

## In Vitro Biocompatibility Testing

The EAG In Vitro Biocompatibility Laboratory offers a comprehensive battery of biocompatibility and consumer product safety testing services.

### Why do In Vitro Testing?

In vitro biocompatibility analysis is a set of methods used to identify potential health hazards from a sample without the use of in vivo animal testing. The results of biological models in response to test samples help indicate the physiological outcomes that could occur during the real-world use of the product.

Traditional models that rely heavily on animal testing face ethical and stringent regulatory challenges. In vitro models offer a more humane, and cost-effective alternative. Thorough in vitro testing can help identify potential safety hazards during the earliest stages of product development, saving time and cost.

### Strengths of In Vitro Testing

- Rapid results
- Suitable for high throughput testing
- Economically and ethically favorable compared to animal (In Vivo) testing (helps fulfil the FDA's "3Rs approach" to replace, reduce, and/or refine animal testing)
- Less sample devices needed than with In Vivo
- Minimized presence of biological variables
- 3D tissues results include the effects of cell-cell interaction
- Several endpoints can be measured
- Customization of study details during early-stage sample development

### Ideal uses of In Vitro Testing

- Biocompatibility testing for regulatory submission
- Research & development of products and materials
- Impact of manufacturing and cleaning processes
- Design change testing
- Safety testing for consumer products and wearable technology
- Raw material screening
- Lot release testing

In Vitro Testing at EAG	
Cytotoxicity	MEM Elution
	Direct Contact
	Agar Diffusion
	Growth Inhibition IC <sub>50</sub>
Skin Irritation	EpiDerm™ RhE model
Skin Sensitization	
Genotoxicity	Micronucleus Assay (OECD 487)
	Ames Bacterial Reverse Mutation Assay (OECD 471)
Custom Assays	

	Cytotoxicity Assessment	Irritation Assessment
Determine the safety of a final product before market release	X	
Meet FDA regulations for medical devices	X	
Quality control of product batch variation	X	X
Determine if contaminants identified in chemical characterization are present at potentially cytotoxic dose	X	
Demonstrate that materials of construction are of the marketed biocompatible quality	X	X
Risk management measure for consumer product companies		X
Ensure cleaning processes used on the product do not leave irritating residues		X
Check that changes to the manufacturing process do not integrate irritants into the product		X
Evaluate the product after packaging to ensure shipping conditions/materials do not introduce irritants		X

## Why choose EAG Laboratories for In Vitro?

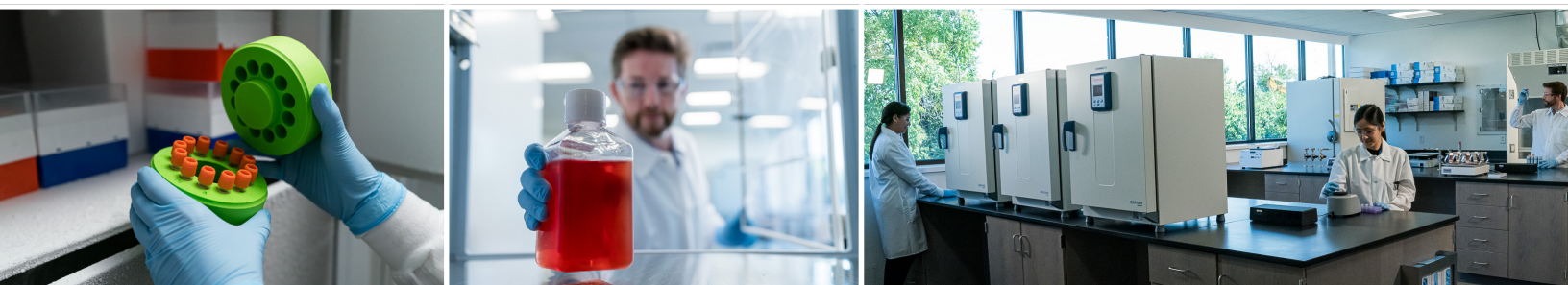
From R&D design screening to lot release and regulatory submission, manufacturers and suppliers are looking for in vitro testing that provides materials expertise with quick turnaround.

At EAG, our scientists approach in vitro testing from a different direction. As materials experts, we understand the technical aspects of the assays and the chemistry of materials. This allows us to offer a greater understanding of why a certain material failed an assay.

The team at EAG can customize our In-Vitro testing for complex devices. We understand the client's particular requirements and demands in order to produce high quality results.

## Reach out to our team for help with your In Vitro Biocompatibility Testing project.

Visit [EurofinsEAG.com](http://EurofinsEAG.com), call 1-800-366-3867, or talk with your EAG Account Manager.



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