

**Eye Irritancy Testing Method using “LabCyte CORNEA-MODEL24”
Human 3-Dimensional Cultured Corneal Epithelium Included in OECD Test Guideline**

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Japan Tissue Engineering Co., Ltd.

An eye irritancy method using human 3-dimensional cultured corneal epithelium “LabCyte CORNEA-MODEL24”, developed by Japan Tissue Engineering Co., Ltd. (a Fujifilm Group company; President: Ken-ichiro Hata, “J-TEC”, hereafter) has been included in Organisation for Economic Co-operation and Development Test Guideline 492 (OECD TG492*).

J-TEC will be proposing safety testing with “LabCyte CORNEA-MODEL24” as a more reliable alternative to animal testing methods for corporations that handle a broad array of chemical substances, such as makers of commodities, pharmaceuticals, cosmetics, and chemicals.

J-TEC manufactures and markets products such as autologous culture epidermis, Japan’s first regenerative medical product. It is also developing the human cultured tissue “LabCyte Series” for use in research, by drawing the cell culture technology and knowhow it has accumulated.

The “LabCyte Series” is a lineup of tissue models from cultured human cells that can be used in research. It includes skin and corneal epithelial models. The “LabCyte” series is widely used because it reconstructs a structure that is extremely close to that of human tissue and can substitute for animal testing for cosmetic and commodity development, etc. In particular, “LabCyte CORNEA-MODEL24”, a model of the corneal epithelium, is used in eye irritancy testing for chemical substances contained in commodities such as shampoos and hair dyes, as well as in eye drops.

Through validation studies conducted by the Japanese Society for Alternatives to Animal Experiments and the Japanese Center for the Validation of Alternative Methods, as well as third-party evaluations, an eye irritancy testing method using “LabCyte CORNEA-MODEL24” has been found to meet OECD TG492 criteria as a method for evaluating the eye irritancy of chemical substances.

* The OECD Test Guideline was developed by the Organisation for Economic Co-operation and Development to create common international guidelines for testing methods for the evaluation of the properties and safety of chemical substances. OECD TG492 is a testing method that uses a human corneal epithelium model designed to be extremely similar to human corneal epithelium in biochemical and physiological properties, to evaluate the eye irritancy of chemical substances. For details, please refer to the website of the OECD (English language).

For inquiries on information in this media release, contact:

Japan Tissue Engineering Co., Ltd.

Corporate Planning Department, Corporate Management Division

TEL :+81-533-66-2020