Antigens– FAQ's*

August 2020

This FAQ sheet refers only to the products supplied directly by BBI and not those supplied by DIARECT AG. For information about these products please see 'DIARECT Antigens' FAQs

What are Antigens and how are they used?

Antigens are a range of mostly human purified proteins that are commonly used in In-Vitro diagnostic tests as critical reagents to add to a base to create calibrators and Quality Control material for specific biomarkers (a measurable indicator of some biological state or condition). Certain products will have additional biological functionality that can be used for other applications.

What is the source material for the antigens?

Recombinant (prokaryotic/eukaryotic) or native from human tissue (sourced with informed consent), human cancer cell line grown in culture or human body fluids such as blood, plasma, serum and urine. All samples are given with informed consent from the donor.

Where does the material originate?

The material is purified in our laboratories in Sittingbourne UK. The site is registered to design, develop, manufacture and supply in-vitro diagnostic reagents, blood and plasma products and operates a quality management system which complies with the requirements of ISO: 13485. the raw material is sourced from various territories, where this is specific this is detailed on the Certificate of Analysis (C of A). In general, material prepared from blood plasma is sourced from US-based blood donations. Our Sittingbourne site also holds a Human Tissue Authority license for the storage of human tissues for the purpose of Research.

Do you manufacture all the products that you supply?

Most of the products we supply are made on site however there are a few specific products that are contracted out to carefully selected partner laboratories.

How is the material purified?

The specific methodologies are proprietary to BBI however a general purification methodology can be provided after execution of a non-disclosure agreement.

What purities are available?

Extract grade – Less than 40%, immunoassay recovery as a percentage of total protein.

Part-pure – Greater than 40%, immunoassay recovery as a percentage of total protein. A band on SDS-PAGE or Native PAGE corresponding to the pure protein molecular weight to be visible.

Pure grade – Greater than 90%, band corresponding to protein visible clearly on Coomassie stained SDS-PAGE or Native PAGE with no more than 2 other bands which are not multimers of the protein occurring as minor bands. These bands should represent an intensity judged to be faint in comparison to the main band. One band only or no contaminating bands on cellulose acetate electrophoresis. This information needs to be backed up with at least one other technique such as HPLC or Immunoassay as percentage of total protein which shows a purity of > 90%.

High Pure grade – Greater than96% band corresponding to protein visible clearly on Coomassie stained SDS-PAGE or Native PAGE with no other bands which are not multimers of the protein occurring as minor bands. One band only or no contaminating bands on cellulose acetate electrophoresis. This information needs to be backed up with at least one other technique such as HPLC or Immunoassay as percentage of total protein which shows a purity of >96%.

Very High Pure grade – Greater thank98% band corresponding to protein visible clearly on Coomassie stained SDS-PAGE or Native PAGE with no other bands which are not multimers of the protein occurring as minor bands. One band only or no contaminating bands on cellulose acetate electrophoresis. This information needs to be backed up with at least two other techniques such as HPLC or Immunoassay as percentage of total protein which shows a purity of >98%.

Ultra-pure grade – Greater than99% band corresponding to protein visible clearly on Coomassie stained SDS-PAGE or Native PAGE with no other bands which are not multimers of the protein occurring as minor bands. One band only or no contaminating bands on cellulose acetate electrophoresis. This information needs to be backed up with at least two other techniques such as HPLC or Immunoassay as percentage of total protein which shows a purity of >99%. Product should also be tested for likely contaminating proteins and show a level of less than 0.1%. Also, Western blot or immunoelectrophoresis should show no bands other than the specific protein or its multimers.

How is the material supplied? (What is the product's appearance?)

The appearance will vary between products depending on the formulation and protein characteristics, please consult the example Certificate of Analysis (found in the 'Technical Documents' section of the product page) for this information. Where possible the product is presented in a liquid format, where this is not possible it is formulated for ease of use and maximum shelf-life. BBI will consider custom re-formulation to meet specific requirements, contact an account manager for further information.

What should I use to reconstitute/dilute the products?

This varies between products, please consult the example Certificate of Analysis (found in the 'Technical Documents' section of the product page) for this information. These can be found by visiting https://www.bbisolutions.com/en/products/antigens.html, clicking on the specific product of interest and then navigating to the 'Technical Documents' section at the bottom of the product page. If any further technical information is required, this can be requested by emailing technicalsupport@bbisolutions.com.

Do you have stability data on lyophilised products once they have been reconstituted?

We do not have stability data on our lyophilised products once they have been reconstituted or liquid products after dilution. There are too many variables, such as diluent used and environmental controls to be able to give specific advice. Once reconstituted, the product falls outside of our recommended storage parameters as stated on the product C of A and the stability should be determined by the user in the specific application.

Is there a possibility of infection occurring from human-derived proteins?

Although all our products are screened to test for the infectious agents listed on the product's C of A, they are derived from human materials and should be treated as potentially hazardous. Our purification processes will partition infectious agents and so the likelihood of these products containing infectious agents is extremely low however the all material should be handled using appropriate precautions. Safety data sheets are available on request.

What aliquot sizes are available, will we be able to have material packaged to our requirements?

Each specific product is presented in a range of aliquot sizes, usually based around the 1mg size as a base unit and normally in "factors of 10" from this base however there are some exceptions. The material cannot be re-dispensed, should a specific dispensation be required this can be accommodated if enough notice is given.

Where will the material be shipped from?

All of our human antigen products will be sent from our Sittingbourne facility directly, our terms are "FCA (free carrier)" meaning it is the customers responsibility to ensure the package is delivered safely. We use an air courier service and we will make a charge for this service or pass the shipping charges forward.

How will the material be transported?

In general material is supplied packed on cool-pack or frozen on dry ice. This varies between products, please consult the example Certificate of Analysis (found in the 'Technical Documents' section of the product page) for this information.

How will the material be packaged?

The primary packaging is product specific and appropriate to the product. The secondary packaging is a cardboard outer box with a Styrofoam outer containing appraise materials to maintain product integrity (e.g. Dry ice/cool pack).

What information is supplied with the product?

The product is shipped with a Certificate of analysis (the product specifications, the formulation, the expiry date, handling/storage information, infectious disease testing) and a delivery note/commercial invoice. Safety data sheets are available on request (by emailing technicalsupport@bbisolutions.com).

How do I store the supplied material?

This varies between products, please consult the example Certificate of Analysis (found in the 'Technical Documents' section of the product page) for this information.

How is the concentration of the material determined prior to dispensing and how does this equate to the recovery expected by immunoassay?

The material is dispensed by the method specified in "determination method" section of the C of A. A small dispensing overage is included, so the vial may contain more material than is specified on the label. The recovery by immunoassay will be dependent on the matrix and antibody used in the assay.

How is the shelf-life of the products determined?

Finished Goods shelf life from date of manufacture have been determined by specific stability trials or by reference to similar formulations/scientific literature and are generally defined as follows.

- Liquid stock (2-8°C) 2 years
- All other stock (liquid frozen stock, lyophilized) 5 years

Exceptions to this will be detailed on the C of A template where shelf lives will be supported by stability data. BBI tests the product stability by immunoassay and lists the shelf-life and storage conditions on the Certificate of Analysis. The stability of freeze-dried products after re-constitution is not determined as there are too many potential variables to make this practical.

Additionally, stability trials are carried out in order to confirm or extend current stated shelf life periods.

What should I do if the material I have goes past its stated shelf-life?

In some cases, BBI has data to show products have a longer shelf-life. When a product comes close to the end of a shelf-life BBI has a programme of re-certification however most products are consumed before the end of shelf-life. BBI recommends that products are not used past the shelf-life stated.

How can I get further information about the product?

Technical information and product specifications can be found in the product-specific Certificate of Analysis and the Product Information Sheet. These can be found by visiting https://www.bbisolutions.com/en/products/antigens.html, clicking on the specific product of interest and then navigating to the 'Technical Documents' section at the bottom of the product page. If any further technical information is required, this can be requested by emailing technicalsupport@bbisolutions.com.

Where should I send quality agreements/supplier assessment questionnaires?

These should be sent to technicalsupport@bbisolutions.com for completion. Due to the high number of requests received, BBI has compiled a document of frequently requested information of this nature, which is available upon request.

Where can I find product pricing?

For larger volumes BBI does not publish list prices as often product pricing is dependent on volumes and recovery testing. Please contact your local account manager for a product price quotation. If you are new to purchasing from BBI please contact Customer Services customerservices@bbisolutions.com

How can I find out about the stock holding of a product?

BBI carries stock of most of the listed products however some specific products are made to order please contact your account manager for specific up to date stock information. If a product is not available from stock, then the preparation will need to be scheduled. It is essential to ensure forecasts are communicated to BBI in good time (at least 6 months' notice) to ensure material is available. Stock can be reserved for a maximum of 3 months pending testing of samples.

How can I order/sample the products?

These requests can be sent directly to your designated account manager who will be happy to advise of current stock availability and advise on appropriate samples. For products ordered from stock or against an approved sample orders can be sent directly to customerservices@bbisolutions.com who will direct your request appropriately.

What should I do if I have a complaint?

Our products are fully tested for quality and prepared in ISO 13485:2016 controlled laboratories however in the unlikely event of having an issue with the product performance we will endeavor to find a satisfactory resolution. In the first instance contact your account manager who will advise on the course of action to resolve any issue.