

Cosmetic Application

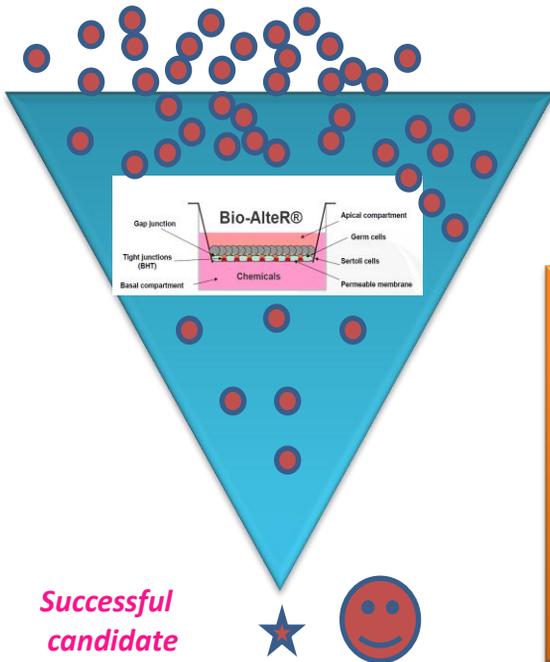
Background

Since March of 2013, European cosmetic products cannot be tested on animal for reproductive toxicity (the 7th amendment to the European Union's Cosmetics Directive). Non-animal *in vitro* alternative tests for the exploration have been developed and validated. Tests that address specific aspects such as embryotoxicity or endocrine disrupting effects of the overall reproductive system are helpful for investigating specific mechanisms of action. However, these models are often not fully reflective of physiological processes and need to be complemented with additional tests to accurately illustrate the overall reproductive function.

Kallistem has developed alternative *ex vivo* methods for assessing the effect of cosmetics on male fertility. Such alternative methods improves upon the physiological relevance of cell based assays, and simultaneously answers several key questions on aspects of male fertility.



FROM A SCREENING PLATFORM...



Bio-AlteR® adult or juvenile model

Blood testis barrier (BTB) integrity
Trans-epithelial resistance (TEER) measurement

✓ Modification of cell number populations
Cell viability and FACS analysis
Specific cell gene expression analysis
(6 different testicular cellular population and BTB components)

✓ Endocrine Disruptor effects
Specific cell gene expression analysis
(hormones & signalling pathway)
✓ Bio-AlteR® Sertoli Focus
✓ Sertoli cell culture / Leydig cell culture
(primary cells or cell line)

.....TO A MODE OF ACTION DETERMINATION

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Why is Bio-AlteR® the solution to testicular toxicity issues ?

- Bio-AlteR® is a **3D cell based assay unique on the market.**
- Bio-AlteR® is an ex vivo non animal alternative method which provides **reliable and validated safety data** on male fertility.
- Bio-AlteR® is prepared using animal tissue surgery waste from veterinary clinic or with **Human 3D cell culture** and it is therefore compliant with the EU cosmetic directive.
- Bio-AlteR® allows substance testing at **«physio-toxicological» concentrations.**
- Bio-AlteR® is a **medium throughput assay** allowing the testicular toxicity screening of a large number of compounds, (8 weeks in average between the compound reception and the data report sending).
- Bio-AlteR® provides a deep understanding of the **mechanisms of toxicity in male fertility.**
- Bio-AlteR® is a **cost effective** solution for reprotox studies during the REACH Process.