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An interlaboratory validation trial of the ToxTracker Assay for Genotoxic Mode of Action Assessment according to OECD guidelines.

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ToxTracker is a mammalian stem cell-based reporter assay that detects activation of specific cellular signaling pathways upon chemical exposure. ToxTracker contains six different GFP-tagged reporter cell lines that together allow the accurate identification of genotoxic substances and discrimination between induction of DNA damage, oxidative stress and/or protein damage in a single test. More recently, the assay was extended to allow the discrimination between clastogenic and aneugenic compounds.

The ToxTracker assay is currently being evaluated in a large international inter-laboratory validation study, approved by the OECD. The goal of this prospective validation study is to explore the applicability of ToxTracker for regulatory applications, establish the transferability and reproducibility of the assay and to explore how it can be applied to improve the in vitro genotoxicity testing strategies. The validation has been conducted strictly following OECD guidance document 34.

ToxTracker was transferred to seven laboratories. The validation labs were trained to perform the assay and tested a training set of compounds to show their proficiency to run ToxTracker. Next, the labs evaluated a selection of 64 coded, well-established genotoxic and non-genotoxic chemicals with each compound being tested in three labs independently. All the experimental work has been completed and data have been analyzed. The accuracy to predict genotoxicity, as well as the intra- and inter-laboratory reproducibility were determined. In this poster, we will give an overview how the ToxTracker validation was performed and the most important results from this interlaboratory validation.