



HUMAN SERUM

Selection Guide

for IVD Assay Development & Cell Culture

The 7 supplier criteria · Switching protocol · Batch reservation calculator · Variant comparison · IVDR documentation checklist

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Supplier Criteria

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How to use this guide: Work through the 7 criteria (p.4) to evaluate any supplier, then use the switching protocol (p.6) to run your parallelism study. The decision tree (p.7) helps you select the right serum format for your application.

01

Why Human Serum Supplier Selection Matters

Human serum is not a commodity reagent. Unlike synthetic media components, it is a biological material with inherent lot-to-lot variability — and that variability directly affects your assay performance, cell culture reproducibility and regulatory documentation.

Switching suppliers mid-project — or discovering documentation gaps after submission — is one of the most common and costly mistakes in IVD development and ATMP manufacturing. This guide gives you the framework to get it right the first time.

IVD Development

Matrix mismatch between calibrators and clinical samples inflates assay error and may require full revalidation under CLSI EP7 and IVDR 2017/746.

Cell Culture / ATMP

Uncontrolled batch switches cause unexplained variability in cell growth, differentiation or functional assays — and require documented change control in GMP.

Diagnostics / Regulatory

Donor origin (EU vs. US) affects your IVDR technical file. EU-qualified donors are processed under EU Blood Directive 2002/98/EC — directly cited in regulatory submissions.

Key insight: The cost of re-validating a new human serum lot — in time, materials and regulatory documentation — almost always exceeds the cost of getting the supplier selection right at the start. Invest the time upfront.

02

The 7 Criteria for Evaluating a Human Serum Supplier

1 Donor Origin & Regulatory Framework

For EU manufacturers under IVDR 2017/746, EU-qualified donors processed under EU Blood Directive 2002/98/EC provide the clearest regulatory path.

Ask: "Which country are your donors from and under which regulatory framework are they qualified?"

2 Donor Screening Panel

Minimum: HIV 1/2 (Ab + NAT), HBsAg, anti-HCV + HCV RNA, syphilis, HTLV I/II. Request the full screening certificate — not just a COA summary.

Ask: "Can you provide full NAT screening results for each lot?"

3 Lot-to-Lot Consistency & Batch Reservation

Batch reservation — reserving a validated lot without prepayment and calling it off over time — is the single most important operational tool for managing long-term consistency.

Ask: "Can I reserve a specific lot without prepayment, in partial call-offs?"

4 Documentation Quality

Minimum: COA + donor screening. For regulated applications also: origin certificate, processing batch records, sterility results, technical file or DMF number.

Ask: "What documentation is provided per lot and what is available on request?"

5 Processing Options & Variants

Native, heat inactivated, delipidated, IgG-depleted, charcoal stripped, gamma irradiated. One supplier for all variants reduces qualification burden significantly.

Ask: "Which variants are in stock vs. available on request and what are lead times?"

6 Volume Flexibility & Minimum Orders

Development needs 100 ml; production needs bulk. No minimum order quantity with flexible volumes is ideal for validation through commercialisation.

Ask: "What is the minimum order and can I order 100 ml for initial validation?"

7 Supply Security & Lead Times

Rare formats (delipidated, IgG-free, male-only) are particularly vulnerable to supply disruption. EU stock with batch reservation significantly reduces risk.

Ask: "Where is stock held and what happens if my reserved lot runs out?"

03

Human Serum Variants — Comparison Table

Choose the right human serum format for your application. All SeamlessBio variants are available from EU-qualified donors with full documentation and batch reservation.

Variant	Processing	Key Application	IgG	Complement	Lipids
Human Serum AB (Native)	Off-the-clot, sterile filtered	CAR-T, MSC expansion, malaria culture, hybridoma	Intact	Active	Present
Human Serum Heat Inactivated	56degC / 30 min	Complement-sensitive cells, hybridoma production	Intact	Inactivated	Present
Human Serum Delipidated SP1010	Defibrinated + lipoprotein removal	Lipemia interference studies, IVD matrix (CLSI EP7)	Intact	Varies	Removed
Human Serum Delipidated + IgG-free	Delipidated + IgG depletion	Antibody detection assay development	Depleted	Varies	Removed
Human Serum Double Charcoal F12010	Double charcoal treatment	Hormone/steroid assay calibrators, endocrine research	Intact	Varies	Removed
Human Serum Universal Negative	Screened negative matrix	IVD negative controls, calibrator base matrix	Intact	Varies	Present
Human Platelet Lysate (HPL)	Platelet lysis, sterile filtered	MSC expansion (xeno-free), NK cell differentiation	N/A	N/A	Present

SeamlessBio tip: All variants from EU stock in Passau. Free test samples for all formats. Batch reservation without prepayment — from 100 ml, no minimum order quantity.

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Supplier Switching Protocol — Step by Step

- 1 Define acceptance criteria — BEFORE testing**

Specify minimum cell growth (%), maximum CV between lots, minimum analyte recovery in your assay. Write these down before opening the test sample. Never set criteria retrospectively.

- 2 Request test samples from at least 2 different lots**

Single-lot evaluation does not reveal batch variability. Request minimum 2 lots. SeamlessBio test samples are free — contact info@seamlessbio.de.

- 3 Run parallel cultures or parallel assays**

Test new supplier lot side-by-side against your current validated lot in the same experiment. Same passage, same conditions, same readout.

- 4 Evaluate against your pre-defined criteria**

Compare results against your Step 1 criteria. If results meet criteria on both lots tested, proceed to Step 5. If not, request additional lots or consider alternative formats.

- 5 Request full documentation for your QA file**

COA, donor screening records, origin certificate, sterility results. For IVDR: confirm EU donor origin. For GMP: confirm DMF or technical file availability.

- 6 Initiate batch reservation**

Calculate your required volume (see p.8 calculator). Reserve your validated lot without prepayment. Define call-off schedule. Maintain overlap with old lot.

- 7 Document the switch**

For GMP / IVDR: a supplier change is a documented change control event. Prepare your comparability report summarising parallelism data, acceptance criteria outcome and documentation review.

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Application Decision Tree — Which Human Serum for Your Protocol?

Use the table below to identify the right human serum format for your application. If your application spans multiple rows, choose the most specific format.

Application	Recommended Format	Critical Requirement	Concentration
CAR-T / T cell expansion	Human Serum AB, native or HI	Xeno-free, EU origin, lot reservation	2-5%
MSC expansion (research)	Human Serum AB, native	Xeno-free, EU origin, high growth factor	5-10%
MSC expansion (clinical GMP)	HPL or Human Serum AB + GMP docs	Xeno-free, GMP documentation, lot reservation	0.75-5%
NK cell differentiation	Human Serum AB or HPL	Supports NK maturation, no xenogenic components	5%
Hybridoma production	Human Serum AB, Heat Inactivated	Complement inactivated, low IgG background	5-10%
P. falciparum culture	Human Serum AB, native (type AB only)	Type AB mandatory; lot qualified by parasitaemia	10%
Lipemia interference (CLSI EP7)	Human Serum Delipidated SP1010	Lipoprotein-free, IgG intact	Matrix use
Antibody detection assay (IVD)	Human Serum Delipidated + IgG-free	IgG and lipid background eliminated	Matrix use
Hormone/steroid assay calibrator	Double Charcoal Treated F12010	Hormones + steroids removed	Matrix use
IVD negative control	Human Serum Universal Negative	Screened negative: HIV, HBsAg, HCV, Syphilis	Matrix use
Lipid metabolism research	Human Serum Delipidated SP1010	Lipid-free baseline for defined lipid addition	5-10%

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Batch Reservation Calculator

Use this calculator to determine how much volume to reserve. Under-reserving is the most common mistake — re-validating a new lot almost always costs more than holding buffer stock.

FORMULA

$$\text{Reservation Volume} = \text{Weekly usage (ml)} \times \text{Project duration (weeks)} \times \text{Safety factor 1.5}$$

Project Type	Weekly Usage	Duration	Base Volume	x1.5 Buffer	Reserve
IVD assay development	50 ml	12 weeks	600 ml	900 ml	1 L
CAR-T process validation	200 ml	16 weeks	3,200 ml	4,800 ml	5 L
MSC expansion research	100 ml	24 weeks	2,400 ml	3,600 ml	4 L
Hybridoma production	75 ml	20 weeks	1,500 ml	2,250 ml	2.5 L
IVDR clinical study matrix	150 ml	52 weeks	7,800 ml	11,700 ml	12 L

Your calculation:

Your Project	Weekly Usage (ml)	Duration (weeks)	Base Volume	x1.5	Reserve

SeamlessBio batch reservation: No prepayment required. No minimum order quantity. Reserve your validated lot and call off in partial deliveries as needed. Contact info@seamlessbio.de.

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IVDR Documentation Checklist

Under EU IVDR 2017/746, manufacturers must document that raw materials including human matrix materials are appropriate for their intended use. Use this checklist when qualifying a new supplier or lot.

Lot-Level Documentation (required for every lot)

Certificate of Analysis (COA)

- [] Protein concentration, sterility, pH, osmolality, lot number, expiry

Donor Screening Records

- [] HIV 1/2 Ab + NAT, HBsAg, anti-HCV + HCV RNA, syphilis, HTLV I/II

Sterility Test Report

- [] Ph.Eur. 2.6.1 or equivalent; no growth result

Mycoplasma Test (cell culture use)

- [] Ph.Eur. 2.6.7 or equivalent; negative result

Supplier-Level Documentation (for supplier qualification)

Origin Certificate

- [] Confirms donor country and compliance with applicable blood directive

EU Blood Directive Compliance Statement

- [] Compliance with EU Directive 2002/98/EC for EU-origin material

Manufacturing Site Certificate

- [] ISO 13485 or GMP certificate of the manufacturing facility

Quality Agreement / Supply Agreement

- [] Documents supplier obligations for notification of changes

Regulatory Support (for IVDR technical file)

Technical File / DMF Reference

- [] Supports your IVDR technical documentation for matrix materials

Change Notification Policy

- [] Supplier commitment to notify you of any changes to processing or donors

Comparability Protocol (on lot change)

- [] Defines what data is generated when supplier changes a lot

IVD Calibrators & Controls (application-specific)

Matrix Matching Statement

- [] Confirms material is equivalent to clinical sample matrix

Lot-to-Lot Consistency Data

- [] Historical CV data for total protein and key analytes across lots

CLSI EP7 Suitability (delipidated)

- [] For use in lipemia interference studies per CLSI EP7

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SeamlessBio — Human Serum Portfolio & Contact

All human serum variants in this guide are available from SeamlessBio — EU-qualified donors, EU stock in Passau, no minimum order quantity, batch reservation without prepayment.

Product	Code	Key Application	Stock	MOQ
Human Serum Type AB	HS-AB-100	CAR-T, MSC, malaria, hybridoma	EU stock	No MOQ
Human Serum Heat Inactivated	HS-AB-HI	Complement-sensitive applications	EU stock	No MOQ
Human Serum Delipidated	SP1010	Lipemia interference, IVD matrix	EU stock	No MOQ
Human Serum Delipidated + IgG-free	Humser_delip	Antibody assay development	EU stock	No MOQ
Human Serum Double Charcoal	F12010	Hormone/steroid assay calibrators	EU stock	No MOQ
Human Serum Universal Negative	UN1000	IVD negative controls	EU stock	No MOQ
Human Platelet Lysate (HPL)	2319ML050	MSC expansion (xeno-free)	EU stock	No MOQ
Human Plasma Pooled	HPPool	Plasma-matrix IVD assays	EU stock	No MOQ


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ORDER & SAMPLES

Free test samples — all variants
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