



ISTI

# **Blood Sample Collection Guidelines**

**Version 5.0**

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# 1.0 Introduction

These Blood Sample Collection Guidelines expand upon the World Anti-Doping Agency's (*WADA's*) International Standard for Testing and Investigations (ISTI).

The processes outlined in this document promote good practice moving forward, assisting *Anti-Doping Organizations (ADOs)* in the development of systems and protocols to support intelligent, effective *Testing* programs.

Withstanding exceptional and justifiable circumstances, No Advance Notice Testing shall be the method for Blood Sample collection. While the *Sample* collection process may vary slightly from the recommendations provided, mandatory ISTI provisions apply to maintain the integrity of the *Sample* and to ensure that the health and safety of the *Athlete* and Sample Collection Personnel are not compromised.

Blood Sample collection shall be consistent with the local standards and regulatory requirements regarding precautions in healthcare settings where those standards and requirements exceed the requirements set out in ISTI Annex E - Collection of Blood Samples. The procedure should be carried out by experienced professionals who 1) possess qualifications in phlebotomy recognized by the relevant public authorities, and 2) maintain the highest standards of hygiene and safety at all times.

## 1.1 Scope

The Guidelines cover the Blood Sample collection process, from roles and responsibilities; planning and preparation; *Athlete* selection, notification and chaperoning; venipuncture, *Sample* provision and after-care; post-*Sample* collection processing, sealing and storage; to transport of the *Sample(s)* to the Laboratory for analysis.

*ADOs* get practical advice on integrating *Athlete Biological Passport (ABP) Testing* into 'traditional' *Testing* activities. For detailed guidance on the implementation of an *ABP* Program, refer to *WADA's ABP Operating Guidelines*, the ISTI Annex K and L and the International Standard for Laboratories (ISL).

Tips on how to use *WADA's Anti-Doping Administration and Management System (ADAMS)* are also included.

For requirements specific to urine *Sample* collection, refer to the *Urine Sample Collection Guidelines*.

## 1.2 References

### 1.2.1 Defined Terms

The Guidelines include defined terms from the *Code* and these *International Standards (IS)*: *ISTI*, *ISL*, and International Standard on Personal Privacy and Personal Information (ISPPPI). *Code* terms are written in italics. Terms from the *IS* are underlined.

Definitions are provided in Guidelines Section 11.0.

### 1.2.2 Documentation

The following are considered main references for the Blood Sample Collection Guidelines, all of which are available on [WADA's Web site](#):

- 2015 World Anti-Doping Code
- International Standard for Testing and Investigations
- ABP Operating Guidelines
- WADA's Guidelines for Implementing an Effective *Testing* Program

Related support documentation is provided in Appendix 1:

- Integration of Multiple Blood *Testing* Types

## 2.0 Roles and Responsibilities

### 2.1 Testing Authority / Sample Collection Authority

ADOs contracting other ADOs or third parties to act as Sample Collection Authorities are considered *Testing Authorities*.

The Sample Collection Authority is responsible for the overall conduct of the *Sample Collection Session*. Main activities are listed below, some of which may be performed by the Testing Authority or delegated to the Doping Control Officer (DCO).

Unique to the Testing Authority role is instituting ISTI Annex A – Investigating a Possible Failure to Comply.

#### Preparation:

- Determine the necessary competence and qualification requirements of Sample Collection Personnel, establish an accreditation / re-accreditation system, and develop duty statements that outline their respective responsibilities.
- Appoint and authorize Sample Collection Personnel, ensuring personnel have been trained for their assigned responsibilities, have no conflict of interest in the outcome of the *Sample* collection and are not *Minors*.
- Maintain records of education, training, skills, and experience of all Sample Collection Personnel.
- Delegate specific responsibilities to the Doping Control Officer (DCO).
- Provide official documentation to Sample Collection Personnel validating their authority to collect a *Sample* from the *Athlete*, e.g. an authorization letter from the Testing Authority.
- Obtain the necessary information to ensure the effective conduct of the Sample Collection Session, including identifying if the *Athlete* has special requirements (ISTI Annex B - Modifications for *Athletes* with Impairments and Annex C - Modifications for *Athletes* who are *Minors*).

#### Athlete notification:

- Establish a system for locating the selected *Athlete*, planning the approach and timing of notification, and recording in detail *Athlete* notification attempt(s) and outcome(s).
- Establish criteria to validate the notified *Athlete's* identity.

- Determine if a third party is required for notification prior to notification of the *Athlete* when the *Athlete* is a *Minor* or where required by an *Athlete's* impairment (ISTI Annex B and C), or in situations where an interpreter is required.

### Sample collection:

- Establish criteria for the authorization of who may be present during the Sample Collection Session in addition to Sample Collection Personnel.
- Develop a system to ensure that documentation is completed for each *Sample* and is securely handled.

### Post-test administration:

- Define criteria ensuring that each *Sample* collected is stored in a manner that protects its integrity, identity and security prior to transport from the Doping Control Station. Minimum criteria include detailing and documenting the location where *Samples* are stored and who has custody of the *Samples* and/or is permitted access to the *Samples*.
- Authorize a transport system that ensures *Samples* and documentation are transported in a manner that protects their integrity, identity and security.
- Develop a system for recording Chain of Custody of the *Samples* and *Sample* collection documentation, including confirmation that both the *Samples* and collection documentation have arrived at their intended destinations.
- Develop a system to ensure that, where required, instructions for the type of analysis to be conducted are provided to the Laboratory conducting the analysis.
- Store documentation related to a Sample Collection Session and or an anti-doping rule violation in accordance with the International Standard for the Protection of Privacy and Personal Information (ISPPPI).



## 2.2 Doping Control Officer

One lead/senior DCO oversees the Sample Collection Session, ensuring that each Sample is properly collected, identified and sealed, and that all Samples have been properly stored and dispatched in accordance to the relevant analytical guidelines.

If professionally qualified, a DCO may also perform the duties of a Blood Collection Officer. This Guidelines document allows for both scenarios.

### On-site preparation:

- Organize equipment, including all relevant documentation.
- Organize and brief Sample Collection Personnel on their roles and responsibilities prior to or upon arrival at the Blood Collection Facility, including Athlete notification, chaperoning and Sample collection (also urine collection, if applicable).
- Ensure that Chaperones are trained in carrying out relevant activities.
- Assess and organize the Testing facilities.

### Athlete notification:

- Arrange or perform notification and escorting of Athletes.
- Liaise with sport representatives, if relevant.
- Ensure that the Athlete's rights and responsibilities are explained.
- Explain, or arrange explanation of, the process for Blood Sample collection to Athletes and Athlete Representatives, as necessary.

### Sample collection:

- Collect and/or oversee the Sample collection.
- Coordinate collection of accompanying urine Sample, if necessary.
- Witness, or arrange the witnessing of, Sample provision [for urine Sample].
- Ensure that each Sample is properly collected, identified and sealed.

### Post-test administration:

- Oversee the post-collection process.
- Ensure all Samples have been properly stored and dispatched (accompanied by a temperature data logger) in accordance with the relevant analytical guidelines.

- Complete, or arrange completion of, and verify, the relevant documentation.
- Verify the Chain of Custody.
- Organize courier services, if necessary, and transport the *Sample/s*. Or organize on-site screening of *Sample*.

## 2.3 Blood Collection Officer

As mentioned, a qualified DCO may perform the duties assigned to the BCO.

### Qualifications:

- Possesses qualifications in phlebotomy recognized by the relevant public authorities, with experience in *Sample* collection.
- Approved by the authorized collection agency to conduct the Blood Collection Procedure.

### Sample collection:

- Answer relevant questions from *Athletes* about the procedure.
- Prepare the *Athlete*, collect a Blood Sample and advise the *Athlete* on aftercare procedures.
- Perform first aid on the *Athlete* if required.

### Post-test administration:

- Dispose of the Sample Collection Equipment used in *Sample* collection as per the required local standards for handling blood.
- Verify the collection procedure and sign the relevant documentation.

## 2.4 Chaperone

A Chaperone may be assigned additional duties for urine *Sample* collection. The duties listed below relate to Blood Sample collection only.

### On-site preparation:

- Receive training from the DCO. Chaperones with no experience are to be trained by the DCO on site.
- Training will include the requirements for notification, chaperoning and witnessing *Sample* provision (if applicable), and confidentiality obligations.

**Athlete notification:**

- Notify the *Athlete* in person as instructed by the DCO.
- Escort the *Athlete* from notification until arrival at the Blood Collection Facility.

**2.5 Sample Collection Personnel****Sample collection:**

- Conduct or assist with the Sample Collection Session.
- These individuals must:
  - Be trained and authorized for their assigned responsibilities;
  - Not have any conflict of interest in the outcome of the *Sample* collection; and
  - Not be a *Minor*.

**2.6 *Athlete*****Athlete notification:**

- Request the presence of an Athlete Representative, if desired.
- Be escorted from notification to *Sample* provision.

**Sample collection:**

- Report for *Doping Control* as soon as possible, and within the specified time frame, unless there are valid reasons for a delay (ISTI Article 5.4.4 (a), (b) and Guidelines Section 5.1.3).
- Provide valid ID.
- Remain within direct observation of the DCO/Chaperone at all times from the point of initial contact with the DCO/Chaperone to completion of the Blood Collection Procedure.
- Be accountable for any food or beverage consumed prior to *Sample* provision.
- Be familiar and comply with the *Sample* collection process.
- Be responsible at all times for his/her *Sample(s)* from provision to sealing.

- Observe the procedure and ensure there are no irregularities (e.g. insufficient choice or inadequate equipment).
- Declare if remained in a normal seated position with feet on the floor for at least 10 minutes prior to providing a *Sample*.

[Important: Blood Samples should not be collected within 2 hours of training or *Competition* where *ABP Testing* is to be conducted or within 30 min of training or *Competition* where the analysis for Growth Hormone (GH) is to be conducted.]

- Declare any medication and/or supplements used in the past 7 days.
- Declare any blood transfusion(s) received, and/or blood lost due to accident, pathology or donation during the previous 3 months.
- Respond to questions related to the *ABP* such as use of hypoxic devices and training at an altitude greater than 1,500 meters in the previous 2 weeks, if applicable, or whether the *Sample* was collected immediately following at least three consecutive days of an intensive endurance *Competition*, such as a stage race in cycling.
- Declare any extreme environmental conditions the *Athlete* was exposed to during the last two hours prior to blood collection, including any sessions in any artificial heat environment, such as a sauna.
- Comment on the *Sample* collection process in the area(s) provided on the *Doping Control* documentation, if applicable; ask questions as needed.
- Sign documentation as requested by the DCO.

## 2.7 **Athlete Representative**

The presence of an *Athlete Representative* is optional, but strongly recommended for *Athletes* who are *Minors* or where required by an *Athlete's impairment* (ISTI Annex B - Modifications for *Athletes* with Impairments and Annex C - Modifications for *Athletes* who are *Minors*).

### **Athlete notification:**

- Accompany the *Athlete* during notification.
- Accompany the *Athlete* to the Blood Collection Facility.

### **Sample collection:**

- Assist in the selection of equipment and the sealing process, if requested by the *Athlete*.

- Assist the *Athlete* in the completion of documentation, if requested by the *Athlete*.
- Be familiar and comply with the *Sample* collection process.
- Observe the *Sample* collection process and ensure there are no irregularities (e.g. insufficient choice or inadequate equipment).
- Sign documentation as requested by the DCO.

## 3.0 Preparation for the Sample Collection Session

The protocol for the Sample Collection Session is divided into the following areas.

### 3.1 Required Equipment and Supplies

The DCO ensures that required equipment and supplies are in place for the Sample Collection Session.

There may be slight variations in equipment. As a general rule, the following are to be available:

- a. Sterile needles.
- b. Butterfly Needles.
- c. Disposable plastic syringes.
- d. Appropriate Vacutainer<sup>®</sup> collection tubes to draw a predetermined volume of blood. These may include serum separator tubes or and/or EDTA (anti-coagulant) tubes, as required.
- e. Sterile disinfectant pads.
- f. Disposable gloves providing barrier protection.
- g. Tourniquets.
- h. A disposal container for bio-hazardous waste.
- i. A bio-hazard spill kit.
- j. Adhesive bandage and gauze.
- k. A refrigerator, insulated cool box or isotherm bag.\*
- l. Secure courier transport bags and seals.
- m. Transport temperature data logger.
- n. Soap, hand wash or anti-bacterial gel/liquid.
- o. Paper towels or other absorbent material.
- p. Garbage bin/ bags.
- q. Individually sealed non-alcoholic beverages.
- r. Scissors, pens and other applicable stationary.
- s. All *Doping Control* documentation.\* \*
- t. Other equipment specified by the relevant Laboratory.

\* Or any other storage and transport device capable of maintaining Blood *Samples* at a cool temperature during storage. Whole blood *Samples* shall not be allowed to freeze.

\*\* Includes *Doping Control* forms, *Athlete* notification forms (if not part of the *Doping Control* form), supplementary report forms, Chain of Custody forms, DCO report forms, etc.

## 3.2 Sufficient Quantities

Sufficient quantities of Sample Collection Equipment should be made available to ensure:

- An *Athlete* selected for *Testing* has a choice of at least 3 Blood Sample collection kits at all times.
- The amount of *Doping Control* documentation supplied is based upon the number of tests being conducted.

Insufficient choice will not invalidate the legitimacy of the collection process, however it is recommended that both the *Athlete* and DCO or Athlete Representative (as assigned by the DCO) attest in writing to the adequacy of the equipment used.

## 3.3 System Criteria

Sample Collection Equipment systems are to:

1. Incorporate unique numbering systems into all bottles, containers or other items used to identify the *Sample*.
2. Provide a tamper-evident sealing system.
3. Ensure the identity of the *Athlete* is not evident from the equipment itself.
4. Ensure that all equipment is clean and intact prior to use by the *Athlete*.

## 3.4 Sample Collection Personnel Briefing

The DCO briefs the Sample Collection Personnel on their roles and responsibilities prior to or upon arrival at the Blood Collection Facility.

This includes *Athlete* notification, chaperoning, Blood Sample collection, and urine *Sample* collection, if applicable. (See ISTI Article 7 and WADA's Sample Collection Personnel: Recruitment, Training, Accreditation, and Re-Accreditation Guidelines.)

Sample Collection Personnel appointed to conduct or assist with the Sample Collection Session must meet the qualifications listed in Guidelines Section 2.5.

Chaperones with no experience are trained by the DCO on site. Training requirements are listed in Guidelines Section 2.4.

During the briefing, the DCO presents official documentation (e.g. an authorization letter from the Testing Authority) to Sample Collection Personnel that details the DCO's authority to collect a Sample from the Athlete.

ADOs provide and control the official authorization documentation used. Doping Control authorization letters can be automatically generated from ADAMS.

## 3.5 Facilities

Privacy, sole use and a high standard of cleanliness are required for a facility to be used as a Blood Collection Facility. The requirements are necessarily more stringent than for a Doping Control Station used for urine Sample collection.

If the facility does not meet these minimum requirements, the DCO may decide not to proceed with Testing.

The DCO documents the reasons for such a decision. ADOs can request that a sketch of the Blood Collection Facility be included in the DCO's report.

### 3.5.1 In-Competition Testing Criteria

In addition to meeting privacy, sole use and cleanliness requirements, Blood Collection Facilities are to:

- a. Maintain Athlete confidentiality.
- b. Be well lit and well ventilated.
- c. Provide managed entry with access restricted to authorized personnel.
- d. Be lockable and provide secure storage for Samples and Sample Collection Equipment.
- e. Contain a comfortable chair or bed for Sample provision and any aftercare that may be required.
- f. Contain a refrigerator, insulated cool box or isotherm bag.\*
- g. Include a waiting area with chairs; a separate administration work area with a table and chairs for completion of paperwork; and adjacent toilet facilities for Sample provision that allow the Athlete to wash his/her hands, with cubicles large enough to accommodate the Witness (if applicable) and the Athlete.
- h. Be sized according to the number of Athletes, Athlete Representatives and Sample Collection Personnel who will occupy the area.



- i. Be suitably located in relation to the field of play or other location where *Athletes* will be notified.
  - j. Contain a selection of sealed, non-alcoholic drinks for *Athletes*, if possible.
- \* Or any other storage and transport device capable of maintaining Blood Samples at a cool temperature during storage. Whole blood *Samples* shall not be allowed to freeze.

### **Athlete Transportation**

Should the Blood Collection Facility be some distance from the sporting venue where the *Athletes* compete/finish, the DCO is to arrange with the *Event* organizer appropriate transportation for *Athletes*, Athlete Representatives and Sample Collection Personnel – both to the Blood Collection Facility and either back to the venue or other agreed location/s upon completion of the *Sample* collection process.

### **3.5.2 Out-of-Competition Testing Criteria**

Blood Collection Facilities used are to:

- a. Meet the privacy, cleanliness and sole use requirements; and
- b. Provide a suitable waiting area and work station, where possible.

For *Out-of-Competition Testing*, the facility serving as the 'Blood Collection Facility' might be an *Athlete's* home or a hotel room vs. an officially designated Blood Collection Facility.

### **3.5.3 Access Restrictions**

The DCO can assign Sample Collection Personnel to monitor access to the Blood Collection Facility to ensure admission of authorized persons only, or request the *Event* organizer to assign personnel.

Doping Control Station access is restricted to the *Athlete*, the Athlete Representative, an interpreter (if required), and Sample Collection Personnel, unless otherwise approved by the DCO.

Additional personnel requesting access may include an International Federation (IF) representative, an *ADO* observer, a Testing Authority or Sample Collection Authority observer, an auditor, or a *WADA* observer, where applicable under the *Agency's Independent Observer Program* (ISTI 6.3.3 (d)).

These personnel are required to present the DCO with adequate identification and accreditation upon arrival at the Blood Collection Facility.

**Members of the media are not allowed entry** to the Blood Collection Facility at any time.

## 4.0 Athlete Selection

The DCO follows the *Athlete* selection policy of the Testing Authority or Sample Collection Authority. This may include one or all of the following:

- *Target Testing* (named *Athletes* or categories)
- Random Selection.

Following *Athlete* selection, the DCO ensures that selection decisions are disclosed on a need-to-know basis only to ensure No Advance Notice Testing.

### 4.1.1 Target Testing

For *Target Testing*, the Testing Authority or Sample Collection Authority specifies to the DCO which *Athletes* they require for *Testing*. Selections and/or selection methods are to be clearly communicated to the DCO (e.g. detailing selections in an *ADAMS* mission order).

In some instances, the Testing Authority or Sample Collection Authority may choose to give the DCO discretion to select additional *Athletes* for *Target Testing*.

Such an arrangement is to be agreed upon prior to the Sample Collection Session, and comprehensive guidance provided to the DCO in writing by the Testing Authority or Sample Collection Authority. The DCO does not discuss *Target Testing* or the selection criteria with an *Athlete* or Athlete Representative.

See ISTI Article 4.5.2 for factors a Testing Authority or Sample Collection Authority are to consider when selecting *Athletes* for *Target Testing*.

### 4.1.2 Random Selection

The Testing Authority or Sample Collection Authority may use one of the following selection criteria for Random Selection.

The selection criteria chosen should be fair, transparent and appropriate for the sport, e.g.:

- Finishing position.
- Vest/jersey number.
- Entry number.
- Lane number.

Once the criteria have been determined, the actual selection method may be one of the following, or any other fair and transparent method of selection:

- Numbered cards placed face-down on a table.

- Random draw of numbers (or names) from a closed container such as a cloth bag.
- Use of an electronic random number generator.

To provide transparency and accountability, Random Selection made in the field may be witnessed by a coach or sporting official, or may be shown to the selected *Athlete* or coach or sporting official if requested, after the *Athlete's* notification.

In addition to determining the selection criteria, the Testing Authority or Sample Collection Authority may wish to put in place certain contingencies for specific scenarios, e.g.:

- A signature on the back of numbered cards;
- Randomly drawing of an additional 'reserve' *Athlete* to be tested in the event that a serious injury inhibits an *Athlete* from conducting *Doping Control*; or
- Putting a contingency in place for 'dead-heats' or disqualifications. All contingencies put in place are to be fully communicated and provided in writing to all relevant Sample Collection Personnel.

## 4.2 **Sample Collection Timing**

### 4.2.1 *ABP Testing*

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.

If 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 other designated Sample Collection Personnel shall chaperone the *Athlete* until this two-hour period has elapsed.

If the *Sample* was collected within two hours of training or *Competition*, the nature, duration and intensity of the exertion shall be recorded by the DCO/BCO to make this information available to the APMU and subsequently to the Experts.

### 4.2.2 GH testing

Tests to analyze for the presence of exogenous Growth Hormone (GH or its *Markers*) are not to be scheduled within 30 minutes of physical exertion (training or *Competition*). the *Athlete's* whereabouts information shall be consulted to ensure that *Testing* does not occur within 30 minutes of such activity.

If the *Athlete* has trained or competed less than 30 minutes prior to his/her selection notification, the DCO, BCO or other Sample Collection Personnel are to chaperone the *Athlete* until this 30 minute period has elapsed.

If a *Sample* is taken within 30 minutes of training or *Competition*, the DCO/BCO records the nature, duration and intensity of the exertion in the mission documentation, then provides this information to the Testing Authority.

## 5.0 Athlete Notification

The Sample Collection Authority, DCO or Chaperone, as applicable, performs the following sequence of actions:

1. Establish the location of the selected *Athlete*, and plan the approach and timing of notification, taking into account the specific circumstances of the sport/*Competition*/training session/etc., and the situation, as per No Advance Notice Testing.

The DCO takes into consideration all logistical factors, (e.g. venue-specific, sport-specific, etc.) when planning the appropriate timing and approach for *Athlete* notification. Among the factors to consider:

- Challenges faced in sports with mass finishes.
  - The presence of a mixed zone at the venue.
  - Using Technical Delegates of the *Competition* to assist in identifying/confirming final positions.
  - Sports where it's common that *Athletes* are *Minors* and/or have an impairment that may require a third party present during notification.
2. The DCO communicates relevant factors to all Sample Collection Personnel in advance.
  3. The DCO identifies himself/herself and shows the *Athlete* the official authorization documentation provided by the Testing Authority or Sample Collection Authority that has granted the authority to test.

Additional photo ID is carried by the DCO that includes name, photograph, and the documents' expiry date, i.e. ID card from the Sample Collection Authority, driver's license, passport, or similar valid ID.

Chaperones are not required to provide name or photo ID, but are to produce official authorization documentation that is provided by the Testing Authority or Sample Collection Authority (e.g. authorization letter).

4. The DCO/Chaperone ensures that the *Athlete* is the first person notified that he/she has been selected for *Sample* collection.

#### Exceptions:

- The *Athlete* is a *Minor*, has a impairment and/or an interpreter is needed, and the Testing Authority or Sample Collection Authority/DCO/Chaperone considers it a requirement to notify a third party prior to the notification of the *Athlete*.

Any third party notification must be conducted in a secure and confidential manner so that there is no risk that the *Athlete* will receive any advance notice of his/her selection for *Sample* collection. Generally, notification should occur at the end of the *Competition* in which the *Athlete* is competing.

- The DCO/Chaperone requires assistance from a third party (e.g. sport representative) in locating, identifying and/or notifying the *Athlete(s)* selected for *Testing*, due to the DCO/Chaperone being unfamiliar with the *Athlete* or the venue at which the Sample Collection Session is taking place (e.g. *In-Competition Testing* or *Testing* at training camps).

In either scenario, the DCO/Chaperone provides the initial notification directly to the *Athlete* and, where applicable, through an interpreter.

5. The DCO/Chaperone verbally confirms the *Athlete's* identity as per the criteria set by the Testing Authority or Sample Collection Authority and records the form of ID in the *Doping Control* documentation (ISTI Article 5.3.4).

#### Formal identification:

Formal identification can be established by photo ID, starting number, accreditation, third party Witness, or other viable method as established by the Testing Authority and Sample Collection Authority.

If the *Athlete's* identity is unknown and cannot be confirmed, the DCO decides if it is appropriate to follow up in accordance with ISTI Annex A – Investigating a Possible Failure to Comply. The DCO documents this and contacts the Testing Authority or Sample Collection Authority for instructions.

DCOs with a cell phone can take a photograph of the *Athlete* and forward the photo with their report.

An *Athlete's* inability to provide photo ID shall not invalidate a test.

6. The DCO/Chaperone shows the *Athlete* the notification form (which may be part of the *Doping Control* form), and then notifies the *Athlete* of the following:
  - a. The *Athlete* has been selected for *Testing* and is required to undergo *Sample* collection.
  - b. The authority conducting the *Sample* collection. (The Testing Authority is the *ADO* that initiated and authorized the Sample Collection Session.)
  - c. The type of *Sample* collection (i.e. blood, urine or both) and any mandatory conditions prior to *Sample* collection, including the requirement for the *Athlete* to provide their *Sample* in direct observation of a DCO/Chaperone.
  - d. The requirement to undergo *Testing* without delay.
  - e. The DCO shall use their discretion if an *Athlete* cannot undergo a test without delay. The DCO/Chaperone shall inform the *Athlete* of the possible *Consequences of Anti-Doping Rule Violations (Consequences)* for failing to submit to Blood Sample Testing.
  - f. The *Athlete's* rights, including the right to:
    - Have an Athlete Representative present throughout the course of the entire *Sample* collection process (other than *Sample* provision) and, if available, an interpreter.
    - Ask questions and request additional information about the *Sample* collection process.
    - Request a delay in reporting to the Blood Collection Facility for valid reasons (ISTI Article 5.4.4 (a), (b) and Guidelines Section 5.1.3).
    - Request modifications to the *Sample* collection procedure if the *Athlete* is a *Minor* and/or has an impairment (ISTI Annex B - Modifications for *Athletes* with Impairments and Annex C - Modifications for *Athletes* who are *Minors*).
  - g. The *Athlete's* responsibilities (Guidelines Section 2.6), including the requirement to:

- Remain within direct observation of the DCO/Chaperone at all times from the point of notification by the DCO/Chaperone until the completion of the *Sample* collection process.
  - Produce appropriate and valid ID.
  - Be familiar and comply with the *Sample* collection procedures. (The *Athlete* should be advised of the possible *Consequences of Failure to Comply*.)
  - Report for *Doping Control* immediately, unless there are valid reasons for a delay (ISTI Article 5.4.4 (a), (b) and Guidelines Section 5.1.3).
- h. The location of the Blood Collection Facility.
- i. The *Athlete* consumes food or fluids prior to providing a *Sample* at his/her own risk.
7. The DCO/Chaperone provides the *Athlete* notification form to the *Athlete* to read and sign.
8. If an *Athlete* copy of the official notification record exists, the DCO/Chaperone provides it to the *Athlete*.

The DCO/Chaperone is to encourage the presence of a third party during the notification process if an *Athlete* is a *Minor* and/or has an impairment, and requests an interpreter and/or *Athlete Representative*.

## 5.1 Reporting Delays

The DCO or other authorized *Sample* Collection Personnel documents any reasons for the *Athlete's* delay in reporting to the Blood Collection Facility and/or reasons for leaving the Blood Collection Facility that may require further investigation by the Testing Authority and/or *Sample* Collection Authority. Failure of the *Athlete* to remain under constant observation is also recorded in the DCO report.

### 5.1.1 Inability to Locate the *Athlete*

If a selected *Athlete* is not located based on available Whereabouts Filing, the DCO attempts to locate the *Athlete* by other means, based on the circumstances (i.e. the nature of the specified location), with No Advance Notice Testing the method of

notification. The DCO contacts the Testing Authority or the Sample Collection Authority for further instructions if he/she is unable to locate the *Athlete*.

If the DCO attempts to locate the *Athlete* for *Out-of-Competition Testing* during a specific 60-minute timeslot designated in the *Athlete's Whereabouts Filing*, the DCO follows the procedures in the ISTI I.4.3 (b) and (c)

To determine what is reasonable in such circumstances, see WADA's Guidelines for Implementing an Effective Testing Program.

### **5.1.2 Athlete Failure to Comply**

If the *Athlete* refuses to sign that he/she has been notified, or evades notification, the DCO/Chaperone shall make all reasonable attempts to persuade the *Athlete* to comply, including re-informing the *Athlete* of the *Consequences* of refusing or Failure to Comply.

If the *Athlete* continues to refuse, the DCO/Chaperone report all relevant facts to the DCO immediately, and the DCO attempts to notify the *Athlete*.

The DCO shall endeavor to obtain Witness signatures to confirm the *Athlete's* refusal, and shall contact the Testing Authority and/or Sample Collection Authority for further instructions as soon as possible.

### **5.1.3 Requests for Delay or Departure**

The DCO may at his/her discretion consider any reasonable third party requirement or *Athlete* request for permission to:

- a. Delay reporting to the Blood Collection Facility following acknowledgment and acceptance of notification; and/or
- b. Leave the Blood Collection Facility temporarily after arrival.

Such permission shall only be granted if the *Athlete* can be continuously chaperoned and kept under direct observation during the delay.

Delayed reporting to and/or temporary departure from the Blood Collection Facility may be permitted for? the following activities:

#### ***In-Competition Testing:***

1. Participating in a presentation ceremony.
2. Fulfilling media commitments.
3. Competing in further *Competitions*.
4. Performing a warm down.



5. Receiving necessary medical treatment.
6. Locating a representative and/or interpreter.
7. Obtaining photo ID.
8. Any other reasonable circumstances, as determined by the DCO, taking into account any instructions of the Testing Authority.

#### **Out-of-Competition Testing:**

1. Locating an *Athlete* Representative.
2. Completing a training session.
3. Obtaining and receiving necessary medical treatment.
4. Obtaining photo ID.

Any other reasonable circumstances, as determined by the DCO, taking into account any instructions of the Testing Authority.

## **6.0 Athlete Chaperoning**

### **6.1 Prior to Arrival at the Blood Collection Facility**

The DCO/Chaperone ensures that the *Athlete* remains under continuous observation from notification to completion of the Blood Collection Session. A DCO/Chaperone may swap with another DCO/Chaperone to maintain continuous observation of the *Athlete*.

#### **6.1.1 Timing of Notification Considerations**

It is recommended that the DCO consider in advance relevant sport-specific and venue-specific factors that could affect the timing of notification and the chaperoning process, e.g.:

- Sports in which *Athletes* frequently compete in more than one *Event*, potentially prolonging the chaperoning process; or
- Post-*Event* activities required to be performed by the *Athlete*, and their timing (i.e. a presentation ceremony or press conference).

### 6.1.2 Food and Drink Precautions

The DCO/Chaperone cannot prevent the *Athlete* from eating or drinking products of his/her choice, but is to recommend that the *Athlete* choose from a selection of individually sealed, non-alcoholic beverages to hydrate.

The DCO/Chaperone should not handle food or drink items for the *Athlete*.

### 6.1.3 Irregularities in Notification and/or Suspicious Behavior

With discretion and without leaving the *Athlete* unattended, the Chaperone is to inform the DCO as soon as possible of any irregularities in notification and/or suspicious *Athlete* behavior during the observation period.

If relevant, the DCO documents the irregularities and determines if Investigating a Possible Failure to Comply (ISTI Annex A) is appropriate, if he/she believes the irregularities and/or suspicious behavior may have compromised the Sample Collection Session.

The Testing Authority is responsible for establishing guidelines for what constitutes suspicious *Athlete* behavior (e.g. by evading observation, ingesting an unidentified substance, making a distressed call to a coach, or other unusual behavior).

The DCO is to attempt to complete the Sample Collection Session.

## 6.2 Arrival at the Blood Collection Facility

Upon the *Athlete's* arrival at the Blood Collection Facility with a DCO/Chaperone and, if applicable, an Athlete Representative and/or interpreter, the *Athlete's* photo ID or other means of identification shall be provided to the DCO.

Inability to provide photo ID does not invalidate a test. Alternative methods of *Athlete* identification are outlined in Guidelines Section 4.0, bullet 5.

If the *Athlete* is also providing a urine *Sample* at the same session, the DCO may request that the *Athlete* provide the Blood Sample first if the *Athlete* is not ready to provide a urine *Sample*.

Irrespective of the Testing type, once the *Athlete* has arrived at the Blood Collection Facility/Doping Control Station he/she must be under observation at all times until *Sample* collection is completed.

The DCO/BCO ensures the *Athlete* is offered comfortable conditions and instructs the *Athlete* to remain in a normal seated position with feet on the floor for at least 10 minutes prior to providing a Blood Sample. Where possible, the DCO assigns the role of monitoring each *Athlete's* 10-minute seated rest period to a member of the

Sample Collection Personnel. This duty may be conducted in conjunction with maintaining an entry and exit log.

A Blood Sample shall be collected from one *Athlete* at a time, and each *Athlete's* privacy ensured.

*[Comment: the Athlete shall not stand up at any time during the 10 minutes prior to ABP Sample collection. To have the Athlete seated during 10 minutes in a waiting room and then to call the Athlete out in a blood test room is not acceptable.]*

### 6.2.1 Entry and Exit

An entry and exit log is maintained to record the names of the persons entering the Blood Collection Facility, their role in the Sample Collection Session, and the arrival and departure times, in instances where multiple *Athletes* will be tested in a short period of time.

The *Athlete* may request to temporarily leave the Blood Collection Facility for a period of time, for reasons defined in Guidelines Section 5.1.3.

If the DCO approves the *Athlete's* request, the DCO shall agree with the *Athlete* on the following conditions of leave:

- a. The purpose of the *Athlete* leaving the Blood Collection Facility;
- b. The time of return upon completion of an agreed activity;
- c. The *Athlete* must remain under continuous observation throughout.

The DCO shall document the time of the *Athlete's* departure and return.

If a Chaperone is not available to escort the *Athlete*, the DCO asks the *Athlete* to remain in the Doping Control Station until one is.

If an *Athlete* insists on leaving the Blood Collection Facility without a Chaperone, the DCO is to advise the *Athlete* of the possible Consequences of Failure to Comply and document the circumstances.

### 6.2.2 Other Considerations

The *Athlete* shall be provided with the opportunity to hydrate. If the *Athlete* is also providing a urine *Sample* at the same session, he/she is to be advised not to hydrate excessively, due to the requirement to provide a *Sample* with a Suitable Specific Gravity for Analysis. *Sample Collection Personnel shall advise the Athlete and Athlete Support Personnel as appropriate of this requirement at the time of Notification in order to discourage excessive hydration prior to the provision of the Athlete's first sample. If his/her first Sample is too dilute, he/she shall be advised*

*to not hydrate any further until a Sample with a Suitable Specific Gravity for Analysis is provided.*

Before *Sample* collection, the DCO asks the *Athlete* whether he/she has been tested before, and whether he/she requires an explanation of the Blood Collection Procedure. If the *Athlete* has not been tested before, or requests an explanation of the procedure, the DCO should explain the Blood Collection Procedure.

At a minimum, the DCO ensures the *Athlete* is informed of the Sample Collection Session requirements and his/her rights and responsibilities.

## 7.0 Conducting the Sample Collection Session

### 7.1 Venipuncture

The type of equipment used for blood collection and the post-collection process differs depending on the type of analysis required.

The Blood Sample collection kit typically includes a sterile needle, syringe and the relevant Vacutainer<sup>®</sup> tube(s) packaged together in a sealed bag. If kits contain only one Vacutainer<sup>®</sup>, and an A and B *Sample* are required, the *Athlete* chooses 2 Blood Sample collection kits.

The recommended Vacutainers<sup>®</sup> identified below have been fully validated by WADA and/or WADA-accredited Laboratories. Alternate equipment that meets the same criteria identified is to be validated by WADA and/or the relevant Laboratory prior to use, and Blood Sample collection is to be consistent with the methodology presented here.

#### 7.1.1 Whole Blood or Plasma

Collection of blood for analysis of *Prohibited Substances* and *Methods* in whole blood (e.g. detection of blood transfusion) or in plasma (e.g. HBOCs and ESAs):

- Number of *Samples*: 2 (*A Sample* and *B Sample*).
- Volume required: 2 x 3mL (or as specified by relevant Laboratory).
- BD Vacutainer<sup>®</sup>: K2EDTA (K2) CE cat no 368856/ref US 367856.
- The tube used contains EDTA as anti-coagulant. The contents must be homogenized as soon as possible after collection (e.g. tubes should be gently inverted at least three times). The contents shall then be sent to Laboratory with no further action.

#### 7.1.2 Serum

Collection of blood for analysis of *Prohibited Substances* and *Methods* in serum (e.g. detection of GH, HBOCs and ESAs):

- Number of *Samples*: 2 (*A Sample* and *B Sample*).
- Volume required: 2 x 5mL (or as specified by relevant Laboratory).
- BD Vacutainer<sup>®</sup> SST<sup>™</sup>-II, EU ref 367955 or BD Vacutainer<sup>®</sup> SST<sup>™</sup>-II Plus *Advance* tubes, EU ref 367954).
- Blood is drawn into a tube that has an inert polymeric serum separator gel and a clotting activation factor.

The contents must be homogenized as soon as possible after collection. The contents shall then be sent to Laboratory with no further action.

### 7.1.3 ***Athlete Biological Passport***

Collection of blood for analysis of the variables of the *ABP*:

- Number of *Samples*: 1 (no B *Sample* required).
- Volume required: 1 x 3mL (or as specified by relevant Laboratory).
- The tube used contains solid EDTA as anti-coagulant.

The contents must be homogenized as soon as possible after collection (e.g. tubes should be gently inverted at least three times). The contents shall then be sent to Laboratory or WADA-Approved Laboratory for the *ABP* with no further action.

Although a single blood *Sample* is sufficient within the framework of the *ABP*, it is recommended to collect an additional "B" *Sample* for a possible subsequent analysis of *Prohibited Substances and Methods* in whole blood (e.g. detection of Homologous Blood Transfusion (HBT), and/or Erythropoiesis Stimulating Agents (ESAs).

## 7.2 **Selection of *Sample* Collection Equipment**

Selection of *Sample* Collection Equipment follows this sequence of actions:

1. After the required rest period, and the DCO/BCO explanation of the Blood Collection Procedure, the DCO directs the *Athlete* to choose the appropriate number of Blood *Sample* collection kits, as required by the *Sample* Collection Authority.
2. The *Athlete* and DCO check that the selected equipment is clean and all seals are intact and have not been tampered with.
3. If either the *Athlete* or DCO is not satisfied with a selected kit, the *Athlete* may select another. If the *Athlete* is not satisfied with any kits and no others are available, the DCO records this.

**Recommended:** Provide the *Athlete* with at least 3 Blood *Sample* collection kits from which to select.

4. If the DCO does not agree with the *Athlete's* opinion that all of the available kits are unsatisfactory, the DCO instructs the *Athlete* to proceed with the *Sample* Collection Session.
5. Should the *Athlete* not wish to proceed with the *Sample* Collection Session, the DCO advises the *Athlete* of the possible Consequences of Failure to Comply.

6. If the DCO agrees that none of the equipment is satisfactory, he/she ends the Sample Collection Session, and records the reasons for termination.
7. Once the *Sample* collection kit has been selected, the DCO/ BCO labels the collection tubes with a unique *Sample* code number if not pre-labelled.
8. If the kit includes pre-printed bar code labels, the *Athlete* removes these labels and verifies with the DCO that the code numbers match.
9. If the *Athlete* or DCO finds that the numbers do not match, the DCO instructs the *Athlete* to choose another kit, and documents the occurrence.
10. The *Athlete* places one label longitudinally on each of the Vacutainer® tubes. The label is to be placed towards the top of the tube(s), near the cap. The *Athlete* may authorize the DCO, or the Athlete Representative to place the labels on the tubes.
11. The DCO records the numbers, and the *Athlete* and the DCO check the documentation to ensure that the DCO accurately recorded the information.
12. The *Athlete* gives the BCO the Blood Sample Collection Equipment, including the Vacutainer(s)®. The BCO assembles the equipment in sight of the *Athlete*.

### 7.3 Sample Provision

*Sample* provision follows this sequence of actions:

1. The BCO assesses the most suitable arm for Venipuncture. This will always be the non-dominant arm, unless the BCO assesses the other arm to be more suitable or the *Athlete* requests a specific arm.
2. If the BCO believes that a Butterfly Needle is required for Venipuncture, the *Athlete* will be asked to select a Butterfly Needle from a selection of sealed needles. The Blood Collection Procedure then continues.
3. The BCO cleans the skin with a sterile disinfectant wipe or swab in a location unlikely to adversely affect the *Athlete* or his/her performance and, if required, applies a tourniquet. The BCO takes the Blood Sample from a superficial vein. The tourniquet, if applied, shall be immediately removed following the Venipuncture. *It is recommended that the tourniquet, if applied, should be released when the blood starts to flow and no more than 1 min after application.*
4. The BCO collects the amount of blood adequate to satisfy the relevant analytical requirements for the type of *Sample* analysis to be conducted. The collection vessel (s) are always to be kept in full view of the *Athlete*.

5. If the BCO is unable to draw sufficient blood from the first attempt, the procedure is repeated up to a maximum of 3 attempts in total. Should all 3 attempts fail to produce a sufficient amount of blood, the BCO informs the DCO, who terminates collection and records the reasons for terminating the collection.
6. The BCO applies a dressing to the puncture site(s).
7. The BCO disposes of used Blood Sample Collection Equipment in accordance with the required standards for handling blood.
8. The recommended temperature data logger used to monitor storage and transport conditions should be turned on to ensure cool conditions before *Samples* are placed inside the cool box.
9. If the *Sample* requires further on-site processing, such as centrifugation or separation of serum (e.g., in the case of a *Sample* intended for use in connection with the *ABP* Program, after the blood flow into the tube ceases, the BCO shall remove the tube from the holder and homogenize the blood in the tube manually by inverting the tube gently at least 3 times), the *Athlete* shall remain to observe the *Sample* until final sealing in secure, tamper-evident kit.

## 7.4 Aftercare Procedure

After withdrawing the needle from the *Athlete's* arm, the BCO places a pad over the puncture site and instructs the *Athlete* to press firmly on the pad. The BCO may also choose to apply pressure to the wound.

If necessary, pressure shall be applied for 2 to 3 minutes prior to the *Sample* sealing procedure. The BCO assesses the wound and indicates to the *Athlete* and the DCO when the *Athlete* is ready to proceed.

The BCO/DCO advises the *Athlete* not to undertake any strenuous exercise using the arm for at least 30 minutes to minimize potential bruising.

The BCO is to be prepared to conduct first aid if necessary.

## 7.5 Post-Collection Processing

### 7.5.1 Analysis of Whole Blood or Plasma

For the analysis of whole blood or plasma, the 2 x 3mL Blood Samples, comprising of an A and B *Sample* (or the *Sample* collected for the purposes of the *ABP*) invert gently at least three times to mix the blood with the anti-coagulant contained in the tube in order to avoid clot formation. This step shall be taken as soon as possible.



The Blood Samples are then be sealed and prepared for transportation as per Guidelines Section 7.6.

## 7.5.2 Analysis of Serum

For the analysis of serum, the 2 x 5mL Blood Samples, comprising of an A and B *Sample* should be inverted gently to initiate clotting and remain at room temperature for the time recommended by the tube manufacturer (15 minutes for BD Vacutainer® SST II advance tubes) before being sealed and made ready for transportation in accordance with Guidelines Section 7.6.

*Samples* collected that require being left at room temperature for a pre-determined length of time (as specified by the tube manufacturer) are monitored by the DCO.

The *Athlete* is asked and encouraged to remain and observe his/her *Samples* during this time. If the *Athlete* declines to do so, this in no way invalidates the test.

The Sample Collection Authority may ask the DCO to record details of any *Athlete* who does not remain to observe their *Samples* during this period.

## 7.6 Sealing of the Blood Samples

The *Athlete* seals his/her *Sample* into the *Sample* collection kit as directed by the DCO. The *Athlete* may request the DCO or the Athlete Representative to complete this process on his/her behalf.

In full view of the *Athlete*, the DCO checks that the sealing is satisfactory.

The DCO ensures the Blood Samples are stored upright in a secure, preferably cool , location (i.e. transport bag) until ready to proceed to transport of *Samples* (Guidelines Section 9.0).

## 7.7 Completing the *Doping Control Form*

The DCO instructs the BCO to sign the *Doping Control form* to confirm that he/she collected a Blood Sample from the *Athlete* in accordance with ISTI mandatory procedures.

The DCO requests the *Athlete* to document any blood transfusions over the last three months and to provide information on all medications and/or supplements taken within the time period specified on the *Doping Control form*, including those which may affect the blood's ability to clot. The recommended period for medication information is 7 days.

The DCO checks all information on the form with the *Athlete* and the *Athlete's Representative* (if applicable) to confirm that it accurately reflects the details of the Sample Collection Session, and fills in any incomplete areas in view of the *Athlete*.

The *Athlete* is given the opportunity to complete the comments section of the form if he/she has any concerns or comments regarding how the Sample Collection Session was conducted. If there is insufficient space on the form, the *Athlete* is provided a supplementary report form.

The *Athlete* and the *Athlete Representative* (if present) are invited to check that all information on the form accurately reflects the details of the Sample Collection Session. The *Athlete* is invited to complete the comments section of the form if he/she has any concerns or comments regarding the procedure. If there is insufficient space on the form, the *Athlete* is provided a supplementary report form.

If present, the *Athlete's Representative* signs the *Doping Control* form.

The *Athlete* and DCO then sign the *Doping Control* form.

The DCO provides the *Athlete* with a full copy of the *Doping Control* form, the supplementary report form (if used) and any other documentation signed by the *Athlete*.

Unless also required to provide a urine *Sample*, the *Athlete* can leave the Doping Control Station.

If an *Athlete* is also required to provide a urine *Sample*, and the *Doping Control* form records both blood and urine collection, the paperwork will not be fully completed until after collection of both urine and blood *Samples*.

A comprehensive list of the information to be recorded on the form at a minimum is provided in ISTI Article 7.4.5.

### **7.7.1 Blood-only *Doping Control* Form**

The DCO, the *Athlete Representative* (if present) and the *Athlete* then sign the *Doping Control* form.

### **7.7.2 ABP *Doping Control* Form**

If the *Sample* is to be used in connection with the ABP Program, the DCO/BCO uses the *Doping Control* form specific to the ABP. If unavailable, the DCO/BCO uses a regular *Doping Control* form, but he/she shall collect and record the following additional information on a supplementary report form to be signed by the *Athlete* and the DCO/BCO:

- a. Confirmation that the *Athlete* did not participate in training or *Competition* in the last 2 hours before the *Sample* was collected (see ISTI Annex E Article E.4.5);
- b. If the *Athlete* trained, competed or resided at an altitude greater than 1,500 meters in the previous 2 weeks. If so, or if in doubt, the name and location of the place(s) where the *Athlete* has been, the duration of his/her stay and the estimated altitude (if known).
- c. If the *Athlete* used any form of altitude simulation (such as a hypoxty tent, mask, etc.) in the previous 2 weeks. If so, as much information as possible on the type of device and the manner in which it was used (frequency, duration, intensity, etc.);
- d. If the *Athlete* received any blood transfusion(s) during the previous 3 months. If there was any blood loss due to accident, pathology or donation in the previous 3 months. In either case, if so, the estimated volume.
- e. If the *Sample* was collected immediately following at least three consecutive days of an intensive endurance *Competition*, such as a stage race in cycling; and
- f. Record any extreme environmental conditions the *Athlete* was exposed to during the last two hours prior to blood collection, including any sessions in any artificial heat environment, such as a sauna.

### 7.7.3 Urine/Blood *Doping Control* Form

If the urine *Sample* has already been collected, the DCO, the *Athlete Representative* (if present) and the *Athlete* sign the *Doping Control* form.

If the urine *Sample* has not yet been collected, the *Athlete* provides a urine *Sample*. The DCO, the *Athlete Representative* (if present) and the *Athlete* then sign the *Doping Control* form.

The DCO gives the *Athlete* a full copy of the form.

The *Athlete* can now leave the Blood Collection Facility.

## 8.0 *Sample* Storage and Laboratory Documentation

The Sample Collection Authority defines criteria ensuring that each *Sample* collected is stored in a manner that protects its identity, integrity and security prior to transport from the Blood Collection Facility.

At a minimum, these criteria should include detailing and documenting up until the *Sample* arrives at its intended destination, the location where *Samples* are stored; how the *Samples* are stored; who has custody of the *Samples*; and/or who is permitted access to the *Samples*. The DCO ensures that any *Sample* stored complies with these criteria.

The DCO shall keep the *Samples* secure and under his/her control until they are passed to the courier.

The Blood Samples must be stored in a cooled state, preferably in a refrigerator or cool box.

If storage conditions did not meet the guidelines for temperature, the DCO shall document this, and shall also contact the Sample Collection Authority immediately to inform them of the variation in temperature, and the length of time the *Samples* were affected.

If the temperature deviates from a cool and consistent temperature as identified by the data logger, for a period of time likely to affect the composition of a Blood Sample as determined by the recipient Laboratory, the Testing Authority and Laboratory determine if *Sample* analysis should proceed

If the *Sample* is intended for use in connection with an *ABP* Program, the DCO/BCO shall place it in a storage device that is capable of maintaining Blood Samples at a cool temperature for the duration of the period of storage and transport but without allowing whole Blood Samples to freeze (such as a refrigerator, an insulated cool box, an isotherm bag, or any other device with such capability).

A temperature data logger shall be used to record the temperature of the *Sample* during storage and transport. In choosing the storage device, the Sample Collection Authority shall take into account the duration of the period of storage and transport, the number of *Samples* to be stored together, and the prevailing environmental conditions (hot or cold temperatures). See ISTI – Annex K.4 for the detailed protocol on the storage and transport of Blood Samples for the *Athlete Biological Passport*.

The DCO completes the appropriate documentation for each transport bag/container to ensure that the Laboratory can verify the contents, and follows the *Sample* Collection Authority's system to ensure that analysis instructions (e.g. type of analysis required) are provided.

The DCO completes the Laboratory advice form/Chain of Custody form, and if relevant, records the time(s) the transport bag is opened and resealed.

The Laboratory copies of this form and the *Doping Control* form are placed in the transport bag with the *Samples*. The transport bag is then sealed, preferably in the presence of a Witness. The minimum level of documentation the Sample Collection Authority provides to the Laboratory is outlined in ISTI Articles 7.4.5 c), f), h), j), k), l), , p), q), y), z), and aa) for result reporting and statistical purposes.

For Blood Samples collected for the analysis of GH in serum using the Biomarkers method, the age of the athlete (rounded down to the nearest year) needs to be included in the documentation that will accompany the *Samples* to the Laboratory.

Documentation identifying the *Athlete* is not included with the *Samples* or documentation sent to the Laboratory analyzing the *Samples*.

All documentation relevant to the Sample Collection Session should be forwarded to the Sample Collection Authority by the approved method as soon as practicable upon completion of the Sample Collection Session.

Documentation related to a Sample Collection Session and/or an ADRV shall be stored by the Testing Authority and/or the Sample Collection Authority for the period specified in the ISPPPI.

Due to the more stringent temperature and analysis requirements for blood, Blood Samples and urine *Samples* may be transported separately. However, the relevant paperwork linking the two *Samples* shall be included with each shipment.

## 9.0 Transport of *Samples*

The DCO is responsible for *Sample* transport and ensures the transport procedure follows ISTI Article 9.0 criteria.

Anti-Doping Organizations should discuss transportation requirements for particular missions (e.g., where the *Sample* has been collected in less than hygienic conditions, or where delays may occur in transporting the *Samples* to the laboratory) with the laboratory that will be analyzing the *Samples*, to establish what is necessary in the particular circumstances of such mission (e.g., refrigeration or freezing of the *Samples*).

*Samples* shall be transported in a device that maintains the integrity of *Samples* and minimizes the potential for *Sample* degradation due to factors such as time delays and extreme temperature variations.

Blood Samples are to be dispatched as soon as possible after collection, ideally arriving at the Laboratory on the same day.

If the *Sample* is intended for GH analysis with the Differential Immunoassays (Isoforms) method, the *Sample* shall be analyzed within 96 hours from collection (for more details, please refer to the TD GH in effect).

If the *Sample* is intended for GH analysis with the Biomarkers method, the *Sample* shall be analyzed with 120 hours from collection (for more details, please refer to the Guidelines on hGH Biomarkers Test in effect).

If the *Sample* is intended for ESAs, HBOCs or Blood transfusions analysis, the *Sample* shall be analyzed with 72 hours from collection.

If the *Sample* is intended for use in connection with an *ABP* Program, see the ISTI – Annex K.4 for the specific transportation requirements.

The Blood Samples shall be transported to the Laboratory in a refrigerated state. No sample should be allowed to freeze.

It is advisable to include a temperature data logger with the transported *Samples* to ensure the appropriate temperature range has been maintained during transport. In addition to capturing the temperature during transport, the temperature data logger should be used to assess the time from *Sample* collection to the time received by the Laboratory ('turnaround time'). Record all time in GMT to address any potential time zone conflicts.

*Samples* should remain in an upright position during transport, whenever possible.

*Samples* may be taken directly to the Laboratory by the DCO, or handed over to a third party for transportation. This third party must document the Chain of Custody of the *Samples*. If an approved courier company is used to transport the *Samples*, the DCO should record the waybill number of the shipment.

## **9.1 Receipt of *Samples* by the Laboratory**

Laboratories are required to document receipt and the subsequent Chain of Custody of *Samples*.

*Samples* are reviewed for evidence of *Tampering* or damage, and stored in appropriate conditions until analysis, in accordance with the ISL.

If the *Samples* with accompanying documentation or the Sample Collection Session documentation are not received at their respective intended destinations, or if a *Sample's* integrity or identity may have been compromised during transport, the Sample Collection Authority and Testing Authority shall check the Chain of Custody, and the Testing Authority shall consider whether the *Samples* should be voided.

## 10.0 Ownership of *Samples*

*Samples* collected from an *Athlete* are owned by the Testing Authority for the Sample Collection Session in question.

The Testing Authority may transfer ownership of the *Samples* to the Results Management Authority (RMA) or to another *ADO* upon request.

## 11.0 Definitions

### 11.1 2015 Code Defined Terms

**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 (ADO):** 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 competes in sport at the international level (as defined by each International Federation) or the national level (as defined by each *National Anti-Doping Organization*). An *Anti-Doping Organization* has discretion to apply anti-doping rules to an *Athlete* who is neither an *International-Level Athlete* nor a *National-Level Athlete*, and thus to bring them within the definition of "Athlete." In relation to *Athletes* who are neither *International-Level* nor *National-Level Athletes*, an *Anti-Doping Organization* may elect to: conduct limited *Testing* or no *Testing* at all; analyze *Samples* for less than the full menu of *Prohibited Substances*; require limited or no whereabouts information; or not require advance *TUEs*. However, if an Article 2.1, 2.3 or 2.5 anti-doping rule violation is committed by any *Athlete* over whom an *Anti-Doping Organization* has authority who competes below the international or national level, then the *Consequences* set forth in the *Code* (except Article 14.3.2) must be applied. For purposes of Article 2.8 and Article 2.9 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 to Athlete: This definition makes it clear that all International- and National-Level 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. The definition also allows each National Anti-Doping Organization, if it chooses to do so, to expand its anti-doping program beyond International- or National-Level Athletes to competitors at lower levels of Competition or to individuals who engage in fitness activities but do not compete at all. Thus, a National Anti-Doping Organization could, for example, elect to test*



*recreational-level competitors but not require advance TUEs. But an anti-doping rule violation involving an Adverse Analytical Finding or Tampering, results in all of the Consequences provided for in the Code (with the exception of Article 14.3.2). The decision on whether Consequences apply to recreational-level Athletes who engage in fitness activities but never compete is left to the National Anti-Doping Organization. In the same manner, a Major Event Organization holding an Event only for masters-level competitors could elect to test the competitors but not analyze Samples for the full menu of Prohibited Substances. Competitors at all levels of Competition should receive the benefit of anti-doping information and education.]*

**Athlete Biological Passport (ABP):** The program and methods of gathering and collating data as described in the International Standard for Testing and Investigations and International Standard for Laboratories.

**Code:** The World Anti-Doping Code.

**Competition:** A single race, match, game or singular sport contest. For example, a basketball game or the finals of the Olympic 100-meter race in athletics. For stage races and other sport contests where prizes are awarded on a daily or other interim basis the distinction between a *Competition* and an *Event* will be as provided in the rules of the applicable International Federation.

**Consequences of Anti-Doping Rule Violations (Consequences, Consequences of ADVRs):** An *Athlete's* or other *Person's* violation of an anti-doping rule may result in one or more of the following: (a) Disqualification means the *Athlete's* results in a particular *Competition* or *Event* are invalidated, with all resulting *Consequences* including forfeiture of any medals, points and prizes; (b) Ineligibility means the *Athlete* or other *Person* is barred on account of an anti-doping rule violation for a specified period of time from participating in any *Competition* or other activity or funding as provided in Article 10.12.1; (c) Provisional Suspension means the *Athlete* or other *Person* is barred temporarily from participating in any *Competition* or activity prior to the final decision at a hearing conducted under Article 8; (d) Financial Consequences means a financial sanction imposed for an anti-doping rule violation or to recover costs associated with an anti-doping rule violation; and (e) Public Disclosure or Public Reporting means the dissemination or distribution of information to the general public or *Persons* beyond those *Persons* entitled to earlier notification in accordance with Article 14. Teams in *Team Sports* may also be subject to *Consequences* as provided in Article 11.

**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, *TUEs*, results management and hearings.

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

**In-Competition:** Unless provided otherwise in the rules of an International Federation or the ruling body of the *Event* in question, "*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*.

[*Comment: An International Federation or ruling body for an Event may establish an "In-Competition" period that is different than the Event Period.*]

**Independent Observer Program (IO):** A team of observers, under the supervision of WADA, who observe and provide guidance on the *Doping Control* process at certain *Events* and report on their observations.

**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*.

**Marker:** A compound, group of compounds or biological variable(s) that indicates the *Use of a Prohibited Substance or Prohibited Method*.

**Minor:** A natural *Person* who has not reached the age of eighteen years.

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

**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.*]

**Tampering:** Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly; obstructing, misleading or engaging in any fraudulent conduct to alter results or prevent normal procedures from occurring.

**Target Testing:** Selection of specific *Athletes* for *Testing* based on criteria set forth in the *International Standard for Testing and Investigations*.

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

**Use:** The utilization, application, ingestion, injection or consumption by any means whatsoever of any *Prohibited Substance* or *Prohibited Method*.

**WADA:** The World Anti-Doping Agency.

## 11.2 ISTI Defined Terms

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

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

**Chaperone:** An official who is trained and authorized by the Sample Collection Authority to carry out specific duties including one or more of the following (at the election of the Sample Collection Authority): notification of the *Athlete* selected for *Sample* collection; accompanying and observing the *Athlete* until arrival at the Doping Control Station; accompanying and/or observing *Athletes* who are present in the Doping Control Station; and/or witnessing and verifying the provision of the *Sample* where the training qualifies him/her to do so.

**Doping Control Officer (DCO):** An official who has been trained and authorized by the Sample Collection Authority to carry out the responsibilities given to DCOs in the International Standard for Testing and Investigations.

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

**Failure to Comply:** A term used to describe anti-doping rule violations under *Code* Articles 2.3 and/or 2.5.

**No Advance Notice Testing:** *Sample* collection that takes place with no advance warning to the *Athlete* and where the *Athlete* is continuously chaperoned from the moment of notification through *Sample* provision.

**Random Selection:** Selection of *Athletes* for *Testing* which is not *Target Testing*.

**Results Management Authority (RMA):** The organization that is responsible, in accordance with *Code* Article 7.1, for the management of the results of *Testing* (or other evidence of a potential anti-doping rule violation) and hearings, whether (1) an *Anti-Doping Organization* (for example, the International Olympic Committee or

other *Major Event Organization*, WADA, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization acting pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation). In respect of Whereabouts Failures, the Results Management Authority shall be as set out in Article I.5.1.

**Sample Collection Authority:** The organization that is responsible for the collection of *Samples* in compliance with the requirements of the International Standard for Testing and Investigations, whether (1) the Testing Authority itself; or (2) another organization (for example, a Third Party contractor) to whom the Testing Authority has delegated or sub-contracted such responsibility (provided that the Testing Authority always remains ultimately responsible under the *Code* for compliance with the requirements of the International Standard for Testing and Investigations relating to collection of *Samples*).

**Sample Collection Equipment:** Containers or apparatus used to collect or hold the *Sample* at any time during the Sample Collection Session. 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;
  - Suitable kit for storing partial *Samples* securely until the *Athlete* is able to provide more urine; and
  - Sealable and tamper-evident bottles and lids for storing and transporting the complete *Sample* securely.
- For blood *Sample* collection:
  - Needles for collecting the *Sample*;
  - Blood tubes with sealable and tamper-evident devices for storing and transporting the *Sample* securely.

**Sample Collection Personnel:** A collective term for qualified officials authorized by the Sample Collection Authority to 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 the point that initial contact is made until the *Athlete* leaves the Doping Control Station after having provided his/her *Sample(s)*.

**Testing Authority:** The organization that has authorized a particular *Sample* collection, whether (1) an *Anti-Doping Organization* (for example, the International

Olympic Committee or other *Major Event Organization*, WADA, an International Federation, or a *National Anti-Doping Organization*); or (2) another organization conducting *Testing* pursuant to the authority of and in accordance with the rules of the *Anti-Doping Organization* (for example, a National Federation that is a member of an International Federation).

**Whereabouts Filing**: Information provided by or on behalf of an *Athlete* in a *Registered Testing Pool* that sets out the *Athlete's* whereabouts during the following quarter, in accordance with Article I.3 of the International Standard for Testing and Investigations.

### 11.3 Guidelines Defined Terms

**Athlete Representative**: A person designated by the *Athlete* to assist with the verification of the *Sample* collection procedure, (not including the passing of the *Sample*). This person may be a member of the *Athlete's Support Personnel*, such as a coach or team doctor, a family member, or other. For *In-Competition Testing* the *Athlete Representative* must have the appropriate accreditation to access the *Doping Control Station*.

**Blood Collection Facility**: The place where the *Blood Sample* is collected. This may differ from the *Doping Control Station* where urine samples are collected, or may be a separate, dedicated area of the *Doping Control Station*.

**Blood Collection Procedure**: The procedure for taking a *Blood Sample* from an *Athlete*, from the *Athlete's* arrival at the *Blood Collection Facility* to the *Athlete's* departure from the *Blood Collection Facility*.

**Blood Sample**: An aliquot of whole blood, plasma or serum appropriately collected to perform one or more *Laboratory* tests.

**Butterfly Needle**: A small needle with two plastic wings attached which are squeezed together to form a tab used to manipulate the needle. A long 6-12" plastic tubing is attached to offer better manipulation.

**Venipuncture**: The process of collecting a sample of blood from an *Athlete's* vein.

**Witness**: The member of *Sample Collection Personnel* who observes the passing of the *Sample* by the *Athlete* in accordance with the procedures for observation.

### 11.4 ISL Defined Terms

**Laboratory(ies)**: (A) WADA-accredited laboratory(ies) applying test methods and processes to provide evidentiary data for the detection of *Prohibited Substances*,

*Methods or Markers on the Prohibited List and, if applicable, quantification of a Threshold Substance in Samples of urine and other biological matrices in the context of anti-doping activities.*

**WADA-Approved Laboratory for the ABP:** Laboratory(ies) not otherwise accredited by *WADA*; applying test methods and processes in support of an *Athlete Biological Passport* program and in accordance with the criteria for approval of non-accredited laboratories for the *Athlete Biological Passport*.

## Appendix 1: Integration of Multiple Blood Testing Types

When planning and conducting a Sample Collection Session, the Testing Authority may want to collect a sufficient volume of blood to enable multiple types of analyses to be conducted simultaneously.

An *Athlete Biological Passport (ABP)* test may reveal abnormal variables that warrant immediate analysis for *Prohibited Substances* or *Methods*. Should a *B Sample* analysis be required, it is strongly recommended to have a complementary *Sample* available.

Conducting multiple types of analyses requires careful consideration, especially regarding the Sample Collection Equipment needed. This Appendix offers *Anti-Doping Organizations (ADOs)* guidance on integrating multiple types of blood *Testing*.

### Blood Collection Equipment

The following matrix details all Blood Collection Equipment required and routine analysis types (including *ABP* tests).

Test	Analysis matrix	Tubes#	V / tube (mL)	No. of tubes	Tube inversion
GH Isoforms and/or GH biomarkers / HBOCs / ESAs <sup>1</sup>	Serum	BD Vacutainer® SST II Plus (cat. # 367955) or BD Vacutainer™ SST-II plus Advance tubes (367954)	5	2 <sup>3</sup>	Recommended
BT <sup>2</sup> / HBOCs / ESAs	Blood <sup>2</sup> / Plasma	BD Vacutainer® EDTA (CE #368856, US #367856)	3	2 <sup>5</sup> , +	At least 3
ABP <sup>2</sup> / HBOCs / ESAs <sup>2</sup>	Blood <sup>2</sup> / Plasma	BD Vacutainer® EDTA (CE #368856, US #367856)	3	1-2 <sup>5</sup> +	At least 3

# The vacutainers identified below are recommended as they have been validated by *WADA*. Alternate equipment that meets the same criteria identified herein may be permissible, but prior to use should be validated by *WADA*, and be consistent with the collection methodology presented herein.

- 1 Analysis for ESAs can be performed in either serum or plasma; however, the recommended matrix is serum.
- 2 For Blood Transfusion (BT) and the *ABP*, whole non-coagulated blood is used; for HBOCs/ESAs the centrifugation of the Blood Sample (e.g. Ficoll gradient) is required to separate the plasma fraction from the cellular components. These tests may be combined by conducting primary *ABP* and/or BT analyses prior to centrifugation.
- 3 One tube is used for collection of the A *Sample*, the other for the B *Sample*, if needed.
- 4 The accessory package includes the specified collection tubes and other accessories (e.g. needle, disinfection pads, etc.).
- 5 When *Testing* the blood variables of the *ABP* only, one (1) EDTA tube is sufficient; however the collection of two (2) EDTA tubes is recommended to allow the simultaneous *Testing* for ESAs/HBOCs, e.g. in cases of abnormal results for the blood variables included in the *ABP*.

*[Comment: Other Analyses not included in the chart above are available at select laboratories. ADOs are advised to contact laboratories regarding the availability of other analysis types in serum/plasma such as Xenon, Insulin analogues, steroid esters, desmopressin, and IGF-1 analogues, and what equipment should be used for sample collection.]*



## Possible Test Combinations

The following matrix details Collection Equipment Requirements for possible combinations of multiple types of analysis.

	GH/ HBOCs / ESAs (Serum)	BT (Whole blood) HBOCs / ESAs (Plasma)	ABP (Plasma)
GH/ HBOCs / ESAs (Serum)	<ul style="list-style-type: none"> <li>• 2 x serum tubes</li> <li>• Total volume: 10mL</li> </ul>	<ul style="list-style-type: none"> <li>• 2 x serum tubes</li> <li>• 2 x EDTA tubes</li> <li>• Total volume: 16mL</li> </ul>	<ul style="list-style-type: none"> <li>• 2x serum tubes</li> <li>• 1-2 EDTA tubes</li> <li>• Total volume: 13-16mL</li> </ul>
BT (Whole blood) HBOCs / ESAs (Plasma)	<ul style="list-style-type: none"> <li>• 2 x serum tubes</li> <li>• 1-2 x EDTA tubes</li> <li>• Total volume: 13-16mL</li> </ul>	<ul style="list-style-type: none"> <li>• 2 x EDTA tubes</li> <li>• Total volume: 6mL</li> </ul>	<ul style="list-style-type: none"> <li>• 2-3 x EDTA tubes</li> <li>• Total volume: 6-9 mL</li> </ul>
ABP (Whole blood)	<ul style="list-style-type: none"> <li>• 2x serum tubes</li> <li>• 1-2 EDTA tubes</li> <li>• Total volume: 13-16mL</li> </ul>	<ul style="list-style-type: none"> <li>• 2-3 x EDTA tubes</li> <li>• Total volume: 6-9mL</li> </ul>	<ul style="list-style-type: none"> <li>• 1 EDTA tube</li> <li>• Total volume: 3mL</li> </ul>
All analysis types	<ul style="list-style-type: none"> <li>• 2 x serum tubes</li> <li>• 2-3 x EDTA tubes</li> <li>• Total volume: 16-19mL</li> </ul>		

*[Comment: The analysis of HBOCs and ESAs can be conducted in either serum or plasma. The analytical matrix used in the assay will vary depending on the Laboratory. Please contact the Laboratory that is to conduct the analysis to determine this information.]*

*[Comment: When using both types of tubes for multiple test types, the specific procedures followed for each type of tube – for example number of inversions – should still be followed.]*

*[Comment: These specifications should serve for general guidance only. When wishing to collect blood to test for different Prohibited Substances and/or Methods at the same Sample Collection Session, it is recommended that the ADO in charge of Sample collection contact the Laboratory that is to conduct the analyses to ascertain the type and total number of tubes and total volume of blood to collect.]*

*[Comment: An Athlete Biological Passport (ABP) test may reveal abnormal variables that warrant immediate analysis for Prohibited Substances or Methods. Should a B Sample analysis be required, it is strongly recommended to have a complementary Sample available.]*