Clinical Performance Evaluation of Platelet Rich Plasma (PRP) Preparation Tube

R & D Department of Zhuhai Longtime Biotechnology Co., Ltd
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1. Objective: To evaluate the clinical performance of platelet rich plasma (PRP) tubes

2. Clinical performance evaluation

2.1 The results of sample separation were as follows:

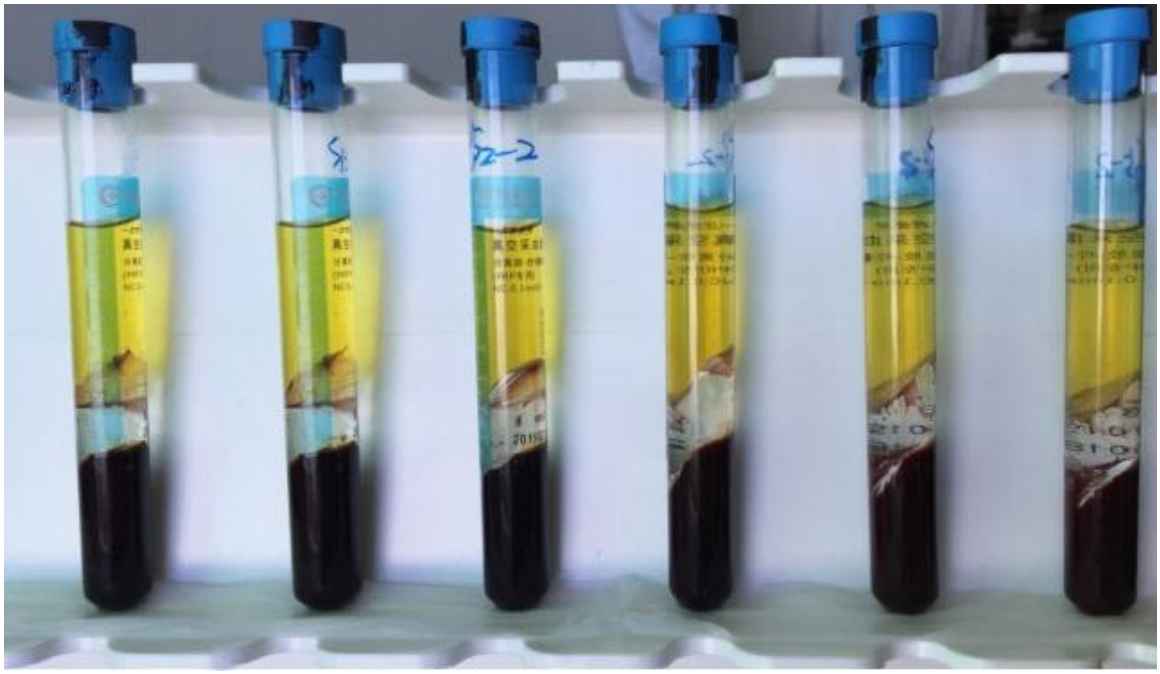

Figure 1　Separation effect of test sample group

After centrifuging the test sample for 10 minutes, the plasma and blood cells can be completely isolated. After mixing according to the instructions, the high concentration platelet rich plasma can be easily, quickly and completely prepared, which can meet the expected use.

2.2 Clinical performance 1 Results：

2.2.1 For 12 blood donors, blood cell analysis results of whole blood samples and test samples were divided into 2 batches in 2 hospitals. See the summary table of blood cell analysis results for details.

Table 1-1 Summary of blood cell analysis results

Product	Volunteer	Whole Blood					PRP				
		Volume (ml)	Platelet ($\times10^9$/L)	Red blood cell ($\times10^{12}$/L)	White blood cell ($\times10^9$/L)	Neutro-phils ($\times10^{12}$/L)	Vol (ml)	PLT ($\times10^9$/L)	RBC ($\times10^{12}$/L)	WBC ($\times10^9$/L)	Neutro-phils ($\times10^{12}$/L)
Test sample group	S1-2	8	332	4.93	6.13	3.73	2.3	873	0.01	1.44	0.07
	S2-2	8	302	5.56	6.45	3.52	1.8	896	0.01	1.41	0.03
	S3-2	8	337	4.79	7.00	3.64	2.3	841	0.02	2.49	0.11
	S4-2	8	229	5.27	6.39	4.03	1.8	659	0.02	2.30	0.18
	S5-2	8	312	4.27	4.04	1.84	2.2	857	0.02	2.75	0.06
	S6-2	8	267	4.27	5.09	3.18	2.2	710	0.02	2.04	0.54

Note: The first batch was tested in Dongguan Donghua Hospita

Table1-2 Summary of blood cell analysis results

Product	Volun-teer	Whole Blood					PRP				
		Volume (ml)	Platelet ($\times10^9$/L)	Red blood cell ($\times10^{12}$/L)	White blood cell ($\times10^9$/L)	Neutro-phils ($\times10^{12}$/L)	Vol (ml)	PLT ($\times10^9$/L)	RBC ($\times10^{12}$/L)	WBC ($\times10^9$/L)	Neutro-phils ($\times10^{12}$/L)
Test sample group	S1-2	8	220	5.30	7.50	4.24	2.5	571	0.01	4.49	0.33
	S2-2	8	298	5.40	5.40	3.20	3.0	634	0.02	1.98	0.14
	S3-2	8	263	4.40	6.70	3.46	3.2	556	0.01	1.26	0.05
	S4-2	8	228	5.70	6.69	3.20	2.4	474	0.01	3.67	0.14
	S5-2	8	309	5.99	8.47	5.72	2.7	618	0.01	2.24	0.11
	S6-2	8	273	4.10	4.29	2.30	3.3	560	0.01	1.02	0.05

Note: The second batch was tested in the Second Affiliated Hospital of Guangzhou Medical University

2.2.2 The calculation results of whole blood samples and test samples of 12 blood donors are as follows:

Table 2 - 1 Statistical analysis of results

Product	Volun-teer	Platelet recovery （%）	Red blood cell recovery （%）	Leukocyte recovery （%）	Neutrophil recovery （%）	Platelet enrichment coefficient
Test sample group	S1-2	75.60	0.06	6.75	0.54	2.63
	S2-2	66.75	0.04	4.92	0.19	2.97
	S3-2	71.75	0.12	10.23	0.87	2.50
	S4-2	64.75	0.09	8.10	1.00	2.88
	S5-2	75.54	0.13	18.72	0.90	2.75
	S6-2	73.13	0.13	11.02	4.67	2.66
	Mean	71.25	0.09	9.96	1.36	2.73
	Standard deviation	4.55	0.04	4.84	1.65	0.1722

Note: The first batch was tested in Dongguan Donghua Hospita

Table 2 - 2 Statistical analysis of results

Product	Volun-teer	Platelet recovery （%）	Red blood cell recovery （%）	Leukocyte recovery （%）	Neutrophil recovery （%）	Platelet enrichment coefficient
Test sample group	S1-2	81.11	0.06	18.71	2.43	2.60
	S2-2	79.78	0.14	13.75	1.64	2.13
	S3-2	84.56	0.09	7.52	0.58	2.11
	S4-2	62.37	0.05	16.46	1.31	2.08
	S5-2	67.50	0.06	8.93	0.65	2.00
	S6-2	84.62	0.10	9.81	0.90	2.05
	Mean	76.66	0.08	12.53	1.25	2.16
	Standard deviation	9.42	0.03	4.48	0.71	0.2176

Note: The second batch was tested in the Second Affiliated Hospital of Guangzhou Medical University

2.3 Clinical Performance 2 Results:

Results of Platelet Aggregation Test (PAgT) and Clot Retraction Test (CRT) of whole blood samples and test samples from 12 blood donors are shown in the table below:

Table 3-1 Summary and analysis of clinical performance tests and results

Product	Volun-teer	PRP-Platelet concen-tration (×109/L)	Correction (PRP:PPP)	PRP-Platelet correction concentration (×109/L)	Platelet aggregation rate ADP (%)	Blood clot contraction rate（%）
Test sample group	S1-2	873	1:3	218	85	82.50
	S2-2	896	1:3	224	80	87.50
	S3-2	841	1:3	210	76	81.25
	S4-2	659	1:2	220	71	83.75
	S5-2	857	1:3	214	74	81.25
	S6-2	710	1:2	237	80	82.5
	Mean				77.7	83.13
	Standard deviation				5.0	2.34

Note: The first batch was tested in Dongguan Donghua Hospita. ADP, adenosine diphosphate

Table 3-2 Summary and analysis of clinical performance tests and results

Product	Volun-teer	PRP-Platelet concen-tration (×109/L)	Correction (PRP:PPP)	PRP-Platelet correction concentration (×109/L)	Platelet aggregation rate ADP (%)	Platelet aggregation rate AA (%)	Blood clot contraction rate（%）
Test sample group	S1-2	571	1：1.3	248	62	72	76.25
	S2-2	634	1：1.5	254	61	73	78.75
	S3-2	556	1：1.2	253	70	80	80.00
	S4-2	474	1：0.9	249	71	67	81.25
	S5-2	618	1：1.5	247	61	67	77.50
	S6-2	560	1：1.3	243	73	89	82.50
	Mean				66.3	74.7	79.38
	Standard deviation				5.6	8.5	2.34

Note: The second batch was tested in the Second Affiliated Hospital of Guangzhou Medical University. ADP, adenosine diphosphate; AA,arachidonic acid