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Kit for the preparation of blood components

Plateltex Prep® is a device for the preparation of platelet-rich plasma (PRP) starting from harvested patient's blood. The obtained PRP is ready to use, or, thanks to the high concentration of the final product, it is suitable for the preparation of platelet gel using **Plateltex Act®**.

Plateltex Prep® should be used exclusively by properly trained medical or nursing staff under medical responsibility. The device and the biological products prepared with it should be employed in the range of a complete and accurate clinical-therapeutic approach, possibly following the criteria of evidence-based medicine (EBM). In no instance self-medication is allowed using the device and the biological derivatives prepared with the device itself.

Following these instructions for use, this kit allows to obtain a PRP with a platelet concentration 4-5 times higher than the original blood sample. (1×10^6 platelets /microliter \pm 20%)

DESCRIPTION OF CONTENTS

POUCH N. 1: *harvesting kit*

1 21G butterfly needle with extension and holder.

6 yellow cap pre-labelled ACD tubes containing 1.5 mL of anticoagulant (ACD); Each tube has a pre-calibrated vacuum for ~9 mL of blood harvesting.

POUCH N. 2: *concentration kit*

1 20 mL luer lock syringe with a plastic needle.

2 15-mL blue cap graduated tubes.

POUCH N. 3: *application kit*

1 20 mL luer lock syringe with a plastic needle.

1 10 mL luer lock syringe with plastic needle.

2 luer lock caps;

INSTRUCTIONS FOR USE

1. Collect the patient's blood using components in pouch n.1.
2. Gently flip the tubes 3-4 times immediately after sampling in order to avoid the formation of microclots.
3. Carefully insert tubes in the centrifuge so that they will be correctly opposed and balanced.
4. Set up the centrifuge with the following parameters:

180 RCF (g) for 10 minutes for tilt or fixed angle rotor centrifuges



The next steps must be carried out working in a strictly aseptic environment, preferably under a sterile hood.

5. Gently remove the tubes from the centrifuge. They will look as in Figure 1
6. Mount the plastic needle on the 20 mL syringe (Pouch N. 2) and uncap the tubes gently.
7. Gently aspirate PRP from each tube transferring it equally in both blue cap tubes. It is supposed to be recovered about 3/3.5 mL of PRP at the concentration of platelets 2x (2 times the baseline value of patient's platelets)
8. Correctly set the blue cap tubes in the centrifuge and ensure that they are properly opposed and balanced
9. Set up the centrifuge with the following parameters:

1200 RCF (g) for 10 minutes for tilt or fixed angle rotor centrifuges

Fig. 1

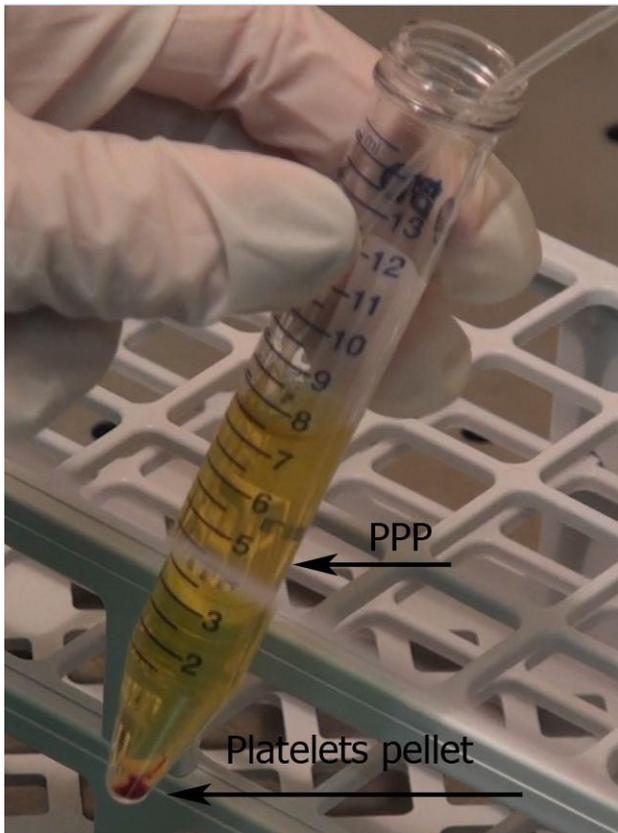


Fig. 2

CAUTION: the presence of a small percentage of red blood cells in the preparation does not interfere with the efficacy of the product because they are autologous.

10. Mount the plastic needle on the 20 mL syringe and gently aspirate the platelet-poor plasma (PPP) in excess, from top to bottom, sucking about 50% of the volume and avoid touching the platelet pellet in the bottom part of the tube. (Fig. 2)
11. Using the same syringe, repeat the same procedure on the second tube.
12. Remove the needle from the syringe containing the collected PPP and close it with the luer lock cap. If necessary this PPP can be used for the preparation of fibrin membranes in association with **Plateltex Act®**.
13. Mount the plastic needle on the 10 mL syringe and gently resuspend the platelets pellet in the plasma residue present in both tubes (a small amount of partial aggregates will remain in the PRP and will be released in a short time)
14. The PRP concentrate is ready for use. Use within 6 hours of collection.

Recommendations for a correct use of the set

Plateltex Prep® is supplied in a sealed and labeled package. The set contains sterile materials. Never use the product after the expiry date. Store the device in a cool and dry place far from the direct sunlight. Never use the device whenever, during the visual inspection, packaging anomalies were found.

Procedure of waste disposal

Wastes should be disposed in compliance with National and local regulations for the Disposal of Health Wastes.

TABLE OF SYMBOLS

CAUTION	DO NOT REUSE	STERILE EO	KEEP AWAY FROM SUNLIGHT	DATE OF MANUFACTURE	DO NOT RESTERILIZE	CONSULT INSTRUCTIONS FOR USE
TEMPERATURE LIMITATION 4°C - 25°C	NON PYROGENIC	MANUFACTURER	KEEP DRY	BATCH CODE	DO NOT USE IF PACKAGE IS DAMAGED	USE BY

Manufacturer:

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