WADA Technical Document – TD2010BAR

Document Number:	TD2010BAR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	November 03, 2009	Effective Date:	January 01, 2010

Blood Analytical Requirements for the *Athlete* Biological Passport

1. Introduction

This Technical Document has been established to harmonize the analysis of blood *Sample*s collected, both In-Competition and Out-of-Competition, for the measurement of individual *Athlete* blood variables within the framework of the *Athlete* Biological Passport (AP).

The International *Standard* for Laboratories (ISL) is applicable to the analysis of blood *Sample*s carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the AP. This Technical Document describes certain specificities of blood analysis related to the AP.

All defined terms used in this Technical Document and not specifically defined herein bear the definitions accorded to them by the World Anti-Doping Code, the ISL and/or the International Standard for Testing (IST). Blood *Sample*s shall be analyzed in a *WADA* accredited laboratory or as otherwise approved by *WADA*. If not reasonably possible for technical and/or geographical reasons, Blood *Sample*s can be analyzed at a satellite facility of a *WADA* accredited laboratory or using mobile units operated under applicable ISO accreditation by *WADA* accredited laboratories.

2. Analytical procedure

In order to standardize analytical results in the *Athlete* Biological Passport framework, it is important to have blood *Sample*s analyzed in an appropriate dedicated network of laboratories (e.g. *WADA* accredited laboratories or as otherwise approved by *WADA*) using analyzers with comparable technical characteristics. It is necessary that the instrumentation is validated to provide comparable results prior to analysis of *Doping Control Sample*s).

3. Instrument check

Before performing any blood analyses, all reagents shall be verified to ensure that they are within their expiration dates and that they comply with the reagent manufacturer's recommendations. Then, the operational parameters of the instrument shall be properly controlled (background level, temperature of the incubation chambers, pressure, etc…) and fall within manufacturer's specifications.

All internal Quality controls shall be analyzed twice following the specifications provided by the manufacturer. These internal Quality controls shall exclusively be furnished by the manufacturer of the instrument. These controls shall be handled in strict accordance with the specifications provided by the manufacturer (e.g. expiration dates, storage conditions, etc.). All results shall be in agreement with reference value ranges provided by the manufacturer.

On a regular basis (as determined by the head of the laboratory), one fresh blood *Sample* shall be homogenized for a minimum period of 15 minutes on an appropriate mixer (e.g. roller mixer) and then analyzed seven consecutive times. Coefficients of variation shall be below 1.5 % for hemoglobin and HCT and below 15 % for percentage reticulocyte count in order to confirm the appropriate precision of the instrument.

At least one internal Quality control from the manufacturer (either level 1, 2 or 3) shall be conducted after every 30 to 50 blood *Sample* analyses. Once a day and after all blood Sample analyses are completed, one internal Quality control (either level 1, 2 and 3) shall be analyzed once again to demonstrate continuous stability of the instrument and the quality of the analyses done.

4. External Quality Assessment Scheme

The Laboratories (or as otherwise approved by *WADA*) shall take part in and meet the requirements of the WADA External Quality Assessment Scheme (EQAS) for blood variables. The external quality controls shall be analyzed seven times consecutively and then the mean results of the following blood variables (full blood count) shall be returned:

Red Blood Cell (Erythrocyte) Count	RBC
Mean Corpuscular Volume	MCV
Hematocrit	HCT
Hemoglobin	HGB
Mean Corpuscular Hemoglobin	MCH
Mean Corpuscular Hemoglobin Concentration	MCHC
White Blood Cell (Leukocyte) Count	WBC
Platelet (Thrombocyte) Count	PLT
Reticulocytes Percentage	%RETI

Laboratories (or as otherwise approved by *WADA*) may also participate in ring tests between laboratories (hospitals, clinics, etc) using the same technology and the same procedure.

5. Analysis of Blood *Samples*

All blood *Sample*s shall be homogenized for a minimum period of 15 minutes an appropriate mixer (e.g. roller mixer) prior to analysis. Each blood *Sample* shall be analyzed twice. Absolute differences between the results of the two analyses shall be equal or less than the following for the relevant analyses to be accepted:

- 0.1g/dL for HGB analysis;
- 0.15 absolute difference for % Reti analysis (if first measurement lower or equal to 1.00%);
- 0.25 absolute difference for % Reti analysis (if first measurement higher than 1.00%).

The data from the second injection is used to confirm the first injection data. Therefore, if the absolute differences between the results of the analyses are within the criteria above, then only the first injection data is reported. If absolute differences between the results of the two analyses are greater than those defined above for a specific *Sample*, the analysis shall be started again in accordance with this section 5. The reason for repetition shall be documented.

The requirements for an Initial Testing Procedure, A *Sample* Confirmation Procedure and B *Sample* Confirmation Procedure as defined in the ISL shall not be applicable to blood *Samples* analyzed for the purposes of the *Athlete* Biological Passport.

6. Reporting

The results of the Laboratory (or as otherwise approved by *WADA*) shall be reported to the relevant Anti-Doping Organization and WADA via ADAMS.