Leinco Technologies, Inc.
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Human CD22 (Inotuzumab) Antibody

Purified No Carrier Protein

Biosimilar Recombinant Human Monoclonal Antibody

Product Information

Product No.:	C1010
Clone:	G5/44
Isotype:	Human IgG4κ
Storage:	Sterile 2° to 8°C

Product Description

Specificity:
This non-therapeutic biosimilar antibody uses the same variable region sequence as the therapeutic antibody Inotuzumab but is not covalently linked to Calich-DMH. Inotuzumab specifically recognizes CD22 on human B cells but not on murine, rat, canine, porcine, or primate (cynomolgus and rhesus) B cells. This product is for research use only.

Antigen Distribution:
CD22 is expressed on the surface of mature B lymphocytes and their malignant counterparts. CD22 is expressed in the cytoplasm of pro-B and pre-B cells, with surface expression increasing in maturing B cells. CD22 expression is lost as B cells mature to plasma cells.

Background:
N-acetyl-γ-calicheamicin is a potent, natural cytotoxic agent produced by Micromonospora echinospora that induces double-strand DNA breaks and apoptosis in rapidly proliferating cells, independent of cell cycle progression, and is therefore also of interest as a chemotherapeutic agent[2]. The semisynthetic derivative N-acetyl-γ-calicheamicin dimethyl hydrazide (Calich-DMH; calicheamicin) is used as an enediyne antitumor antibiotic in CD22-based chemotherapy[3].

Inotuzumab is composed of humanized CD22-directed monoclonal antibody G5/44 covalently attached to Calich-DMH via an acid-cleavable linker[2, 4, 5, 6]. The acetyl butyrate linker attaches via an amide bond to surface-exposed lysines of G5/44 and is further stabilized by two methyl groups[2]. When Inotuzumab binds CD22-expressing tumor cells, the inotuzumab-CD22 complex is rapidly internalized and the acidic intracellular environment triggers the release of Calich-DMH[6, 7]. Calich-DMH then binds to the minor groove of DNA, undergoes a structural change in its enediyne moiety that generates diradicals, and induces double-strand DNA breakage, cell cycle arrest and apoptosis[2].

Humanized G5/44 was derived from murine m5/44 by grafting the complementarity-determining regions plus key framework residues onto human acceptor frameworks and then expressing in Chinese hamster ovary cells[4, 5]. The CD22-specific targeting antibody G5/44 carries a S229P mutation in its hinge region that allows it to form stable interchain disulfide bonds and removes the potential for Fab exchange with natural IgG4[5].

Inotuzumab has been approved for the treatment of some patients with CD22-positive B-cell precursor acute lymphoblastic leukaemia[6].

This research-grade biosimilar is not covalently bound to Calich-DMH.

Known Reactivity Species:
Human

Expression Host:
HEK-293 Cells

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Format:
Purified No Carrier Protein

Immunogen:
Human CD22

Formulation
This biosimilar antibody is aseptically packaged and formulated in 0.01 M phosphate buffered saline (150 mM NaCl) PBS pH 7.2 - 7.4 with no carrier protein, potassium, calcium or preservatives added. Due to inherent biochemical properties of antibodies, certain products may be prone to precipitation over time. Precipitation may be removed by aseptic centrifugation and/or filtration.

Purity
≥95% by SDS Page, ≥95% monomer by analytical SEC

Endotoxin
< 1.0 EU/mg as determined by the LAL method

Storage and Stability
Functional grade preclinical antibodies may be stored sterile as received at 2° to 8°C for up to one month. For longer term storage, aseptically aliquot in working volumes without diluting and store at ≤ -70°C.

Avoid Repeated Freeze Thaw Cycles

Product Preparation
Recombinant biosimilar antibodies are manufactured in an animal free facility using only in vitro protein free cell culture techniques and are purified by a multi-step process including the use of protein A or G to assure extremely low levels of endotoxins, leachable protein A or aggregates.

Pathogen Testing
To protect mouse colonies from infection by pathogens and to assure that experimental preclinical data is not affected by such pathogens, all of Leinco's recombinant biosimilar antibodies are tested and guaranteed to be negative for all pathogens in the IDEXX IMPACT I Mouse Profile.

Other Applications Reported in Literature:
ELISA

Country of Origin
USA

References
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