



The Premier Raw Material Supplier for IVD Manufacturing

Plasma and Serum Diluents



PLASMA AND SERUM DILUENTS AND DERIVATIVES

Count on SeraCare for the biological materials you need to achieve consistent product quality. From human serum and processed plasma to derivatives such as human serum albumin (HSA), human gamma globulin (HGG) and bovine serum albumin (BSA), we offer a diverse range of products to meet your assay development needs.

EXPEDITE ASSAY DEVELOPMENT

SeraCare ensures a continuous supply of biomaterials. We deliver the quality and consistency you demand, in any quantity, when you need it. All biologic products have documented traceability to simplify compliance requirements and offer lot-to-lot consistency to maintain quality standards for your end products.

EXPERIENCE AND RELIABILITY

SeraCare offers a long history of innovation in the development of reagents for use as: diluents in the design of test kit controls and calibrators, blocking agents for ELISA methods, cell culture media supplements, and excipient use in research products.

FLEXIBLE OPTIONS

To support the scale-up and commercialization of your diagnostic assays, SeraCare offers custom processing services. We partner with our customers to develop client-defined product specifications to ensure you receive the materials that you need to effectively manufacture and commercialize your products.



**SeraCare
serves more
than 90% of the
world's top IVD
manufacturers.**



PROCESSED HUMAN PLASMA AND SERUM PRODUCTS

NORMAL HUMAN PLASMA

SeraCon and BaseMatrix are both derived from normal human plasma, well suited for use as a negative diluent for the production of controls and calibrators, and possess the following characteristics.

- HUMAN MATERIAL**

Manufactured from human plasma obtained from FDA-licensed donation centers with full traceability. A cost-effective human serum substitute.

- VIRAL TESTED AND CERTIFIED**

Plasma has been tested per FDA guidelines and certified negative for anti-HIV-1/2, anti-HCV, HBsAg and HIV-1 RNA. Further certification available for anti-HBc, anti-HTLV-I/II, Syphilis, anti-HAV, anti-HBc, HCV RNA and HBV DNA can be provided.

- CUSTOMIZABLE**

SeraCare can satisfy specialized needs with custom materials processing.

- CONSISTENT LOT-TO-LOT PERFORMANCE**

Produced according to cGMPs in ISO 13485-certified facilities.

SeraCon and Basematrix products are both formulated from human plasma and processed to resemble a serum-like state, however the processing differs slightly based on intended use of the material. Refer to **Table 1: Diluent Reference Guide** for details. SeraCon is recommended for use in serological assays. It is also preferred when the intended application requires a matrix that is either free of lipids or hormones.

BaseMatrix is recommended for use in molecular-based assays as a negative diluent for control and calibrator formulations.

POOLED HUMAN SERUM

Ideal as a negative diluent for assay development and manufacturing, the pool represents thousands of donors and provides a normalized population. Pooled human serum contains no anticoagulants or preservatives. Refer to page 9 for ordering details.

Table 1: Diluent Reference Guide

Product	Defibrinated				Dialyzed				Delipidated				Charcoal Stripped				0.2 mm Filtered				Serological EIA				Molecular PCR/NAT				Molecular - NGS			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4				
SeraCon I	●				●				●	●			●	●			●	●			●	●			●	●			●	●		
SeraCon II	●	●			●	●			●	●			●	●			●	●			●	●			●	●			●	●		
SeraCon II D	●	●	●		●	●	●		●	●			●	●			●	●			●	●			●	●			●	●		
SeraCon II CD	●	●	●	●	●	●	●	●	●	●			●	●			●	●			●	●			●	●			●	●		
Basematrix	●	●			●	●			●	●			●	●			●	●			●	●			●	●			●	●		
Matribase									●	●			●	●			●	●			●	●			●	●			●	●		
SeraCon Vitamin D Depleted	●	●			●	●			●	●			●	●			●	●			●	●			●	●			●	●		
Pooled EDTA Plasma									●	●			●	●			●	●			●	●			●	●			●	●		
Pooled True Human Serum									●	●			●	●			●	●			●	●			●	●			●	●		

DEFINITION OF TERMS

Defibrinated: Removal of clotting factors to mimic a serum-like state.

Dialyzed: Adjustment to normal physiological serum profile via buffer exchange across membrane (retains large molecule proteins.)

Delipidated: Removal of lipid components.

Charcoal Stripped: Removal of hormones.

0.2 mm Filtered: Final product filtration.



BLOOD-DERIVED PRODUCTS

SeraCare offers a number of key components for use in assay production, including purified blood-based proteins derived from human and bovine sources. Available offerings include:

- Human Serum Albumin (therapeutic and diagnostic grade available)
- Human Gamma Globulin (HGG)
- Male AB
- Buffy Coat/Leukopacks
- Whole blood
- Bovine serum albumin (BSA)

These purified proteins are suitable for use in controls, calibrators, diluents, and buffer formulations. They are available in a variety of sizes as well as liquid and powder formats. As with our SeraCon and Basematrix products, blood derived products are manufactured from human plasma, tested negative by FDA-approved methods for viral markers and can be customized to meet your specific needs. To help determine which Blood products will meet your needs and where to get more information about the products, please refer to **Table 2**.

Table 2: Bulk and Customizable Blood Products

Product	Application	Ordering Details
Normal Human Plasma		
SeraCon Processed Plasma Products	Negative diluent or control	See page 9
Basematrix Processed Plasma Products	Negative diluent or control	See page 9
Pooled True Human Serum	Normalized true serum for use as negative diluent or control	See page 9
Blood Derived Products		
Human: HSA, HGG, Male AB Bovine: BSA	Quality components for drug, vaccine or diagnostics products and cell culture applications	See page 10
Additional Blood Components: Leukopacks, Whole Blood Collections	Capability to provide components based on specific needs	See page 6*

*Inquire: Products produced as custom orders.

CUSTOM AND BULK MANUFACTURING

Unlike many other suppliers, SeraCare understands the need for flexibility in order to provide the specialized products you need at the scale that you require, and with a commitment to consistent reliable performance. Our Custom and Bulk Manufacturing services will help you:

- Bring your assays to market more quickly
- Control product development costs
- Improve your design and development efficiency
- Ensure consistent component quality, from commercial launch to end-of-life

FLEXIBLE AND ADAPTABLE

We know that project and product needs can change over time, and nowhere is this more evident than during the development of a novel diagnostic. That's why SeraCare takes a team-based approach to partnering with our clients to ensure we're designing materials and tools to meet your exact specifications. From R&D to Manufacturing to Regulatory Affairs, our experts will collaborate in tandem with yours to ensure we're delivering product that meets your needs. And when those needs change, we'll be right there to work with you to make the required modifications.

CUSTOM SERVICES (FOR ALL MANUFACTURED PRODUCTS)

- Custom controls and reference materials
- Custom Proficiency testing panels
- Bulk antibodies, diluents, and supporting reagents
- Disease state material sourcing
- Real-time and stress stability studies
- Use life studies
- Labeling and Packaging design
- Quality Systems support
- Feasibility and Validation studies*
- Risk Management file preparation*
- Design History/Technical file preparation*

**When SeraCare designs product for customer*

SCALE SEAMLESSLY FROM PROOF-OF-CONCEPT TO COMMERCIALIZATION

One of the biggest challenges in IVD development is ensuring small-scale performance is maintained when transferring an assay to manufacturing for large-scale lot production. SeraCare has the facilities and expertise to deliver biological materials and assay components of the same exacting high quality, whether you require milliliters, or thousands of liters.

TRUSTED SUPPLIER

SeraCare has been providing critical custom reagents to the world's leading diagnostic developers for over 30 years — enabling creation of higher performing, more robust diagnostics. Our unique combination of IVD component manufacturing expertise and deep knowledge of the clinical lab environment explains why SeraCare serves more than 90% of the world's top IVD manufacturers.

QUALITY AND CONSISTENCY

We understand your need to meet strict quality requirements, every day. At SeraCare, we hold ourselves to the same high standard. Our facilities and quality systems are among the most robust in the industry, meeting the stringent ISO 13485 medical device standard, cGMP, FDA QSR and additional applicable MDSAP requirements. Our commitment to consistent, documented quality helps ensure the continued performance of your diagnostic products, controls, and reference materials—lot to lot, year after year.





ASSAY COMPONENT DEVELOPMENT SERVICES

Focus your efforts on assay design and validation, leaving the development and production of key components to our experts. Extensive experience across most assay types.

CUSTOM MANUFACTURING AND PACKAGING

Large lot capacity with custom vialing, product fill and packaging options. Design and scale up support provided.

CUSTOM RECOMBINANT VIRAL CONTROLS

AccuPlex™ recombinant viral control materials. Non-infectious, high titer, RNA and DNA viral vectors handling large (~4kb) insert sequences.

ANTIBODY SERVICES

We offer services to develop, produce and affinity purify custom polyclonal antibodies suitable for immunoassays. We also provide antibody and protein conjugation services leveraging a variety of enzymes and tags.

**For more information
on any of our Custom
and Bulk Manufacturing
Services, contact us at
[+1-800-676-1881](tel:+18006761881) or
www.seracare.com**

SPECIALIZED VERIFICATION KITS

We develop specialized verification kits to aid adoption of your new assay by your customers on new instrument platforms. Provides a plug and play solution to your customers.

PROFICIENCY PANEL DESIGN

We design and formulate custom proficiency panels providing expert advice for suitable target level definitions, randomization schemes for participants and cost optimization strategies.

PROSPECTIVE COLLECTIONS

Custom sample collection managed through our worldwide network of collection facilities. Infectious and non-infectious donor specimens collected to your unique specifications with options for collection under certified IRB protocols.





SeraCon™ and Basematrix Plasma-Derived Diluents

Material #	Product Name	Fill Size
1800-0009	SeraCon I Negative Diluent	1 L
1800-0063	SeraCon I Negative Diluent	3 L
1800-0002	SeraCon II Negative Diluent	3 L
1800-0011	SeraCon II Negative Diluent	100 mL
1800-0012	SeraCon II Negative Diluent	1 L
1800-0003	SeraCon II Lipid Depleted Negative Diluent	3 L
1800-0016	SeraCon II D Lipid Depleted Negative Diluent	100 L
1800-0017	SeraCon II D Lipid Depleted Negative Diluent	1 L
1800-0006	SeraCon II CD Hormone Depleted Negative Diluent	3 L
1800-0026	SeraCon II CD Hormone Depleted Negative Diluent	100 mL
1800-0027	SeraCon II CD Hormone Depleted Negative Diluent	1 L
1800-0035	SeraCon II CD Hormone Depleted Double-Stripped Negative Diluent	3 L
1800-0057	SeraCon II CD Hormone Depleted Double-Stripped Negative Diluent	100 mL
1800-0058	SeraCon II CD Hormone Depleted Double-Stripped Negative Diluent	1 L
1800-0049	SeraCon Vitamin D Depleted Negative Diluent	100 mL
1800-0050	SeraCon Vitamin D Depleted Negative Diluent	1 L
1800-0051	SeraCon Vitamin D Depleted Negative Diluent	3 L
1800-0005	SeraCon Matribase Negative Diluent	1 L
1800-0022	SeraCon Matribase Negative Diluent	100 mL
1805-0074	Basematrix Diluent	12 x 3.5 mL
1805-0075	Basematrix Negative Diluent	1 L
1805-0076	Basematrix Negative Diluent	50 mL

Human Serum

Material #	Product Name	Fill Size
1830-0002	Pooled Human Serum	100 mL
1830-0003	Pooled Human Serum	1 L
1830-0005	Pooled Human Serum	3 L
0100-0050	Human Serum, Off-the-Clot (Single Donor Units)	Variable

Human Plasma

Material #	Product Name	Fill Size
0100-0009	K2 EDTA Plasma	Full unit (180 - 340 mL)
0100-0011	Heparinized Plasma	Full unit (180 - 340 mL)
0100-0013	Human Plasmapheresis Plasma	Full unit (-700 mL)
0100-0030	K3 EDTA Plasma	Full unit (180 - 340 mL)

Male AB Serum (plasma converted to serum)

Material #	Product Name	Fill Size
1810-0001	Human Male AB Plasma	100 mL

Human Serum Albumin (HSA)

Material #	Product Name	Fill Size
1850-0026	Human Serum Albumin, Powder	1 kg
1850-0027	Human Serum Albumin, Powder	5 kg
1850-0028	Human Serum Albumin, Powder	100 g
1850-0020	Human Serum Albumin Low B12/Low Folate, Powder	1 kg
1860-0035	Human Serum Albumin Low B12/Low Folate, Powder	5 kg
1860-0037	Human Serum Albumin Low B12/Low Folate, Powder	100 g
1860-0039	Human Serum Albumin, Fatty Acid Free, Powder	1 kg
1860-0040	Human Serum Albumin, Fatty Acid Free, Powder	5 kg
1860-0042	Human Serum Albumin, Fatty Acid Free, Powder	100 g
1860-0016	5% Human Serum Albumin Diagnostic Grade, Liquid	100 mL
1860-0017	5% Human Serum Albumin Diagnostic Grade, Liquid	1 L
1860-0020	20% Human Serum Albumin Diagnostic Grade, Liquid	100 mL
1860-0021	20% Human Serum Albumin Diagnostic Grade, Liquid	1 L
1860-0025	25% Human Serum Albumin Diagnostic Grade, Liquid	100 mL
1860-0026	25% Human Serum Albumin Diagnostic Grade, Liquid	1 L
1880-0002	20% Human Serum Albumin Therapeutic Grade, Liquid	100 mL
1880-0004	25% Human Serum Albumin Therapeutic Grade, Liquid	50 mL
1880-0005	25% Human Serum Albumin Therapeutic Grade, Liquid	100 mL

Human Gamma Globulin (HGG)

Material #	Product Name	Fill Size
1860-0047	Human Gamma Globulin, Powder	100 g
1860-0048	Human Gamma Globulin, Powder	500 g
1875-0006	5% Human Gamma Globulin Diagnostic Grade, Liquid	100 mL
1875-0007	5% Human Gamma Globulin Diagnostic Grade, Liquid	1 L

Bovine Serum Albumin (BSA)

Material #	Product Name	Fill Size
1900-0002	Bovine Serum Albumin Standard Grade	1 kg
1900-0003	Bovine Serum Albumin Standard Grade	5 kg
1900-0004	Bovine Serum Albumin Standard Grade	10 kg
1900-0007	Bovine Serum Albumin Standard Grade	100 g


Bovine Serum Albumin (BSA) (continued)


Material #	Product Name	Fill Size
1900-0011	Bovine Serum Albumin Reagent Grade	1 kg
1900-0012	Bovine Serum Albumin Reagent Grade	5 kg
1900-0013	Bovine Serum Albumin Reagent Grade	10 kg
1900-0016	Bovine Serum Albumin Reagent Grade	100 g





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