



TEST REPORT
For
IN-VITRO PERFORMANCE STUDY
T-LAB PRP TUBE

Document No	RPR.PTN.06
Revision No	00
Release Date	07.02.2019
Revision Date	
Page	1 of 5

IMCAS 2019, Comparison Study of PRP Session.

PRP Session 069, IMCAS Annual Congress 2019

01.02.2019

1. ABSTRACT

This performance test analyzes the characterization of T-LAB PRP KIT/ TUBES' preparation quality of platelet-rich plasma milieu.

PRP is used for many years in order to enhance the stimulation of soft and hard tissue (including bone). The prepared plasma has been proven as safe & efficient on various clinical publications. The clinical safety and efficacy have already been determined with substantially equivalency data on our Clinical Evaluation report of this device.

The aim of this report is a wide range characterization analysis due to quality of the final product. The admired volume in clinical usage is about 5-10 ml in general PRP injections.

Characterization study was performed during IMCAS 2019, Comparison Study of PRP Session. This session hosted several key companies and results of the study includes all participant results. Due to binding confidentiality agreement, results may not be shared as an attachment to this report.

2. MATERIALS & METHODS

In order to identify the quality of a platelet-rich plasma milieu as a final product, EDTA whole blood count was used as a control data. The whole blood is harvested into the vacuumed blood tube with EDTA (Becton Dickinson, NJ, USA) as 2ml standardized whole blood count parameters by using routine phlebotomy. The whole blood count was performed on HORIBA hematology analyzer (*HORIBA, Kyoto, Japan*). The whole blood count results are recorded.

To identify the performance of T-LAB PRP KIT/ TUBES (T-Biyoteknoloji Ltd, Bursa, Turkey), blood harvesting is performed up to 9ml for a single tube and 18ml for 2 tubes. Following EO sterile samples was used for the characterization study.


Sample	Product LOT / Expiration Date
T-LAB PRP KIT/ T 1000	1061218 / 06 2020

And the harvested blood is aimed immediately to be centrifugated. The steps to obtain PRP is done according to manufacturer instructions.

After centrifugation, a significant plasma separation is obtained with the naked eye. The plasma is discarded and performed by the hematology analyzer.

2,7ml final platelet-rich plasma milieu per tube and 5,4ml milieu was obtained in total from two tubes. In case of 2 tubes used for centrifugation balance, simply there was 5,4 ml of platelet-rich plasma. The plasma is re-suspended by gently shaking action in order to form a homogenized milieu. The re-suspension process took 15 seconds. And, in order to prevent the possible clumping during cell count, EDTA coated Microtainer Tubes (BD, NJ, the USA) are used just before performing the cell counts.

The analysis of PRP in the frame of quality regarding the final product is for Pure Platelet Rich Plasma. We eliminated the serious population of RBC and leucocyte contents.

	TEST REPORT For IN-VITRO PERFORMANCE STUDY T-LAB PRP TUBE	Document No	RPR.PTN.06
		Revision No	00
		Release Date	07.02.2019
		Revision Date	
		Page	2 of 5

The preparation of platelet-rich plasma within the meaning of pure-platelet-rich plasma is also determined as a final product with the data of Platelet Purity in the final platelet-rich plasma, Platelet efficacy rate as a result and the useful dose data.

3. RESULTS

	Whole Blood Count	PRP data after using T-LAB PRP KIT / TUBES
Date	01.02.2019	01.02.2019
Material	EDTA Tube – Becton Dickinson	T-LAB PRP KIT / TUBES
Ref Platelet (PLT) Count	150 – 400 * 10 ⁹ /l	150 – 400 * 10 ⁹ /l
Platelet Count	299 * 10⁹/l	717* 10⁹/l

3.1. Summary of PRP Enhancement Factor Table

Whole Blood PLT Count	PRP PLT Count
299.000 / microliter	717.000 / microliter
Enhancement Factor	2,40-fold in 5,4 ml total PRP

The analyzed counts are mean values from 3 different counts.

Enhancement Factor indicating the PLT count by simplifying the comparison of PLT Count from whole final product and/or from Whole Blood Count. The control data is the whole blood count and the final product which is within the admired volume for clinical purposes and the enhancement factor is analyzed and concluded as 2,40 folds.

The enhancement factor of T-LAB PRP KIT / TUBES shows evidence of proving the performance of increasing PLT counts.

3.2. (Useful) Dose of Injected Platelets

(Useful) dose of injected platelets classification is the identification of total platelets in numbers to be used in single injection.

Dose of injected platelets which is calculated by multiplying the platelet concentration in PRP by the obtained volume of PRP. The injected dose of platelets should be measured in billions. And within this performance test, the results show the following platelet dose identification from T-LAB PRP KIT / TUBES.


The mean PLT Count in final product is 717.000 PLTs/microliter. The final platelet-rich plasma milieu is the re-suspended final product. Meaning homogenized plasma milieu is offering 717.000 PLTs/microliter in each microliter valued volume.

Since the calculation is based on milliliters, we have 717 million of platelet cells in 1 ml. Totally, we had 2,7 ml of platelet-rich plasma milieu from two tubes which leads us the result of 1.935.900.000 cells/ tube.

In case of centrifugation balance and admired quantity/volume of PRP, 2 tubes are used, therefore, we simply have 3.871.800.000 (3,87 billions) cells. In clinical practice, injectable count of platelets, namely platelet dose is 3,87 billion.

3.3. Platelet Recovery Rate

This classification corresponds to the efficiency of the production used to obtain PRP. The recovery rate in platelets corresponds to the percentage of platelets recovered in the PRP from the whole blood.

	TEST REPORT For IN-VITRO PERFORMANCE STUDY T-LAB PRP TUBE	Document No	RPR.PTN.06
		Revision No	00
		Release Date	07.02.2019
		Revision Date	
		Page	3 of 5

This efficiency is directly related to the combination of the device used and the knowledge of PRP. The efficacy of the device is performed. Platelet recovery rate is also known as Platelet Capture Efficiency.

3.3.1. The Performance Results of Platelet Recovery Rate from T-LAB PRP KIT / TUBES

The formula:

$\frac{\text{Volume of PRP (ml)} \times \text{PLT Concentration (10}^9\text{/l)}}{\text{Volume of Whole Blood(ml)} \times \text{PLT Concentration from W.B. (10}^9\text{/l)}}$
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5,4ml from 2 tubes is the final product. PRP concentrated PLT count is 717.000/microliter. 2 tubes can collect 16ml of blood along with 2ml of anticoagulant and initial EDTA PLT count was 299.000/microliter.

$\frac{5,4 \times 717.000\text{/microliter}}{16 \times 299.000\text{/microliter}}$
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The result is: 3,87 billion/ 4,78 billion.

The platelet recovery rate is 80,1%. This means initially harvested platelets from 16 ml of total blood + anticoagulant (total 100% platelets in numbers) inside the tubes are recovered at the rate of 80% only in 5,4 ml.

3.4. Purity of the PRP

This criterion of the classification corresponds to the relative composition of platelets, leucocytes and erythrocytes in the obtained PRP. It presents the advantage of assessing the global purity of the PRP.

As Purity level analyses, we need the following cell population data.

- Leucocytes
- Erythrocytes (Red Blood Cells)

This is basically a comparison of the percentage of Platelet purity level in the final re-suspended platelet-rich plasma milieu within the consideration of population of leucocyte and erythrocyte percentages.

The categorization is as the following;


- Very Pure:** If Platelets are more than 90%
- Pure PRP:** If platelets are in between 70% and 90%
- Heterogenous PRP:** If platelets are 30% to 70% compared the Leucocytes and Erythrocytes.
- Whole Blood:** If platelets are less than 30%.

3.4.1. The result of Platelet Purity from T-LAB PRP KIT/TUBES

To characterize and identify the Platelet Purity, as indicated, we needed the data of populated Erythrocytes and Leucocytes volume along with the data of PLT count.

The centrifugated and prepared PRP milieu was performed already and we had the data of Erythrocytes & Leucocytes Counts.

	Platelet Count	Erythrocytes Count	Leucocytes Count
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	TEST REPORT For IN-VITRO PERFORMANCE STUDY T-LAB PRP TUBE	Document No	RPR.PTN.06
		Revision No	00
		Release Date	07.02.2019
		Revision Date	
		Page	4 of 5

Whole Blood	299 X 10 ⁹ /l	5,50 X 10 ¹² /l	6,10 X 10 ⁹ /l
PRP	717 X 10 ⁹ /l	0,03 X 10 ¹² /l	2,50 X 10 ⁹ /l

After obtaining PRP, since the PRP is Pure PRP, the RBCs and Leucocytes are almost depleted compared to initial counts.

Equalization of Erythrocytes count to other cell types, Erythrocytes count on PRP is 30 X 10⁹/l. All units are same.

Total: 717 X 10⁹/l Platelets, 30 X 10⁹/l Erythrocytes and 2,50 X 10⁹/l cells are 100% as 749,50 X 10⁹/l.

From 749,50 X 10⁹/l, we calculate the Platelet purity as PLT count is 717 X 10⁹/l.

Platelet Purity Rate is 95,6%.

In the frame of Platelet Purity, the performance result from T-LAB PRP KIT/TUBES is considered as "Very Pure".

4. CONCLUSION:

With the evidence available, we can safely say T-LAB PRP KIT/TUBES increases the performance of the Platelet Volume as indicated with 2,40 folds of enhancement compared to the whole blood. This process is also within the meaning of Pure Platelet-Rich Plasma by depleting the most part of the population of erythrocytes and leucocytes. Also, as a final product the plasma milieu is re-suspended which eliminates the possibility of clumped cells.

The T-LAB PRP KIT/TUBES is a single use medical device and within the means of a protocol and variable needs of volume; doctors and users have the choice to use single or multiple syringes for a single procedural act. IFU of the device clearly explains how to use the device and the device is very suitable for common and well-known practices.

The T-LAB PRP KIT/TUBES offers a high efficacy result of platelet dose performances. By this study, in order to balance the centrifugation, we used 2 PRP Tubes and we indicated the platelet dose of 3,87 billion.

The Platelet Recovery Rate is directly related with the performance of the device in the frame of efficiency of the use of the device. The platelet recovery rate performance of the T-LAB PRP KIT/TUBES is considered very good by obtaining the result of 80% of the platelet recovery compared to the initial harvested total volume of blood.

The purity analyses of the final product were performed. For the purity analyses, we added to discuss the different cell population comparison either from the whole blood count or the final re-suspended platelet-rich plasma. The categorization is made from "Very Pure" to "Whole Blood". The erythrocytes population in the whole blood is way further than Platelets and Leucocytes. For the calculation, the equalization is performed. All cell groups were analyzed as "... X 10⁹/l". The calculation is concluded as %95,6 of Platelet Purity Rate. This performance result is for assessing the global purity level of a prepared PRP.

We conclude, in all aspects, the performance of T-LAB PRP KIT/TUBES is high-end and it is a very efficient device for the preparation of Platelet-Rich Plasma.



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Document No	RPR.PTN.06
Revision No	00
Release Date	07.02.2019
Revision Date	
Page	5 of 5

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