clastogenicity and aneugenicity. A positive outcome in this battery is usually followed up by *in vivo* genotoxicity studies. To avoid the use of experimental animals, or in case legislation (cosmetics in Europe) does not permit animal usage, new technologies can be introduced to de-risk the positive outcome. In this way a compound can be saved, in an ethical way, through molecular information.

### The GENOMARK innovation

In close collaboration, VUB and WIV-ISP have generated an easy-to-use 96-well RTqPCR array for detecting genotoxicity, providing an additional *in vitro* tool to de-risk false positives emerging from the very sensitive standard genotoxicity battery of Ames and micronucleus tests. At the basis, the GENOMARK chip translates a genotoxic-specific transcriptomics signature into a qPCR array of 84 biomarker genes. The assay is based on the well-established human HepaRG™ cell line and can be run in any lab with basic PCR equipment. Using IC<sub>10</sub> concentrations, the GENOMARK chip showed 100% specificity and sensitivity for non-equivocal compounds, and was also able to provide mechanistic information on compounds under debate. This assay provides an output that allows further exploration of the mechanisms of genotoxicity at the gene level and investigation of human relevance.

### GENOMARK potential

Though recently developed, the GENOMARK chip has generated promising results indicating its potential value in strategies for *in vitro* genotoxicity testing. This chip allows the incorporation of gene expression profiling for genotoxicity outcomes in routine testing. Compounds that show positive results in the regulatory *in vitro* battery - known to generate a high proportion of false positive results – might still be saved by using this tool in a weight-of-evidence approach. The GENOMARK chip is valuable in all sectors, where compound development is hampered by excessive, expensive and time-consuming *in vivo* testing.

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