The World Anti-Doping Code

ATHLETE BIOLOGICAL PASSPORT OPERATING GUIDELINES

AND COMPILATION OF REQUIRED ELEMENTS

January 2010

Version 2.1

TABLE OF CONTENTS

1.0 Introduction and Scope

The idea of an '*Athlete* Biological Passport' (AP) was first proposed by the World Anti-Doping Agency in 2002. The typical *Doping Control* approach based on the detection of *Markers* of a substance or its *Metabolites* remains an effective approach. However it has limitations when an *Athlete* may be using substances on an intermittent and low-dose basis which may therefore go undetected under even the most robust *Out-of-Competition Doping Control* program. Both the nature of many substances susceptible to abuse (particularly endogenous ones) and the increasing sophistication of *Athlete* intake protocols underscore the need for a more sophisticated methodology to be made available. Over recent years, doping regimes have become much more scientifically planned and have taken full advantage of the weaknesses in traditional protocols with all available pharmaceutical resources. Therefore the complementary strategy outlined in this document is aimed at ensuring an increasingly efficient fight against intentional doping at the most sophisticated level.

The passport concept is based on the knowledge of drug effects or side effects in medical practice. Regular and frequent monitoring of *Doping Control* data facilitates indirect detection of doping substances and methods on a longitudinal basis. From this perspective, the substance itself is not detected but rather its effects on the body become apparent. Typically, the effect of the drug remains perceptible and detectable longer in the body than the substance itself, which may otherwise be quickly excreted and therefore go undetected unless *Testing* is carried out at a very specific time.

In order to establish a systematic and robust longitudinal monitoring program, the list of relevant and significant variables for a specific class of substance (e.g. substances enhancing oxygen transfer, such as EPO) must be identified and then monitored on a regular basis for any given *Athlete*. The collection and monitoring of values corresponding to these identified variables will constitute an individual and longitudinal profile. Such profiles are the cornerstones of the *Athlete* Biological Passport with a subject becoming his/her own reference. This contrasts the traditional approach of the *Athlete*'s variables being measured against norms in the *Athlete* population at large.

The variables to be monitored will vary, according to the purpose of the detection. For instance, haematological variables in the blood will be taken into consideration to confirm blood manipulation or aerobic performance enhancement. Steroid *Markers* in urine on the other hand may be used to demonstrate the use of anabolic steroids. The purpose of this guideline is to support any *Anti-Doping Organization* wishing to set up the *Athlete* Biological Passport program described in this document based on a blood matrix only

(the “Haematological module”). As further research and evidence is assessed regarding how this “intra-individual reference model” may be applied to a urine matrix, a similar “Endocrine module” will be developed as well as other possible modules. The appropriate steroid *Markers* are still under development whereas the blood component can be utilised immediately. Other variables are likely to be added and monitored in the near future.

The *Athlete* Biological Passport concept does not replace or invalidate any existing blood ‘screening’ or medical protocols which an *Anti-Doping Organization* may currently operate. Rather, the *Athlete* Biological Passport is presented in order to equip *Anti-Doping Organization*s with a robust and viable framework in which to pursue anti-doping rule violations in accordance with Article 2.2 of the World Anti-Doping *Code* and support intelligent, targeted *Testing*. The *Athlete* Biological Passport is not intended to act as a mechanism for “no start” or “health check” protocols.

This document is divided into two sections. The first section is the text of the guideline which aims to explain how the *Athlete* Biological Passport works and how to establish it. Like any guideline, this element is to foster consistency and harmonization in the application of the *Athlete* Biological Passport within the anti-doping community, but is not mandatory. The second section is comprised of annexes which are a compilation of the mandatory protocols which must be followed by the *Anti-Doping Organizations* choosing to use the *Athlete* Biological Passport to ensure consistency in application, the sharing of information and the standardization of procedures. These annexes are included herein for ease of reference only and have been incorporated into the *International Standard* for *Testing* and *International Standard* for Laboratories as Technical Documents.

These mandatory protocols have been established to harmonize the results of monitored variables within the *Athlete* Biological Passport to ensure both legal fortitude and scientific certainty. Additionally, a global scheme of organization is proposed as a recommendation to ensure the most harmonized approach possible. Each *Anti Doping Organization* remains free to adapt the global process to its own needs and goals, but any protocol attached as an annex must be rigorously applied to ensure the validity of the *Athlete* Biological Passport. Finally, although this guideline seeks to harmonize longitudinal profiling programs, it in no way undermines the validity or efficacy of existing *Anti-Doping Organization* programs. There are a number of useful and sound methodologies available to review blood data and in turn manage intelligent *Doping Control* programs, and the description offered in this document is one such model.

2.0 Terms and Definitions

2.1 Defined Terms from the 2009 *Code*

ADAMS: The Anti-Doping Administration and Management System is a Web-based database management tool for data entry, storage, sharing, and reporting designed to assist stakeholders and *WADA* in their anti-doping operations in conjunction with data protection legislation.

Anti-Doping Organization: A *Signatory* that is responsible for adopting rules for initiating, implementing or enforcing any part of the *Doping Control* process. This includes, for example, the International Olympic Committee, the International Paralympic Committee, other *Major Event Organizations* that conduct *Testing* at their *Events*, *WADA*, International Federations, and *National Anti-Doping Organizations.*

***Athlete*:** Any *Person* who participates in sport at the international level (as defined by each International Federation), the national level (as defined by each *National Anti-Doping Organization,* including but not limited to those *Persons* in its *Registered Testing Pool*), and any other competitor in sport who is otherwise subject to the jurisdiction of any *Signatory* or other sports organization accepting the *Code*. All provisions of the *Code*, including, for example, *Testing* and therapeutic use exemptions, must be applied to international- and national-level competitors. Some *National Anti-Doping Organizations* may elect to test and apply anti-doping rules to recreational-level or masters competitors who are not current or potential national-caliber competitors. *National Anti-Doping Organizations* are not required, however, to apply all aspects of the *Code* to such *Persons.* Specific national rules may be established for *Doping Control* for non-international-level or non-national-level competitors without being in conflict with the *Code.* Thus, a country could elect to test recreational-level competitors but not require therapeutic use exemptions or whereabouts information. In the same manner, a *Major Event Organization* holding an *Event* only for masters-level competitors could elect to test the competitors but not require advance therapeutic use exemptions or whereabouts information. For purposes of Article 2.8 (Administration or *Attempted* Administration) and for purposes of anti-doping information and education, any *Person* who participates in sport under the authority of any *Signatory*, government, or other sports organization accepting the *Code* is an *Athlete*.

[Comment: This definition makes it clear that all international- and national-calibre athletes are subject to the anti-doping rules of the Code, with the precise definitions of international- and national-level sport to be set forth in the anti-doping rules of the International Federations and National Anti-Doping Organizations, respectively. At the national level, anti-doping rules adopted pursuant to the Code shall apply, at a minimum, to all Persons on national teams and all Persons qualified to compete in

any national championship in any sport. That does not mean, however, that all such Athletes must be included in a National Anti-Doping Organization's Registered Testing Pool. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond national-caliber athletes to competitors at lower levels of competition. Competitors at all levels of competition should receive the benefit of anti-doping information and education.]

Code: The World Anti-Doping *Code*.

***Doping Control*:** All steps and processes from test distribution planning through to ultimate disposition of any appeal including all steps and processes in between such as provision of whereabouts information, *Sample* collection and handling, laboratory analysis, therapeutic use exemptions, results management and hearings.

***Event**:* A series of individual *Competitions* conducted together under one ruling body (e.g., the Olympic Games of the Olympiad and the Winter Games, FINA World Championships, or Pan American Games).

***In-Competition*:** Unless provided otherwise in the rules of an International Federation or other relevant *Anti-Doping Organization*, "*In-Competition"* means the period commencing twelve hours before a *Competition* in which the *Athlete* is scheduled to participate through the end of such *Competition* and the *Sample* collection process related to such *Competition*.

International Standard: A standard adopted by *WADA* in support of the *Code*. Compliance with an *International Standard* (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures addressed by the *International Standard* were performed properly. *International Standards* shall include any Technical Documents issued pursuant to the *International Standard.*

No Advance Notice: A *Doping Control* which takes place with no advance warning to the *Athlete* and where the *Athlete* is continuously chaperoned from the moment of notification through *Sample* provision.

Out-of-Competition: Any *Doping Control* which is not *In-Competition*.

Prohibited List: The List identifying the *Prohibited Substances* and *Prohibited Methods*.

Prohibited Method: Any method so described on the *Prohibited List*.

Prohibited Substance: Any substance so described on the *Prohibited List*.

Sample or Specimen: Any biological material collected for the purposes of *Doping Control*.

[Comment: It has sometimes been claimed that the collection of blood Samples violates the tenets of certain religious or cultural groups. It has been determined that there is no basis for any such claim.]

Target Testing: Selection of *Athletes* for *Testing* where specific *Athletes* or groups of *Athletes* are selected on a non-random basis for *Testing* at a specified time.

Testing: The parts of the *Doping Control* process involving test distribution planning, *Sample* collection, *Sample* handling, and *Sample* transport to the Laboratory.

WADA: The World Anti-Doping Agency.

2.2 Defined Terms Specific to the *International Standard* for *Testing* (IST)

Adaptive Model: Model developed in which evidence or observations are used to update or to newly infer the probability that a hypothesis may be true or to discriminate between conflicting hypotheses. It was designed to identify unusual longitudinal results from *Athlete*s.

***Athlete* Biological Passport:** The method of gathering and evaluating data described in this document including the Technical Documents of the *International Standards* for *Testing* and Laboratories.

Blood Collection Officer (BCO): An official who is qualified to and has been authorized by the *Anti-Doping Organization* to collect a blood *Sample* from an *Athlete.*

Chain of Custody: The sequence of individuals or organizations who have the responsibility for a *Sample* from the provision of the *Sample* until the *Sample* has been received for analysis.

***Doping Control* Officer (DCO)**: An official who has been trained and authorized by the *Anti-Doping Organization* with delegated responsibility for the on-site management of a *Sample* Collection Session.

Expert Panel: The experts, with knowledge in the concerned field, chosen by the *Anti-Doping Organization* (independent experts, medical commission

members, etc.) who are responsible for providing an evaluation of the haematological or endocrine modules of the passport. Experts will have knowledge in the field of clinical haematology (diagnosis of blood pathological conditions), Laboratory medicine/haematology (Quality controls of data, analytical and biological variability, instrument calibration,…) and sports medicine or exercise physiology specialized in heamatology (review of *Athlete* biological results *In-* or *Out-of-Competition*).

This panel may include a pool of permanently-appointed experts and any additional ad-hoc expert who may be required upon request of the *Anti-Doping Organization*. All members of the commission are required to sign a conflict of interest agreement. The passports are sent to a panel composed of three experts chosen from the pool by a secretariat of the *Anti-Doping Organization.*

***Doping Control* Station:** The location where the *Sample* Collection Session will be conducted.

International Federation (IF): An international non-governmental organization administering one or more sports at world level.

***Sample* Collection Equipment:** Containers or apparatus used to directly collect or hold the *Sample* at any time during the *Sample* collection process. *Sample* Collection Equipment shall, as a minimum, consist of:

- For urine *Sample* collection:
  - Collection vessels for collecting the *Sample* as it leaves the *Athlete's* body;
  - Sealable and tamper-evident bottles and lids for securing the *Sample*;
  - Partial *Sample* kit;

- For blood *Sample* collection:
  - Needles for collecting the *Sample*;
  - Blood tubes with sealable and tamper-evident devices for holding the *Sample*.

***Sample* Collection Personnel:** A collective term for qualified officials authorized by the *Anti-Doping Organization* who may carry out or assist with duties during the *Sample* Collection Session.

***Sample* Collection Session:** All of the sequential activities that directly involve the *Athlete* from notification until the *Athlete* leaves the *Doping Control* Station after having provided his/her *Sample/s*.

Test Distribution Plan: As defined in Clause 4.2.1.

2.3 Defined Terms Specific to the *International Standard* for Laboratories

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or concentration of one or more specific *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Method* in a *Sample*. [*Comment: A Confirmation Procedure may also indicate a quantity of Prohibited Substance greater than a threshold value and quantify the amount of a Prohibited Substance in a Sample.*]

Initial Testing Procedure (Screen Testing Procedure): An analytical test procedure whose purpose is to identify those *Sample*s which may contain a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* or the quantity of a *Prohibited Substance*, *Metabolite*(s) of a *Prohibited Substance*, or *Marker(s)* of the *Use* of a *Prohibited Substance* or *Prohibited Method* in excess of a defined threshold.

***International Standard* for Laboratories (ISL):** The *International Standard* applicable to Laboratories as set forth herein.

Laboratory Internal Chain of Custody: Documentation of the sequence of *Persons* in custody of the *Sample* and any Aliquot of the *Sample* taken for Analytical *Testing*.

[Comment: Laboratory Internal Chain of Custody is generally documented by a written record of the date, location, action taken, and the individual performing an action with a Sample or Aliquot.]

Laboratory(ies): *WADA*-accredited Laboratory(ies) applying test methods and processes to provide evidentiary data for the detection of *Prohibited Substances, Methods* and *Markers* on the *Prohibited List*, and if applicable, quantification of a Threshold Substance, in urine and other biological *Sample*s in the context of anti-doping activities.

Testing Authority(ies): The International Olympic Committee, World Anti-Doping Agency, International Federation, National Sport Organization, *National Anti-Doping Organization*, *National Olympic Committee*, *Major Event Organization*, or other authority defined by the *Code* responsible for *Sample Testing* either *In-Competition* or *Out-of-Competition* and/or for management of the test result.

3.0 Scientific Bases of the Athlete Biological Passport

3.1 Objective

The objective of the *Athlete* Biological Passport is to monitor and identify possible doping in order to intelligently target an *Athlete* for traditional *Doping Control*s and where appropriate to establish an anti-doping rule violation. The following information is intended to support the medical, biological, scientific and statistical evidence which gives weight to such an approach.

3.2 General

The *Athlete* Biological Passport is a collection of carefully selected individual information which will assist *Anti-Doping Organizations* in differentiating between deviations of *Markers* that may be naturally occurring from those deviations likely caused by doping. The *Athlete* Biological Passport therefore becomes a matter for evaluation of the multiple pieces of scientific evidence.

3.3 Requirements for the Haematological Module

3.3.1 The haematological module should collect information on *Markers* of erythropoiesis. It has the sensitivity to identify among other doping methods, enhancement of oxygen transport, including recombinant erythropoietin abuse and any form of blood transfusion or manipulation. As part of a hemogram which should be established, the following *Markers* should be considered in an *Athlete* Biological Passport haematological module:

HCT:	Hematocrit
HGB:	Hemoglobin
RBC:	Red blood cells count
RET%:	The percentage of reticulocyte
RET#:	Reticulocytes count
MCV:	Mean corpuscular volume
MCH:	Mean corpuscular hemoglobin
MCHC:	Mean corpuscular hemoglobin concentration
OFF-hr Score[1]:	Index of stimulation
	Blood profile score

[1] Gore C, Parisotto R, Ashenden M, Stray-Gundersen, J, Sharpe K, Hopkins W, Emslie K, Howe C, Trout G, Kazlauskas R, Hahn A. Second-generation blood tests to detect erythropoietin abuse by athletes. Haematologica 2003; 88: 333-43.

4.0 Optimal Test Implementation

4.1 Objective

The objective of integrating the *Athlete* Biological Passport program into the larger framework of a robust anti-doping program may include the following:

a) Identification of target *Athletes* for further analytical *Testing* (recombinant EPO test, homologous blood transfusion test, etc.);
b) To pursue possible *Anti-Doping Rule Violation*s in accordance with *Code* Article 2.2.

An *Anti-Doping Organization* is free to build its own structure to implement the *Athlete* Biological Passport program. However, the framework proposed in this guideline aims to build upon existing anti-doping infrastructure rather than requiring it to be supplanted in its entirety. *Anti-Doping Organization*s should therefore consider how to best integrate the *Athlete* Biological Passport program into existing programs taking into consideration the required resources and capacity to operate such a program without jeopardizing the effectiveness of traditional programs.

4.2 General

The sensitivity of the *Athlete* Biological Passport model to detect doping is improved as the number of tests considered together increases and where both *In-* and *Out-of Competition* tests are distributed throughout the year. Data points are most statistically independent when *Samples* have been collected at least five days apart.

Intra-individual variations can be reduced to an acceptable level after the collection of three initial values. As additional *Samples* are collected, the sensitivity of the *Athlete* Biological Passport improves.

4.3 Requirements

The *Athlete* Biological Passport *Testing* program shall be in compliance with the *International Standard* for *Testing* (IST) and applicable Technical Documents specific to the *Athlete* Biological Passport.

4.3.1 Definition of the targeted population

The following criteria may be considered to determine the targeted population upon whom to apply the *Athlete* Biological Passport program and

should be considered within the context of an *Anti-Doping Organization*'s overall Test Distribution Plan.

a) Number of *Athletes* who may warrant such a program;
b) Sports and/or disciplines at higher risk for blood-based doping;
c) Level of *Competition*;
d) Age.

4.3.2 Resources

In evaluating what resources may be required in order to adopt and implement the *Athlete* Biological Passport program, the following should be considered as essential:

a) Access to a network of *Doping Control* Officers (DCO) and Blood Collection Officers (BCO) operating in locations where target *Athletes* will be present
b) An effective whereabouts management system to facilitate *Athlete* location (i.e. *ADAMS*)
c) Database management capacity for storage and sharing of relevant anti-doping data (i.e. *ADAMS*)
d) Access to relevant experts and related management required;
e) Results management capacity.

5.0 *Athlete* Biological Passport Administration

5.1 Objective

Although the administrative organization of the *Athlete* Biological Passport program may be adapted to best suit the relevant *Anti-Doping Organization*, this guideline seeks to foster harmonization in the area of program administration in the interests of mutual recognition of *Athlete* Biological Passport data, standardized practice and to ensure overall efficiency in program application more generally.

The majority of administrative standardization should be achieved via the processing of all steps and data in *ADAMS* to ensure that all mandatory requirements are met and that *Athlete* data is shared and stored appropriately in accordance with the *International Standard* for the Protection of Privacy and Personal Information. Furthermore, *ADAMS* will facilitate prompt exchange of information between *Anti-Doping Organization*s, *WADA*-accredited Laboratories, *Sample* Collection Personnel and *WADA*. *ADAMS* functionality should support full implementation of the *Athlete* Biological Passport in this respect.

5.2 General Sequence

The following outlines the proposed relationship between the various mechanisms, requirements and organizations as they relate to the *Athlete* Biological Passport in sequence:

1. The *Anti-Doping Organization* identifies the *Athlete* of interest (referencing the 'target group') and identifies what may be required to update his or her passport. In order to perform additional tests, the *Anti-Doping Organization* collects the relevant and necessary information stored in the administrative management system (such as their past *Testing* history, existing passport data and available whereabouts information).

2. *Sample* collection request: the *Anti-Doping Organization* issues a *Sample* collection request ("mission order") for a predefined period to a *Sample* collection agency or to *Doping Control* Personnel, preferably via *ADAMS* to restrict the dissemination of this information.

3. The *Sample* collection agency accesses the pertinent whereabouts information of the *Athlete* via *ADAMS* for only the period defined by the issuing organization.

4. The *Doping Control* Officer and/or Blood Collection Officer locate the *Athlete* and withdraw the biological *Sample* following the appropriate standard protocol (Annex A herein). This *Sample* is accompanied by passport specific documentation to be completed in addition to, or in lieu of a *Doping Control* form as required.

5. The *Sample* Collection Personnel are responsible for the transport of the biological *Sample*(s) to a *WADA*-accredited Laboratory following the appropriate protocol (Annex B herein).

6. Following the *Sample* Collection Session, the *Sample* collection agency or the *Sample* Collection Personnel should transcribe the *Athlete* Biological Passport *Doping Control* Form into *ADAMS* immediately to provide instant access to the data for the relevant Laboratory and *Anti-Doping Organization* as required.

7. The *WADA* accredited Laboratory analyzes the *Sample*(s) following the appropriate analytical protocol (Annex C herein) and reports the biological results into *ADAMS*.

8. All raw data coming from the *WADA*-accredited Laboratories (scattergrams, internal and external quality controls etc.) should be made available to the *Athlete* and relevant *Anti-Doping Organization*

upon request and in accordance with the *International Standard* for the Protection of Privacy and Personal Information.

9. The biological profiles are made available to the *Athlete* and the *Anti-Doping Organization* via *ADAMS* in order to be processed by the Adaptive Model and to follow the mandatory results management protocol identified in the Technical Document of the IST (and outlined in Annex D herein).

6.0 The *Athlete* Biological Passport and the Role of the Expert

6.1 Objective

It is essential that experts in the relevant field review all passport data and results in order to identify any possible pathological or confounding conditions which may have impacted an *Athlete*'s results. This expert review protects the *Athlete*'s right to thorough and qualified review prior to the possible assertion of an *Anti-Doping Rule Violation* in that it ensures that all possible factors, causes and circumstances are considered thoroughly.

6.2 General

The Adaptive Model is capable of triggering "alerts" and self-identifying abnormal profiles that warrant further attention and review. All such activities should be tracked, monitored and managed via *ADAMS* to ensure accurate, consistent and secure transfer of data to only the relevant and appropriate organizations and individuals.

7.0 *Athlete* Biological Passport Documentation

7.1 Objective

Given that additional information is required from *Athletes* beyond what is collected on traditional anti-doping documentation pursuant to the IST, supplemental or revised documentation may be required. The *Athlete* Biological Passport documentation therefore should ensure that the required information is collected on-site to accompany all *Athlete Samples* for Laboratory information and *Anti-Doping Organization* assessment as required.

7.2 General

Depending on whether *Samples* are also being collected for conventional analysis and the *Athlete* Biological Passport at the same time, some information for the *Athlete* Biological Passport may already be included in the standard collection form.

7.3 Requirements[2]

The following information, at a minimum, should be included on the *Athlete* Biological Passport *Doping Control* Form:

a) Location of *Testing*;
b) Approximate ambient temperature;
c) Date and time of sampling;
d) Sport;
e) *Event* (if relevant):
f) Discipline;
g) License (if relevant);
h) Nationality;
i) Date of birth;
j) Full *Athlete* name;
k) "In" or "out" of competition;
l) Gender;
m) Declaration of medication/supplements taken;
n) *Athlete* comments on procedure;
o) *Athlete* consent and signature;
p) Bottle code number;
q) Blood transfusions during the previous six months (with estimated volume);
r) Blood donation or blood loss during the previous three months (with estimated volume);
s) Use of simulated hypoxic conditions in the previous two weeks. If so, the type of device and the manner in which it was used (frequency, duration, simulated altitude) shall be recorded;
t) Information in relation to latest training or physical activity session.

The following information, at a minimum, should be included on the Passport Chain of Custody/lab advice form:

a) Type of *Sample* (blood, urine);

[2] WADA shall make available to *Anti-Doping Organizations* wishing to implement the *Athlete* Biological Passport program, template documentation which meets the requirements of 7.3.

b) Required analyses;
c) *Sample* code(s)
d) Temperature of transport;
e) Chain of Custody information: name/company/function/date-time/signature etc;
f) *Testing* Authority;
g) *Sample* collection agency;
h) Results management authority.

PART THREE: ANNEXES

Adoption of the following Technical Documents (level two documents) is mandatory in order to comply with the requirements of the *Athlete* Biological Passport Program. All technical requirements identified herein are found in the relevant *International Standards* as Technical Documents but are consolidated herein and as follows as annexes for ease of reference. The requirements of this Annex are applicable to the *Athlete* Biological Passport only and are not applicable to any other approach to blood profiling or to blood collected for any other *Doping Control* purpose.

ANNEX A
Blood Collection Requirements for the *Athlete* Biological Passport

WADA Technical Document – TD2010BSCR

Document Number:	TD2010BSCR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date: 03.11.2009		Effective Date:	01.01.2010

Blood *Sample* Collection Requirements for the *Athlete* Biological Passport

1. Objective

This Protocol is intended to assist in the collection of blood *Samples* for the measurement of individual *Athlete* blood variables within the framework of the *Athlete* Biological Passport.

2. Scope

This Protocol covers the collection of blood *Samples* both *In-Competition* and *Out-of-Competition*.

3. Responsibility

Annex E of the *International Standard* for *Testing* (IST) is applicable to tests carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the *Athlete* Biological Passport. This protocol describes certain additional specificities of blood collection related to the *Athlete* Biological Passport in particular.

4. The *Doping Control* Station

The *Doping Control* Officer (DCO) is responsible for the selection of an appropriate blood *Doping Control* Station. For the purpose of this Protocol the DCO and the Blood Collection Officer (BCO) can be the same *Person*.

The size of the room, the material, equipment, furniture, hygiene and temperature conditions for an optimal blood collection are determined by and are under the responsibility of the DCO/BCO.

5. The Timing of the *Sample* Collection

If collection occurs after training or competition, test planning shall consider the *Athlete*'s whereabouts information to ensure *Testing* does not occur within two hours of such activity. In case the *Athlete* has trained or competed less than two hours before the time the *Athlete* has been notified of his/her selection, the DCO or the BCO or a Chaperone shall monitor the *Athlete* until this two hour period has elapsed, after which the blood collection shall take place. The nature of the exertion (*Competition*, training, etc.) as well as the duration and general intensity shall also be recorded by the *Doping Control* Officer.

6. The Commencement of the Collection Process and the 10 Minute Time-out

The DCO/BCO welcomes the *Athlete* and his representative (if any):

a) The DCO introduces himself/herself as well as the BCO;
b) The DCO/BCO verifies the identity of the *Athlete* and his/her representative;
c) The DCO/BCO explains the *Sample* collection process and, with the BCO, answers any question which the *Athlete* may have concerning the process;

d) The DCO/BCO asks the *Athlete* to remain in a normal seated position with feet on the floor for at least 10 minutes prior to providing a *Sample* ("time-out").

7. The *Athlete* Biological Passport *Doping Control* Form

The DCO/BCO shall use the *Doping Control* form related to the AP, if such a form is available. If a *Doping Control* form related to the *Athlete* Biological Passport is not available, the DCO/BCO shall use a regular *Doping Control* form but he/she shall collect and record the following additional information on a related form to be signed by the *Athlete* and the DCO/BCO:

a) Did the *Athlete* have a training session or a *Competition* in the past two hours? If yes can the *Athlete* specify the type of training session or *Competition*?

b) Did the *Athlete* train, compete or reside at an altitude greater than 1000 meters within the previous two weeks? If so, or if in doubt, the name and location of the place where the *Athlete* had been as well as the duration of this/her stay shall be recorded.

c) Did the *Athlete* use any form of altitude simulation such as a hypoxic tent, mask, etc. during the previous two weeks and, if so, the type of device and the manner in which it was used (frequency, duration, intensity, etc.)?

d) Did the *Athlete* donate blood or lose blood as a result of medical or emergency condition during the previous three months? If so, when and what was the cause of the blood loss as well as the estimated volume?

e) Did the *Athlete* give or receive any blood transfusion(s) during the previous six months and, if so, when and what was the estimated volume?

8. The *Sample* Collection Equipment

The DCO/BCO instructs the *Athlete* to select the *Sample* Collection Equipment in accordance with Article E.4.6 of the IST. Vaccutainers shall be labelled with a unique *Sample* code number by the DCO/BCO prior to the blood being drawn if they are not pre-labelled and the *Athlete* shall check that the code numbers match.

Comment: The WADA Blood Collection Guidelines have been revised to reflect these requirements and include practical information on the integration of Athlete Biological Passport *Testing into 'traditional' Testing activities. A table has been included which identifies which particular equipment is appropriate when combining particular test types (*The *Athlete* Biological Passport *+ hGH,* the *Athlete* Biological Passport *+ HBT etc.)*

9. The *Sample* Collection Procedure

a) The BCO visually examines the *Athlete*'s arms and selects to draw the *Sample* from a location on one arm. The *Athlete's* arm shall be the preferred site of collection and good reason shall be recorded by the DCO to justify collection from elsewhere (e.g. amputee).

b) Manual palpations may be carried out to determine the pathway and the structure of the *Athlete*'s veins.

c) A tourniquet, if required, shall be put in place approximately 10 cm above the vein puncture location. The tourniquet shall not be tightened yet.

d) Once the *Sample* collection location is selected and the tourniquet applied (though not yet tightened), the BCO disinfects the skin in the area of the vein puncture location.

e) The BCO assembles the venipuncture equipment.

f) The BCO ensures that the 10 minute (or more) time-out period has elapsed. If a tourniquet is used, the BCO tightens the tourniquet while ensuring that the arterial circulation is not interrupted and the pulse is still perceptible. Once the BCO determines that the vein is sufficiently dilated (superficial venous circulation blocked), he/she proceeds to collect the blood *Sample*.

g) After verifying that the vein puncture location is dry (the disinfectant solution has evaporated), the BCO inserts the needle into the vein and observes if blood appears in the tube connecting the needle and the holder.

h) Once the BCO is satisfied that the needle is in the vein, he/she introduces the tube into the holder. As soon as blood begins entering

into the tube, the BCO releases the tourniquet as quickly as possible, and in accordance with Article E.4.9 and E.4.10 of the IST.

i) After the blood flow into the tube ceases, the BCO removes the tube from the holder and gently homogenizes the blood in the tube manually by inverting the tube gently at least three (3) times.

j) The BCO carefully removes the needle from the vein by neutralizing the needle and disposes of the used blood *Sample* Collection Equipment in containers specially designed for that purpose.

k) The BCO compresses the vein puncture location with a sterile compress, and asks the *Athlete* to continue gently compressing the blood *Sample* collection location for approximately five (5) minutes and to avoid bending the arm.

l) The BCO applies a dressing to the vein puncture location, if necessary.

m) The BCO or the DCO shall advise the *Athlete* not to undertake any strenuous exercise using the arm (or other site of collection) for at least 30 minutes in order to minimize any potential bruising. If collection occurs prior to *Competition*, the BCO or the DCO shall take this factor into account.

10. Post Venipuncture Procedure

a) The *Athlete* and the DCO/BCO sign the blood collection form(s).
b) The blood *Sample* is deposited and sealed in the *Sample* collection container in accordance with the IST.

ANNEX B
Blood Transport Requirements for the *Athlete* Biological Passport

WADA Technical Document – TD2010BSTR

Document Number:	TD2010BSTR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	03.11.2009	Effective Date:	01.01.2010

Blood Sample Transport Requirements for the *Athlete* Biological Passport

1. Objective

This Protocol is intended to assist the storage and transport of blood *Samples* collected for the measurement of individual *Athlete* blood variables within the framework of the *Athlete* Biological Passport.

2. Scope

This Protocol covers the storage and transport of blood *Samples* both *In-Competition* and *Out-of-Competition*.

3. Responsibility

The *International Standard* for *Testing* (IST) is applicable to the storage and transport of blood *Samples* carried out in connection with the measurement of individual *Athlete* blood variables within the framework of the AP. This Protocol describes certain specificities of blood storage and transport related to the *Athlete* Biological Passport.

4. Storage

Once a blood *Sample* has been collected in accordance with the Blood *Sample* Collection Requirements for the *Athlete* Biological Passport, it shall be stored in accordance with Article 8 of the IST and the present Protocol.

The storage procedure is the responsibility of the *Doping Control* Officer.

5. Type of Storage Devices

The DCO shall place the blood *Sample* in a storage device, which may be:

a) A refrigerator;
b) An insulated cool box ;
c) An isotherm bag;
d) Any other device that possesses the capabilities mentioned below.

6. Capabilities of the Storage Device

The storage and transport device shall be capable of maintaining blood *Samples* at a cool temperature during storage. Whole blood *Samples* shall not be allowed to freeze. A temperature data logger shall be used to determine whether temperature conditions are met. In choosing the storage device the DCO shall take into account the time of storage, the number of *Samples* to be stored in the device and the prevailing environmental conditions (hot or cold temperatures).

6.1 Security of the storage device

The storage device shall be located in the blood *Doping Control* Station and shall be kept secured appropriately.

7. Transport Procedure

Blood *Samples* shall be transported in accordance with Article 9 of the IST, consistent with the practices of the *WADA* Blood Collection Guideline and in conjunction with this Protocol. The transport procedure is the responsibility of the DCO. Blood *Samples* shall be transported in a device that maintains the integrity of *Samples* over time due to changes in external temperature.

7.1 Security of the transport device

The transport device shall be transported by secure means using an *Anti-Doping Organization* authorized transport method.

7.2 Remarks concerning the storage and transport procedure

Blood *Samples* shall be analyzed within 36 hours of *Sample* collection.

Comment: The WADA Blood Collection Guidelines have been revised to reflect these protocols and include practical information on the integration of Athlete Biological Passport Testing into 'traditional' Testing activities. A table has been included which identifies which particular timelines for delivery are appropriate when combining particular test types (the Athlete Biological Passport + hGH, the Athlete Biological Passport + HBT etc) and which types of Samples may be suited for simultaneous transport.

ANNEX C
Blood Analytical Requirements for the *Athlete* Biological Passport

WADA Technical Document – TD2010BAR

Document Number:	TD2010BAR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date: 03.11.2009		Effective Date:	01.01.2010

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 *Sample*s

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.

ANNEX D
Results Management Requirements for the *Athlete* Biological Passport

WADA Technical Document – TD2010RMR

Document Number:	TD2010BAR	Version Number:	1.0
Written by:	WADA	Approved by:	WADA Executive Committee
Date:	03.11.2009	Effective Date:	01.01.2010

Results Management Requirements for the *Athlete* Biological Passport

1. Administrative Management

A secretariat should be responsible for administering and managing the *Athlete* Biological Passport program within or on behalf of an *Anti-Doping Organizatio*n. This mechanism should allow for all *Athlete* Biological Passports to be distributed to experts for review as soon as the analysis results are known and the *Athlete*'s profile has been updated by the *Anti-Doping Organization*. Sharing of this information is the responsibility of the *Anti-Doping Organization* and shall be stored and communicated via *ADAMS*. The *Anti-Doping Organization* is in charge of sending data anonymously, and experts shall initially review all profiles without reference to a specific *Athlete* by name. The members of the *Anti-Doping Organization* involved in this task will conduct all their activities in strict confidence. In particular all medical information and data provided by the *Athlete* will be treated as confidential medical information.

2. Initial Review

A profile in which the Adaptive Model has identified the Hb or Off-hr score abnormal with a 99.9% probability or more shall be reviewed by a panel of three experts. However, individual *Anti-Doping Organizations* may choose a lower probability score to identify *Samples* for further results management.

Other profiles not flagged by the Adaptive Model should be reviewed by one expert on a systematic basis. This expert alone can decide if the profile is initially normal or not. Normality means that both the individual values and the profile itself are within the expected ranges. The initial review in and of

itself may trigger follow-up *Testing*, targeting or the collection of additional passport information, however without further review, it should not lead to the initiation of an anti-doping rule violation proceeding.

3. Formal Review by Three Experts

In case of abnormal values identified by the Adaptive Model or profiles identified by one expert during the initial review, the file shall then be reviewed by a panel of three experts for advice and further recommendation. This panel shall include three experts with knowledge in the fields of clinical haematology (diagnosis of blood pathological conditions), Laboratory medicine/haematology (assessment of quality control data, analytical and biological variability, instrument calibration…) and sports medicine or exercise physiology specialized in haematology (review of *Athlete* biological results *In-* or *Out-of-Competition*).

If more information is required to review the file, the Expert Panel can request the *Anti-Doping Organization* to provide further medical information or data related to sport practice and training. To subsequently be considered an abnormal value or profile, a unanimous opinion among the three experts is necessary in order to proceed with possible results management.

Typically, a profile will be flagged by the Adaptive Model for a review by a panel of three experts if the profile deviates from the norm by 99.9%, however, an individual *Anti-Doping Organization* may choose to use a lower probability score, which will cause more profiles to be reviewed by their Expert Panel.

The Expert Panel will conduct an initial review based on the *Athlete*'s blood profile data, and any additional information that the panel may choose to request from *Anti-Doping Organizations* or Laboratories relating to any *Sample* in the profile. The panel's review shall also include a review of any confounding factor that might cause individual *Sample* results to be inappropriate to use in the *Athlete*'s profile without adjustment. Based on that review, the panel shall render one of the following opinions:

a. In the panel's unanimous opinion, absent a satisfactory explanation from the *Athlete*, it is highly likely that the *Athlete* has used a *Prohibited Substance* or *Prohibited Method*; or
b. That the information received is suspicious for doping and additional investigation shall be pursued. The panel may advise what additional information it recommends; or
c. That the information does not warrant any special additional *Testing* effort or investigation at this time.

Simultaneously with the Expert Panel's review, the *Anti-Doping Organization* will conduct the review described in Article 7.1 of the *Code*.

4. Follow Up on Expert Panel Opinion

If the panel expresses the opinion set forth in 3 a) above, and the *Anti-Doping Organization* review under Article 7.1 of the *Code* does not provide an explanation for the result, the *Anti-Doping Organization* will:

a. Advise the *Athlete* that the *Anti-Doping Organization* is considering bringing an anti-doping rule violation against the *Athlete*;
b. Give the *Athlete* a copy of any document provided to the Expert Panel;
c. Invite the *Athlete* to provide his/her own explanation for the data provided.

Alternatively, if the panel expresses the opinion set forth in 3 b) above, then the *Anti-Doping Organization* shall conduct any investigation recommended by the Expert Panel and such other investigation as the *Anti-Doping Organization* may deem appropriate.

5. Review of Explanation from *Athlete*

Upon receipt of explanatory information from the *Athlete* (or if no explanatory information is provided), the Expert Panel shall further review the information provided by the *Anti-Doping Organization*, the information provided by the *Athlete* (if any), and any additional information that the panel considers necessary to render its opinion. This review may not be anonymous anymore. The panel shall then issue an opinion that includes one of the following statements:

a. Unanimous opinion of the panel that there is no known reasonable explanation for the blood profile information of this *Athlete* other than the use of a *Prohibited Substance* or *Prohibited Method*; or
b. Based on the available information, the panel is unable to unanimously reach the opinion set forth in 5 a) above and, in such case, the panel may or may not recommend further investigation.

6. Disciplinary Proceeding

If the panel expresses the opinion set forth in 5 a) above, then the *Anti-Doping Organization* shall proceed with the case as an asserted anti-doping rule violation in accordance with Article 8 of the *Code*.

ANNEX E
Additional Terms Required to be Incorporated into the *International Standard* for *Testing* (IST)

Adaptive Model: Model developed in which evidence or observations are used to update or to newly infer the probability that a hypothesis may be true or to discriminate between conflicting hypotheses. It was designed to identify unusual longitudinal results from *Athlete*s.

***Athlete* Biological Passport:** The method of gathering and evaluating data described in this document including the Technical Documents of the *International Standards* for *Testing* and Laboratories.

Expert Panel: The experts, with knowledge in the concerned field, chosen by the *Anti-Doping Organization* (independent experts, medical commission members, etc.) who are responsible for providing an evaluation of the haematological or endocrine modules of the passport. Experts will have knowledge in the field of clinical haematology (diagnosis of blood pathological conditions), Laboratory medicine/haematology (quality controls of data, analytical and biological variability, instrument calibration,…) and sports medicine or exercise physiology specialized in haematology (review of *Athlete* biological results *In-* or *Out-of-Competition*).

This panel may include a pool of permanently-appointed experts and any additional, ad-hoc expert who may be required upon request of the *Anti-Doping Organization*. All members of the commission are required to sign a conflict of interest agreement. The passports are sent to a panel composed of three experts chosen from the pool by a secretariat of the *Anti-Doping Organization.*