

PRODUCT BROCHURE

CytoPure™ Human Platelet Lysate

Fibrinogen-depleted cell culture supplements for research and cell therapy development

PLUS · XF · GI



CytoPure™ PLUS

- ✓ Fibrinogen-Depleted



CytoPure™ XF

- ✓ Fibrinogen-Depleted
- ✓ Xeno-Free



CytoPure™ GI

- ✓ Fibrinogen-Depleted
- ✓ Xeno-Free
- ✓ Gamma-Irradiated

Three formulations. One CytoPure™ platform.



All three formulations



XF and GI



GI

Manufactured in the United States from platelet units collected at FDA-licensed and AABB-accredited U.S. blood centers.

Why human platelet lysate

The case for moving an expansion workflow from fetal bovine serum to human platelet lysate

Fetal bovine serum (FBS) has been a workhorse of mammalian cell culture for decades, and it remains a proven growth supplement. But as researchers move toward more controlled, human-relevant cell culture workflows, the bovine origin and lot-to-lot variability of FBS can become important considerations.

Human platelet lysate offers a human-origin alternative derived from human platelet units. CytoPure™ is fibrinogen-depleted during manufacturing, providing a streamlined approach to cell culture without the need for supplemental heparin at the bench.

Human, not bovine	Human platelet lysate replaces bovine serum with a supplement derived from human platelet units—bringing the expansion workflow closer to the biology of the cells being cultured.
More expansion at a lower supplement concentration	In MSC studies conducted at Cytologics, CytoPure™ XF at 5% (v/v) produced approximately twice the cumulative population doublings of 10% FBS over 50 days, while also reducing doubling time. A meta-analysis of thirty-five studies reports a similar effect for human platelet lysate preparations generally.
Cell identity and function retained	Cells expanded in CytoPure™ retain the standard ISCT surface marker profile and trilineage differentiation capacity. Proliferation rate increases; but their defining characteristics remain intact.
A traceable U.S. supply chain	CytoPure™ is manufactured from platelet units collected at FDA-licensed, AABB-accredited U.S. blood centers. Each lot can be traced back to the source units used in its manufacture.

What changes when you switch

	Fetal bovine serum	CytoPure™
Species origin	Bovine	Human
Xenogeneic material in the workflow	Present by definition	None in CytoPure™ XF or CytoPure™ GI
Typical working concentration	10% (v/v)	2–10% (v/v); 5% is the usual starting point
Supplemental heparin	Not applicable	Not required — the product is fibrinogen-depleted
Lot screening by the user	Commonly performed	Generally unnecessary; every lot is released against a published specification
Documentation per lot	Varies by supplier	Lot-specific Certificate of Analysis with every shipment

A step-by-step account of the transition from FBS — what to change, what to expect in the first two weeks, and what does not change at all — is available in our FBS-to-hPL Transition Guide (Document CYT-TRG-003).

The CytoPure™ family

Three formulations, one manufacturing process

CytoPure™ PLUS, XF and GI are manufactured from the same source material using the same core process and released against the same quality specification. The formulations differ only in the processing steps that determine their xeno-free and terminally gamma-irradiated characteristics.

	CytoPure™ PLUS	CytoPure™ XF	CytoPure™ GI
Fibrinogen-depleted	Yes	Yes	Yes
Supplemental heparin required	No	No	No
Heparin used in manufacture	Yes — porcine origin	No	No
Xeno-free	No	Yes	Yes
Terminal gamma irradiation	No	No	Yes — 25–38 kGy
Best Suited for	Routine research expansion where a xeno-free workflow is not required	Xeno-free research and cell therapy development workflows	Workflows requiring terminal gamma irradiation processing step

Choosing CytoPure™ XF is used for xeno-free research and cell therapy development and is the most direct alternative to FBS. Choose CytoPure™ PLUS when xeno-free is not required, or CytoPure™ GI when terminal gamma irradiation is required.



CytoPure™ PLUS

Contains porcine heparin



CytoPure™ XF

Xeno-free — no animal-derived component



CytoPure™ GI

Xeno-free, terminally gamma-irradiated

Common to all three

- Manufactured in the United States from human platelet units collected at FDA-licensed and AABB-accredited U.S. blood centers.
- Pooled from typically greater than 300 individuals per lot.
- Released against one published specification, with a lot-specific Certificate of Analysis in every shipment.
- Working concentration of 2–10% (v/v); 5% (v/v) is the usual starting point for culturing primary human MSC.
- Three fill volumes: 50 mL, 100 mL and 500 mL. 3 years from date of manufacture when stored at ≤ –20°C.

Fibrinogen depletion

Why no heparin is added at the bench

The problem	Human platelet lysate contains fibrinogen carried over from the platelet source. Under conditions that promote coagulation—such as temperature fluctuations during thawing or exposure to divalent cations in culture media—fibrin can form, resulting in visible strands, precipitate, gels, or clots.
The conventional approach	Fibrin formation in platelet lysate is commonly controlled by adding heparin to the culture medium. Because conventional heparin is typically porcine-derived, this introduces an additional animal-derived component and an extra variable into the cell culture workflow.
What CytoPure™ does instead	CytoPure™ removes fibrinogen during manufacturing in a controlled, verified step before the product is filled. By reducing the source material for fibrin formation, CytoPure™ eliminates the need for supplemental heparin in culture.
What that means at the bench	No heparin to add, dissolve, sterilize, or document. Fewer preparation steps, fewer variables, and a simpler workflow—while maintaining a fibrinogen-depleted supplement from the start.

Where the two workflows differ

Conventional human platelet lysate

- Platelet pool
- ↓ Lysis
- ↓ **Fill — fibrinogen still present**
- ↓ **User adds heparin to complete medium**
- ↓ Culture

CytoPure™

- Platelet pool
- ↓ Lysis
- ↓ **Fibrinogen depleted in manufacture**
- ↓ Fill
- ↓ **Culture — no need to add anticoagulant**

Published position This is not a claim Cytologics makes alone. Fibrinogen-depleted human platelet lysate has been shown to support heparin-free expansion of mesenchymal stromal cells (Kee et al., *Biology* 2023;12:1085). A joint working group of the AABB and the International Society for Cell & Gene Therapy has stated that fibrinogen-depleted human platelet lysate, requiring no heparin addition, is desirable (Bieback et al., *Transfusion* 2019;59:3448–3460).

References

1. Bieback K, Fernandez-Muñoz B, Pati S, Schäfer R. Gaps in the knowledge of human platelet lysate as a cell culture supplement for cell therapy: a joint publication from the AABB and the International Society for Cell & Gene Therapy. *Transfusion* 2019;59(11):3448–3460. doi:10.1111/trf.15483
2. Palombella S, Perucca Orfei C, Castellini G, et al. Systematic review and meta-analysis on the use of human platelet lysate for mesenchymal stem cell cultures: comparison with fetal bovine serum and considerations on the production protocol. *Stem Cell Research & Therapy* 2022;13:142. doi:10.1186/s13287-022-02815-1
3. Kee LT, Lee YT, Ng CY, et al. Preparation of fibrinogen-depleted human platelet lysate to support heparin-free expansion of umbilical cord-derived mesenchymal stem cells. *Biology (Basel)* 2023;12(8):1085. doi:10.3390/biology12081085
4. Shih DT-B, Burnouf T. Preparation, quality criteria, and properties of human blood platelet lysate supplements for ex vivo stem cell expansion. *New Biotechnology* 2014;32(1):199–211. doi:10.1016/j.nbt.2014.06.001

Performance

More expansion at half the supplement concentration

CytoPure™ XF was evaluated against fetal bovine serum in primary human mesenchymal stromal cells using matched culture conditions. Unless otherwise stated, CytoPure™ XF was used at 5% (v/v) and FBS at 10% (v/v)—half the supplement concentration.

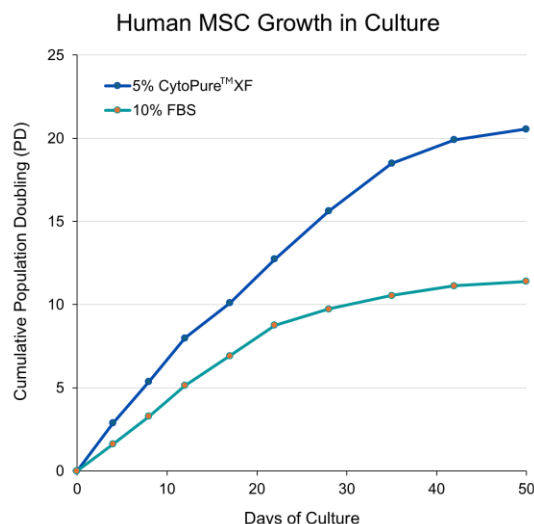


Figure 1. Cumulative population doublings of adipose-derived MSC in α -MEM supplemented with 5% CytoPure™ XF or 10% FBS over 50 days of culture. CytoPure™ XF reached 20.6 cumulative population doublings against 11.4 for FBS, at half the supplement concentration.

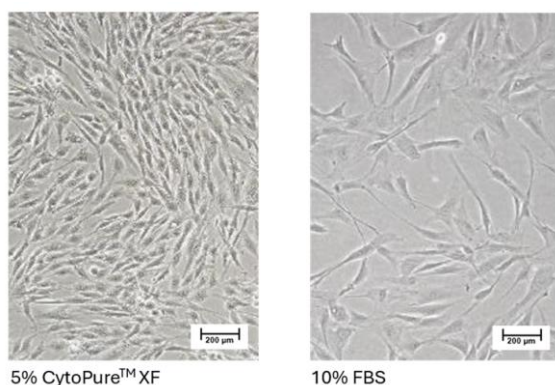


Figure 2. Matched-passages morphology. Adipose-derived MSC seeded at 4×10^3 cells/cm² in α -MEM supplemented with 5% CytoPure™ XF or 10% FBS, imaged three days after seeding at identical magnification. Morphology is unchanged; density is not.

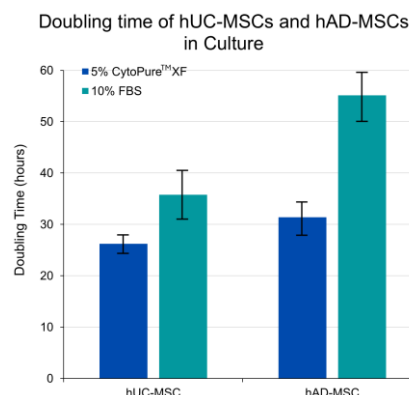


Figure 3. Doubling time of umbilical cord-derived (hUC-MSC) and adipose-derived (hAD-MSC) mesenchymal stromal cells in medium supplemented with 5% CytoPure™ XF or 10% FBS. Doubling time was calculated by standard exponential growth at each of four passages and is reported as the mean, with the range observed across those passages. CytoPure™ XF gave a shorter mean doubling time for both cell sources — 26.2 h versus 35.8 h and 31.4 h versus 55.1 h — at half the supplement concentration.

Consistency, phenotype and function

What stays the same from lot to lot, and what stays the same about the cells

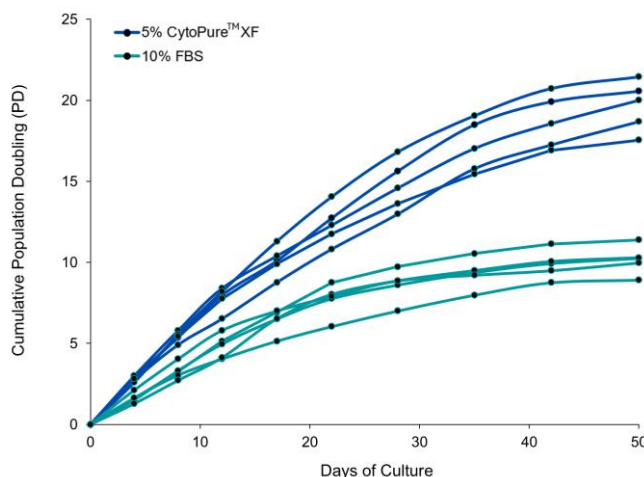


Figure 4. Lot-to-lot consistency. Five independent CytoPure™ XF production lots at 5% (v/v) and five independent FBS lots at 10% (v/v), each expanded in parallel over 50 days of culture. The five CytoPure™ XF lots span 17.6–21.5 population doublings at day 50 and form a band that does not overlap the FBS lots at any timepoint. No lot pre-screening is applied.

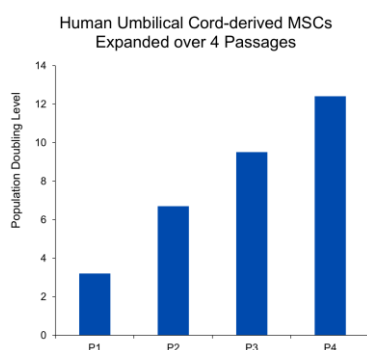


Figure 5. Cumulative population doubling level of umbilical cord-derived MSC (hUC-MSC) expanded in DMEM/F-12 supplemented with CytoPure™ XF, reaching 12.4 population doublings by the fourth passage.

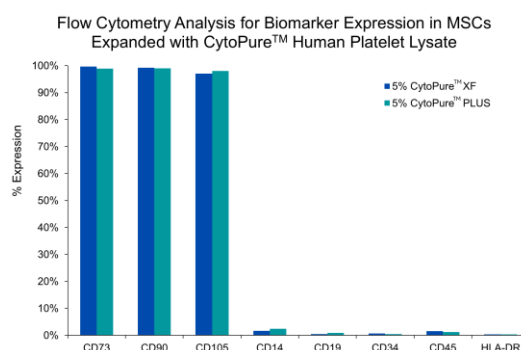


Figure 6. Surface marker expression after four passages in α -MEM supplemented with 5% CytoPure™ XF or 5% CytoPure™ PLUS, measured by antibody labeling and flow cytometry. CD73, CD90 and CD105 were expressed above 97%, and CD14, CD19, CD34, CD45 and HLA-DR below 3%, in both conditions — the profile the ISCT defines for mesenchymal stromal cells.

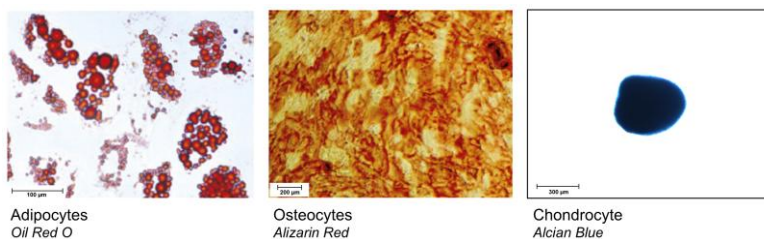


Figure 7. Trilineage differentiation of mesenchymal stromal cells expanded in α -MEM supplemented with 5% CytoPure™ XF, then induced toward the adipogenic, osteogenic and chondrogenic lineages and stained with Oil Red O, Alizarin Red and Alcian Blue respectively. Induced conditions are shown.

Applications

Where CytoPure™ is used

Application	What it covers	Where to start
Mesenchymal stromal cell expansion	Bone marrow, adipose and umbilical cord-derived MSC. The cell type the CytoPure™ performance data was generated in, and the largest use of the product family.	See Performance and Consistency. Start at 5% (v/v).
Other primary adherent human cells	Dermal fibroblasts, keratinocytes and endothelial cells are supported by human platelet lysate preparations, at concentrations that differ by cell type.	See the published concentrations in the CytoPure™ Technical Data Sheet (CYT-TDS-078), then titrate.
Cell therapy process development	Pre-clinical development and process definition, where removing bovine material early avoids re-validating a process later.	CytoPure™ XF is the direct FBS replacement. Research grade — see Quality, sourcing and traceability.
Suspension immune cell culture	T-cell and NK-cell cultures have been evaluated at Cytologics over multi-day culture, assessing viability, cell count and activation; high viability and normal function were observed. Expansion kinetics have not been characterized for these cell types and no performance data is published for them. Published studies report 5% (v/v) for T lymphocytes and 10% (v/v) for NK cells.	Start at 5–10% (v/v). Optimize for the specific cell type and culture system.



CytoPure™ GI supplementing cell culture medium in a biological safety cabinet. All three products are supplied frozen and are added directly to basal medium after thawing.

Working concentration

Add CytoPure™ to basal medium at 2–10% (v/v). For primary human mesenchymal stromal cells, 5% (v/v) is the recommended starting point and is the concentration used in the performance data published by Cytologics.

Find the optimal concentration The ideal CytoPure™ concentration depends on the cell type and culture system. Increasing the concentration beyond the optimal range may provide no additional performance and, for some cell types, may reduce proliferation or alter phenotype. Published studies report optimal hPL concentrations both below and above the range commonly used for mesenchymal stromal cells. Titrate both up and down to determine the optimal concentration for your application.

Published starting concentrations for five cell types, with references, are tabulated in the CytoPure™ Technical Data Sheet (CYT-TDS-078) and Transition Guide (CYT-TRG-003), section 4.

Quality, sourcing and traceability

How a lot is made, tested, released and traced

At the blood center	1	Donor screening and eligibility determination
	2	Platelet collection
	3	Donor infectious disease testing
Incoming	4	Unit release by the collecting center
	5	Receipt and incoming acceptance
Manufacture	6	Multi-donor pooling
	7	Controlled lysis
	8	Fibrinogen depletion
	9	Heparin addition CytoPure™ PLUS only
	10	Sterile filtration (0.2 µm)
	11	Aseptic fill and closure
	12	Terminal gamma irradiation CytoPure™ GI only
Release	13	Quality control release testing
	14	Quality assurance review and release
Storage and shipment	15	Frozen storage
	16	Shipment

Released against a published specification

Test	Method	Acceptance criteria
pH	USP <791>	7.0–7.8
Osmolality	USP <785>	250–350 mOsm/kg
Total protein	USP <1057>	4.0–7.0 g/dL
Sterility (bacteria and fungi)	USP <71>	No growth
Mycoplasma	Enzymatic	Not detected
Endotoxin	USP <85>	< 5.0 EU/mL
Cell growth verification	Primary human cell proliferation	Pass
Donor viral testing	21 CFR Part 610	Negative / non-reactive

U.S. sourcing	Every platelet unit is collected in the United States at an FDA-licensed, AABB-accredited blood center, from donors screened and tested under 21 CFR Parts 610 and 630. No step is performed outside the United States.
Traceability	Blood center unit identifiers → pool record → manufacturing lot number → fill → Certificate of Analysis → shipment. Traceback to the collecting center is possible for any released lot. Records are retained for 7 years.
Research grade	CytoPure™ is intended for research use and cell culture process development. Each lot is manufactured, tested, and released against a defined quality specification and is accompanied by a lot-specific Certificate of Analysis.

Documentation per lot Every shipment carries a lot-specific Certificate of Analysis reporting the measured result for every test above. The full account, with each step described, is in CYT-MTO-005 (Manufacturing & Traceability).

Ordering and support

Catalog numbers, samples, quotes and the documentation library

Fill volume	CytoPure™ PLUS	CytoPure™ XF	CytoPure™ GI
50 mL	1908-C050	1909-C050	1910-C050
100 mL	1908-C100	1909-C100	1910-C100
500 mL	1908-C500	1909-C500	1910-C500

Bulk and custom fill volumes are available on request. To request a sample, a quote, or technical support, contact info@cytologicsbio.com or call +1 (866) 298-6077, Monday–Friday, 8:00 a.m.–5:00 p.m. Pacific Time.

The documentation library

Every document below is a controlled document at the revision and effective date printed on it. Product documentation is published at cytologicsbio.com; the rest is available on request.

Product documentation

- **CYT-TDS-078** Technical Data Sheet — CytoPure™ Human Platelet Lysate
- **CYT-HPL-1908** Product Information Sheet — CytoPure™ PLUS
- **CYT-HPL-1909** Product Information Sheet — CytoPure™ XF
- **CYT-HPL-1910** Product Information Sheet — CytoPure™ GI
- **CYT-TRG-003** Transition Guide — Fetal Bovine Serum to CytoPure™
- **CYT-TRB-012** Troubleshooting Guide — CytoPure™ Human Platelet Lysate

Quality, sourcing and traceability

- **CYT-QTS-031** Quality and Testing Standards — CytoPure™ Human Platelet Lysate
- **CYT-MTO-005** Manufacturing and Traceability Overview
- **CYT-COO-016** Certificate of Origin — CytoPure™ Human Platelet Lysate
- **CYT-COA-1909** Certificate of Analysis and Release — CytoPure™ XF
- **CYT-VSD-009** Viral Safety and Donor Qualification Statement
- **CYT-TSE-002** TSE/BSE Risk Mitigation Statement

Safety

- **CYT-SDS-1908** Safety Data Sheet — CytoPure™ PLUS
- **CYT-SDS-1909** Safety Data Sheet — CytoPure™ XF
- **CYT-SDS-1910** Safety Data Sheet — CytoPure™ GI

IMPORTANT For research use only. Not for use in diagnostic or therapeutic procedures. Not for human or animal use. This product contains human-derived material and must be handled as potentially infectious; observe universal precautions and handle at Biosafety Level 2 or higher.