

IIVS Offering EpiSensA for Dermal Sensitization

We are thrilled to announce that IIVS is now offering the **EpiSensA (Epidermal Sensitization Assay)** as a GLP-compliant method in our sensitization testing portfolio. **EpiSensA** offers a reliable, human-relevant method for assessing skin sensitization potential, increasing our ability to provide New Approach Methodology (NAM) testing solutions that address industry challenges. EpiSensA quantifies the changes in the expression of genes associated with the activation of keratinocytes, corresponding to the key event 2 (KE-2) in the skin sensitization Adverse Outcome Pathway.

The **EpiSensA** analyzes the fold induction of four marker genes: ATF3, GCLM, DNAJB4, and IL-8, through qPCR and has received approval under OECD Test Guideline (TG) 442D. Utilizing a reconstructed human epidermis (RhE) model, this assay effectively assesses a broad spectrum of chemicals, including lipophilic and hydrophilic materials, pre-haptens, pro-haptens, and other previously difficult-to-test substances. IIVS will bring nearly 30 years of experience in the GLP-compliant testing of in vitro methods to this new option for our clients.

Additionally, we continue to make progress transferring the **GARD Skin assay** to our laboratory. This innovative genomic-based approach has been implemented into OECD TG 442E, adding yet another robust test option for the OECD TG 497, “2 of 3” Defined Approach for Skin Sensitization. Stay tuned for more updates as we push forward with more innovative testing capabilities.

Contact **Client Services** if you are interested in learning more about the EpiSensA.

EpiSensA



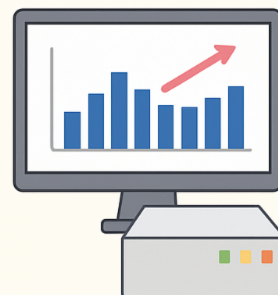
Chemical application



24-hour incubation



RNA extraction



Gene expression analysis

Image generated with DALL·E 3 via ChatGPT.



SAVE THE DATE: ToxTracker Hands-on Workshop at IIVS

Right before the ASCCT Meeting!
Registration opening soon.

Education and Training Update

In February of this year, IIVS scientists and study directors traveled to Ottawa, Canada and Sacramento, California to offer bespoke training workshops to pesticide authorities.

First, we collaborated with Health Canada Pest Management Regulatory Authority (PMRA) to design a two-day workshop covering standardized methods for skin and eye irritation and skin sensitization, provided a demonstration of the publicly available physiologically-based kinetic (PBK) tool QIVIVE Tools, and offered a look at



methods being developed for acute systemic toxicity, templates for interpreting advanced approaches such as 'omics, and methods for assessing systemic toxicity, with speakers from IIVS and other organizations.

Later that month, we worked with the Physicians Committee for Responsible Medicine to provide a similar workshop, tailored to the audience's needs, for the California EPA Department of Pesticide Regulation toxicology staff.

We have also held two Practical Methods Workshops. The January workshop hosted 10 regulatory scientists from US EPA. The May workshop hosted scientists from regulatory agencies, industry, and CROs in India, and was supported by PETA Science Consortium and Colgate.

Finally, IIVS President Amanda Ulrey led a course on quality assurance for NAMS with Mark Seaton from the US FDA at the Society for Quality Assurance in Orlando, FL on April 7th. The course provided an overview of GIVIMP principles, increasing understanding by QA professionals to ensure that NAMs are based on strong science and audits of NAMs are effective while navigating the complexities of in vitro methods.

If you would like to learn more about our bespoke training courses or regular Practical Methods workshops, [please contact us](#).



Recent Publications

- The Development of an Animal Product-free, Precision-cut Lung Slice Cryopreservation and Post-thaw Culture Method
- Defined approaches to predict GHS and EPA classifications for ocular irritation potential of agrochemical formulations
- Evaluation of a non-animal toolbox informed by adverse outcome pathways for human inhalation safety

IIVS-led Article Wins SOT Award

A recent paper co-authored by IIVS's Hans Raabe, Gertrude-Emilia Costin, and Kristie Sullivan was awarded the Cutaneous and Ocular Toxicology SOT Dermal Toxicology Specialty Section Best Paper Award.

The paper, titled "Human relevance of in vivo and in vitro skin irritation tests for hazard classification of pesticides", outlines the mechanisms of skin irritation, physiological features of human and animal skin, the characteristics, human relevance, benefits, and limitations of all available methods for assessing the skin corrosion and irritation potential of pesticide formulations.

Many thanks to Cutaneous and Ocular Toxicology for the recognition, and congratulations to our co-authors! Thanks to the Physicians Committee for Responsible Medicine, the paper is open-access [here](#).



IIVS Engaged in Validation Qualification Network Design

This year, the National Institutes of Health Complement-ARIE program is launching the design phase of the Validation Qualification Network, and IIVS is a founding partner in this public-private partnership organized by the Foundation for the National Institutes of Health (FNIH).

During the design phase, members of the network will determine the scope and goals of the efforts related to validation that Complement-ARIE will undertake, develop a governance structure and working groups, and create approach selection criteria. This will lead into implementation years 1 to 5, in which the effort will aim to fund validation studies for 4-8 approaches for defined use cases. The efforts will engage with NIH institutes and centers, the Food and Drug Administration (FDA), the Environmental Protection Agency, and other regulatory agencies, as well as academic laboratories to facilitate a more efficient process for the development, evaluation, and validation of new approaches.

Now Accepting Manuscripts!
Special Issue on NAMs for Skin Sensitization

IIVS' Toxicologists Dr. Gertrude-Emilia Costin and Dr. Argel Islas-Robles, are co-guest editing a Special Issue of the open-access MDPI journal *Toxics* (Impact Factor 3.9). The Special Issue, titled "Applicability of New Approach Methodologies (NAMs) to Skin Sensitization: Insights from Industry and Regulatory Perspectives," will focus on recent scientific and regulatory progress in the use of non-animal methods to assess skin sensitization potential.

This Special Issue provides a platform to showcase the implementation of in vitro, in chemico, and in silico methods, including defined approaches and integrated testing strategies aligned with the skin sensitization adverse outcome pathway (AOP). Submissions are encouraged that explore the use of NAMs across diverse sectors such as industrial chemicals, cosmetics, agrochemicals, wearable and medical devices, and botanical formulations. The guest editors also invite regulatory case studies, practical applications, and comparative evaluations of available test methods, as well as expert perspectives on the global regulatory landscape for NAM adoption and acceptance.

The goal is to highlight innovative science and practical experience that support the continued replacement, reduction, and refinement of animal testing through the use of scientifically advanced and human-relevant methodologies. Original research articles, reviews, short communications, and regulatory viewpoints are all welcome.

The submission deadline is December 31, 2025.

Find out more information, including how to submit a manuscript, [here](#).

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We Want to Hear From You

IIVS is always interested in the needs and requests from researchers interested in advancing the awareness, acceptance and use of alternative methods. If you have any input on methodologies of interest, please don't hesitate to contact us at clientservices@iivs.org.

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