

# **DIARECT Antigens - FAQs\***

September 2020

\*This FAQ sheet refers only to the products supplied directly by DIARECT GmbH. For information about our other antigen products please see 'Antigens' FAQ sheet

# How do I order DIARECT products through BBI Solutions?

For our European customers please contact your BBI sales representative or reach out to our customer services team. For our US and Asia customers you can also contact your BBI representative for support however sales enquiries, where relevant, will be routed through a local representative. In the US for DIARECT catalogue products, these should be ordered from our US distribution partner Surmodics.

### How should I handle antigens / antibodies upon receipt?

Upon receipt, our antigens / antibodies should be stored frozen at - 70°C or below until use. We recommend thawing at room temperature, but thawed products should not remain at room temperature for extended periods of time. Mix products gently before use. If you plan on using only a portion of the product, please thaw and dispense it into aliquot volumes that are most practical for your application and store frozen at - 70°C or below. Please note that we cannot guarantee the shelf life after the antigens / antibodies have been re-dispensed and advice against repeated freeze thaw cycles.

#### What buffer is recommended for antigen / antibody storage?

While general recommendations for antigen / antibody storage conditions and buffers are given in the antigen's / antibody's specification sheet, which can be found in the "+INFO" section associated with each antigen / antibody on DIARECT's website, the detailed buffer composition is available together with the lot-specific Certificate of Analysis (CoA).

### Can I use antigens / antibodies that arrive unfrozen?

No, we do not recommend using antigens / antibodies without a guaranteed cold chain. If you receive a thawed product please inform our customer service immediately. Regarding dry ice shipments please visit section "shipping information" on our website for detailed information on temperature tests

### Where can I find supplementary information about an antigen / antibody?

For each antigen / antibody, DIARECT created a "+INFO" section on its website, which contains the antigen's / antibody's material safety data sheet (MSDS) and specification sheet. The latter provides general recommendations regarding antigen / antibody storage and buffers. For select antigens / antibodies, the "+INFO" section also contains a brochure offering some background information and immunological test data. You can also contact your local representative or <a href="info-dia@bbisolutions.com">info-dia@bbisolutions.com</a> for more details.

## What is the shelf life of your products?

Most of our antigens have a guaranteed shelf life of five years unless otherwise noted on our Certificates of Analysis (CoA) and data sheets, and providing that they are kept frozen at -70°C or below. For the shelf life of our antibodies, please check the expiry date on the lot-specific CoA provided with the product.

#### How can I benefit from DIARECT's reservation system?

We guarantee the reservation of a specified amount of antigen(s). Typically, customers reserve the amount of antigen(s) needed for a manufacturing period of up to 18 months. You simply inform us of your antigen requirements for this period, and every 4 months you will receive an updated overview regarding the accuracy of your estimate. The reservation system also includes the allocation of early enough samples of new lots of the respective antigen(s). This enables the customer to evaluate the new lot at an early stage for future reservations and allows a smooth transition to this new lot.

Advantages provided by DIARECT's reservation system:

- Security of supply with no additional costs
- No need for continual readjustment and fine tuning of your assay because of new antigen lots

#### What does Ec/BV stand for?

BV and Ec represent the type of expression system that was used to produce the antigen of interest. BV stands for DIARECT's baculovirus/insect cell expression system, while Ec stands for DIARECT's *E. coli* expression system.

### What kind of technique does DIARECT use for purification?

For purification, the preferred technique is the very effective, yet gentle immobilized metal-ion affinity chromatography (IMAC) in combination with His-tag technology, which yields physiologically and immunologically active proteins. Our native proteins are purified using appropriate standard chromatography purification methods including ion exchange, size exclusion and immunoaffinity.

## How does DIARECT ensure lot-to-lot consistency of its antigens / antibodies?

DIARECT's recombinant and native antigens / antibodies - always produced according to documented procedures (SOPs) and manufactured per EN ISO 13485 and 9001 standards - undergoing a rigorous series of tests in our quality control laboratory. Prior to its approval and release, each lot is subjected to various biochemical and immunological analyses to assure conformance to our strict product specifications. The goal of these extensive inspections is to ensure lot-to-lot conformance, which guarantees consistent results.

#### Where can I find sequence information about an antigen?

General information regarding the origin and expression constructs of antigens are provided in the respective specification sheets, however, exact sequence data are considered proprietary information. Most recombinant antigen preparations are supplied with a 6xHis-tag as part of the sequence.

### Where are DIARECT antigens manufactured and shipped from?

DIARECT antigens are manufactured in our EN ISO 13485 and EN ISO 9001 audited facility in Freiburg, Germany. Supply is either direct from our Freiburg facility or may be managed by our local representatives in specific territories.

### Where can I find information about pricing and ordering of samples?

If you would like information about price, ordering of samples or placing an order please either fill out a form on the following page: <a href="https://www.diarect.com/contact.html">https://www.diarect.com/contact.html</a> or alternatively contact us via <a href="mailto:info-dia@bbisolutions.com">info-dia@bbisolutions.com</a>.