

Launch of Contract Testing Services for Skin Sensitization Tests Using Animal Testing Alternatives

Japan Tissue Engineering Co., Ltd. (Headquarters: Gamagori, Aichi; President: Kenichiro Hata; hereinafter "J-TEC") will start a contract testing service from April 2025, in collaboration with an external contract testing organization for "EpiSensA", a skin sensitization testing method*, that uses our alternative to animal testing product "LabCyte". We will collaborate with the Teijin Structural Analysis Center of our parent company, Teijin Co., Ltd. (Hino City, Tokyo) as our first partner to expand the sales of "LabCyte" by increasing the range of applications for the testing method "EpiSensA" which is growing in demand as an alternative to animal testing.

* Test method to detect chemical substances that may induce allergies when chemical substances come into contact with the skin

1. Background and Rationale

- (1) In the development of pharmaceuticals and cosmetics, experiments on animals have been conducted to estimate the effects of chemicals on humans before clinical trials. However, in recent years, due to the concerns about the accuracy of results obtained from animal testing, there has been a global shift toward alternative testing methods for drug development. In particular, from an animal welfare perspective, laws banning animal testing have been enacted mainly in Europe.
- (2) In response to this trend, J-TEC has developed a three-dimensional human culture tissue that has been reconstructed by culturing human skin and corneal cells using regenerative medicine technology. Since 2005, we have been manufacturing and selling the "LabCyte" series of human cultured tissues for research to assess the effects of chemical substances on the human body, and currently have the top market share for cellular products used as alternatives to animal testing in Japan.
- (3) "EpiSensA" is a skin sensitization test method developed by Kao Corporation that does not use animals. This test method is a test to evaluate the risk of inducing skin allergies, and uses the "LabCyte EPI-MODEL 24", which is a three-dimensional culture of human skin cells. In 2024, it will be the first in the world to be included in the Organization for Economic Co-operation and Development's (OECD) test guidelines as a skin sensitization test method using 3D cultured epidermis, and it will be recognized as a global standard test method.
- (4) On the other hand, in order to implement "EpiSensA", it requires the introduction of specialized analytical instruments and technical training for test personnel. As a result, compared to other tests, the hurdles for conducting the test are high, making it difficult to start testing quickly.
- (5) J-TEC has been exploring the creation of an environment using an external contract testing

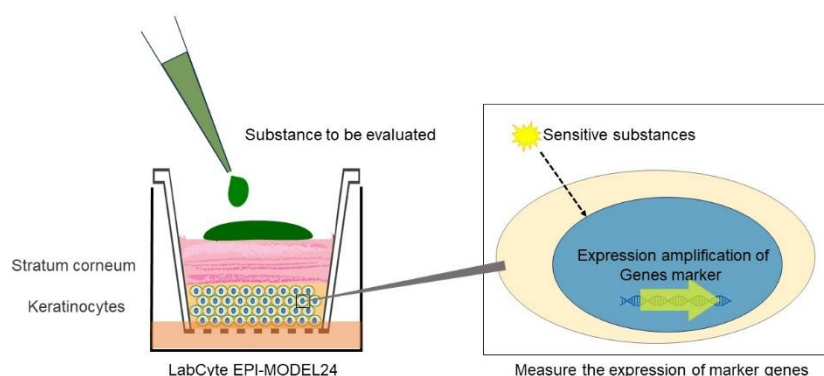
organization to solve these problems and further expand the use of “EpiSensA”, an excellent test method. The Teijin Structural Analysis Center, which has been in charge of structural analysis of material products at its parent company, Teijin, has sufficient resources for the equipment and human resource training required for “EpiSensA”, so we have decided to start a contract testing services in collaboration.

2. Future Outlook

- (1) J-TEC will establish a testing framework for “EpiSensA” at Teijin’s Structural analysis Center and launch contract testing services for external pharmaceutical and cosmetics companies starting in April 2025.
- (2) By establishing an outsourced environment for “EpiSensA” and lowering the barriers to use, we will establish positioning as a standard test method for skin sensitization of topical drugs and cosmetics, and contribute to providing safer and more reliable products for users.
- (3) In the future, we will develop an ordering service for alternative test methods other than "EpiSensA" in cooperation with testing agencies, aiming to expand sales of the "LabCyte" series and spread alternative methods to animal testing.
- (4) As a pioneer in regenerative medicine in Japan, J-TEC remains committed to leveraging its cutting-edge technologies to address unmet medical needs worldwide. The company continues to strive towards its vision of creating a future for regenerative medicine.



LabCyte EPI-MODEL (Reconstructed Human Epidermis)



Test image of “EpiSensA”

[Contact information for inquiries about this announcement]

Japan Tissue Engineering Co., Ltd.

E-mail. jtec-info@jpte.co.jp