

UltraGRO™-PURE GI

Gamma Irradiated PRT hPL for Immune Cell Culture

Xeno-free Serum Substitute, Safe, Consistent, Cost-Effective

AventaCell BioMedical has adopted a state-of-the-art gamma irradiation process, as a pathogen reduction treatment (PRT), for viral inactivation to create an UltraGRO™-PURE GI (UG-P GI) product. The xeno-free fibrinogen-depleted human platelet lysate, **UG-P GI** offers minimized pathogen contamination risk while preserving potent cell culture performance with human immune cells and other applicable cell types for clinical applications.

Benefits of UltraGRO™-PURE GI

- US FDA FMD# 34284
- JAPAN PMDA Certificate
- Ph. Eur. General Chapter 5.2.12.4 Compliance
- · Non-xenogeneic serum substitute
- · Abundant natural growth factors and proteins
- Gamma irradiation has been accepted by regulatory agencies as a PRT
- GI safeguard of 99.99%+ viral clearance
- Viral inactivated products w/o loss of potency
- · Ideal for producing clinical grade immune cells

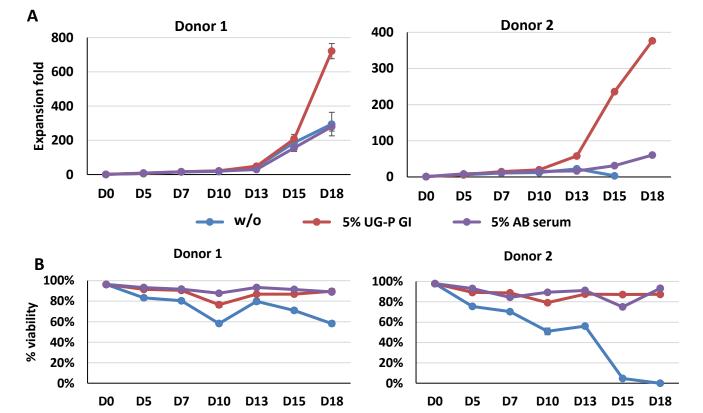


Figure 1. T cell expanded from PBMC in medium (supplier B) supplemented with gamma-irradiated human platelet lysate or autologous plasma. (A) Total cell fold expansion (B) Percentage of live cells.



Manufacturing Site: 8727 S 212th Street, Kent, WA 98031, USA

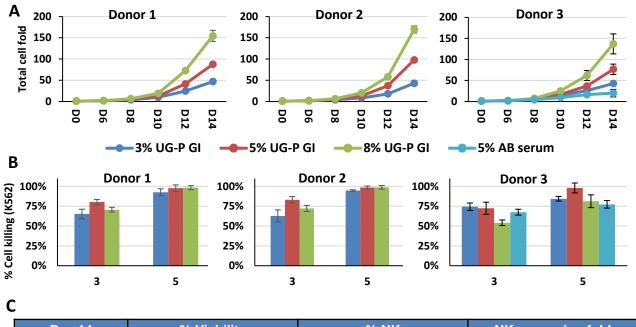
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Day 14	% Viability			% NK			NK expansion fold		
donor	1	2	3	1	2	3	1	2	3
3% UG-P GI	95	95	96	93.0	84.6	86.2	227	250	440
5% UG-P GI	95	97	93	89.0	69.2	74.8	405	465	680
8% UG-P GI	94	96	96	88.0	54.6	60.7	708	635	985
5% AB serum	na	na	95	na	na	62.8	na	na	149

Figure 2. NK cell expanded from PBMC in medium (supplier C) supplemented with gamma-irradiated human platelet lysate (UG-P GI) or AB serum. (A) Total cell fold expansion. (B) Cytotoxicity of NK cells against K562 cells at 3:1, 5:1 of effector: target ratios. (C) Percentage of live cells, percentage of NK cells, specific expansion fold of NK cells.

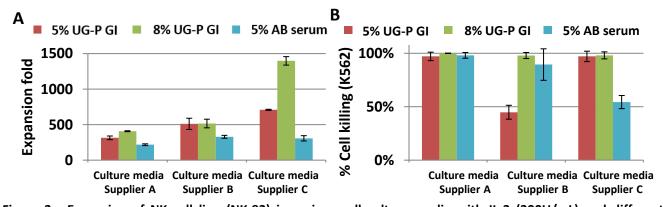


Figure 3. Expansion of NK cell line (NK-92) in various cell culture media with IL-2 (200U/mL) and different supplements. After 12 days in culture, expended cells were analyzed for (A) Expansion fold of NK cells (B) Cytotoxicity of NK cells against K562 cells at 5:1 of effector: target ratio.



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