

## USER MANUAL

### PRODUCT: 5PRF

**Components:** 5-PRF tube; Vacuum blood collection needle; Needle holder; Alcohol pad; Sterile forceps; Sterile scissors; Bandage; Product containing tube.

**Reference Number:** 390 (5PRF kit V1); 389 (5PRF kit V2).

**Size:** Kit

#### Intended use:

For research and/or manufacturing purposes only.

5PRF is a kit designed for the production of platelet-rich fibrin (PRF) from peripheral blood.

#### Overview Product:

5PRF is a kit consisting of instruments and chemicals necessary for blood collection and the production of platelet-rich fibrin.

5PRF employs a vacuum blood collection method and isopycnic centrifugation. The product is utilized in accordance with a technological protocol developed by the Stem Cell Institute. The resultant product, platelet-rich fibrin, boasts a high concentration of platelets and ensures a high level of safety.

The kit meets the sterility requirements (0 CFU) and exhibits a low endotoxin level  $\leq 1$  EU/mL.

#### Known Applications:

The efficacy of 5PRF in blood collection and the production of platelet-rich fibrin from peripheral blood has been rigorously assessed.

#### Reconstitution, Dilution, Mixing:

Not applicable.

#### Materials and Chemicals Required (but not provided):

Not applicable.

#### Handling and Storage:

Store and transport at room temperature.

Recommended shelf life: determined by the shortest shelf life of the ingredients.

#### Precautions before Proceeding:

After blood collection, promptly proceed to the centrifugation step within 30 seconds. Ensure that the parameters of the centrifuge, such as time and speed, are set in advance and that the centrifuge machine is ready for use. Prepare the counterbalance centrifuge tubes in advance and have them readily available.

During the centrifugation process, promptly prepare the instruments (including the forceps, the scissor, and the Product containing tube); the Product containing tube should be opened and positioned vertically on a stand.

#### Instructions for Use:

- 1. Prior to proceeding, conduct a thorough inspection to ensure the components are intact and within their expiration dates.**
- 2. Blood Collection**
  - 2.1. Attach the Vacuum blood collection needle to the Needle holder.
  - 2.2. Use the Alcohol pad to cleanse the area of skin surrounding the vein. Then, perform venous blood collection.
  - 2.3. Apply firm pressure to insert the 5-PRF tube into the Needle holder, allowing the blood to flow automatically into the 5-PRF tube.
  - 2.4. Collect a sufficient volume of blood in the 5-PRF tube..

### 3. Centrifugation

- 3.1. Place the blood-containing 5-PRF tube in the centrifuge, ensuring a counterbalance tube is positioned symmetrically.
- 3.2. Centrifuge the tubes at **1500 g for 8 minutes**. If the centrifuge has a brake mode, disable it.
- 3.3. Gently remove the 5-PRF tube from the centrifuge and place it on a stand designed for 15 mL tubes. At this point, the blood will separate into two parts: the red blood cells will settle at the bottom, while the yellowish plasma layer will be found on top, separated from the blood cell fraction by the white opaque gel layer in the tube. The platelet layer will be situated just above the gel layer.
- 3.4. During the centrifugation process and immediately after, the platelet rich plasma will have already begun to coagulate into fibrin gel.

To check the characteristic features of the gel, tilt the tube and observe its flowability:

- If the gel does not flow when the tube is inverted, proceed to the next step.
- The gel coagulation will be finished within 3-15 minutes after centrifugation.

- 3.5. Use a forcep to rotate the fibrin gel mass inside the tube and lift it out of the tube.
- 3.6. Use the scissor to remove the tube's inherent gel portion (opaque white) from the fibrin gel (yellow), hold the fibrin gel mass with the forcep, and transfer it to the product containing tube or sites of application.

Note: The fibrin portion that is located adjacent to the inherent gel layer is rich in platelets.

#### Precautions:

Do not use the product if the packaging appears damaged or compromised, or if any of the components exhibits abnormalities.

The PRF manufacturing process involves an open manipulation step (cutting the gel), thus performing









it in a cleanroom or a Class II biological safety cabinet is imperative to ensure a sterile final product.

#### First Aid Measure:

Not applicable.

#### Interpretation of symbols

The symbols on the product label are explained below

			
Use By:	Batch code	Keep away from light	Catalog number
			
Temperature Limitation	Consult instructions for use	Caution, consult accompanying documents	Sterilized using aseptic processing techniques

#### Related Product:

<i>Product Name</i>	<i>Reference Number</i>
<b>5-PRP KIT</b>	146
<b>5-PRP KIT V1</b>	376
<b>SPRP KIT</b>	170
<b>SPRP KIT V1</b>	190
<b>RGML PRP KIT</b>	146
<b>RGML PRP KIT V1</b>	166
<b>5PRP – F KIT V1</b>	416
<b>5PRP – F KIT V2</b>	417
<b>SPRP – F KIT V1</b>	418
<b>SPRP – F KIT V2</b>	419
<b>SPRF KIT V1</b>	393
<b>SPRF KIT V2</b>	388
<b>COOL PRP</b>	175
<b>HEMAGEL</b>	404

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[contact@sci.edu.vn](mailto:contact@sci.edu.vn);

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