

Genesis PRP Indication For Use

- FDA cleared 510(k) Class II medical device, # BK170136
- Designed to be used for the safe and rapid preparation of autologous platelet-richplasma (PRP) from a small sample of peripheral blood at the patient point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Genesis Platelet Rich Plasma (PRP)

- "Gel-Separator" Style PRP kit utilizing small to large blood draws.
- Only Platform on the market that provides a 15ml and 30ml single spin gel isolation system to produce a High-Density product.
- Completely closed system that provides high PLT capture rate (80-90+%) while still maintaining a high safety profile.
- Cleanest PRP available, with no residual gel particulate and by reducing hematocrit levels to less than 1% and white blood cell (WBC) counts to just over 2%.



The Offering: 2 Volumes of Blood Collection



15ml yielding approx. 6ml at 1.8-2 times baseline concentration



30ml yielding approx. 6ml at 4 times baseline concentration



Ensuring the right concentration above whole blood and adequate volume for every indication.



15 mL Tube - Platelet Gradient It's ALL PRP

"PPP"

Swing Bucket 1100G -- 10 min

"PRP"

Donor/Sample	PRP Vol.	Baseline Ct.	PRP Ct.	Fold	% recovery
	OUT (ml)	(x10e6)	(x10e6)	Increase	70 recovery
1-ALL	6.4	272	462	1.70	83.62
1-PPP	3	272	405	1.49	34.36
1-PRP	3.6	272	534	1.96	54.37
2-ALL	6.7	302	483	1.60	82.43
2-PPP	3	302	446	1.48	34.08
2-PRP	3.2	302	533	1.76	43.44
Mean				1.67	83.08
STDEV				0.18	4.60



30 mL Tube – Platelet Gradient

Level	Spin Speed (G)	PRP Vol. OUT (ml)	Baseline Ct. (x10e6)	PRP Ct. (K/uL)	Fold Increase	% recovery
P1	1100	3	195	84	0.4	4
P2	1100	3	195	93	0.5	5
Р3	1100	3	195	94	0.5	5
P4	1100	3	195	97	0.5	5
P5	1100	3.5	195	1293	6.6	77
Total			_			96

Level	Spin Speed (G)	PRP Vol. OUT (ml)	Baseline Ct. (x10e6)	PRP Ct. (K/uL)	Fold Increase	% recovery
P1	1600	3	195	48	0.2	2
P2	1600	3	195	37	0.2	2
P3	1600	3	195	34	0.2	2
P4	1600	3	195	39	0.2	2
P5	1600	4.5	195	1037	5.3	80
Total						88



PRP Kit Components





- 15mL & 30mL Separating Tube
- 2 10mL Syringes
- Tourniquet
- 21g Butterfly Needle w/Tube Adapter
- 18g needle
- Alcohol prep and bandage

