Quick Guide to the Use of Custom HuCAL® Recombinant Antibodies

The following information describes how you can use custom antibodies generated from the HuCAL® recombinant monoclonal antibody service. This information is intended as an informal guide. Bio-Rad Terms and Conditions (T&C) are available on request and define the use of custom HuCAL antibodies in detail. The T&C are included in a formal quotation for a custom project.

Use of the antibody
The antibody, any part of it or any recombinant molecule derived from it, may be used for your internal in vitro research purposes without any further license from Bio-Rad GmbH.

HuCAL antibodies are not intended for use in humans, and may not be used for therapeutic, prophylactic or palliative purposes.

Sharing the antibody with collaborators and third parties
Before sharing the antibody with a collaborator or other third party outside your organization, and/or allowing a collaborator or third party to order the custom antibody from Bio-Rad for their internal in vitro research use, contact us to agree this in writing. The use of the antibody by the collaborator or third party remains subject to the T&C.

When is an additional license needed?
- Clinical Monitoring: If the antibody is to be used in a clinical setting for the purpose of patient screening or monitoring of a therapeutic product or drug, a Clinical Monitoring License is required. The license must be in place when the first clinical trial begins.
- Diagnostics: If the antibody is used as a component in an in vitro diagnostic (IVD) assay and the IVD assay becomes FDA approved, CE marked or other equivalent diagnostic approval, an In Vitro Diagnostic License is required.
- Selling the antibody: If the antibody is to be commercialized, i.e. made available for customers to buy, a Commercialization License is required before the product is launched. The antibody must be sold for in vitro research purposes only.

Antibody clone and sequence
The custom HuCAL technology generates recombinant Fab antibodies and fully human immunoglobulins in vitro, without the immunization of animals. With traditional custom monoclonal antibody generation in animals, the product received is typically a hybridoma cell line. In the case of the custom HuCAL service, the main product received is purified recombinant antibody.

The unique Fab antibody DNA sequence and amino acid sequence are also available to you on request (light chain, Fd chain and tags). Using the sequence information you may produce the antibody at your facility for your internal use. The use of the antibody, any part of the original antibody or any other recombinant molecule derived from it, remains subject to the T&C and licenses.

You are responsible for obtaining any additional intellectual property rights that may be required for production and use of your antibody.

Intellectual property rights
All intellectual property (IP) rights arising from the permitted uses of the antibody are owned by you. IP may be generated on the use of the antibody in your application. IP cannot be claimed on the antibody sequence itself because you are not the inventor of the antibody sequence. All uses of the antibody remain subject to the T&C.

Antibodies of the same specificity
Bio-Rad has the right to generate antibodies against any target for itself or for a third party, provided that these antibodies are made independently, without the use of any antigen materials supplied to us by a customer or made by us for any customer’s custom project.

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