ycellbio

Platelet Rich Plasma

PRP USER'S MANUAL

YCBM
Ycellbio Medical

Contents

Ⅰ. Guidelines for PRP Usage

1. Precautions to PRP Users

- This product is sterilized with Ethylene oxide gas
- This device should be used for Single-use.
- After use, discard this product which is disposable.
- Observe the process of waste disposal.
- Shelf-life: 3 years
- Use certified product.
- Don't use a product which is broken or open already.
- Only doctor who has a medical license is allowed to use this product.
- Don't use it for other purposes except for the medical purpose.
- Don't reuse it which is disposable.
- Confirm the validity date before use.
- Use separated Plasma(PRP) immediately after extraction.

2. Precautions To Patients

- Stop taking anticoagulant or antithrombotic medicine such as Aspirin 2 weeks before from the PRP treatment.
- Consult your doctor in advance if you have any blood disease, thrombotic disease, or arrhythmia.
- Notify your doctor in advance If you are suffering from serious anemia.
- Don't drink alcohol too much and refrain from smoking before the PRP treatment.
- Eat lots of fruit especially containing vitamin-C a lot.
- Take a deep sleep.
- Try to get away from much stresses.

The better conditions the patient has, the better result will be shown when harvesting buffy coat. If the patient is in a bad condition, buffy coat might not be concentrated well.

3. Blood Donor's Characteristics

1) Male

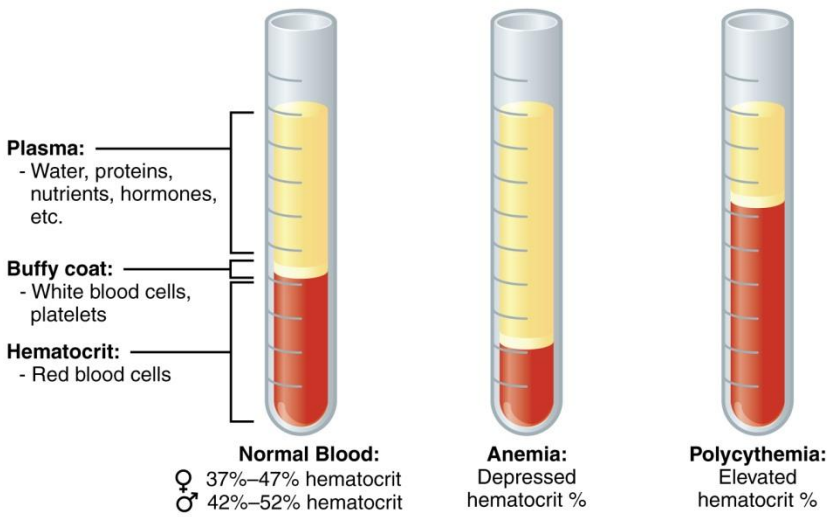
- A young and healthy man is the best blood donor for PRP treatment.
- Normally, the size of male's Red Blood Cells(RBC) tends to be larger than that of female's or anemia patient', therefore; the height of RBC can relatively be high after the spin.

2) Female

- Normally, the platelet counts of female's are lesser than that of male's.
- The size of female's RBC tends to be smaller than that of males.

3) Anemia Patient

- A young and healthy man is the best blood donor for PRP treatment.
- Normally, the size of male's Red Blood Cells are larger than female's or anemia patients'.



4) Old-aged Patient

- A young and healthy man is the best blood donor for PRP treatment.
- Normally, the size of male's Red Blood Cells are larger than female's or anemia patient'

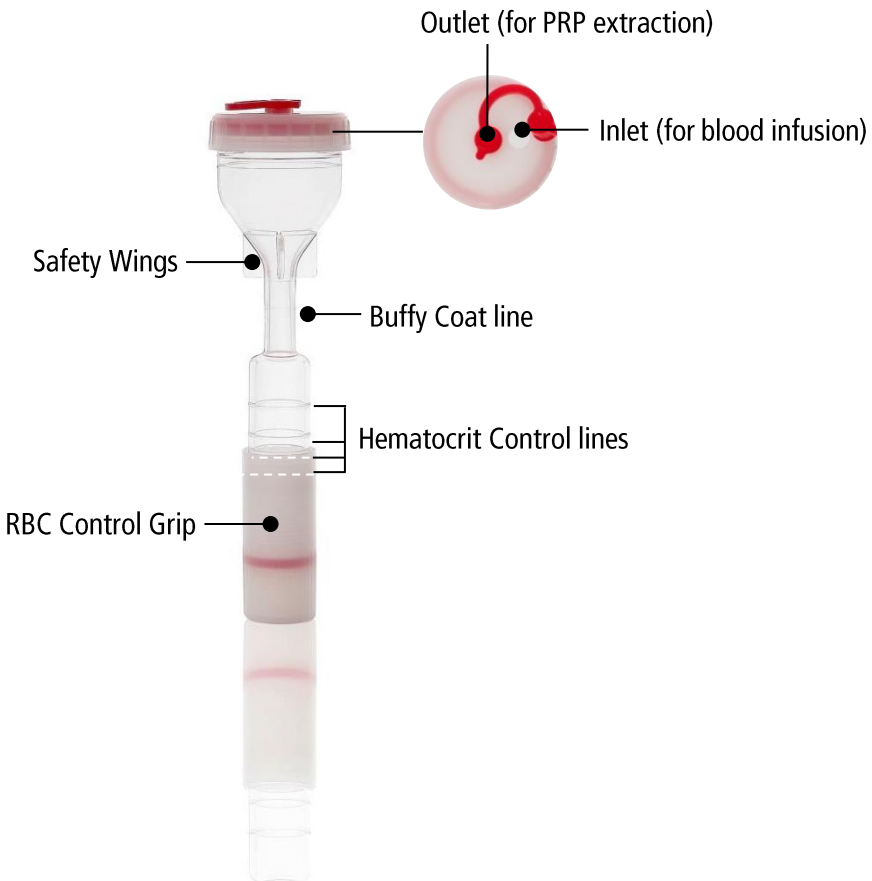
The operator of PRP treatment should check if the blood donor has any particular conditions that must be considered before drawing blood.

II . Preparation

1. Needed Supplies (for 1 EA)

- Ycellbio Tube (1 pcs)
- Blood (15 ml)
- Anticoagulant (1.5 ml)
- 20cc Syringe (1 pc)
- 5cc Syringe (1 pc)
- 3cc Syringe (1 pc)
- 21G Needle or Butterfly Needle (1 pc)
- 18G 1 ½ Needle (2 pcs)
- Alcohol-soaked cotton / Forceps

2. Features of YCELBIO Tube



3. Anticoagulants To Use

There are several choices of anticoagulant that support the metabolic needs of platelets and the viable separation of platelets in an undamaged manner.

ACD-A


Sodium Citrate
(4g / 100ml)

II -3-1. Preferred Anticoagulant

- ACD-A (Anticoagulant citrate dextrose Solution- A)
- Sodium Citrate

II -3-2. Inhibited Anticoagulant

- Heparin : Heparin may obstruct PRP activation.
- EDTA :EDTA is poisonous and it may damage platelet membrane.

4. How Much Of Anticoagulant is Required?

II -4-1. 1.5ml of anticoagulant is needed for 15ml blood sample.

Draw anticoagulant

Syringe coating

II -4-2. Coat the inside wall of syringe with anticoagulant.

1. Before drawing anticoagulant, push the syringe plunger in and out several times to get rid of the air pressure inside the syringe.
2. Draw 1.5cc anticoagulant in 20cc syringe in advance before taking blood, and coat inside walls of the syringe with anticoagulant.

Ⅲ. Blood Collection

1. Blood Draw

Ⅲ-1-1. Draw 15 ml blood.

21G Needle

Butterfly Needle

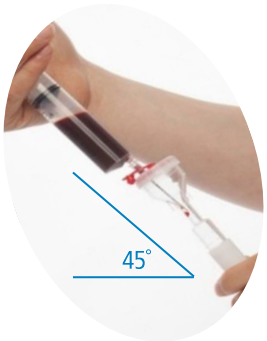
1-2. Mix blood and anticoagulant by swinging the syringe slowly.
(15ml blood + 1.5ml anticoagulat)

※ Cautions

- Don't draw blood too strongly and fast. When you draw blood, take it softly and slowly. If you force blood to be taken with too much strength or speed, cells in blood could be broken.

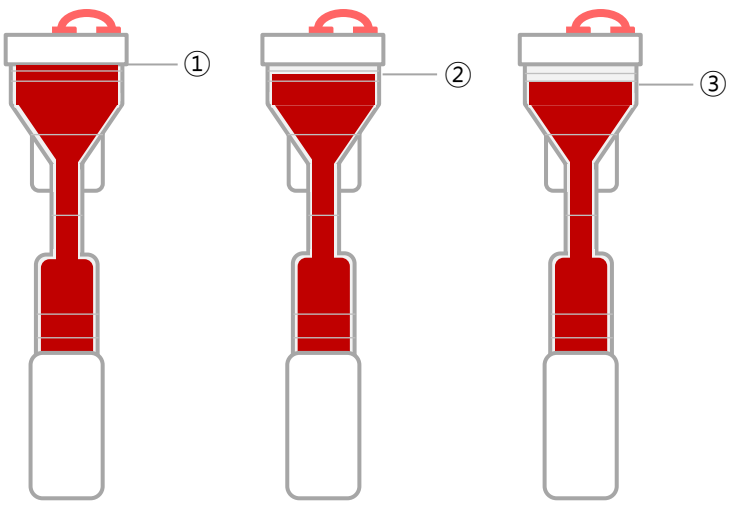
2. Blood Transfusion Into Tube

Ⅲ-2-1. Blood Collection



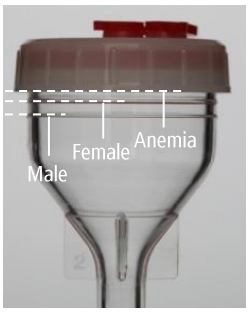
1) Use **18G** needle.

2) Transfuse the gathered blood into YCELLBIO tube (maintaining a slope of 45°)



III-2-1. Cautions

1) Blood Volume Guidelines



As mentioned earlier, Anemia patient's blood tend to get easily depressed after centrifugation.(Anemia > Female > Male). Therefore, more blood should be gathered for patients whose blood is vulnerable to Hematocrit depression.

2) Blood clogged in the middle of the slim neck

If the blood is clogged in the middle of the slim neck while transfusion, press the syringe a little harder.

IV. Centrifugation

1. Centrifuge Protocol

Type	Digital		Non-digital
	Swing	Angle	Angle
			
	 	 	 
RPM	3200~3300	3600~3800	3400~3600
RCF	1888*g ~ 2008*g		
Time	6 min ~ 10 min		

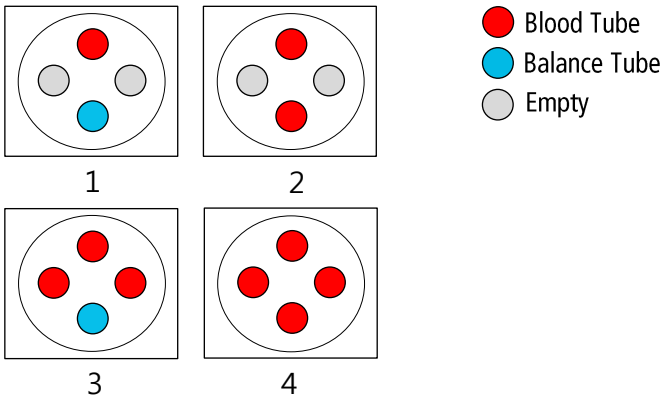
1-1. Digital type set automatically RPM following RCF. Therefore, set RCF first as the above instructed RPM can be different depending on each machine.

2. Centrifuge Balance

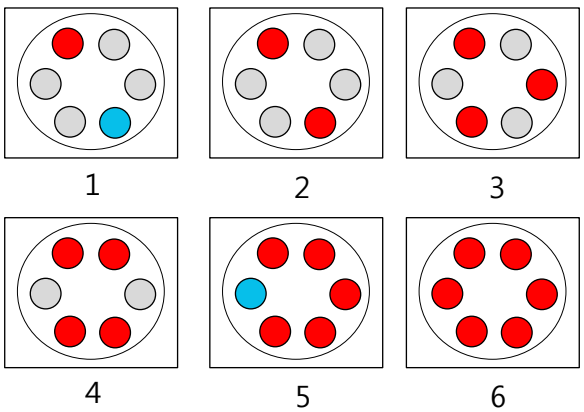
IV-2-1. Centrifuge Balance

Centrifuge balance is one of the most significant factors in the blood separation process. Centrifuge imbalance can cause breakage of tubes in the centrifuge or a blood leak in the course of a spin.

4 Hole Centrifuge

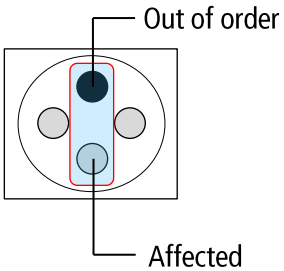


6 Hole Centrifuge



IV-2-2. Centrifuge Bucket Defect

If one bucket of a centrifuge has a defect, the opposite bucket can be affected while spinning. As a result, tubes in both buckets may be broken and blood leaks.



3. Centrifuge Adapter

A

IV-3-1.
If you have this kind of centrifuge seen in the photo A, check if the head of the tube reaches the central rotor. If so, tubes might be broken while spinning.

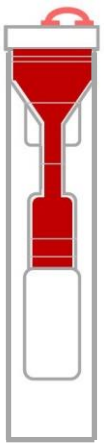
IV-3-2. An adaptor should cover the tube up to the safety wings.

Without an adaptor

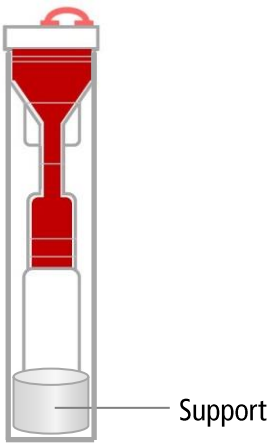
With an adaptor

IV-3-3. You can take a spin not using adaptors, but adaptors protect tube making it stable during the spin if the bucket size of the centrifuge is larger than the diameter of the tube bottom.

IV-3-4.
If the depth of centrifuge buckets are deeper than the height of the tube , applying a support to make it stable during the spin. Without a support in this case, it might be the cause of blood leakage or tube breakage as the tube hits the wall of a bucket inside a centrifugation while spinning.



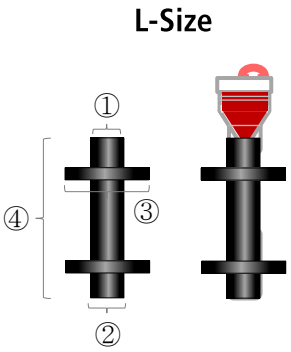
Unstable



Stable

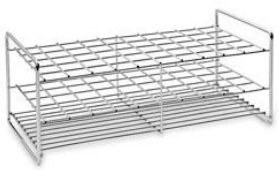
Ⅳ-3-5. YCELLBIO Accessories

Adapters



Size	① Inner diameter	② External diameter	③ Wings' diameter	④ Length
L	17 mm	21 mm	40 mm	80 mm
S	17 mm	21 mm	30 mm	80 mm

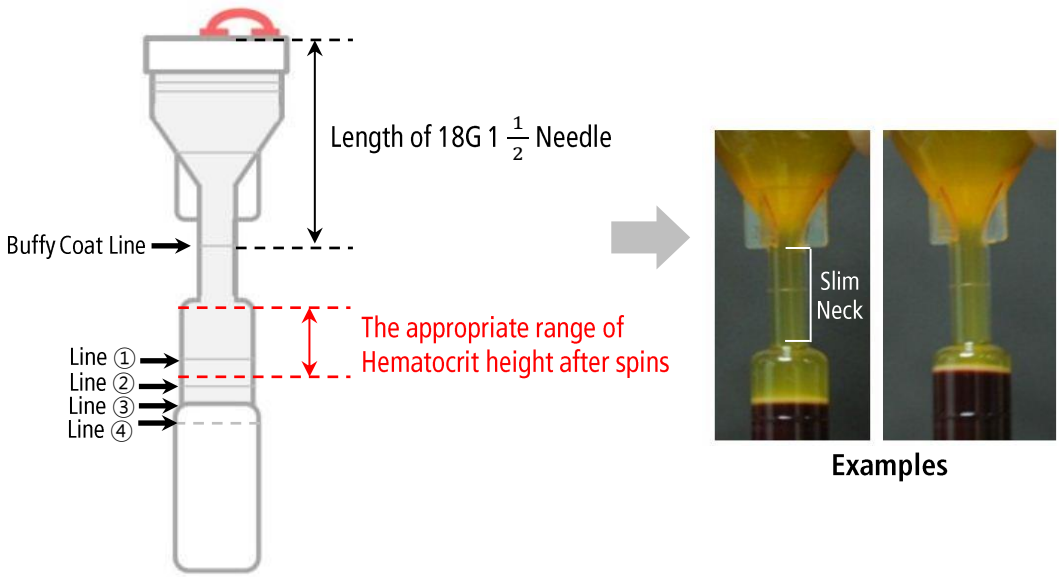
YCELLBIO Tube Rack



- Materials : Stainless Steel
- Capacity : 40 tubes (20 YCELLBIO tubes)
- Dimension: 203 mm(W) x 84 mm(L) x 95 mm(H)

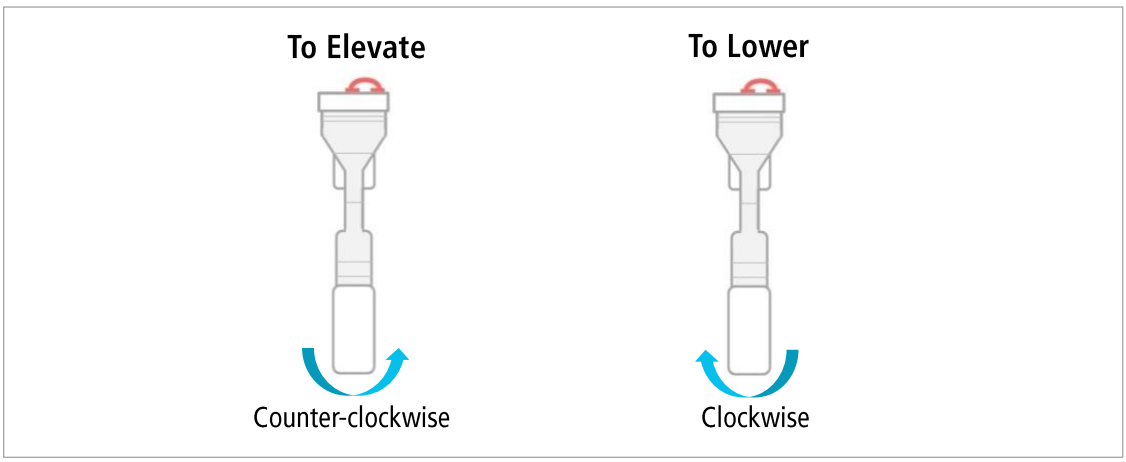
4. Purpose Of Centrifugation

IV-4-1. The purpose of centrifugation is to situate Hematocrit below the slim neck.



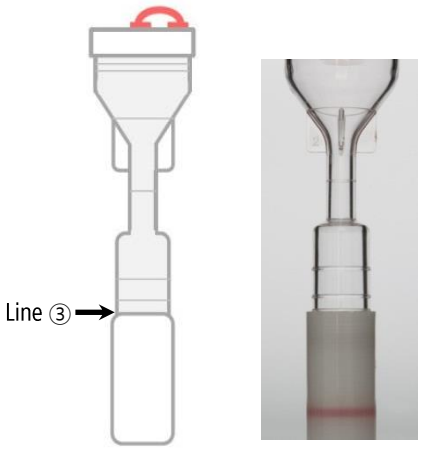
5. How to Use the Control Grip

IV-5-1. How To Use Hand Control Grip



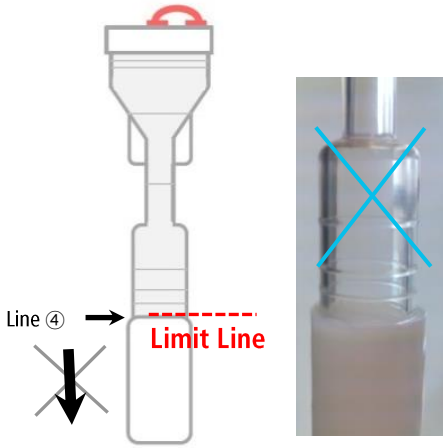
Ⅳ-5-2. Start Position

Line ③ is the start position of the control grip when packed.



Ⅳ-5-3. Limit Line of the Control Grip

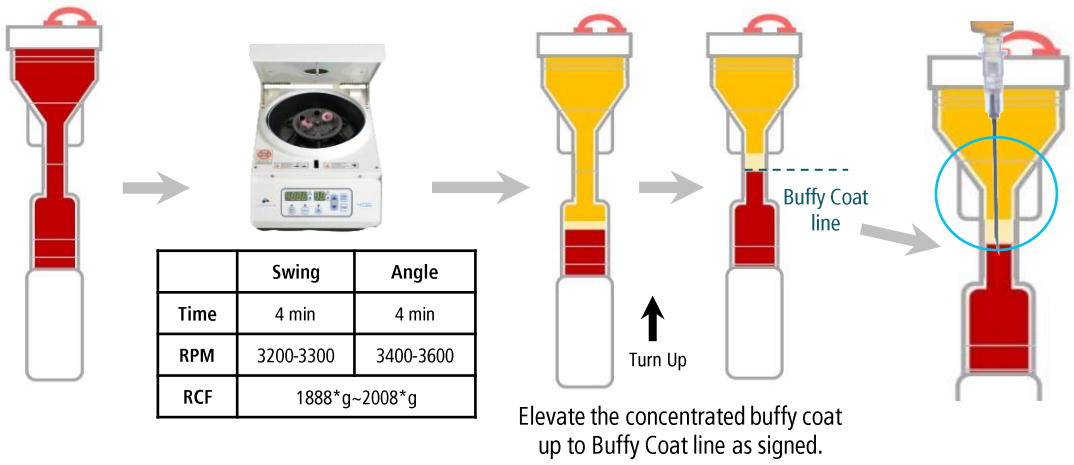
If the grip is turned down below Line ④, blood might leak during spins.



6. Centrifugation Cases

Ⅳ-6-1. Standard Case – 1 Time Spin

Case A – Clearly separated after the 1st spin



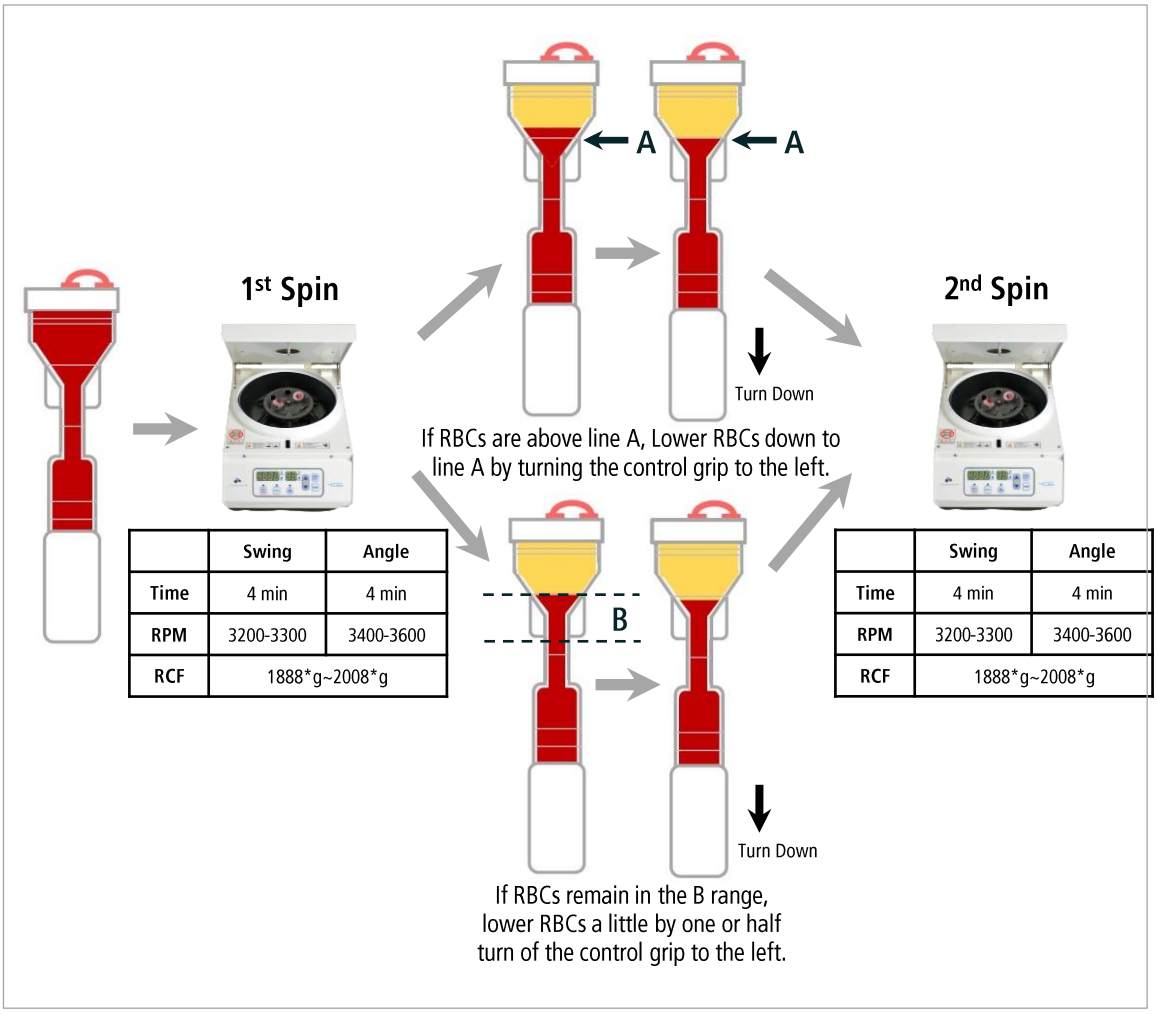
	Swing	Angle
Time	4 min	4 min
RPM	3200-3300	3400-3600
RCF	1888*g~2008*g	

Elevate the concentrated buffy coat up to Buffy Coat line as signed.

IV-6-2. Non-standard Cases – 2 Time Spins

Case B – Elevated Hematocrit

- Case B happens when RBCs remain above the slim neck after the 1st spin.
- It's usually shown in male's blood.



	Swing	Angle
Time	4 min	4 min
RPM	3200-3300	3400-3600
RCF	1888*g~2008*g	

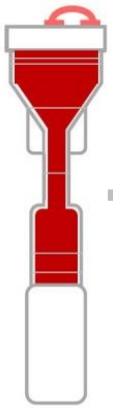
	Swing	Angle
Time	4 min	4 min
RPM	3200-3300	3400-3600
RCF	1888*g~2008*g	

Q. What if RBCs are not lowered below the slim neck after 2 time spins?

→ Take one more spin with the same speed and time.

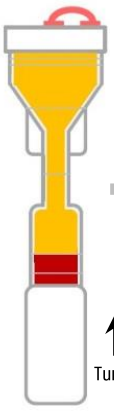
Case C – Depressed Hematocrit

Case C happens when RBCs are depressed lower than the slim neck after the 1st spin. It's usually shown in anemia patients' or female's blood.



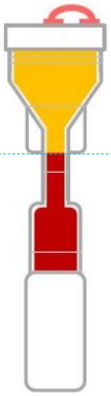
1st Spin

	Swing	Angle
Time	4 min	4 min
RPM	3200-3300	3400-3600
RCF	1888*g~2008*g	



Turn Up

Elevate RBCs up to the signed line that is right below the safety wing.

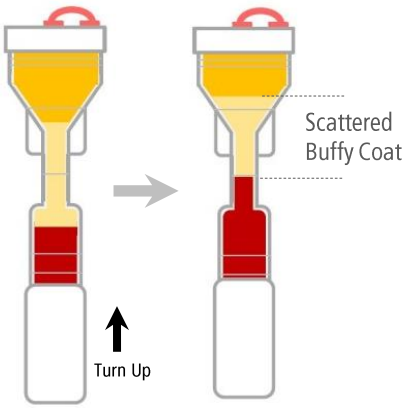


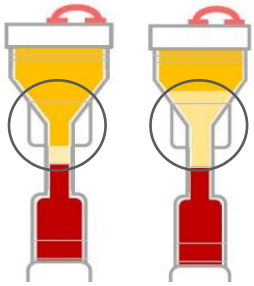
2nd Spin

	Swing	Angle
Time	2 min	2 min
RPM	2200-2300	2400-2600
RCF	892*g ~ 975*g	

Case D – Buffy Coat is not concentrated clear after 2 time spins

Case D is a still good result even if you can't see clear buffy coat layer after spins. In this case, elevate buffy coat layer up to Buffy Coat Line and extract it.



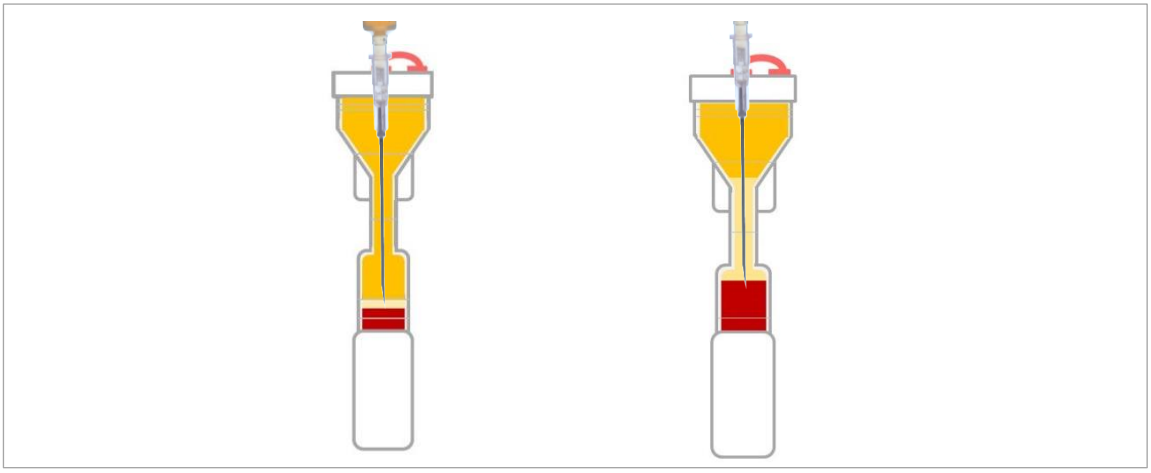


Consequentially, you will harvest the similar platelet counts in both cases.

Clear Foggy

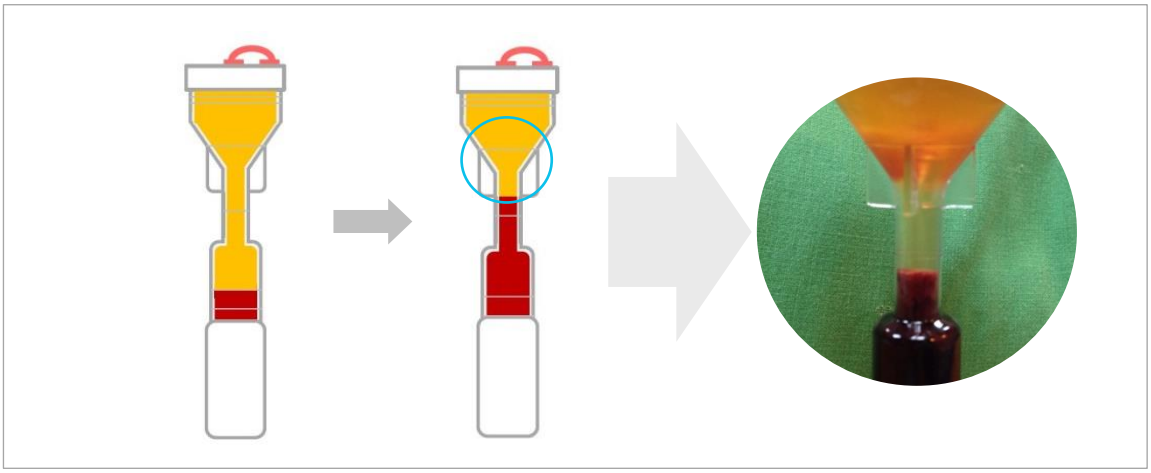
Case E – The control grip can't be turned up any more

Use a **long needle** to extract PRP If it's impossible to elevate buffy coat any more as the control grip has already been turned up to maximum.



Case F – No buffy coat seen

There are some patients who have few platelets. If you can't see any buffy coat at all after several spins, stop taking spins and just extract plasma part near RBCs.



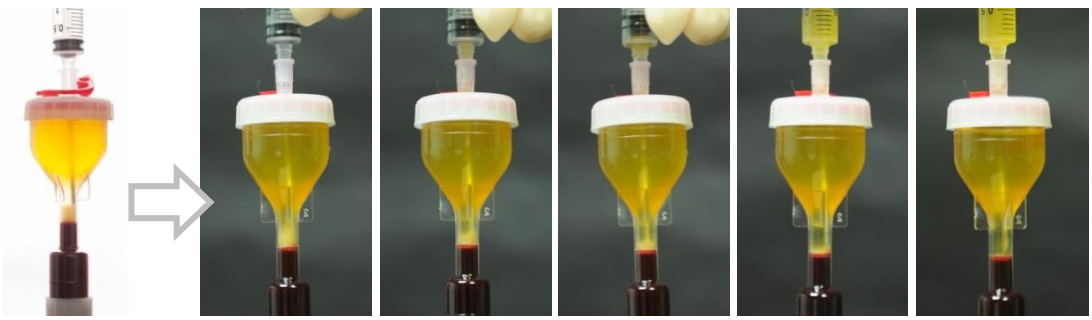
Ⅴ. PRP Extraction

1. How To Extract PRP

Ⅴ-1-1. Elevate buffy coat up to the Buffy Coat Line by turning right the control grip.

Ⅴ-1-2. Prepare 3cc syringe / 18G 1 $\frac{1}{2}$ Needle for PRP extraction.

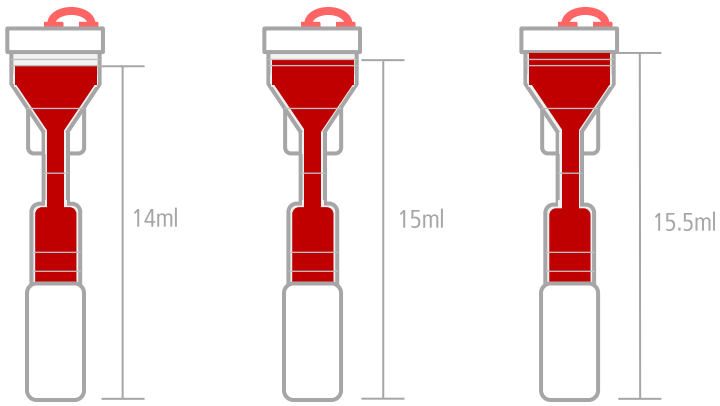
Ⅴ-1-3. Draw 1.5~2ml PRP from the slim neck where Buffy Coat is concentrated, making Tornado inside the tube by stirring up Buffy Coat using needle, so that sunk platelets can be drawn easily.



Ⅴ-1-4. Draw the remaining PPP(platelet poor plasma) in 5cc syringe. PPP is used to spray on the entire face to relieve the stimulated skin.

3. PRP Volume for Enrichment Test

V -**3-1.** $\frac{1}{10}$ of the total blood sample volume is required for enrichment test.



	Male	Female	Anemia
Blood Vol.	12.5 ml	13.5 ml	14 ml
Anticoagulant Vol.	1.5 ml	1.5 ml	1.5 ml
PRP Vol. PRP / Blood 1 / 10	1.25 ml	1.35 ml	1.4 ml

V -3-2. If You Use a Needle for Extraction,

Normally, about 0.05ml of buffy coat might remain clinging to the inside hole of the needle. Therefore, about 0.05ml loss of buffy coat should considered when you count platelets in PRP, and deduct loss volume of 0.05ml from 1/10 of the total blood sample volume.

	Male	Female	Anemia
PRP	1.25 ml	1.35 ml	1.4 ml
Loss Vol.	- 0.05	- 0.05	- 0.05
PRP Test Vol.	**1.2 ml**	**1.3 ml**	**1.35 ml**

YCBM
Ycellbio Medical

Instructions for Use

Description of the intended use

- Intended use of the product
  This product is intended for a blood collection container which can take the blood sample securely for medical examination or extract plasma of platelet using centrifugation for transplantation PRP.

  ① The intended patient population:
  The patient needed for PRP treatment
  ② The intended user :
  This medical device should be used by the qualified doctor

Indication for use

: The Ycellbio PRP is designed to be used intraoperatively at the point of care for the preparation of autologous platelet rich plasma (PRP) from a small sample of peripheral blood. The PRP is mixed with auto-graft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Classification applied

- The product has been classified as Class II a according to MDD07/47/EC Annex IX, Rule2.

Characteristic

- Ethylene oxide gas be sterilized by JUNG RIM MEDICAL INDUSTRIAL CO.,LTD
- This device should be used for Single-use.
- Shelf-life : 3years

Contraindications

The use of YCELLBIO system is contraindicated in patients: The following conditions should be considered as contraindications for PRP injection: hematologic blood dyscrasias with platelet dysfunction; septicemia or fever; cutaneous infections in the area to be injected; anemia (hemoglobin less than 10 deciliters; malignancy, particularly with hematologic or bony involvement; allergy to bovine products if bovine thrombus is to be used.

Warning and precautions

- Use proper safety precautions to guard against needle sticks.
- Follow manufacturer instructions when using centrifuge.
- Follow manufacturer package insert for ACD-A Anticoagulant.
- Do not use sterile component of this kit if package is opened or damaged.
- Single use device, do not reuse.
- The surgeon is to be thoroughly familiar with the equipment and the surgical procedure prior to using this device.
- The patient is to be made aware of general risks associated with treatment and the possible adverse effects.
- Use prepared platelet concentrate material within 1 hour after drawing blood from patient.

How to use

1. Draw 1.5ml of Anticoagulant into 20ml syringe first then draw 15ml of blood from patient. Thoroughly mix the whole blood and anticoagulant upon collection to prevent coagulation.
2. Load: Slowly load blood-filled 20 ml syringe (1.5mls of citrate anticoagulant and 15ml of whole blood) into inlet blood port. Once all the blood is loaded, seal the inlet blood port of the tube with a silicon cork.
3. Balance: Fill a counterbalance tube with 15ml of sterile saline or water (equal to amount of the collected blood), and place into opposite side of centrifuge.
4. Spin: Close lid and set RPM for 3200 (g force = 1,888) and time to 6 minutes. Press the start button to start spin. Once spin is complete, press open button to open lid.
5. PRP Extraction: After the spin, adjust the height of blood cells to situate PRP in the thin neck part by using bottom control knob. Open a silicon cork of the outlet in the middle and extract 2 ml of PRP into 3ml syringe using an 18 gauge needle.
6. PPP Extraction: Extract 4 ml of PPP(platelet poor plasma) into 5ml syringe using an 18 gauge needle.

Storage

- Store this product at room temperature
- Away from humid and sun-exposed areas.
- Store it separately from other products and don't put any heavy stuff on it.
- Always keep the storage clear.

YCBM
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CE FDA

YCMB PRP kit is entered in the ARTG, 279546

www.ycellbio.com.au