

www.tlabprpkit.com

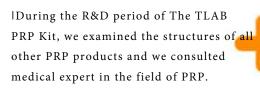


GOLDEN RATIO IN PRP

T-lab, accelerates
your treatment by
providing optimum
platelet concentration.



INNOVATION TO YOU, SAFE TO USE



Due to the lack of science and proven efficacy of many products on the market, we have focused on working with experienced doctors and scientists in developing safe, effective, injectable resuspension featured quality PRP products.



PURPOSELY DESIGNED AS A PRP KIT

We are not offering an IVD Tube or imported products with no clear proven functionality.

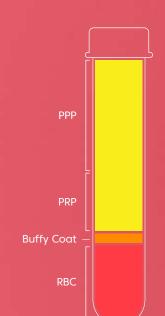
We are offering products and services,
developed for the purpose of PRP focused
applications for safe, sterile and effective use

WHAT IS PRP?

Prp is an abbreviation of platelet-rich plasma. Prp can be obtained through a strong centrifugal force by separating the cells according to their molecular weights layer by layer.

Platelets can be determined as the reparative cells in our bodies. Remember how they act even on a small wound on your skin. PRP is simple as that such a concentration of those cells collected in a plasma milieu. T-LAB PRP Tubes offer 2 ml of PRP from 9ml of whole blood. Platelets cause coagulation but also secrete growth factors.

The average platelet count can be considered as 200.000/microliter however after a series of steps, you can recover up to 90% of the initial platelet and concentrate the platelet present in 9ml of the whole blood in 2 ml of PRP solution. It is strongly recommended that only Doctors and Trained medical staff go on about using this device.

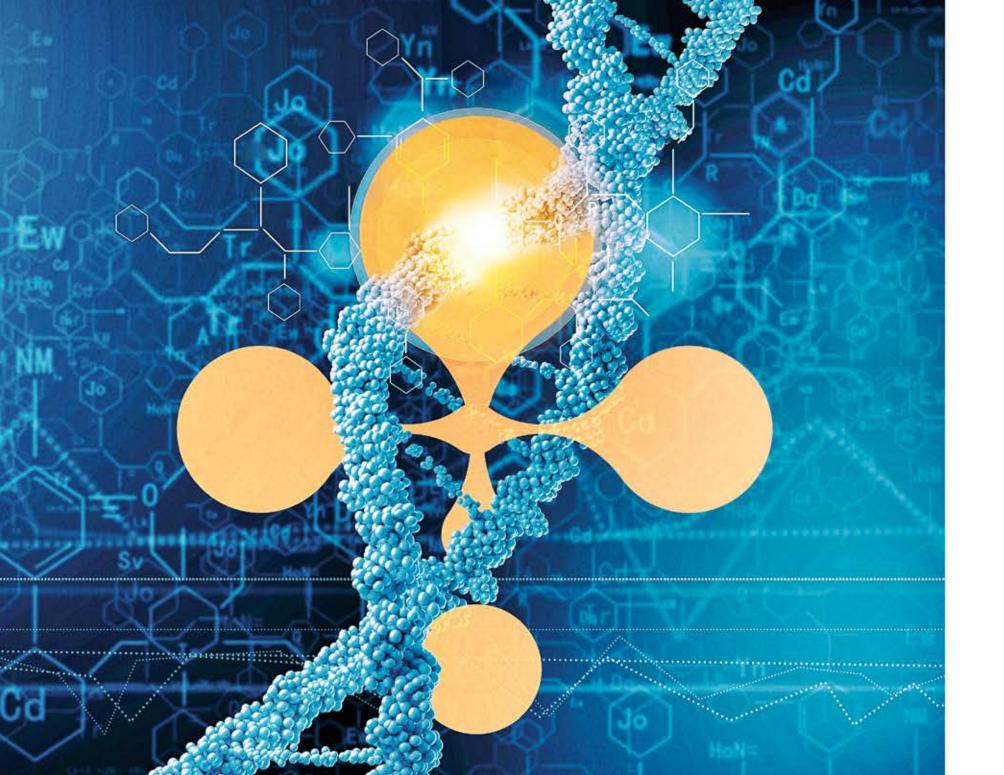


IS PRP CONSIDERED AS STEM CELL TREATMENT?

PRP shouldn't be considered or marketed as a Stem Cell treatment.
But, PRP can lead the stem cells to be join in the healing process of the tissue. Due to the activation of the platelets, growth factors are secreted.

Application may lead to fibroblast generation, fibroblasts may generate collagen and elastin as a chain reaction. Also, on autologous fat graft and PRP combination procedures, PRP may help the viability of the grafted tissue on its new place.







WHAT DOES PRP FEATURE?

PRP does not have a very long history, but in a short time period its treatment range has been expanded.
PRP can be used to stimulate and accelerate the healing of soft and tissue and bone in various areas in the body.

Commonly, aesthetic plastic and reconstructive surgery, dermatology and orthopedics are the key branches of medicine on which PRP applications are being performed.

Microneedling and PRP combinations, Laser and PRP combinations in plastic surgery and dermatology, Fat graft and PRP combinations in Plastic Surgery, joint applications in orthopedics are the example of PRP commonly used.

CONTENT

T-LAB PRP TUBES

The TLAB PRP Kit includes 2 TLAB Tubes. The TLAB Tube is a 10 ml vacuumed tube which includes 1 ml of anticoagulant. The PRP Tube is sterile and does not contain Ficoll or gel. The TLAB Tubes are nonhemolytic and non-pyrogenic. It is recommended that 2 ml of PRP is harvested from each T-LAB Tube, which will equal 4 ml of PRP from 2 (two) TLAB Tubes



T-LAB RE-SUSPENSION TUBE



The TLAB PRP kit includes 1 Re-Suspension Tube in each kit. It is a 5 ml volume sterile tube. The tube is non-hemolytic and non-pyrogenic. A total of 4 ml of PRP is collected in the 5 ml TLAB Re-suspension tube and the recommended process is to gently turn and twist the tube for 30 seconds to 1 minute to prevent any clumping of the PRP, which may have occurred during the spin cycle





INJECTORS AND NEEDLES

There are 2 sterile syringes in each kit, one 5 ml and one 1 ml.The 5 ml syringe is used to collect the PRP and transfer İT to the TLAB Re-Suspension tube. The 1 ml syringe is used to inject the PRP into the patient. There are sterile 3 needles in each kit. One long needle, one 21 G needle and a 30 G needle. The long needle is used to harvest the PRP from

the TLAB Tube and to transfer the PRP from the TLAB Tube to the Re Suspension Tube. The 21 G needle is used to harvest the resuspended PRP inside from the Re Suspension Tube. The 30G needle is used for injecting the PRP into the treatment area.





PHLEBOTOMY SET

There is a 2 piece Phlebotomy set in the kit, which is used for drawing blood from the patient into the TLAB Tube. No other equipment is needed to draw blood from the patient.



<u>01</u>

Injectable

The TLAB kit is not a blood storage tube or a blood separation kit unlike many other products offered by importers. The product is CE class II b.

02

Does not include Ficoll

Unfortunately some IVD tubes are marketed as PRP products. IVD tubes are intended as diagnostic products outside the human body. These tubes are clearly labeled as "do not use and

inject into humans"

03

CE Class IIb Certificate

According to 93/42/ EEC directive Annex IX and MEDDEV guidance document Classification of the Medical Devices MEDDEV 2.4/1 Rev 9, June 2010, expresses on Rule 3: Non-Invasive devices that modify biological or chemical composition of blood, body-liquids or other liquids intended for infusion into the body are in Class IIb. T-LAB PRP Kit has Class IIb medical device certificate.

<u>04</u>

Not a Tube, a PRP Kit

There are various products in the market sold as PRP tubes or mixed with a collection of products marketed as PRP devices. Many of them are unregistered as being used for indications where PRP is the treatment choice. The TLAB PRP KIT is registered and contains the crucial products used in successful PRP treatments.

05

Includes Anticoagulant

Blood storage tubes and blood separation kits do not include anticoagulant. The user has to collect anticoagulant from other sources that eliminates the standardization of quality control and in many cases anticoagulant is not readily available. The TLAB Kit ensures the correct anticoagulant is used and is readily available since it is supplied in the tubes.

<u>06</u>

Re-Suspension mechanism

Due to strong centrifugal force, clump formation of the platelets can occur.

Re-suspension of the

Re-suspension of the platelets helps to homogenize the platelets in the plasma milieu.

07

Cell-Cell Interaction

Cell-Cell interaction determines that the platelets' role to become proaggregator and interact with the other cells around the microenviroment.

No Gel

Some competitive products contain gel in the tubes. RBCs are molecular structures than platelets and during the centrifugational movement of the cells, The RBCs collect many Platelets under the gel along with the RBCs. Also, it is a risk that the gel may be allergen. In some cases, there may be some risks of collecting the gel inside the and re-inject to patients. Due those risks, T-LAB PRP Tubes do not include gel..



HARVESTING THE WHOLE BLOOD

The whole blood is harvested into the TLAB PRP Tube from the patient's arm, using the phlebotomy set in the PTLAB PRP Kit. Each TLAB PRP Tube allows 10 ml volume including 1 ml of anticoagulant, already in the tube. The Tubes provide easy harvesting of the blood as they are vacuumed tubes. Combined, 18 ml of blood is harvested in the tubes. After harvesting the blood, gently shake both tubes to ensure the anticoagulant is mixed in with the blood.

CENTRIFUGATION

The tubes should be placed in the centrifuge to ensure a balanced spin. It is important to centrifuge at 830 G for 4 minutes. RPM (Repeat Per Minute) can also be used but a careful conversion from G to RPM needs to be done to ensure correct spin time and rate. A table provided on the T-Lab website, converts G to RPM. Swing rotor centrifuge devices are recommended but fixed angle is acceptable.



HARVESTING THE PRP

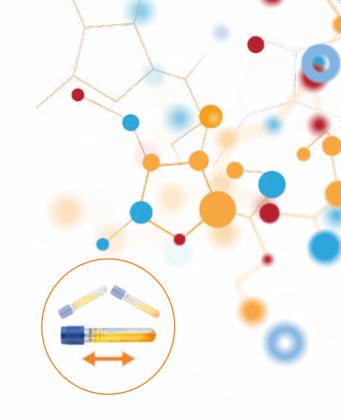
This section is the crucial part to obtain the platelet rich plasma. Please do not shake or move the tubes upside down after the centrifugation process. After centrifugation you shall see 3 layers in the tube. It means the centrifugation process is done properly.

UNDERSTANDING THE PRP LAYER

The Centrifugation process separates the cell layers according to the molecular weight of the cells. The RBC (Red Blood Cell) layer is formed at the bottom of the tube as RBCs are bigger cells in comparison to the other component of the whole blood. Right above the RBC layer, however as opposed to many devices there is little to no buffy coat layer formation meaning that the PRP obtained is Pure and the white and Red blood cells contamination is almost non existent .The Upper Layer is the yellowish colored layer. This layer includes both PRP and PPP layers . But those layers can not be recognized with the naked eye. PRP is defined as the 2-2,5ml volume right above the line between the two layers.

HARVESTING THE PRP

The Long needle is attached to 5ml injector and this equipment is put vertically into the tube. The PRP is collected by means of a tornado movement of the needle and the injector. 2-2,5 ML of PRP shall be collected.



RE-SUSPENSION PROCESS

The PRP collected into the 5ml Syrnge is carried to the PRP HD Re-Suspension Tube. the Re-suspension Tube is plain and sterile. This tube is 5ml in volume and totally the 4-5ml of PRP collected from the TLAB PRP Tubes (2-2,5ml each as recommended) are placed in this tube. After carrying the PRP into The TLAB Resuspension tube, gently shake the tube for about 30 seconds to 1 minute to avoid possible cell Clumps. This process supports the homogenization of the cells in the plasma milieu. Attach the 21G needle to the 1ml injector and collect the PRP inside from the TLAB Resuspension tube. Change the needle to 30G and you are ready to apply the injection method to the patient.





OPHTALMOLOGY









The use of PRP is getting increased in the field of ophthalmology lately. Many peer reviewed journals has published various articles regarding the use of PRP has reached to safe and effective results on Cornea Ulcers and Dry Eye Syndrome cases. There are some minor issues on Eye treatments as PRP is basically an injection method but on Dry Eye Syndrome, it is not injected into eye but dropping method is used. Especially on

Cornea Ulcers, PRP is important to prevent the inflammation.

AESTHETIC PLASTIC SURGERY

Aesthetic, Plastic and Reconstructive Surgery is one of the most common field that PRP is being applied. Usage of PRP in Plastic Surgery is mostly aimed to accelerate the stimulation of soft tissue healing along with Fat Graft combinations. Principally, according to the effectiveness of PRP locally; PRP is used in order to achieve the acceleration of the stimulation of soft tissue, fine wrinkle treatments by the stimulation of tissue elasticity and collagen reproductivity, hair-prp applications on various hair problems (alopecia treatments)

DERMATOLOGY

In Dermatology field, mostly, PRP is aimed to stimulate the quality of the skin. The usage of PRP in Dermatology has similar features with Aesthetic Plastic and Reconstructive Surgery without surgical procedures. But both fields can be expressed in medical-aesthetic frame.

VETERINARY

As mostly, PRP is used on humans but also it is used on animals with very promising results. PRP is systematically also effective on animals. Especially the orthopedic disorders on horses are commonly used area of the PRP in Veterinary medicine. Also, it is known that PRP is safe and effective on other animals too.

ORAL AND MAXILLOFACIAL SURGERY

PRP is used to accelerate the stimulation of soft tissue and bone. Many other branches are commonly interested in soft tissue recovery. But, Oral and Maxillofacial surgery field is interested in the bone and oral soft tissue both. Since PRP is very safe and effective on bone healing, it is also used in oral surgery applications to various bone defects such as from gingival applications to osteonecrosis of the jaw. Also, oral area is very open to risks of inflammation which PRP decreases the risks of inflammations as published on various articles.

ORTHOPEDICS AND SPORTS MEDICINE

This field can be expressed as the most amount of PRP applications can be applied whole around the world. The most common use of PRP in this field is relieving the pain, decreasing the need of drug injections, decreasing the need of surgical procedures which lead the patients to keep going on their daily lives. Generally PRP in Orthopedics and Sports Medicine; Tendinosis, Ligament defects, Plantar Fasciitis, Achilles Tendon damages, Cartilage defects, Rotator Cuff Injuries, Joint treatments, BMSCs combinations related to bone.

WHO WE ARE?

T-Biotechnology was established as
T-Biotechnology Laboratory Aesthetics and Co
in 2012. T-LAB's main activity is regenerative
medicine. T-LAB's personnel is qualified and has
many years of experience in the sector ,T-LAB is also
working as partners with the quality companies
such as manufacturers and suppliers, experienced
luminary doctors, Medical dealers. T-LAB's first
experience is acquired by manufacturing the PRP
Kit according to all related standards.

GOALS OF T-LAB IN MEDICINE

T-LAB specifically researches and develops autologous systems, T-LAB dedicates into researching innovative ways on how to obtain the regenerative group of tissue/cells in a safe, effective, easy and sterile in order to achieve the stimulation of soft tissue and bone healing. It is totally targeted to safe and effective procedures. It aims help to improve the future's medicine with minimal invasive procedures.

GOALS OF T-LAB IN COMMERCE

Our company's mission is to research and develop the autologous systems with technology and knowledge in the framework of regenerative medicine; and to become one of the sector leaders with its distributors, doctors and other partners.

T-LAB PRP KIT COMPARED TO OTHER CONVENTIONAL TUBES FOR IN VITRO DIAGNOSTIC

IVD – In Vitro Diagnostic	MDD – Medical Device Directive
EU Directive 98/79/EC	Directive 93/42/EEC
List A ve B devices of list.	Class I, Is, Im, Ila, IIb , III
Special symbol IVD required	Special symbol required CE. (CE 2195)
Not allowed for clinical use.	Approved for clinical use.
No test required for biocompatibility.	Complete required biocompatibility. (ISO 10993)
No clinical assessment.	Clinical evaluation required.



As it is expressed on the table, the IVD Tubes do not require any clinical evaluation process and they are not tested within the framework of biocompatibility. For this reason, IVD tubes are prohibited for clinical applications. T-LAB PRP Kit is CE marked of Class IIb according to European Commission's Medical Device Directive, Classification Document Annex IX with the Rule 3 that requires clinical evaluation and biocompatibility tests that leads the permission of clinical applications.



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NEW CONVENIENT PRP KIT