

What range of Serum and plasma products are available from BBI, what are they generally used for?

BBI supplies the following human serum and plasma products:

Pooled normal human serum and plasma for use as calibrator/control bases and product testing

Pooled specific disease state plasma used for calibrators/controls for immunology products

Analyte depleted serum and plasma used as negative base for calibrators/controls

What is the difference between serum and plasma?

Plasma and serum are both the liquid portion of blood that remains once the cells are removed.

Plasma is the liquid that is formed when the cellular components are removed, and clotting is prevented with the addition of an anticoagulant. There may be residual anticoagulant remaining in the plasma.

Serum is the liquid that remains after the blood has been allowed to clot, then the cellular components are removed. It does not contain fibrinogens as these are removed as part of the blood clot. The resulting serum will not contain any anticoagulant.

What volumes of serum and plasma products are available?

Typical volumes depend on the specific product however in general individual unit volumes for Disease state plasma range between 1ml samples and up to 1L however generally these are available as 200-240ml remnants and 850-950ml units with samples of 1-5ml. Depleted serums and pooled normal human serums are available in lots of up to 50L.

Are the Disease state plasma serum and plasma products sourced by BBI from plasmapheresis or are they "remnant" materials collected from blood transfusion and other procedures?

Disease state serums and plasmas are collected as remnants and as plasmapheresis units, the availability is specific to the analyte. Please contact your account manager for details.

How are the analyte levels determined in BBI serum and plasma products?

Specific immunoassays are normally used to determine the levels of the analytes. These are specified on the Certificate of Analysis. In some cases it is possible to offer an alternative method to those stated, please contact your account manager for details. In certain cases, the materials are tested by LC-MS (Liquid chromatography mass spectroscopy).

Are samples available from all serum and plasma prior to purchase?

Plasma and serum samples can normally be provided however to ensure that the product is likely to meet the requirement it is essential to agree the titre requirement and testing methodology as well as any other specifications prior to sampling. Units of the bulk can be held for a maximum of 3 months pending sample approval.

How is analyte-depleted serum and plasma processed?

These products are processed at our ISO13485 accredited site in Sittingbourne.. The specific methodologies are proprietary to BBI however a general depletion methodology can be provided after execution of a Non-disclosure agreement.

How do I store and transport the material?

Serums and plasmas should be stored below -15°C and the use of dry ice is recommended for shipping. Repeated freeze-thaw cycles should be avoided as this can cause the material to become “cloudy” due to residual Fibrinolysis.

How is it supplied? (What is the products appearance?)

This is product specific and is described in the Certificate of Analysis of each individual product. Normally the product is supplied 0.2µm filtered and tested for bioburden however this is not always the case for Disease state plasma units.

Where do BBI collect the serum and plasma?

BBI’s Serum and plasma is collected at hospitals and blood banks worldwide, specific sources can be used if requested however bespoke collections can take additional time to facilitate. Most Pooled normal human serum and plasma and depleted serum are from US sourced paid blood donations.

How are the units screened for infectious disease markers?

Most of our products are screened for the current World Health Organisation (WHO) list of recognised infectious agents (<https://www.who.int/bloodsafety/ScreeningDonatedBloodforTransfusion.pdf>) and the results are listed on the product C of A, however as they are derived from human materials they should be treated as potentially hazardous and only handled in laboratories with appropriate biological containment facilities.

Some Disease State Plasma products may be positive for specific infectious agents which will be reported on the product Certificate of Analysis. These materials should be handled in laboratories with appropriate biological containment facilities.

Where will the material be shipped from?

All our serum and plasma products will be dispatched directly from our Sittingbourne facility. 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 is the shelf-life of the products determined?

Specific stability trials are not carried out on serum and plasma products. In general, it is the responsibility of the client to determine the stability using the specific assay linked to their application. As human Serum and plasma products are generally considered to be stable for at least 5 years when stored frozen.

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/technical-support/biobank.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.

What should I do if I have a complaint?

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 (technicalsupport@bbisolutions.com). Your inquiry will then be routed to the most appropriate department.