iLite® HER2 (+) Target Assay Ready Cells

REF: BM5011

For research use only. Not for use in diagnostic procedures.

DESCRIPTION

iLite® HER2 (+) Target Assay Ready Cells are based on a human embryonic kidney cell line, HEK293[1] (ATCC# CRL-1573), and have been genetically engineered and optimized to express high and constant levels of the surface antigen HER2. The cells are to be use as target cells together with *iLite*® ADCC Effector (V) Assay Ready Cells for measuring the ADCC activity of anti-HER2 antibodies.

CONTENT

>250 µL of *iLite*® Assay Ready Cells suspended in cryoprotective medium from Gibco (cat no 12648-010).

RECEIPT AND STORAGE

Upon receipt confirm that adequate dry-ice is present, and the cells are frozen. Immediately transfer to -80°C storage. Cells should be stored at -80°C **(do not store at any other temperature)** and are stable as supplied until the expiry date shown. Cells should be used within 30 min of thawing.

BACKGROUND

Antibody-dependent cell-mediated cytotoxicity (ADCC) is a mechanism whereby pathogenic cells are lysed by lymphocytes, most often Natural Killer (NK) cells. The mechanism involves binding of antibodies to surface antigens on the pathogen. Crosslinking of these antibodies to NK cells through the binding of the Fc-portion to Fc receptors on the NK cells leads to activation of the NK cell and formation of an immune synapse with the pathogenic cell. The NK cell releases cytotoxic granules containing granzymes and perforin into the synapse, leading to apoptosis of the targeted cell (1).

Breast cancer is the most common cancer in women worldwide, and the second most common cancer overall. Survival rates have improved in the recent years, and stratification of patients into subgroups has vastly improved treatment options for many patients. As an example, patients with HER2 positive breast cancer generally have a poor prognosis, but treatment with trastuzumab, a monoclonal antibody targeting the HER2 receptor, has shown to increase both overall survival and disease-free survival when given together with chemotherapy (2). Trastuzumab's mechanism of action is mediated in part by inducing ADCC when crosslinking HER2 positive cells with the patient's immune cells. The drug was FDA approved for treatment of breast cancer patients in 1998, and many biosimilars are currently in development (3, 4).

[1] The HEK-293 cell line has been used under a license obtained from AdVec Inc.

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APPLICATION

The *iLite*® HER2 (+) Target Assay Ready Cells can be used together with *iLite*® ADCC Effector (V) and *iLite*® HER2 (-) Target Assay Ready Cells for the quantification ADCC activity of anti-HER2 antibodies. Application notes for the following assays are available:

- Quantification of anti-HER2 ADCC activity (LABEL-DOC-0402)

RELATED PRODUCTS

REF	Product name
BM5001	*iLite*® ADCC Effector (V) Assay Ready Cells
BM5016	*iLite*® HER2 (-) Target Assay Ready Cells
BM5090	*iLite*® anti-HER2 ADCC Activity Set

REFERENCES

1. Weiner GJ. *Building better monoclonal antibody-based therapeutics.* Nat Rev Cancer 15: 361-70 (2015)
2. Advani PP, Ballman KV, Dockter TJ, Colon-Otero G, Perez EA. *Long-Term Cardiac Safety Analysis of NCCTG N9831 (Alliance) Adjuvant Trastuzumab Trial.* J Clin Oncol, 34(6):581-7, (2016)
3. Vu T., & Claret, F.X. *Trastuzumab: Updated Mechanisms of Action and Resistance in Breast Cancer*. Frontiers in Oncology 2:62 (2012).
4. Rugo HS, Linton KM, Cervi P, Rosenberg JA, Jacobs I. *A clinician's guide to biosimilars in oncology*, Cancer Treat Rev, 46:73-79, (2016)

SYMBOLS ON LABEL

LOT	Lot number		Temperature limitation
REF	Catalogue number		Biological risk
	Use by		Manufacturer

PRECAUTIONS

For research use only. This product is intended for professional laboratory research use only. The data and results originating from using the product, should not be used either in diagnostic procedures or in human therapeutic applications.

iLite® HER2 (+) Target Assay Ready Cells are a stable transfected cell line of human origin classified as a Class 1 Genetically Modified Microorganism. This is based on the conclusion that neither insert nor vector adds anything to the biosafety level since the cells cannot produce active virus. They should be handled in accordance with EU regulations (2009/41/EC) and disposed of in a licensed contained-use facility in accordance with these regulations. When used in accordance with the manufacturer's product specification, the requirements of EC Directive 2009/41/EC on the contained-use of genetically modified microorganisms are deemed to have been met.

Residues of chemicals and preparations generally considered as biohazardous waste and should be inactivated prior to disposal by

autoclaving or using bleach. All such materials should be disposed of in accordance with established safety procedures.

PROPRIETARY INFORMATION

In accepting delivery of *iLite*® Assay Ready Cells the recipient agrees not to sub-culture these cells, attempt to sub-culture them or to give them to a third party, and only to use them directly in assays. *iLite*® cell-based products are covered by patents which is the property of Svar Life Science AB and any attempt to reproduce the delivered *iLite*® Assay Ready Cells is an infringement of these patents.

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