

Transferrin– FAQ's August 2020

### What is Transferrin and how is it used?

Human transferrin is a major constituent of blood plasma. It is an iron binding glycoprotein that serves as the transport protein for iron delivery in the body. Each molecule of transferrin specifically binds two Fe3+ molecules through a bicarbonate mediated site-specific binding. Transferrin is required by many mammalian cells during growth to regulate iron uptake and it has been shown that when added to cell culture media it promotes cell proliferation. In culture media, transferrin has a secondary role to bind endogenous metal ions which may cause cell toxicity.

## What is the source material for the Transferrin?

BBI derives it's purified Transferrin products from pooled normal human plasma from predominantly US based paid blood donations.

### What are the different forms of Transferrin available?

The standard Transferrin products supplied by BBI are lyophilised products, material is available with different levels of iron saturation. Circulating Transferrin is partially Iron saturated however for cell culture use BBI adjusts the iron content to provide the following options:

Holo-transferrin (product code T101-5) is adjusted to give near 100% saturation (1200-1700 μg/gm).

Apo-transferrin (product code T100-5) is depleted to give near zero iron bound (<50μg/gm).

Customised Transferrin formulations are available on request.

### What controls are in place for the collection of the blood used as the raw material?

Human plasma used for the manufacture of the BBI product human transferrin is collected at blood centers in the United States of America which are licensed by the United States Food and Drug Administration (FDA). The material is manufactured from a large pool of plasma donated by multiple donors, although the donor's information is not made available, all donations are traceable back to the donor.

All plasma donations are screened for infectious diseases by FDA approved methods at the donor level. Donations are ethically sourced and informed consent forms are signed by each donor prior to donation, the forms are kept on file by the approved collection facility. Further details on the collection process are available on specific information sheets or can be requested from technicalsupport@bbisolutions.com.

What regulatory system covers the Transferrin production? Are the transferrin products GMP/ clinical grade products and can it be used for therapeutic products?

BBI prepares Transferrin under it's ISO13485, 2016 quality system however the transferrin products are prepared in open laboratories and the material is not GMP/clinical grade. Transferrin is intended for research and cell culture use only and is not suitable for use in pharmaceuticals.

#### 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.

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

Our standard Transferrin products are supplied as lyophilised powder packed in PET bottles in sealed pouches to protect the material from moisture. The product 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 will the material be shipped from?

All our transferrin products will be sent from our Sittingbourne facility directly. Our terms are "FCA" 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?

Transferrin products are shipped on cool-pack packaged in Styrofoam containers with secondary cardboard outers.

## How do I store the supplied material?

Transferrin products should be stored at 2-8°C. After the Transferrin has been removed from the sealed packaging the material should be used immediately, it should not be stored for re-use.

### How is the shelf-life of the products determined?

A shelf-life of a minimum of 5 years from manufacture date is applied. The shelf life is based on immunological potency.

#### 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 <a href="https://www.bbisolutions.com/en/products/cell-culture-reagents.html">https://www.bbisolutions.com/en/products/cell-culture-reagents.html</a> 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 <a href="technicalsupport@bbisolutions.com">technicalsupport@bbisolutions.com</a>.

#### What should I do if I have a complaint?

Our products are fully tested for Quality and prepared in ISO:13485 controlled laboratories however in the unlikely event of having an issue with the product performance we will endeavour 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.

## Where can I get further technical product information?

Refer to our website, contact your account manager or contact technical support (<a href="mailto:technicalsupport@bbisolutions.com">technicalsupport@bbisolutions.com</a>). Your inquiry will then be routed to the most appropriate department.

### Where should I send quality agreements/supplier assessment questionnaires?

These should be sent to <u>technicalsupport@bbisolutions.com</u> 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?

BBI do 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 have not yet have an account manager please contact <a href="mailto:customerservices@bbisolutions.com">customerservices@bbisolutions.com</a>.

# 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 <a href="mailto:customerservices@bbisolutions.com">customerservices@bbisolutions.com</a> who will direct your request appropriately.