



## YOUR DEDICATED PARTNER IN DRUG SAFETY

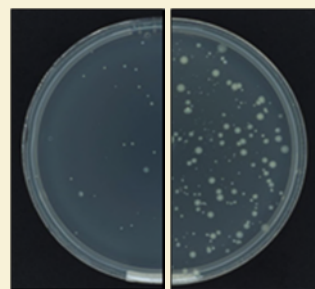
Genetic Toxicology studies are requested by all regulatory agencies as part of the investigational drug risk assessment as they provide critical information regarding any potential deleterious effects of the product towards the genetic material.

ITR Laboratories continues to add to the list of Genetic Toxicology services that are in accordance with international guidelines (ICH S2 (R1)/ OECD/ US EPA OPPTS/ US FDA Redbook). For many of these following tests we also offer non-GLP screening assay.

### Bacterial reverse mutation test (Ames test)

Assay using *S. typhimurium* strains TA1535, TA1537, TA98, and TA100, and *E. coli* strain WP2 *uvrA* with either plate incorporation or pre-incubation method.

The Ames test is routinely used at the discovery stage (drug screening) or as part of the genetic toxicology battery for regulatory submission.



Negative Positive

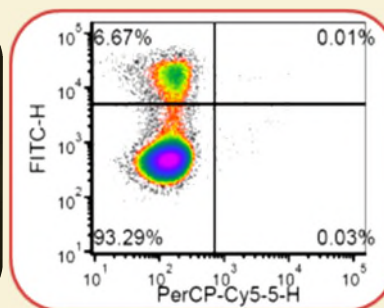
### *In vivo* mammalian erythrocyte micronucleus test

ITR offers great study design flexibility: The test could be done in rat or mouse, bone marrow or peripheral blood. Micronuclei may be evaluated by microscopic method or by flow cytometry.

This assay can be offered either as an independent study or integrated into the design of a routine toxicology study.



Microscopic method



Flow cytometry

## Mammalian chromosome aberration test

*In vitro* test using cultures of human peripheral blood, or *In vivo* test using rat bone marrow.

This method detects clastogenicity, and can give an indication as to aneugenicity.

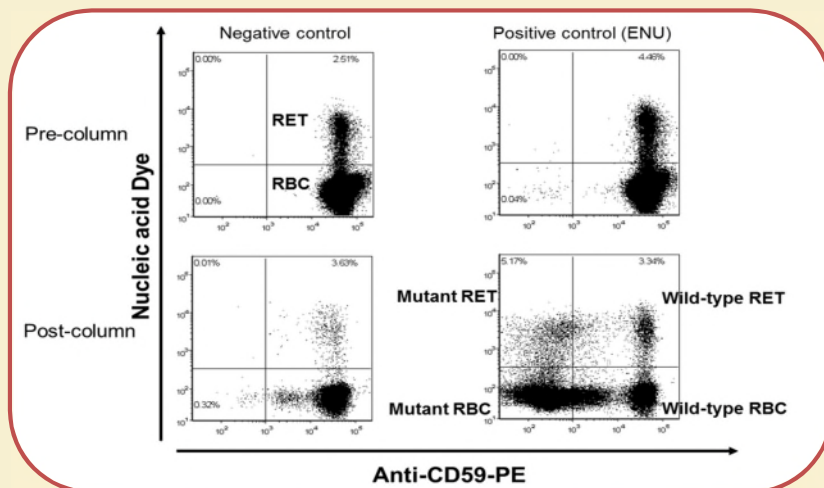


## The most recent addition:

### *PigA* gene mutation test

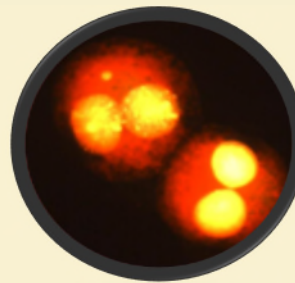
*In vivo* assay detecting mutations of the *pigA* gene in blood cells of treated animals.

Assessed using flow cytometric methods.

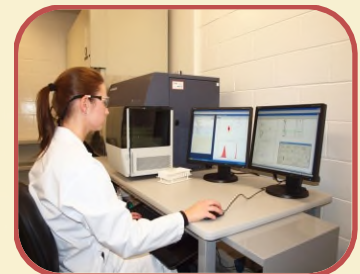


## *In vitro* Mammalian cell micronucleus test

*In vitro* test using cultures of human peripheral blood. Micronuclei may be evaluated by microscopic method or by flow cytometry.



Microscopic method



Flow cytometry

## COMING SOON

The **Comet assay** is currently under validation at ITR and should be available by fall 2015