

Certificate of Analysis and Release

CytoPure™ XF — Human Platelet Lysate, Fibrinogen-Depleted, Xeno-Free

RECOMMENDED STORAGE



≤ -20°C

-80°C beyond 12 months

Catalog number 1909-C500

Lot number 26C31

Fill volume 500 mL

Expiration Date July 2029

Format / shipping Frozen; shipped at ≤ -20°C

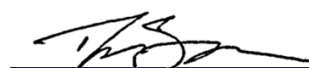
Origin and sourcing	United States of America (source material, manufacture, and final processing). Platelet units were collected at FDA-licensed, AABB-accredited U.S. blood centers and pooled from multiple donors to reduce lot-to-lot variability.
Donor testing	Each platelet unit was approved for human use and tested in accordance with 21 CFR Part 610. The complete donor testing panel is described in CYT-VSD-009.
Formulation and grade	Fibrinogen-depleted, xeno-free, research grade. Heparin was not used at any stage of manufacture.
Appearance and filtration	Sterile filtered (0.2 µm). Particulates may be observed after thawing; this is normal and does not affect performance.

Release testing

Test	Method	Acceptance criteria	Result
pH	USP <791>	7.0–7.8	7.3
Osmolality	USP <785>	250–350 mOsm/kg	328 mOsm/kg
Total protein	USP <1057>	4.0–7.0 g/dL	6.1 g/dL
Sterility (bacteria and fungi)	USP <71>	No growth	No growth
Mycoplasma	Enzymatic	Not detected	Not detected
Endotoxin	USP <85>	< 5.0 EU/mL	< 1.0 EU/mL
Cell growth verification	Primary human cell proliferation	Pass	Pass
Donor viral testing	21 CFR Part 610	Negative / non-reactive	Negative / non-reactive

Quality Assurance release

The test results performed as part of this lot release have been reviewed by Cytologics Quality Assurance personnel, who confirmed that the testing meets the specifications presented on this Certificate of Analysis. Cytologics warrants conformance to these specifications when the product is stored and used as directed and will replace non-conforming product; replacement is the purchaser's sole remedy.



Cytologics Quality Assurance

31 July 2026

Date of release

IMPORTANT For research use only. Not for human or animal use, or for diagnostic or therapeutic procedures. Contains human-derived material; handle as potentially infectious at Biosafety Level 2 or higher. Sold for the purchaser's internal research use; not for resale.

Related documentation [CYT-HPL-1909](#) · [CYT-SDS-1909](#) · [CYT-QTS-031](#) · [CYT-COO-016](#)