

The *In Vitro* Skin Sensitization Test Method EpiSensA Using the Human 3-Dimensional Cultured Tissue Model LabCyte EPI-MODEL24 Becomes an International Standard

Japan Tissue Engineering Co., Ltd. (Headquarters: Gamagori, Aichi Prefecture; President and CEO: Ken-ichiro Hata) is pleased to announce that the *in vitro* skin sensitization test method EpiSensA, which Kao Corporation has developed by using Japan Tissue Engineering's human 3-dimensional cultured tissue model LabCyte EPI-MODEL24, has been listed (standardized) in the Organization for Economic Cooperation and Development Test Guidelines (OECD TG442D)*1.

In vitro skin sensitization tests assess the risk of chemicals inducing skin allergies when they come into contact with the skin. In recent years, moves have been accelerating worldwide to use alternatives to animal testing in the research and development of cosmetics, chemicals, drugs, medical devices, agricultural chemicals, etc. Particularly, there is an immense need for sensitization tests to assess allergic reactions, and the market for these tests is expected to expand. EpiSensA, which uses LabCyte EPI-MODEL24, is an *in vitro* skin sensitization test method developed by Kao Corporation. It is a test method for evaluating skin sensitization potential of chemicals that has been recognized to meet the OECD TG442D criteria. It was the first time in the world for an *in vitro* skin sensitization test method using human 3-dimensional cultured tissue model to be standardized.

We develop, manufacture, and market regenerative medical products, such as autologous cultured epidermis and autologous cultured cartilage for medical use. Leveraging the technologies and know-how concerning cell culture and other applications that we have amassed through these activities, we provide the cultured human tissue for research use LabCyte (epidermal model and corneal model). The LabCyte series products are widely used because they reproduce a structure closely similar to the human tissue and can be utilized as alternatives to animal testing in safety tests during the development of cosmetics and other daily commodities. The *in vitro* skin irritation test and *in vitro* skin corrosion test methods using EPI-MODEL24 and the *in vitro* eye irritation test method using CORNEA-MODEL24 are listed in the OECD Test Guidelines*2.

We will continue to promote the use of alternatives to animal testing by providing the LabCyte series products and to support the development efforts of domestic and overseas manufacturers of daily commodities, drugs, cosmetics, chemicals, etc. that deal with a wide variety of chemical substances. We also aim to contribute to the further development of regenerative medicine and the improvement of the quality of life (QOL) of patients.

*1 The Organization for Economic Cooperation and Development Test Guidelines are intended for the Organization for Economic Cooperation and Development (OECD) to internationally standardize test methods to assess the properties and safety of chemicals. OECD TG442D describes a test method to assess the sensitization of chemicals by using a human skin model designed to closely resemble the biochemical and physiological characteristics of the human skin. For details, visit the website of the OECD.

*2 The *in vitro* skin irritation test using EPI-MODEL24 is listed in OECD TG439, and the *in vitro* skin corrosion test in OECD TG431. The *in vitro* eye irritation test using CORNEA-MODEL24 is listed in OECD TG492.

(Reference: About J-TEC)

J-TEC is a maker of regenerative medical products. Our vision is “Creating a Future for Regenerative Medicine”, and we have been a member of the Teijin Group since March 2021.

As the top runner in Japan’s regenerative medicine industry, we provide a stable supply of regenerative medical products, and of the regenerative medical products that have been approved in Japan, the following five are J-TEC products.

- ü Approved Oct. 2007: Autologous Cultured Epidermis JACE®
– Japan’s first regenerative medical product
- ü Approved July 2012: Autologous Cultured Cartilage JACC®
– Japan’s first regenerative medical product in the orthopedics field
- ü Approved March 2020: Autologous Cultured Corneal Epithelium NEPIC®
– Japan’s first regenerative medical product in the ophthalmology field
- ü Approved June 2021: Autologous Cultured Oral Mucosal Epithelium OCURAL®
– The world's first regenerative medical product using oral mucosal epithelial cells
- ü Approved March 2023: Autologous Cultured Epidermis Maintaining Melanocytes JACEMIN.
– Second regenerative medical product in Japan in the skin field

Please visit www.jp-te.com/en/

[Contact information for inquiries about this announcement]

Japan Tissue Engineering Co., Ltd.

E-mail. jtec-info@jp-te.com