

1. Introduction

1.1 The IAAF's blood testing programme is focussed in the following two areas:

1.1.1 Blood sample screening for the measurement of individual Athlete blood variables within the framework of the Athlete Biological Passport; and

1.1.2 Blood sampling for the detection of Prohibited Substances and Prohibited Methods.

Under IAAF Rules¹, Athlete blood profile information collected for anti-doping purposes may be used for:

- **Target Testing:** if the result of a blood screening indicates the possible administration of an erythropoiesis-stimulating agent² or possible blood manipulation, or if the result of the blood screening indicates an atypical value or profile, the Athlete may be subject to Target Testing for the Presence/Use of Prohibited Substances and Methods on the Prohibited List, including erythropoiesis-stimulating agents;
- **Supporting an anti-doping rule violation under Rule 32.2:** Athlete blood profile information may further or alternatively be used as evidence in support of an anti-doping rule violation under Rule 32.2 (see further Part IV below).

1.2 In conducting its blood testing programme, the IAAF may collect blood samples for either or both of the purposes identified in 1.1 above. In other words, the IAAF may collect a blood sample either for the purpose of collecting profile data within the framework of the Athlete Biological Passport or for the purpose of detecting a Prohibited Substance or Prohibited Method, or for both purposes at the same time. Where a blood sample is collected for the purposes of collecting profile data for the Athlete Biological Passport (either as a standalone sample or at the same time as detecting for Prohibited Substances/Methods), the provisions of this Blood Testing Protocol must be applied.

1.3 This Blood Testing Protocol ("the Protocol") outlines certain specificities applicable to the collection of blood samples for screening purposes in connection with the measurement of individual Athlete

¹ IAAF Rule 36.1(b).

² References hereafter in this Protocol to erythropoiesis-stimulating agents shall also include references to their releasing factors and other substances with a similar chemical structure or similar biological effect(s).

blood variables within the framework of the Athlete Biological Passport. The Protocol, which should be read in conjunction with the IAAF Anti-Doping Rules and Regulations, is intended to assist in the practical organisation and conduct of blood testing for this purpose. The Protocol is divided into the following four parts:

Part I	-	Blood Collection
Part II	-	Blood Storage and Transport
Part III	-	Blood Analysis
Part IV	-	Results Management

- 1.4 Where applicable, the Protocol is intended to cover the collection of blood samples for screening purposes both In and Out-of-Competition.
- 1.5 The defined terms in this Protocol are the same as those used in the IAAF Anti-Doping Rules and Regulations.

PART I BLOOD COLLECTION

2. Preparations for a Blood Sampling Session

- 2.1 The organisation of a blood sampling session requires careful and detailed planning in advance. The following practical considerations must be taken into account at an early stage by any Meeting/Testing Organiser that intends to conduct such testing:
- 2.1.1 **Qualified Staff:** Only qualified persons (medically qualified personnel or phlebotomists) are entitled to collect blood samples under the IAAF Anti-Doping Rules. Meeting/Testing Organisers must therefore ensure that their Doping Control staff includes at least one phlebotomist or other medically qualified person to undertake the blood sampling (Blood Collection Official). The Blood Collection Official (BCO) must be able to provide the Athlete with evidence of his qualification to collect blood samples before the start of any session. A DCO may also perform the duties of a BCO if qualified to do so. The BCO may be assisted in other blood sample collection duties by an assistant(s).

2.1.2 **Training of Staff:** Meeting/Testing Organisers must ensure that BCOs/assistants are adequately trained in (or re-familiarise themselves with) the relevant blood sampling procedures set out in the IAAF Anti-Doping Rules and Regulations and in this Protocol.

2.1.3 **Adequate Blood Sampling Facilities:** Meeting/Testing Organisers must ensure at the outset that an adequate blood sampling facility can be made available for use. A room or facility equipped for blood sampling may be set up at the Doping Control Station and/or at any other site at which the Athletes are to be located for Testing (hotel, medical centre, training centre, competition venue etc.).

The actual size of the room, the material, equipment, furniture, hygiene and temperature conditions for an optimal blood collection shall be determined by and under the responsibility of the BCO. The blood sampling room or facility should be designed to maintain an Athlete's privacy and confidentiality at all times.

2.1.4 **Blood Sampling Materials:** All necessary blood sampling materials can be ordered in advance from Berlinger³. It is recommended to use the small single BEREG-KITS (ref: art. 94-1098, art. 94-1093 and art. 94-1099) in the case of a single tube collection (where the sampling is for Athlete Biological Passport only) and the small BEREG-KITS for whole blood (ref: art 94-1094 and art 94-1095) and/or the small BEREG-KITS for blood serum (ref: art 94-1094 and art 94-1096) where two tubes need to be collected (where the sampling is for the combined purpose of the detection of Prohibited Substances and Methods and the Athlete Biological Passport).

2.1.5 **Blood Sampling Documentation:** All necessary IAAF Forms (Blood Sampling Forms and Chain of Custody Forms e.g. Blood Sample Transfer Form) that are required for blood sampling under this Protocol can be provided to Meeting/Testing Organisers by the IAAF upon request.

2.2 Unless otherwise agreed with the IAAF, no later than 7 days before the blood sampling session, the Meeting/Testing Organiser shall confirm to the IAAF that all practical arrangements set out

³ Berlinger Special AG: Mitteldorfstrasse 2, Postfach 67, CH 9608 Ganterschwil, Switzerland (Attention: Mrs. Andrea Berlinger) - Tel: 41 71 982 88 11 / Fax: 41 71 982 88 39.

above are in place. The IAAF reserves the right to appoint an IAAF representative to verify that the arrangements in place are acceptable. The Meeting/Testing Organiser shall comply in a timely manner with any and all requests for information from the IAAF representative, if so appointed.

- 2.3 In advance of the blood sampling session, the Meeting/Testing Organiser shall discuss with the IAAF the optimal time for the collection of samples at the scheduled blood sampling session. For the purposes of such discussion, the Meeting/Testing Organiser shall take all reasonable steps to ensure that the whereabouts of the Athletes (including hotel locations) have been provided in advance.

3. Sample Collection Session

- 3.1 All blood samples must be collected in strict accordance with the requirements of IAAF Anti-Doping Rules and Regulations and the additional provisions of this Protocol. The most up-to-date versions of all three documents are available for downloading on the IAAF Website: www.iaaf.org/Downloads/Anti-Doping. If there is any doubt as to the relevant procedures to be followed, clarification should always be sought from the IAAF (tel: +377 93 10 88 56 or +33 678 637 107/+33 6 78 63 07 94). In the event of any differences between the IAAF Anti-Doping Rules and Regulations and this Protocol, this Protocol prevails.

- 3.2 The following is a summary of some of the key points to be followed in the course of the Sample Collection Session:

3.2.1 Timing of the blood sample collection

Blood samples shall not be collected for a period of 2 hours following an Athlete's training session or competition. In the event that an Athlete has trained or competed in the 2 hour period prior to his notification for a blood sample, the BCO/assistant shall keep the Athlete under direct observation until the 2 hour period has elapsed, after which time the blood sample collection shall take place. The nature of the exertion (competition, training etc.) as well as the duration and general intensity should be recorded by the BCO/assistant.

3.2.2 Preparation for sample collection

The following steps are to be taken in preparing for the Sample Collection Session:

- the BCO introduces himself to the Athlete;
- the BCO/assistant verifies the identity of the Athlete and his representative (if any);
- the BCO must be able to show the Athlete evidence of his qualification to collect the sample upon request;
- the BCO/assistant provides the Athlete with information about the Sample Collection Session if available and explains the sample collection procedure (if it is the first time that the Athlete has provided a blood sample or if the Athlete so requests). The BCO/assistant answers any questions that the Athlete may have concerning the process;
- the Athlete is requested to provide his written consent for the sample to be collected (normally recorded on the Blood Sampling Form)⁴;
- the Athlete remains in a normal seated position with feet on the floor for a 'time-out' period of at least 10 minutes prior to providing a sample.

3.2.3 The Blood Sampling Form

The BCO/assistant may use the 10 minute 'time-out' period to complete the sample collection documentation.

The BCO/assistant official shall use the IAAF Blood Sampling Form, if such a form is available. If an IAAF Blood Sampling Form is not available, the BCO/assistant shall use another Blood Sampling Form or a regular Doping Control Form but shall collect and

⁴ If an Athlete refuses to provide a blood sample upon request, this fact should immediately be reported to the IAAF and the Athlete may be subject to disciplinary proceedings under IAAF Rules. An Athlete who refuses to provide a blood sample will nevertheless be required to provide a urine sample. The urine sample shall be analysed for the substances and methods prohibited under the Prohibited List, including erythropoiesis-stimulating agents.

record the following additional information on a supplementary form that is to be signed by the Athlete and the BCO/assistant:

- whether the Athlete has used any form of altitude simulation such as an hypoxic device during the previous 2 weeks, and, if so, as much as information as possible should be recorded about the type of device and the manner in which it was used (frequency, duration, intensity, etc.);
- whether the Athlete has trained, competed or resided at high altitude (>1000m) during the previous 2 weeks? If so (or if there is any doubt about it), details of all relevant location(s) should be provided, together with the duration of the Athlete's stay. The estimated altitude of the location(s) should be entered, if known;
- whether the Athlete has lost blood as a result of any donation, accident or medical condition during the previous 3 months? If so, details should be provided of the estimated volume of blood lost and details of the accident or medical condition concerned;
- whether the Athlete has given or received any blood transfusion(s) during the previous 3 months? If so, details should be provided of when the transfusion took place and the estimated volume of blood concerned;
- confirmation that the Athlete has had no training session or competition in the last two hours before the sample collection?

3.2.4 Selection of Blood Sampling material

The BCO/assistant shall instruct the Athlete to choose the blood sampling material to be used (kit, butterfly/needle) from a selection of material. The Athlete shall check that the material selected has not been tampered with and is intact. If the Athlete is not satisfied with the selected material, he may select another one.

The BCO/assistant shall prepare the blood sampling material in front of the Athlete and/or his representative.

3.2.5 Venipuncture

The BCO/assistant (as the case may be) shall decide upon the exact sample collection location and then carry out the sample collection procedures as follows:

- The Athlete is seated at the time of venipuncture.
- The BCO visually examines the Athlete's arms and chooses to draw the sample from a location on one arm.
- Manual palpations may be carried out to determine the pathway and the structure of the Athlete's veins.
- A tourniquet, if required, is put in place approximately 10 cm above the vein puncture location (but not tightened at this point).
- 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.
- The BCO/assistant ensures that the 10 minute '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 proceeds to collect the blood sample.
- The BCO/assistant assembles the sample collection equipment and places the bar code labels on the tube(s).
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- After verifying that the vein puncture location is dry (i.e., 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.
- Once the BCO is satisfied that the needle is in the vein, he introduces the tube into the holder. As soon as blood begins entering into the tube, the BCO releases the tourniquet.
- Where 3 tubes of blood are taken (2 x serum and 1x whole blood), the BCO ensures that they are filled one after the other.
- For whole blood samples, after the blood flow into the tube containing the EDTA ceases, the BCO removes the tube from the holder and immediately starts to homogenize the blood gently in the tube by manually inverting it 8-10 times (if need be, the homogenization of the whole blood may be carried out by the assistant).
- Once the tube(s) of blood are filled as required, 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.
- 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 5 minutes whilst avoiding bending the arm.

3.2.6 Post-Blood withdrawal procedures

After withdrawal of the blood sample, post-withdrawal procedures are to be carried out as follows:

- The BCO/assistant checks the label(s) of the tube(s) of blood taken ensuring that it is the same number as recorded on the Blood Sampling Form and this number is verified by the Athlete.

- The BCO applies a dressing to the vein puncture location, if necessary.
- The tube(s) of blood is deposited and sealed in the sample collection container(s) in the presence of the Athlete and the Athlete is given the opportunity to check that it is secure.
- The Athlete, the Athlete's representative (if any) and BCO/assistant sign the Blood Sampling Form once it has been completed in all respects.

3.2.7 Troubleshooting

- What to do in case no blood enters into the tube?

If the BCO determines that the needle has failed to enter in the vein, the BCO delicately tries to get it into the vein. In case this does not succeed, the BCO removes and discards the needle. He selects another blood sample collection location, preferably on the other arm. The BCO shall not perform more than three attempts to collect blood in accordance with the IAAF Anti-Doping Regulations.

- What to do in case the blood stops flowing?

If the blood flow ceases before the tube is filled, it may be because the vein has collapsed. The BCO removes the tube from the holder and waits until the vein recovers. Then, the BCO introduces the same tube again into the holder and continues with the blood sample collection. If the vein does not recover, the BCO removes and discards the needle and tube and selects another blood sample collection location.

PART II BLOOD STORAGE AND TRANSPORT

4. Sample Storage

- 4.1 The BCO/assistant shall place the sample collection container in a suitable storage device pending analysis on-site or pending transportation to the laboratory off-site. Blood samples shall be

transported rapidly to a laboratory so that analysis can be performed as soon as possible and, ideally, within no more than 36 hours of the sample collection

4.2 In choosing the storage device, the BCO/assistant 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). The storage device may be:

- a refrigerator
- an insulated cool box
- an isotherm bag
- any other device that possesses the capabilities in 4.3 below.

4.3 The storage device shall be capable of maintaining blood samples at a cool and constant temperature during storage (ideally between 2 and 12^o C⁵).

4.4 Whole blood samples must not be allowed to freeze.

4.5 A temperature data logger should be used to determine whether temperature conditions are met.

4.6 The storage device shall be located in the Doping Control Station and shall be kept under secured conditions.

5. **Sample Transport** (where samples to be analysed off site)

5.1 Blood samples shall be transported in a device that ensures the integrity of samples during transportation and minimises the potential for sample degradation due to factors such as time delays and extreme temperature variations.

⁵ In the case of rapid delivery of the sample to the Laboratory (maximum 2 hours between sample collection and arrival of sample at the Laboratory), the sample may be maintained at between 5-25°C during storage and transport.

- 5.2 In choosing the transport device, the BCO/assistant shall take into account the time of transport, the number of samples to be stored in the device and the prevailing environmental conditions (hot or cold temperatures). The transport device may be:
- a portable refrigerator
 - an insulated cool box
 - an isotherm bag
 - any other device that possesses the capabilities in 5.3 below.
- 5.3 The transport device shall be capable of maintaining blood samples at a cool temperature during transport (ideally between 2 and 12° C)⁶.
- 5.4 Whole blood samples must not be allowed to freeze.
- 5.5 A temperature data logger should be used to record the temperature during transportation.
- 5.6 The transport device shall be transported by secure means using an authorised means of transportation. The samples should be placed in a suitable outer container for dispatch to the laboratory.
- 5.7 The BCO/assistant shall complete the Chain of Custody Form.

PART III BLOOD ANALYSIS

6. Blood Screening Analysis

- 6.1 The blood samples must be analysed at a satellite facility (mobile unit or ISO-accredited haematology laboratory approved by WADA/IAAF), at a WADA-accredited laboratory or at another laboratory that is approved by WADA/IAAF. Blood samples for screening purposes should be analysed as soon as possible and, ideally, within 36 hours of sample collection. If a laboratory takes delivery of a sample after 36 hours from the time of sample collection, it shall be analysed as

⁶ In the case of rapid delivery of the sample to the Laboratory (maximum 2 hours between sample collection and arrival of sample at the Laboratory), the sample may be maintained at between 5-25°C during storage and transport.

soon as possible and the IAAF shall be advised of the delay that has occurred so that it may assess the validity of the result.

Instrument Set Up

- 6.2 Before performing any blood screening analyses (on or off-site), the following steps should be taken to ensure that the instrumentation is properly set up.
- 6.3 All reagents must be verified to ensure that they are within their expiration dates and that they comply with the reagent manufacturer's recommendations.
- 6.4 The operational parameters of the instrumentation must be carefully checked to ensure that it is in working order (background level, temperature of the incubation chambers, pressure...) and falls within the manufacturer's specifications.
- 6.5 The Laboratory must analyse all internal quality controls twice following the recommendations provided by the manufacturer.
- 6.6 The internal quality controls must be supplied exclusively by the manufacturer of the instrument. These controls shall be handled in strict accordance with the manufacturer's specifications (e.g., expiration dates, storage conditions etc). All internal quality control results must be in agreement with reference values provided by the manufacturer.
- 6.7 On a regular basis (to be determined by the head of the Laboratory), one fresh blood sample must be homogenized for a minimum period of 15 minutes on an appropriate mixer (e.g., a roller mixer) and then analysed seven consecutive times. Coefficients of variation must be below 1.5% for HGB and HCT and below 15% for percentage reticulocyte count in order to confirm the appropriate precision of the instrument.
- 6.8 At least one internal quality control (level 1, 2 or 3) must be conducted after every 30 to 50 blood sample analyses.
- 6.9 Once a day, after all blood sample analyses are completed, one internal quality control (either level 1, 2 and 3) must be analysed, once again to demonstrate the stability of the instrument and the quality of the analyses performed.

6.10 The Laboratory must take part in and meet the requirements of the WADA External Quality Assessment Scheme (EQAS) for blood variables⁷. The external quality controls must be analysed 7 times consecutively and the mean results of the following blood variables (full blood count) must be returned:

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

Analysis of blood samples:

6.11 All blood samples must be homogenized for a minimum period of 15 minutes using an appropriate mixer (e.g., a roller mixer) prior to analysis.

6.12 Each blood sample shall be analysed twice and screened for a minimum of the following variables: RBC, MCV, HCT, HGB, MCH, MCHC, WBC, PLT and %reticulocytes (or, if the %reticulocytes reading is 0%, the actual reticulocyte count).

6.13 Absolute differences between the results of the two analyses shall be equal or less than the following for the relevant analyses to be accepted:

- 0.1 g/dl for HGB analysis (e.g. 15.0 and 15.1 g/dl = OK; 15.0 and 15.2 g/dl = not OK);

⁷ It is also strongly recommended that the Laboratory participate in ring tests between laboratories (hospitals, clinics...) using the same technology and the same procedure.

- 0.15% absolute difference for %Ret analysis if first measurement lower or equal to 1.00 % (e.g. 0.8 % and 0.95 % = OK; 0.8 % and 0.96 % = not OK); and
- 0.25% absolute difference for %Ret analysis if first measurement higher than 1.00 % (e.g. 1.10 % and 1.35 % = OK; 1.10 % and 1.36 % = not OK).

The data from the second injection is used to confirm the first injection data.

- 6.14 If the absolute differences between the results of the analyses are within the above criteria, then only the first injection data is reported. If the 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. The reason for the repetition shall be recorded.

7. Blood Screening Results

- 7.1 The results of the blood screening shall be submitted for review to the person(s) responsible for the Testing and to the IAAF, either directly to the IAAF Delegate on site (if appointed) or to such other person as may be designated by the IAAF for such purpose. In all cases, the blood screening results should be reported promptly on ADAMS with a copy sent systematically by confidential e-mail to the IAAF Office in Monaco (mail: labresults@iaaf.org).
- 7.2 If the screening result confirms that an Athlete has one or more atypical blood variable(s), the Athlete shall be subject to Target Testing. If the screening result has been obtained using a mobile analyser on-site (or if the screening result from the laboratory has otherwise been obtained in a sufficiently short period of time to allow such a possibility), a urine sample shall be collected from the Athlete in question and analysed for the presence of Prohibited Substances and Prohibited Methods, including erythropoiesis-stimulating agents.
- 7.3 In any case where the responsible person is unsure whether or not a urine sample should be analysed for erythropoiesis-stimulating agents, or is unsure where the sample should be collected and sent for analysis, the IAAF should always be consulted first (+377 93 10 88 10). The IAAF shall have discretion to send urine samples for analysis for erythropoiesis-stimulating agents whenever it considers that such analysis may be appropriate.

8. Documentation

8.1 Meeting/Testing Organisers shall be responsible for ensuring that all relevant documentation recording the blood sampling session is sent to the IAAF as soon as practicable following completion of the session.

8.2 The following minimum documentation must be provided to the IAAF in respect of each sample collected:

- Blood Sampling Form
- Blood Consent Form (if separate to Blood Sampling Form)
- Chain of Custody Form (Blood Transfer Form)
- Blood Screening Results in hard copy form together with:
 - copies of all analyser print outs (scatter grams)
 - copies of all internal quality control documentation
 - copies of external quality control documentation

PART IV RESULTS MANAGEMENT

9. The results management of blood samples analysed under this Protocol within the framework of the Athlete Biological Passport shall be conducted in accordance with paragraphs 6.6-6.17 of the IAAF Anti-Doping Regulations.

10. The results management of blood samples analysed under this Protocol for the detection of Prohibited Substances and Methods shall be conducted in accordance with IAAF Rules.