RegenACR®

Autologous Cellular Regeneration

regenlab®

PRP & CELL THERAPY SPECIALISTS


RegenBC
Vacuum:
Sodium Citrate & Gel
REF R-BCT
LOT 16F06
2018-06
REGEN LAB SA
CH-1052 Mont-sur-Lausa
Switzerland

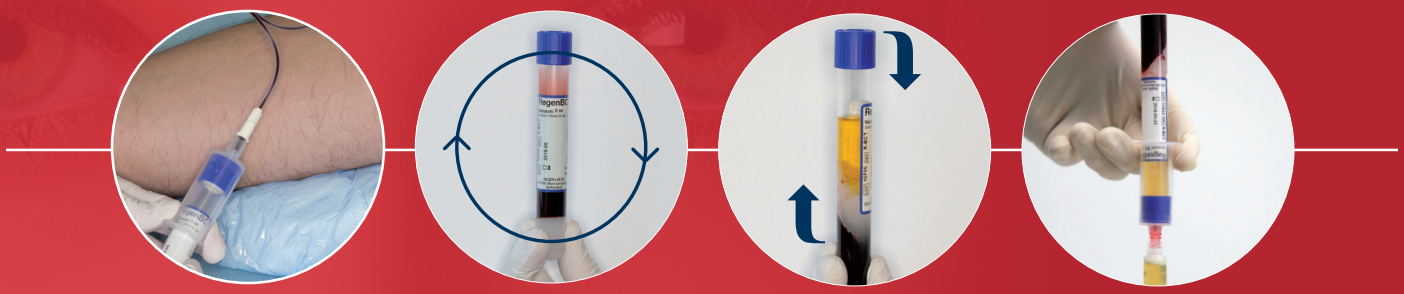
RegenLab® is a leading innovator of medical products for the preparation of platelet rich plasma.

Regen Lab provides expertly designed & patented Medical Devices for platelet-rich plasma preparations, CE certified, registered by most national agencies worldwide.

Regen Lab remains committed to providing products of the highest quality and safety, as well as protecting customers through enforcement of its intellectual property rights.

TECHNOLOGY PLATFORM FOR STANDARDISED AUTOLOGOUS REGENERATIVE MEDICINE

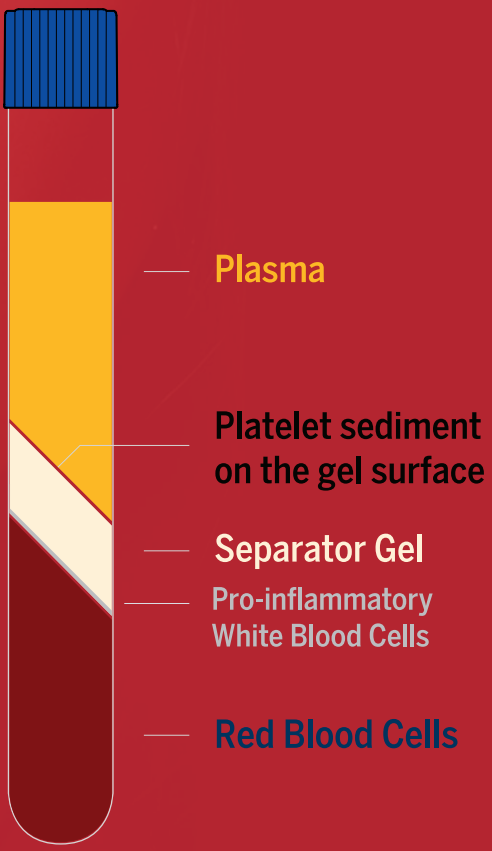
The simple, safe and efficient point of care preparation of autologous platelet-rich plasma



Blood Collection | Centrifugation | Platelet Resuspension | Ready to Use

TECHNOLOGY ADVANTAGES

- User-independent standardised preparation
- Minimum volume of blood required
- Safe closed-circuit system
- Mechanical isolation of PRP using a biologically inert separator gel after a 5-minute centrifugation
- Reversible anticoagulation with a pharmaceutical grade solution of sodium citrate at pH 7
- Minimal learning curve and ease of use
- Operationally and clinically efficient process
- Facilitates and streamlines routine practice



BIOLOGICAL ADVANTAGES

- **RegenPRP is standardised, leucocyte reduced and easily reproducible.**
  RegenLab specific separating gel technology guarantees minimal variability
- **Platelet recovery > 80%**
- **High platelet quality.**
  Viable & functional platelets
- **Full plasma recovery.**
  No loss of plasma growth factors and fibrinogen
- **Leucocyte reduced PRP.**
  Depletion of 96.7% of pro-inflammatory granulocytes, leaving mainly lymphocytes and monocytes
- **Virtually no red blood cells.**
  Depletion of ~ 99.7% of erythrocytes

SCIENTIFIC ADVANTAGES

- Demonstrated safety and efficacy
- Evidence-based outcomes for numerous therapeutic indications.
- Large number of clinical studies, with over 200 publications.

What is RegenPRP® ?

RegenPRP: the platelet concentrate prepared with this RegenLab technology provides an autologous reservoir of growth factors.

Platelets are key factors in tissue repair mechanisms[1]. They provide essential growth factors, such as FGF, PDGF, TGF-β, EGF, VEGF, IGF, which are involved in stem cell migration, differentiation and proliferation. Platelets also stimulate fibroblasts and endothelial cells to induce the deposition of new extracellular matrix and neo-vascularisation, respectively. The platelets are concentrated from the patient's own blood.

Plasma contains many factors essential for cell survival including nutrients, vitamins, hormones, electrolytes, growth factors (such as IGF and HGF), and proteins. Among the plasma proteins, the molecules vital for the coagulation process and fibrin polymer formation will serve as a scaffold for cell migration and new tissue generation[2].

RegenPRP could be considered as an effective procedure for facial rejuvenation as it induces collagen production in the dermis.[3]

RegenACR® technology

The RegenACR kits are medical devices intended for the preparation of RegenPRP. They contain RegenBCT tubes and accessories for blood collection and PRP recovery. RegenBCT tubes consist of pharmaceutical grade glass with a vacuum for automated blood collection. It contains a sodium citrate anticoagulant solution and a separating gel to isolate plasma and platelets from the blood cells and produce RegenPRP with a standardised composition:

RegenBCT® Tube Properties	BLOOD SAMPLE VOL PER TUBE	PRP VOL PER TUBE	PLATELET RECOVERY	RED BLOOD CELL DEPLETION	PLATELET CONCENTRATION FACTOR (NATIVE)
	10 ml	5 to 6 ml	> 80 %	> 99.7 %	1.6 X

Summary of new RegenBCT and A-CP tube performance tests-2017, data on file

RegenACR kits have an excellent safety profile in clinical practice

1 Fountain, John H., and Sarah L. Lappin. Physiology, Platelet. StatPearlsPublishing, Treasure Island (FL), 2019.
2 Mathew, Joscilin, and Matthew Varacallo. Physiology, Blood Plasma. StatPearlsPublishing, Treasure Island (FL), 2019.
3 Abuaf, O.K., et al., Histologic Evidence of New Collagen Formulation Using Platelet Rich Plasma in Skin Rejuvenation: A Prospective Controlled Clinical Study. Ann Dermatol, 2016. 28(6): p. 718-724.

NEW COLLAGEN

Histologic evidence of new collagen formulation using platelet rich plasma in skin rejuvenation[3]

In this prospective controlled clinical study, the authors evaluated the efficacy of an intradermal injection of RegenPRP for human facial rejuvenation (20 patients) by performing histological examinations before and after treatment and measuring the mean optical densities (MODs) of collagen.

• The authors observed that the MOD of collagen fibers was clearly higher on the PRP-treated side compared to the saline injected side ($p < 0.001$). These data are in line with previous in vivo work showing the effect of RegenPRP on the rejuvenation of photoaged skin in nude mice[4].

• The authors observed no serious side effects following RegenPRP treatment.

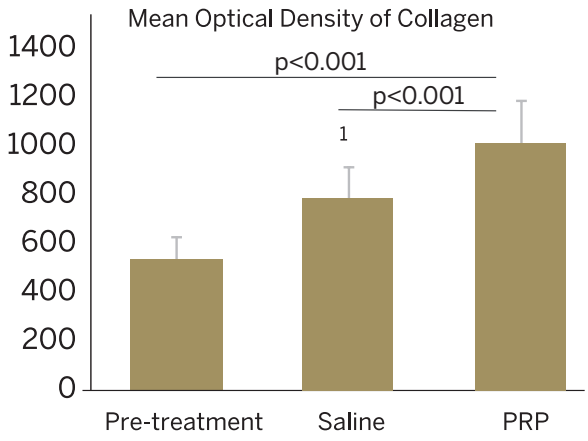


Figure1: Graph illustrating the the mean optical density for collagen measured at pre-treatment, saline- or PRP-treated condition. p<0.001 compared to pre-treatment and saline condition

SKIN REVITALISATION

Face and neck revitalisation with platelet-rich plasma[5]

In this case series of 23 patients, the authors evaluated if there are real outcomes, benefits and side effects following a standardised PRP injection protocol DGS was calculated by comparing the spider improvement score, the pre- and post-improvement photographs, the patient's satisfation score and the doctor's satisfaction score.. Patients received a RegenPRP injection once a month for three months. Patients were evaluated one month after the last injection. A definitive graduated score (DGS) was calculated for each patient.

• The authors concluded that face and neck revitalisation with RegenPRP is a promising, easy-to-use technique, performing favourably in all small skin wrinkles, as well as in skin texture and elasticity assessments.

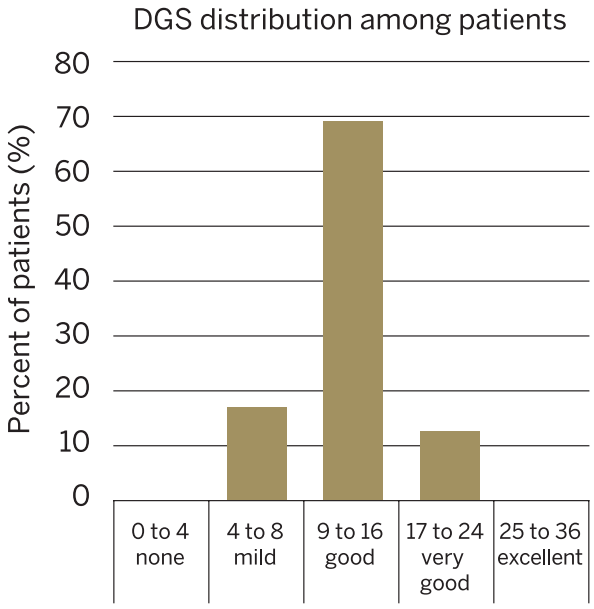


Figure 2: Graph illustrating the persent of patients scored for definitive graduated score. DGS score was good (average 12.8).

4 Cho, J.M., et al., Effect of platelet-rich plasma on ultraviolet b-induced skin wrinkles in nude mice. J Plast Reconstr Aesthet Surg, 2011. 64(2): p. e31-9.
5 Redaelli, A., D. Romano, and A. Marciano, Face and neck revitalisation with platelet-rich plasma (PRP): clinical outcome in a series of 23 consecutively treated patients. J Drugs Dermatol, 2010. 9(5): p. 466-72.

ACNE SCARS

Application of regenerative medicine in treatment of acne scars[6]

© - Dr.Abbas Al T., Australia

The efficacy of a nanofat and plasma rich-platlets injection and fractional CO2 laser resurfacing was evaluated in 30 patients.[6]

- The authors showed that the combined approach of nanofat and RegenPRP injection and CO_2 laser can improve the appearance of atrophic scars. RegenPRP and nanofat injection also significantly increased skin and subcutaneous tissue thickness.
- Patients reported great satisfaction with the treatment and confirmed the impact of facial acne scars on social life and relationships.

KELOID SCARS

Injecting platelet-rich plasma is an effective and safe method as an adjunctive therapy to resection for treating keloid scars refractory to conventional therapy[7]

© - Dr. Lubin S. USA

The efficacy of RegenPRP as a treatment of keloid scars was evaluated in 17 patients.[7] Evaluations were based on the complete remission of the keloid scars, pruritus severity score and the mean Vancouver Scar Scale (VSS) score, two years after treatment with RegenPRP.

- 53% of keloid scars completely resolved at 2 years, and only 29% relapsed following RegenPRP treatment.
- Pruritus severity score was significantly lower at 2 years compared with baseline Pruritus symptom associated with keloid scar disappeared in 60% of patients.
- The VSS score, which assesses 4 variables: vascularity, height/thickness, pliability, and pigmentation, was significantly improved at the 2 year follow-up ($p < 0.001$) and had improved in 88% of patients.

6 Tenna, S., et al., Comparative Study Using Autologous Fat Grafts Plus Platelet-Rich Plasma With or Without Fractional CO2 Laser Resurfacing in Treatment of Acne Scars: Analysis of Outcomes and Satisfaction With FACE-Q. Aesthetic Plast Surg, 2017. 41(3): p. 661-666.
7 Hersant, B., et al., Efficacy of Autologous Platelet Concentrates as Adjuvant Therapy to Surgical Excision in the Treatment of Keloid Scars Refractory to Conventional Treatments: A Pilot Prospective Study. Ann Plast Surg, 2018. 81(2): p. 170-175.

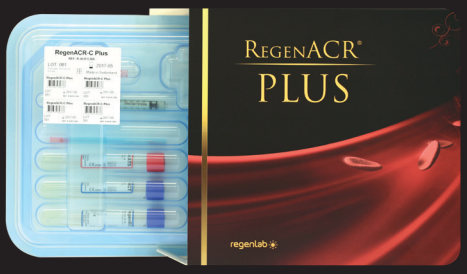
regenlab®

PRP® & CELL THERAPY SPECIALISTS

ALWAYS READ THE INSTRUCTION BEFORE USE

INTENDED USE OF THE DEVICE

Preparation of Autologous Platelet Rich Plasma
& other plasma-derived products



*BCT stands for Blood Cell Therapy.

RegenACR® Classic
Ref: R-ACR-C1/B

1 Safety–Lok™ Butterfly needle
1 Collection holder
1 Transfer device
1 Regen BCT* tube
1 Luer-Lok™ syringe 3 ml
1 transfer needle

RegenACR® Extra
Ref: R-ACR-C2/B

1 Safety–Lok™ Butterfly needle
1 Collection holder
1 Transfer device
2 Regen BCT tubes
2 Luer-Lok™ syringes, 1 ml and 5 ml
1 transfer needle
1 x 80 mm transfer cannula

RegenACR® Plus
Ref: R-ACR-C/BA

1 Safety–Lok™ Butterfly needle
1 Collection holder
2 RegenBCT tubes
1 Transfer device
1 x 1 ml Luer-Lok™ syringe
1 x 80 mm transfer cannula
1 RegenATS tube
1 transfer needle
2 x 5 ml Luer-Lok™ syringes

CE 2797

Class IIb CE certified Medical Devices
Regen Lab SA is an ISO13485 :2016 and MDSAP certified medical device manufacturer

WARNINGS AND PRECAUTIONS.
Strict aseptic technique must be followed during phlebotomy. Use proper safety precautions to avoid contact with patient blood or cross-contamination. Use proper safety precautions to guard against needles or broken tubes. Do not use sterile component of this kit if package is opened or damaged. Do not use components of this kit if they are broken or present a defect. Do not use the tube if it lost vacuum. Do not use the sodium citrate solution or other tube components alone. Store between 5 °C and 30°C; bring kit at ambient temperature before using tubes. Do not re-sterilise, do not use after the expiry date. Single use device, do not reuse any part of the kit. Reuse may lead to infection or other illness / injury. Transfer needles must be used to transfer liquids or prepare injections, it must not be used for injection. The preparation of plateletrich plasma (PRP) must be performed by a physician trained on the device and the procedure, or under his supervision. The treatment with PRP must be performed by a qualified physician. The patient must be informed of the general risks associated with the treatment and of possible adverse effects. The PRP must be prepared from fresh blood and must be used within four hours (extemporaneous use only). Throw away each tube and the other components after use, using the method of elimination for potentially contaminated blood products. Use a horisontal head (swinging bucket) centrifuge or a fixed angle head centrifuge (ex. RegenPRP Centri provided by Regen Lab). Follow manufacturer instructions when using centrifuge. Excessive centrifugation force (over 2200 RCF) may cause tube breakage, exposure to blood, and possible injury. Tubes should be centrifuged, as recommended in the instructions for use, at 1500 RCF. Lower centrifugal force (below 1500 RCF) may lead to incorrect blood separation and red blood cell contamination of PRP. Centrifuge carriers and inserts should be of the sise specific for the tubes. Use of carriers too large or too small for the tube may result in breakage. Care should be taken to ensure that tubes are properly seated in the centrifuge cup. Tubes must be balanced in the centrifuge head to minimise the possibility of glass breakage.

POSSIBLE ADVERSE EFFECTS
Damage to blood vessels, hematoma, delayed wound healing and/ or infection. Temporary or permanent nerve damage that may result in pain or numbness. Early or late operative infection.

Patented by Regen Lab SA - Platelet Rich Plasma
U.S. patent US8529957
European patent EP2073862B
Swiss patent CH696752

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