

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 for compliance with regulatory requirements, while providing comparable 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
- Viral inactivated products w/o loss of potency
- · Ideal for producing clinical grade immune cells

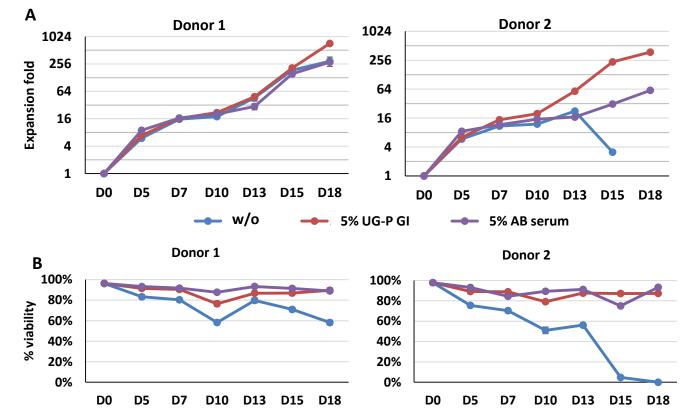


Figure 1. T cell expanded from PBMC in medium (supplier B) supplemented with gamma-irradiated human platelet lysate or autologous plasma. (A) Total cell fold expansion (B) Percentage of live cells.



Manufacturing Site: 575 14th St. NW, Suite 100, Atlanta, GA 30318, USA

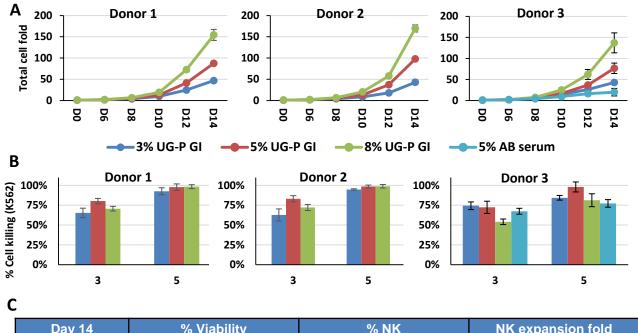
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Day 14	% Viability			% NK			NK expansion fold		
donor	1	2	3	1	2	3	1	2	3
3% UG-P GI	95	95	96	93.0	84.6	86.2	227	250	440
5% UG-P GI	95	97	93	89.0	69.2	74.8	405	465	680
8% UG-P GI	94	96	96	88.0	54.6	60.7	708	635	985
5% AB serum	na	na	95	na	na	62.8	na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

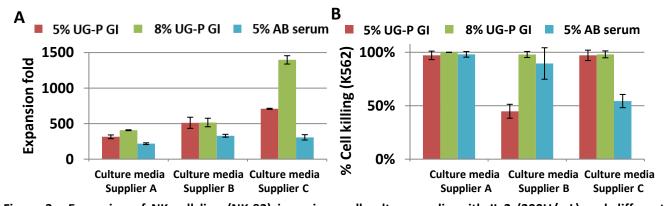


Figure 3. Expansion of NK cell line (NK-92) in various cell culture media with IL-2 (200U/mL) and different supplements. After 12 days in culture, expended cells were analyzed for (A) Expansion fold of NK cells (B) Cytotoxicity of NK cells against K562 cells at 5:1 of effector: target ratio.



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