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1.0 PURPOSE

The purpose of this paper is to define and explain the steps and protocols that need to be followed in order to obtain PRP. These miscellaneous steps include blood harvesting, blood fractionation, collecting and injecting the PRP using HD PRP KIT.

2.0 SCOPE

This Procedure covers in details how to derive PRP using the HD PRP syringe manufactured by T-Lab.

3.0 RESPONSIBLES

The Quality Management Representative, Regulatory Affairs Specialist, Production Planning, Purchasing Officer, the Company Manager and Operations Manager are responsible for the implementation of this procedure.

4.0 DEFINITIONS

4.1 COMPONENTS OF THE KIT:



- Two 10 ml PRP Tubes each including 1 ml of anticoagulant (Sodium citrate), exclusively prepared for PRP
- One Phlebotomy set
- A 21G Needle
- A 30G injection Needle
- 1 Re-suspension Tube
- A long Needle
- A 5 ml injector
- A 1 ml injector

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4.2 PURE PRP PROTOCOL:

T-Lab has researched and developed HD-PRP KIT to yield optimum results and recovery rates. After carrying out different quality and performance tests in our laboratory, this pure PRP protocol is now validated.

This protocol allows you to derive a form of Leukocyte Poor PRP with little to no white nor red blood cells present from the initial blood in the final product.

5.0 APPLICATION

5.1 STANDARD OPERATING PROCEDURE

Pure PRP protocol (continued)

Steps	Description
Blood Collection	Harvest the blood using the phlebotomy set in the kit, The tubes are vacuumed and automatically draws the blood and stops once the volume of the tube is full,gently shake each tubes to permeate the anticoagulant into the blood.
Centrifugation	Place the tubes into a full swing out centrifuge (Highly recommended). The Buckets shall be compatible with the PRP tubes (16x100mm tube size),Set the centrifuge to 830G (2300 rpm) and the timer to 4 minutes. (8 minutes for fixed angle centrifuge)
Harvesting the PRP from the tubes	Use the 21G needle first to puncture the corner of the lid in order to get rid of the vacuum within the tube,do not remove it, attach the long needle to the 5 ml Luer Lock Syringe and puncture though the lid carefully, aspirate between 2-2.5 ml of PRP (Do not open the lid unless the process is performed under Laminar Flow Condition). Repeat the procedure for the second tube.
Re-Suspension Mechanism	Transfer the collected PRP into the re-suspension tube. Gently shake for 30s to homogenize the settlement of possible clumped cells in the plasma milieu.
Harvesting the PRP from the re-suspension tube	Use the 21G green needle in the kit to collect the final PRP. Change the application needle (21G) to the injection needle (30G)