

# Comparison of the Nuo Therapeutics Aurix<sup>®</sup> System and RegenKit<sup>®</sup> PRP (Regen Labs)

## Nuo Therapeutics, Inc. Research and Development Laboratory

### Introduction

The Aurix System utilizes a proprietary 1-minute spin regimen to produce a platelet rich plasma (PRP) from a small sample of a patient's whole blood (WB) at the point of care. The PRP produced by the Aurix<sup>®</sup> System is leukocyte, specifically neutrophil reduced. The PRP comparator product, the Regen Labs RegenKit<sup>®</sup>-BCT is marketed to also produce leukocyte-reduced PRP having platelet concentrations similar to that achieved with the Aurix System. The purpose of this study is to compare the cellular content of the PRP produced by the Aurix System and the RegenKit-BCT.

### Methods

Whole blood from 9 volunteers was drawn, using a 21G butterfly needle, into separate 60mL syringes that did not contain anticoagulant. Immediately following each donor blood draw, the 60mL syringe was inverted to ensure a homogenous mixture and the samples were distributed into the PRP devices using an 18G needle. The WB samples were delivered as follows: 5cc into each of 3 Aurix Syringes containing 0.6mL of ACD-A anticoagulant and 10mL directly into the RegenKit-BCT tube. The tube and syringes were inverted to mix the WB sample and anti-coagulant. One syringe containing anticoagulated whole blood from each donor was set aside as the baseline WB sample used in the CBC analysis. As described below, in accordance with each manufacturer's instructions for use, for each donor, two of the 5mL Aurix syringes and one 10mL RegenKit-BCT tube were processed to produce a sample of PRP. The final PRP output was inverted to ensure a homogeneous sample, and for each technology utilized, two (2) x 0.3 ml aliquots of the PRP sample were transferred to individual 1.5mL microfuge tubes using an 18G needle. Complete blood

counts (CBC) were measured on each aliquot using a Beckman Coulter DxH 500 Hematology Analyzer.

#### Nuo Therapeutics Aurix System

In accordance with the Aurix System Instructions for Use (IFU), the two 5mL anticoagulated WB samples were placed into the Aurix System Centrifuge ensuring balance and centrifuged for one minute at the preset centrifugation speed. The caps were removed from the S-Monovette tubes after centrifugation, and PRP samples for CBC analysis were harvested into a 5cc syringe using a blunt 15G needle.

#### RegenLab RegenKit-BCT

RegenKit-BCT tubes containing the anti-coagulated WB and a counterbalance were placed into the RegenKit-BCT centrifuge and centrifuged at room temperature (18-25°C) for 5 minutes at the preset setting (3500 RPM). After centrifugation, the RegenKit-BCT tube was gently inverted 20 times to resuspend the platelets. The RegenKit-BCT tube again was inverted and a 5 mL syringe affixed to an 18G needle was used to collect the PRP samples for CBC analysis.

### Results

Whole blood (WB) was processed using two commercially available PRP systems: Nuo Therapeutics Aurix System and Regen Labs RegenKit-BCT. Each system was evaluated based on technological characteristics and performance data. The Aurix System is highly portable solution utilizing a lightweight (5lb) centrifuge with a 1-minute spin. The RegenKit-BCT is less portable relying on a 12 lb centrifuge with a 5-minute spin cycle. The Aurix System processes a minimum of 5mL of WB sample while the RegenKit-BCT requires a fixed minimum 10mL volume of WB (**Table I**).

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**Table I: Centrifugation Requirements**

Technology	Minimum Blood Volume Required	Blood Volume Processed	Centrifugation Time	Weight of Centrifuge
Nuo Therapeutics Aurix	5 mL	10 mL	1 minute	5 lbs
Regen Labs RegenKit-BCT	10 mL	10 mL	5 minutes	12 lbs

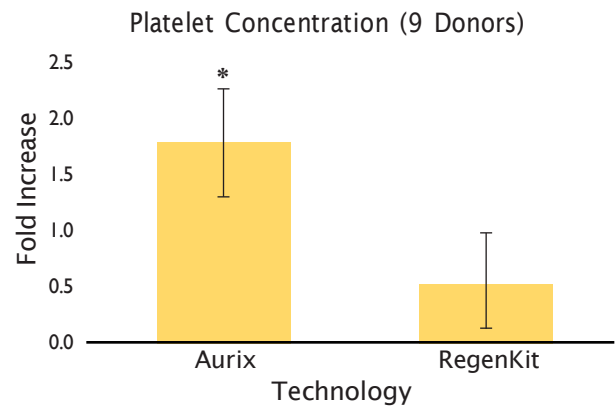
Analysis of CBC data revealed that both systems processed the whole blood samples to effectively separate a PRP fraction from red blood cells (RBC) and leukocytes. In all PRP samples tested, the RBC content was reduced >99% and neutrophils reduced >98% as compared to baseline WB values. Significant differences between technologies with respect to either RBC or Neutrophil concentrations were not observed (**Data on File**).

Analysis of CBC data further revealed that the Aurix System produced PRP samples containing an average platelet concentration 1.8 fold over baseline and PRP samples produced by the RegenKit-BCT contained an average platelet concentration that was lower (0.7 fold) than that observed in the baseline WB samples (**Figure 1**). Furthermore, this difference between the Aurix System for concentrating platelets as compared to the RegenKit-BCT reducing platelet concentration was found to be extremely statistically significant ( $p < 0.0001$ ).

### Conclusion

The Aurix System and the RegenKit-BCT are commercially available systems used to process a sample of whole blood (WB) to produce PRP. The Aurix System offers significant advantages with respect to minimum WB sample input volume requirements and processing speed. Furthermore, the Aurix System utilizes proprietary 5mL blood collection syringes pre-loaded with anticoagulant ACD-A thereby offering flexibility to process 5-20mL of whole blood (WB) using a single 1-minute centrifugation. In contrast, the RegenKit-BCT requires a 10mL minimum WB sample input relies on a significantly longer 5-minute centrifugation cycle.

**Figure 1: Platelet Concentration by the Aurix System and RegenKit-BCT**



\*Differences between the Aurix System and the RegenKit-BCT for concentrating platelets are extremely statistically significant ( $p < 0.0001$ ).

Analysis of CBC data revealed that while both systems produce a sample that is significantly reduced in RBC content and neutrophil content, the devices do not demonstrate the same capability to concentrate platelets. The Aurix System produced PRP containing platelet concentrations higher than observed in the baseline WB samples while the RegenKit-BCT produced a plasma sample containing platelet concentrations that were greatly reduced relative to platelet concentrations present in the baseline WB samples. The results of this study demonstrate that Nuo Therapeutics Aurix System and Regenlab's RegenKit-BCT produce a product containing significantly reduced red blood cells and neutrophils. However, only the Aurix System was able to effectively concentrate platelets. The portability, speed and flexibility of the Aurix System to concentrate platelets and obtain a sample of PRP from as little as 5mL of WB may present advantages in different clinical settings.

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