

***iLite*[®] HER2 (-) Target Assay Ready Cells**

REF: BM5016

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, HEK293¹ and have been genetically engineered and any expression of surface antigen HER2 depleted. The cells are to be used as negative controls (-) of the positive (+) Target Assay Ready Cells for measuring the ADCC or ADCP activity of anti-HER2 antibodies together with *iLite*[®] ADCC Effector (V) Assay Ready Cells or with *iLite*[®] ADCP Effector Assay Ready Cells, respectively.

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 or at lower temperature and are stable as supplied until the expiry date shown. Cells should be diluted and plated immediately after thawing.

BACKGROUND

The immune system uses various mechanisms to kill specific pathogens, infected cells, and cancer cells. Therapeutic antibodies act by binding to a cell surface receptor by the Fab domain resulting in induction/blocking of signaling events. However, Fc engineering strategies to increase the efficacy of anti-cancer antibodies are ongoing (1). The Fc-part of the antibody is involved in inducing antibody-dependent cellular cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), complement-dependent cytotoxicity (CDC), and programmed cell death (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 and ADCP when crosslinking HER2 positive cells with the patient's immune cells. Trastuzumab 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.

APPLICATION

The *iLite*[®] HER2 (-) Target Assay Ready Cells can be used together with *iLite*[®] ADCC Effector (V), *iLite*[®] ADCP Effector and *iLite*[®] HER2 (+) Target Assay Ready Cells for the quantification ADCC and ADCP activity of anti-HER2 antibodies.

Application notes for the following assays are available:

- Quantification of anti-HER2 ADCC activity (LABEL-DOC-0402)
- Quantification of anti-HER2 ADCP activity (LABEL-DOC-0584)

RELATED PRODUCTS

REF	Product name
BM5001	<i>iLite</i> [®] ADCC Effector (V) Assay Ready Cells
BM5004	<i>iLite</i> [®] ADCP Effector Assay Ready Cells
BM5011	<i>iLite</i> [®] HER2 (+) Target Assay Ready Cells

REFERENCES

1. Liu R, Oldham RJ, Teal E, Beers SA, and Cragg MS. *Fc-Engineering for Modulated Effector Functions—Improving Antibodies for Cancer Treatment*. *Antibodies*. 9(4):64 (2020)
2. Advani PP, Ballman KV, Dockett TJ, Colon-Otero G, Perez EA. *Long-Term Cardiac Safety Analysis of NCCTG N9831 (Alliance) Adjuvant Trastuzumab Trial*. *J Clin Oncol*. 2015;34(6):581–7
3. Valabrega G, Montemurro F, Aglietta M. *Trastuzumab: mechanism of action, resistance, and future perspectives in HER2-overexpressing breast cancer*. *Ann Oncol*. 2007;18(6):977–84.
4. Petricevic B, Laengle J, Singer J, Sachet M, Fazekas J, Steger G, et al. *Trastuzumab mediates antibody-dependent cell-mediated cytotoxicity and phagocytosis to the same extent in both adjuvant and metastatic HER2/neu breast cancer patients*. *J Transl Med*. 2013;11(1):307

SYMBOLS ON LABEL

	Lot number		Temperature limitation
	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 directive (2009/41/EC) and disposed of in a licensed contained-use facility in accordance with these regulations. When used in

PROPRIETARY INFORMATION

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.

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.