CMDC Labs

IRRITATION TESTS

MAKING THE UNKNOWN KNOWN...

CMDC Labs, LLC I 105 S. Sunset St, STE O I Longmont I CO I 80501
info@CMDCLabs.com I +1 (720)-378-7387

Irritation studies gauge a device material's propensity for local irritation utilizing locations like the skin or mucous membranes, typically in an animal model. Although the exposure route (skin, eye, or mucosa) and duration of contact should be similar to the device's anticipated clinical use, it is often times beneficial to moderately exaggerate exposure conditions in order to provide patients with a margin of safety. At CMDC Labs, we can handle all your in vitro irritation testing needs.

The Intracutaneous Test

For this evaluation, the test material extracts and control materials are administered subcutaneously. Scores are given for erythema and edema at the injection sites (redness and swelling). Devices that are designed to communicate with the body or its internal fluids or externally are advised to follow this protocol. It accurately picks up the possibility of local discomfort brought on by chemicals that could be drawn out of a biomaterial.

The Primary Skin Irritation Test

Topical devices that come into contact with intact or breached skin should be subjected to the Primary Skin Irritation Test. In this process, the test material or material extract is directly injected into rabbit skin locations that are both intact and abraded. The substance is removed after 24 hours, and the locations are scored for erythema and edema.

Mucous Membrane Irritation Tests

These irritation tests are recommended for devices that will have external communicating contact with intact natural channels or tissues. These studies often use material extracts rather than the material itself. Some common procedures include vaginal, cheek pouch and eye irritation studies.