



Human Platelet Lysate (hPL)

Product	hPL GOLD
Intended use	Clinical grade
Reference number	<i>To be completed</i>
Lot number	<i>To be completed</i>
Expiration date	<i>To be completed</i>
Shipping conditions	Dry ice
Storage temperature	≤ -70°C
Bag volume	100 mL

Origin:

The hPL is derived from human platelet concentrates prepared from donations collected from consenting, non-remunerated voluntary donors of the Belgian Red Cross Flanders. Platelet concentrates were prepared according to Belgian legislation, including pathogen inactivation.

All platelet concentrates have been tested for anti-HIV-1/2, anti-HCV, HBsAg, syphilis, HIV NAT, HBV NAT and HCV NAT.

Analysis of the final product:

Test	Specification	Result
Sterility	No aerobic and anaerobic growth	Pass/Fail
Endotoxin	< 0.500 EU/mL	Pass/Fail
Mycoplasma	Below detection limit	Pass/Fail
Total protein	15 – 30 g/L	Pass/Fail
Ca ²⁺	≤ 1.5mM	Pass/Fail
Osmolality	250 - 320 mOsm/kg	Pass/Fail
pH	6.5 – 8.5	Pass/Fail
Fibrinogen	≤ 30µg/mL	Pass/Fail
Cell growth performance	Proliferation of human adipose-derived stem cells (hADSC)	Pass/Fail

QC testing is complete and the product meets the predefined release criteria.

Signature of Quality Assurance Unit	Date
<i>To be completed</i>	<i>To be completed</i>

