

Biosimilar Antibodies for Research Use

Biosimilar antibodies for research use to complement our most popular anti-biotherapeutic antibodies

Studying the biological effects of a drug or doing proof of concept ligand binding assay development for large molecule biotherapeutics requires a source of the drug, for instance, for use in cell based assays or as a calibration standard in a pharmacokinetic (PK) assay. However, it can be challenging to source original pharmaceutical grade biotherapeutic drugs (also known as reference products) for research use, rather than for use in a clinical application.

Bio-Rad's non-therapeutic biosimilar antibodies for research use enable fast and inexpensive assay development. They avoid the need to use a therapeutic reference product, which can be expensive and only available in large quantities.

Table 1. Biosimilar research antibodies.

Biotherapeutic Antibody	Antibody Specificity	Biosimilar (Catalog #)
Adalimumab	Human Anti-TNF alpha	MCA6141
Alemtuzumab	Human Anti-CD52	MCA6101
Arcitumomab	Human Anti-Carcinoembryonic Antigen	MCA6094
Bevacizumab	Human Anti-VEGF	MCA6089
Brentuximab	Human Anti-CD30	MCA6149
Cetuximab	Human Anti-EGFR	MCA6102
Eculizumab	Human Anti-C5	MCA6145
Infliximab	Human Anti-TNF alpha	MCA6090
Natalizumab	Human Anti-Integrin Alpha 4	MCA6104
Omalizumab	Human Anti-IgE	MCA6105
Rituximab	Human Anti-CD20	MCA6091
Satumomab	Mouse Anti-Tumor Associated Glycoprotein 72	MCA6093
Tocilizumab	Human Anti-IL6R	MCA6106
Trastuzumab	Human Anti-ErbB2	MCA6092

Each biosimilar research antibody, produced using a recombinant platform, incorporates the publicly available sequence of the variable region (specificity) of the original monoclonal antibody drug. These biosimilar products are supplied in research grade format, in PBS buffer with preservative; they are not

manufactured or formulated in the same way as the therapeutic reference product. A comparison of these antibodies with their respective therapeutic reference products was carried out to show biosimilarity (Figures 1 and 2).

Purity and Monodispersity

All of our biosimilar research antibodies show comparable purity and monodispersity with the reference product. Purity was measured by band quantification of a Coomassie stained SDS-PAGE gel; monodispersity was compared using size exclusion chromatography (SEC). Example data for Anti-TNF Alpha Antibody and adalimumab are shown in Figures 1a and 1b. (Detailed comparison data for each antibody with its reference product is available on bio-rad-antibodies.com)

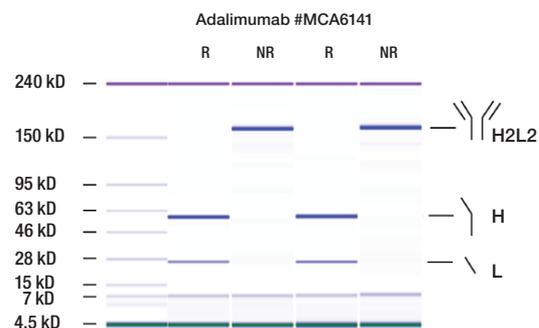


Fig. 1a. Anti-TNF Alpha Antibody (Cat. #MCA6141) and adalimumab (therapeutic reference product) were denatured and analyzed under reducing (R) and nonreducing (NR) conditions. Bands were visualized using Coomassie staining. Full IgG (H2L2), heavy (H), and light chains (L) are indicated.



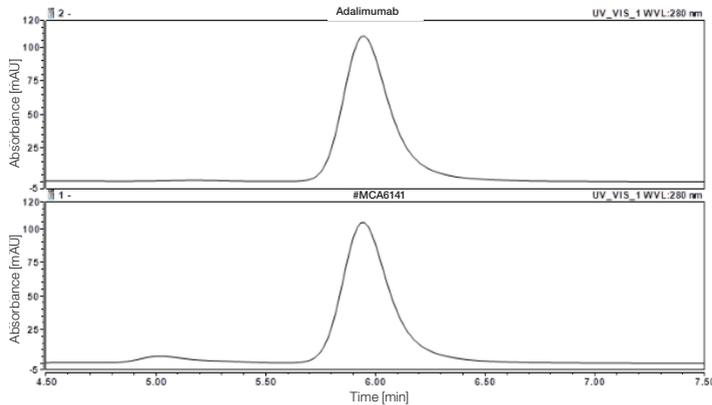


Fig. 1b. SEC of adalimumab (top) and Anti-TNF alpha Antibody (#MCA6141, bottom) was performed on an analytical HPLC instrument. Monomer peaks (H2L2), calculated relative monomer portion and aggregates are shown.

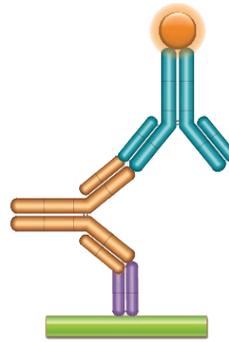


Fig. 2a. Schematic image of PK bridging ELISA. Anti-idiotypic capture antibody, Fab format (purple); monoclonal antibody, reference product or research biosimilar (gold); anti-idiotypic detection antibody, Ig format (blue), labeled with HRP.

Performance in Pharmacokinetic (PK) Bridging ELISA

In Figure 2b, a microtiter plate was coated overnight with Human Anti-Adalimumab Antibody clone AbD18654 (#HCA202) at a concentration of 1 µg/ml. After washing and blocking with PBST + 5% BSA, 10% human serum was added spiked with increasing concentrations of adalimumab (therapeutic reference product; red squares) or Human Anti-TNF alpha Antibody (#MCA6141, adalimumab biosimilar research grade; black circles). Detection was performed using HRP conjugated Human Anti-Adalimumab Antibody, clone AbD18654_hlgG1 (#HCA203) at a concentration of 2 µg/ml in HISPEC Assay Diluent (#BUF049A) and QuantaBlu Fluorogenic Peroxidase Substrate. Data are shown as the mean of three measurements. HRP conjugation of the antibody used in this assay was performed using a LYNX Rapid HRP Antibody Conjugation Kit (#LNK001P-LNK006P).

For in vitro research purposes only. Research grade biosimilar. Not for use in therapeutic or diagnostic procedures for humans or animals.

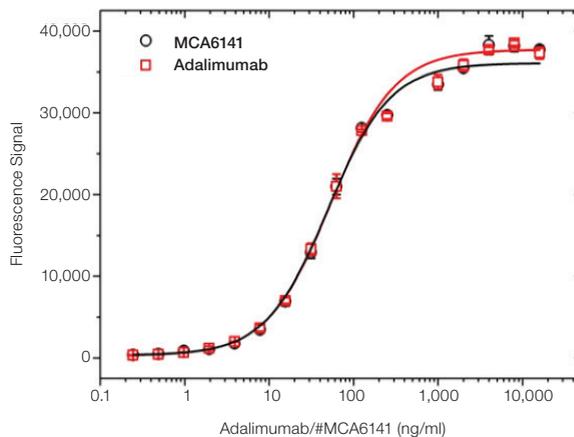


Fig. 2b. Adalimumab bridging ELISA for PK assay development.

Visit bio-rad-antibodies.com for more information.

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