

10-2002: Recombinant anti-human ErbB2/HER2 Antibody (Trastuzumab)

Clonality :	Monoclonal
Clone Name :	ABM2A1G1
Application :	Functional Assay, FACS
Reactivity :	Human
Gene :	ERBB2
Gene ID :	2064
Uniprot ID :	P04626
Format :	Purified
Alternative Name :	ERBB2; v-erb-b2 erythroblastic leukemia viral oncogene homolog 2, CD340; HER 2; HER2; NEU; herstatin; p185erbB2; proto-oncogene Neu; c-erb B2/neu protein; proto-oncogene c-ErbB-2.

Description

Target: ErbB2

Trade name: Samceptin,

Generic name: Trastuzumab

Product Origin: Recombinant in CHO cells

Product Construction: Immunoglobulin G1, anti-(human p185neu receptor) (human-mouse monoclonal rhuMab HER2 g1-chain), disulfide with human-mouse monoclonal rhuMab HER2 light chain, dimer. The drug Trastuzumab (Brand name Herceptin®, From Roche/Genentech) is a monoclonal antibody and works by targeting breast cancer cells that overexpress the HER2 protein. Overexpression (or amplification) of the HER2 protein is associated with accelerated cell division. By binding to the protein receptors on these cells, Trastuzumab interrupts the growth signal, thereby slowing the growth and spread of tumours. Approximately 20% of breast cancers overexpress the HER2 protein. Amplification of HER2 in breast cancer cells has been correlated with adverse prognostic factors such as large tumour size, high nuclear grade, and decreased expression of estrogen and progesterone hormone receptors. HER2 amplification has also been associated with reduced disease free survival, and overall survival, for women with node positive or node negative disease. Trastuzumab (anti-p185, rhuMab HER2), which is a humanised monoclonal antibody that binds to the HER2 protein. HER-2 is a transmembrane spanning receptor-like protein, which is structurally related to the epidermal growth factor receptor and has been shown to inhibit the proliferation of human tumor cells that overexpress HER2 both *in vitro* and *in vivo*.

The developed biosimilar to Herceptin, designated as Samceptin. The biochemical characterizations and the functional assays suggest that Samceptin is highly similar in structure and activity to Herceptin.

**Disclaimer: Herceptin® is a registered trade mark of Genentech, Inc. Samceptin can only be used for research purposes. Not to be used as diagnostic for therapeutic purposes.*

Product Info

Amount :	500ug / 100 µg
Purification :	Purity: >98.0% as determined by SEC-HPLC & SDS-PAGE.
Content :	In Trehalose, Histidine, Histidine-HCl, Tween-20
Storage condition :	Store the antibody at 4°C, stable for 6 months. For long-term storage, store at -20°C. Avoid repeated freeze and thaw cycles.
Amino Acid :	PepMap Analysis of N terminal amino acids sequence: H chain: EVQLVESGGGLVQPG, L chain: DIQMTQSPSSLSASV

Application Note

The biological activities of Samceptin was compared with commercially available innovator drug, Herceptin from Roche.

Recommended dilutions: FACS: 1-2 $\mu\text{g}/10^6$ cells, ADCC: 20-25 mg/ml. However, this need to be optimized based on the research applications.

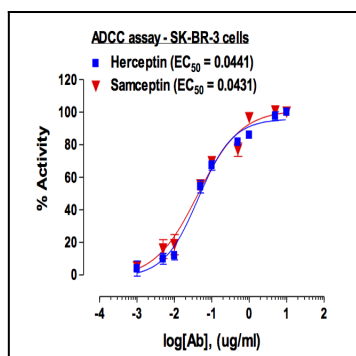


Figure-1: Antiproliferative activity of Samceptin was assayed in comparison with Herceptin using ADCC Reporter Bioassay Kit from Promega (Cat #G7010) in SK-BR-3 cells. Result indicated that Samceptin potency is at par with Herceptin.

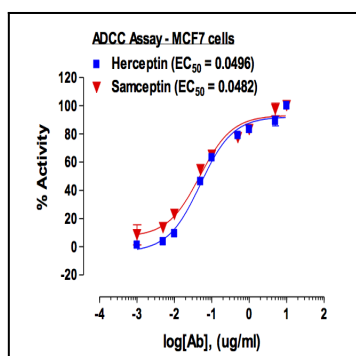


Figure-2: Antiproliferative activity of Samceptin was assayed in comparison with Herceptin using ADCC Reporter Bioassay Kit from Promega (Cat #G7010) in MCF-7 cells. Result indicated that Samceptin potency is at par with Herceptin.

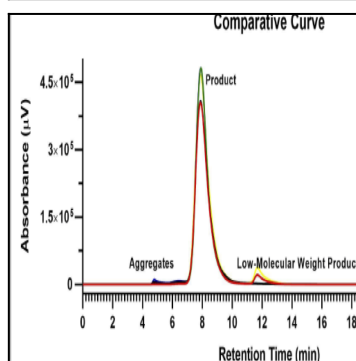


Figure-3: SEC-HPLC analysis of Herceptin and Samceptin. Based on this analysis, Samceptin is highly pure and purity estimated to be >98%

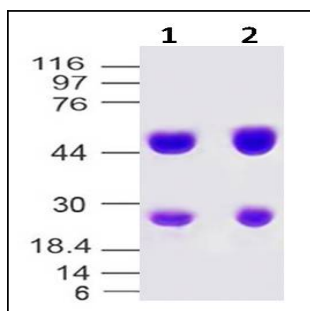


Figure-4: Reducing SDS-PAGE of Samceptin (Lane-1) in comparison with Herceptin (Lane-2). Lanes were overloaded to show the presence of any other protein bands than Samceptin. Both heavy and light chains are well separated.

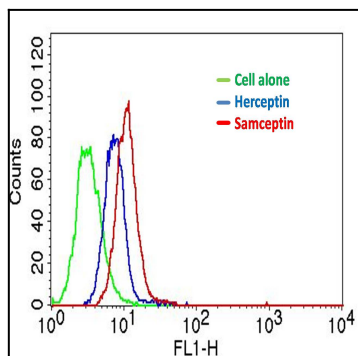


Figure-5: Epitope binding study by flow cytometric analysis. BT-474 cells expressing HER2 antigen were treated with Herceptin and Samceptin (2 μ g/ 10^6 Cells). Surface staining was done using FITC conjugated antibodies.

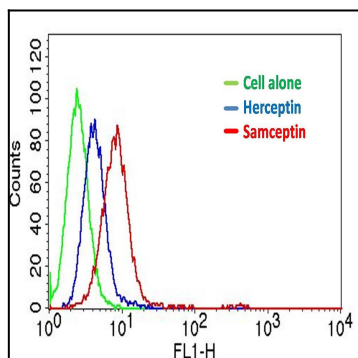


Figure-6: Epitope binding study by flow cytometric analysis. MCF-7 cells expressing HER2 antigen were treated with Herceptin and Samceptin (2 μ g/ 10^6 Cells). Surface staining was done using FITC conjugated antibodies.