

TOWARDS AN AUTOMATED SCORING SYSTEM FOR THE SYRIAN HAMSTER EMBRYO ASSAY

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The Syrian hamster embryo (SHE) assay is actually the most predictive *in vitro* alternative to the 2 year rodent bioassay. It is based on the ability of chemical/physical/biological agents to induce morphological transformation of SHE cells, which correlates with the potential to induce carcinogenesis. It possesses the ability to identify genotoxic as well as non-genotoxic carcinogens. Towards the regulatory acceptance of Cell transformation assays, a detailed review paper (DRP 52) was issued by the OECD in 2006. The SHE assay and the Balb 3T3 assays were recommended for guideline development. A pre-validation exercise lead by ECVAM is near completion on both assays.

Several agents have been tested in the "low pH" version of the SHE assay with a sensitivity of 86 %, a specificity of 83 % and an 83 % overall concordance with rodent bioassay. Despite its good performances, the SHE assay has suffered a lot of criticism. This is partly due to the lack of knowledge on the molecular mechanisms underlying cell transformation. Moreover, the visual scoring of the colonies (which is tedious and subjective) is far more the greatest weakness of this assay.

In order to ease the scoring of the transformed phenotype and make it more objective, we are developing an automated scoring system in collaboration with IMSTAR (a high technology company) through a stepwise approach:

Step 1: Recognition and capture of colonies: Successfully completed.

Step 2&3: Automated scoring of colonies and adaptation of the IMSTAR Pathfinder™ instrument to SHE plate handling: Successfully completed.

Step 4: Still to do: Recognition of transformed phenotype. Proof of concept was successful.

The final product will be a system that can handle (unattended) up to 20 plates at once and 60 plates/day. Therefore, developing an automated scoring system for the SHE assay is feasible (In 1996, Ridder GM *et al.* (Carcinogenesis 18 (1996) 1965-1972) showed a 93% agreement between visual scoring and a computerized image analysis). Doing so may encourage the widespread use of this assay.

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