



LITRON
LABORATORIES

Quality Counts at the Speed of Light



*Tools and Resources for Clinical
Trials - December, 2008*

Genetic Toxicology 101

Rochester BioVenture Center

Jeff Bemis, PhD

Director of Clinical Studies

Litron Laboratories



FDA Drug Submission

➤ Preclinical Toxicology

- Genetic Toxicology
 - Bacterial Reverse Mutation
 - In Vitro Cytogenetic Assay
 - In Vivo Micronucleus Assay

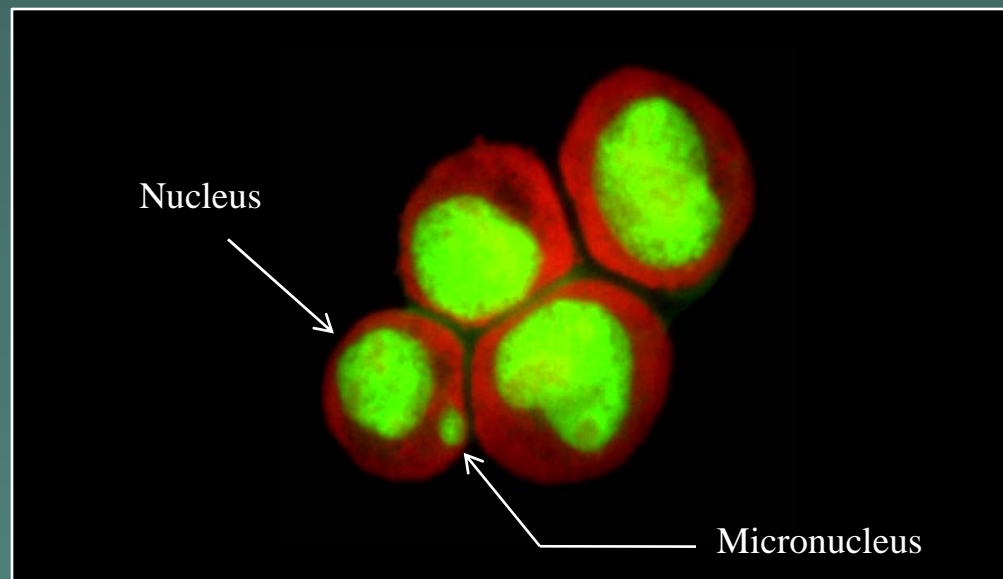
➤ Litron Laboratories

- Started as contract lab
- Evolved to assay development/production
- Focus on micronucleus testing



What is a Micronucleus?

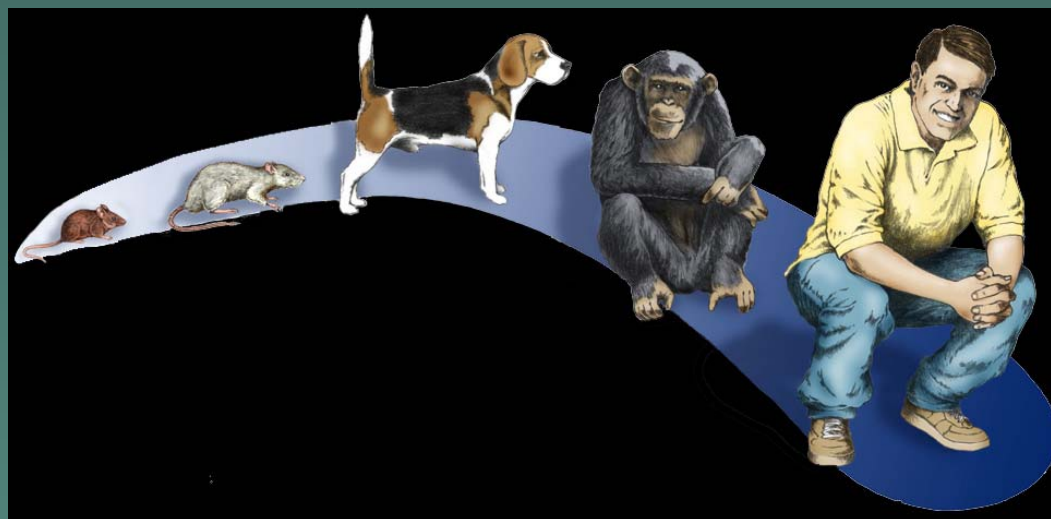
When cells divide, extra-nuclear chromatin resulting from a chromosome break or a lagging whole chromosome may not be incorporated into the daughter nucleus.





MicroFlow[®] Technology

- Flow Cytometric Micronucleus Assessment
 - In Vitro – Cell lines
 - In Vivo – Preclinical Models
 - In Vivo – Humans





Human Micronucleus Testing

➤ Value in:

- Clinical Trials
- Postmarket Surveillance
- Epidemiological Studies

➤ In Vitro Diagnostic Device

- 510(k) clearance required
- Litron gearing up for submission



Resources

- FDA website
 - CDRH Learn, Device Advice

- Local Resources
 - UofR
 - RIT – Clinical Research Management

- Professional Education Services
 - Barnett Education, CfPIE



FDA nixes proposed 'prescription pistol'

'I would assume it's due to political pressure,' said gun's inventor

By Ricardo Alonso-Zaldivar

AP Associated Press

updated 4:43 p.m. ET, Mon., Dec. 8, 2008

WASHINGTON - It could have been the world's first prescription pistol. The single-bullet Palm Pistol set the Internet abuzz with speculation that Medicare might even pay for the elderly and disabled to pack heat.

But on Monday the Food and Drug Administration said the Palm Pistol doesn't have a shot of being listed as a medical device, and revoked the registration issued to its inventor only last week.

"The FDA has determined the product is not a medical device," the agency said in a statement.

[Story continues below ↓](#)



Constitution Arms