Doping Control Sample Collection Equipment

Specification
FTS Ref: 2023/S 000-011162
Date: 18/04/2023

Contents

1. About this Specification

1.1 As explained in the accompanying Selection Questionnaire (SQ), UKAD wishes to appoint a supplier of Doping Control Sample Collection equipment. Any capitalised terms used within this document shall have the meanings ascribed to them in the Glossary of the SQ document.

1.2 The purpose of this document is to provide a description of the services which will be required. Bidders should therefore read this document thoroughly in order to decide whether they wish to bid for this opportunity. The Bidder which enters into the Contract with UKAD following completion of the procurement process shall be referred to as the 'Supplier'.

1.3 For the avoidance of doubt, the services described in this Specification are for the purposes of describing the type of services which may be required by UKAD throughout the duration of the Contract. While some services are required from 'day 1' of entering into the Contract (as more particularly described later in this document), UKAD does not provide any guarantee in respect of any further volume of services that may be required, or that all such services shall be required at all.

1.4 This Specification is divided into the following sections:

1.4.1 **Equipment requirements** – this section is separated into two sections. The provision of equipment in 1.4.1(i) is mandatory for Bidders. The provision of equipment in 1.4.1 (ii) is optional for Bidders. These sections will be evaluated independently of each other:

1.4.1.1 **Part 1 - Equipment requirements: Urine and venous blood Sample collection equipment** – stipulates the requirements for the urine and venous blood Doping Control Sample collection equipment. Bidders will be evaluated against these requirements.

1.4.1.2 **Part 2 - Equipment requirements: Sample Collection Vessels and Partial Sample Equipment** - this section stipulates the requirements for Sample Collection Vessels and Partial Sample equipment. Bidders Sample Collection Vessels and Partial Sample equipment will be evaluated against these requirements.

1.4.2 **Bidder requirements** – stipulates the requirements for a Bidder as an organisation. Bidders will be evaluated against these requirements.

1.4.3 **Customer service/account management requirements** – stipulates the requirements and expectations for customer service and account management. Bidders will be evaluated against these requirements.

1.4.4 **Out of scope services** – details of the services which will not fall within the scope of this contract. It is of utmost importance that the supplier appointed to deliver the services as described within this Specification is sufficiently skilled, has previous experience of acting as a supplier of Doping Control Sample collection equipment to Anti-Doping Organisations (ADOs) and/or Sample Collection Agencies (SCAs) operating within the framework of the World Anti-Doping Code and the International Standard for Testing & Investigations (ISTI), and whose products are compliant with the ISTI.

1.5 Further, UKAD wishes to appoint a supplier which is able to demonstrate its commitment to sustainability and the environment, through the manufacturing and supply of its products and services.

2. Part 1 - Equipment Requirements: Urine and Blood Sample Collection Equipment

2.1 The Bidder's Doping Control Sample collection equipment ('equipment') must enable UKAD to collect both urine and venous blood Samples in accordance with the World Anti-Doping Agency (WADA) ISTI.

2.2 The equipment elements UKAD requires from the Bidders are:

2.2.1 Urine Sample 'A' and 'B' bottles/containers
2.2.2 Venous blood Sample 'A' and 'B' bottles/containers/tubes
2.2.3 Venous blood Sample vacutainers and accessory packs

2.3 For Sample Collection Vessels and Partial Sample equipment, refer to 'Part 2 – Equipment requirements' section below.

2.4 Specifically, a Bidder's equipment must be compliant with clause 6.3.4 of the ISTI. For the avoidance of doubt, a Bidder's equipment for urine and blood Samples must therefore, at a minimum:

2.4.1 Have a unique numbering system, incorporated into all A and B bottles, containers, tubes or other items used to seal the Sample and have a barcode or similar data code which meets the requirements of ADAMS on the applicable Sample Collection Equipment;

2.4.2 Have a Tamper-Evident sealing system;

2.4.3 Ensure the identity of the Athlete is not evident from the equipment itself;

2.4.4 Ensure that all equipment is clean and sealed prior to use by the Athlete;

2.4.5 Are constructed of a material and sealing system that is able to withstand the handling conditions and environment in which the equipment will be used or subjected to, including but not limited to transportation, Laboratory analysis and long-term frozen storage up to the period of the statute of limitations;

2.4.6 Are constructed of a material and sealing system that will;

2.4.6.1 Maintain the integrity (chemical and physical properties) of the Sample for the Analytical Testing;

2.4.6.2 Can withstand temperatures of -80 °C for urine and blood. Tests conducted to determine integrity under freezing conditions shall use the matrix that will be stored in the Sample bottles, containers or tubes i.e., blood or urine;

2.4.6.3 Are constructed of a material and sealing system that can withstand a minimum of three (3) freeze/thaw cycles;

2.4.7 The A and B bottles, containers and tubes shall be transparent, so the Sample is visible;

2.4.8 Have a sealing system which allows verification by the Athlete and the DCO that the Sample is correctly sealed in the A and B bottles or containers;

2.4.9 Have a built-in security identification feature(s) which allows verification of the authenticity of the equipment;

2.4.10 Are compliant with the standards published by the International Air Transport Association (IATA) for the transport of exempt human

specimens which includes urine and/or blood Samples in order to prevent leakage during transportation by air;

2.4.11 Have been manufactured under the internationally recognized ISO 9001 certified process which includes quality control management systems;

2.4.12 Can be resealed after initial opening by a Laboratory using a new unique Tamper- Evident sealing system with a unique numbering system to maintain the integrity of the Sample and Chain of Custody in accordance with the requirements of the International Standard for Laboratories for long term storage of the Sample and further analysis;

2.4.13 Have undergone testing by a testing institution that is independent of the manufacturer and is ISO 17025 accredited, to validate at a minimum that the equipment meets the criteria set out in subsections 2.4.2, 2.4.6, 2.4.7, 2.4.8, 2.4.9, 2.4.10 and 2.4.12 above;

2.4.14 Any modification to the material or sealing system of the equipment shall require re-testing to ensure it continues to meet the stated requirements as 2.4.13 above;

For urine Sample collection:

2.4.15 Have the capacity to contain a minimum of 85mL volume of urine in each A and B bottle or container;

2.4.16 Have a visual marking on the A and B bottles or containers and the collection vessel, indicating:

2.4.16.1 the minimum volume of urine required in each A and B bottle, or container as outlined in ISTI Annex C – Collection of Urine;

2.4.16.2 the maximum volume levels that allow for expansion when frozen without compromising the bottle, container or the sealing system; and

2.4.16.3 the level of Suitable Volume of Urine for Analysis (as defined in the ISTI i.e., a minimum of 90 mL) on the collection vessel.

2.4.17 Include a partial Sample Tamper Evident sealing system with a unique numbering system to temporarily seal a Sample with an

insufficient volume in accordance with Annex E – Urine Samples – Insufficient Volume;

For blood Sample collection:

2.4.18 Have the ability to collect, store and transport blood in separate A and B tubes and containers;

2.4.19 For the analysis of Prohibited Substances or Prohibited Methods in whole blood or plasma and/or for profiling blood parameters, the A and B tubes must have the capacity to contain a minimum of 3mL of blood and shall contain EDTA as an anti-coagulant;

2.4.20 For the analysis of Prohibited Substances or Prohibited Methods in serum, the A and B tubes must have the capacity to contain a minimum of 5mL of blood and shall contain an inert polymeric serum separator gel and clotting activation factor; and

2.5 For urine Sample collection, a Bidder's equipment should facilitate the collection and sealing of a minimum of 180mL in total.

2.6 A Bidder should be able to describe and evidence how its equipment meets the requirements stipulated in clause 6.3.4 of the ISTI.

2.7 A Bidder's equipment should be easy to use from the perspective of key groups involved in using Sample collection equipment, namely:

2.7.1 the Athletes
2.7.2 the Doping Control Officers
2.7.3 the WADA accredited laboratory

2.8 Most importantly, equipment must protect the integrity of the Athlete's Sample(s) and must provide the Athlete with the confidence that the integrity of their Sample(s) is protected.

2.9 A Bidder's equipment must be robust and durable, in order to withstand transportation of Samples to the WADA accredited laboratory by courier (for e.g., UPS, DHL).

2.10 Whilst ensuring that the equipment is of suitable size to meet the volume requirements as stipulated above, size and weight of packaged equipment is an important consideration for UKAD. UKAD has not set a minimum/maximum size

or weight, however packaged equipment should ideally be no larger than 15cm x 15cm x 6cm and weigh no more than 1kg.

2.11 A Bidder's equipment should have clear expiry dates where relevant. To reduce product waste, and assist with efficient stock management, equipment expiry dates should be as long as possible without, however, compromising the integrity of the equipment.

3. Part 2 - Equipment Requirements: Sample Collection Vessels and Partial Sample Equipment

3.1 It is not a requirement for UKAD to have the same supplier for Sample Collection Vessels/Partial Sample equipment and all other core equipment. Whilst a single supplier would be preferable and more efficient, Bidders Sample Collection Vessels and Partial Sample equipment will be evaluated independently of their core equipment (as per section 2).

3.2 A Bidder's Sample Collection Vessel must be compliant with the relevant clauses within clause 6.3.4 of the ISTI, specifically:

- 3.2.1 Be clean and sealed prior to use by the Athlete
- 3.2.2 Be transparent so the Sample is visible
- 3.2.3 Have been manufactured under the internationally recognized ISO 9001 certified process which includes quality control management systems
- 3.2.4 Have a visual marking on the collection vessel, indicating the level of Suitable Volume of Urine for Analysis
- 3.2.5 Furthermore, a Bidder's Sample Collection Vessel should be easy to use, easy to pour, sealed, with clear and accurate laser printed volume markings, and have a separate, sealed lid provided to facilitate the sealing of the collected Sample

3.3 A Bidder's Partial Sample equipment must be compliant with the relevant clauses within clause 6.3.4 of the ISTI, specifically:

- 3.3.1 Have been manufactured under the internationally recognized ISO 9001 certified process which includes quality control management systems
- 3.3.2 Include a partial Sample Tamper Evident sealing system with a unique numbering system to temporarily seal a Sample with an

insufficient volume in accordance with Annex E – Urine Samples – Insufficient Volume

3.3.3 Furthermore, a Bidder's Partial Sample equipment should be easy to use.

3.4 In respect of Sample Collection Vessels, a Bidder must have the capacity and ability to meet the needs of UKAD's testing programme on an annual basis. Currently UKAD uses approximately 13,500 Sample Collection Vessels. As a Non-Departmental Public Body (NDPB), UKAD is government funded, and therefore annual levels of testing are dependent on UKAD funding levels and are therefore subject to change.

3.5 In respect of Partial Sample equipment, a Bidder must have the capacity and ability to meet the needs of UKAD's testing programme on an annual basis. Currently UKAD uses approximately 3,500 units of its current Partial Sample equipment. As a Non-Departmental Public Body (NDPB), UKAD is government funded, and therefore annual levels of testing are dependent on UKAD funding levels and are therefore subject to change.

4. Bidder Requirements

4.1 A Bidder must be ISO 9001 certified process with quality control management systems and clear Quality Assurance processes and procedures. A Bidder must have business continuity plans to demonstrate continuation of supply.

4.2 In order to demonstrate applicable experience and expertise, a Bidder should be able to evidence it acts as a supplier of equipment to other ADOs/SCAs, supplying a minimum of 5,000 urine Sample collection kits and 1,000 venous blood Sample collection kits a year (across all customers). Furthermore, where relevant, a Bidder should be able reference Anti-Doping Rule Violations (ADRVs) that have been sanctioned in accordance with the WAD Code, whereby a Bidder's equipment was used during Sample collection.

4.3 A Bidder must have the capacity and ability to meet the needs of UKAD's testing programme on an annual basis. Currently UKAD collects approximately 9,000-10,000 urine Samples and 2,000-3,000 blood Samples a year. As a Non-Departmental Public Body (NDPB), UKAD is government funded, and therefore annual levels of testing are dependent on UKAD funding levels and are therefore subject to change.

Sustainability

4.4 A Bidder should be able to demonstrate its commitment to sustainability. It is preferred if a Bidder is ISO14001 certified. In the absence of this certification a Bidder can demonstrate its commitment to sustainability in other ways such as through the existence of a Corporate Social Responsibility (CSR) policy, transparency, recyclability of equipment, reduction in waste created when using equipment and monitoring of carbon footprint of equipment manufacturing etc.

5. Customer Service/ Account Management

5.1 A Bidder shall provide a sufficient level of resource throughout the duration of the Contract in order to consistently deliver a quality service. This includes:

- 5.1.1 The provision of a designated account manager/team providing support to UKAD regarding its account and orders. It is expected that an annual meeting (at least) will be held between UKAD and the account manager
- 5.1.2 Ensuring that all staff assigned to the Contract have the relevant qualifications and experience to deliver the Contract to the required standard
- 5.1.3 Ensure that the staff understand UKAD's vision and objectives and will provide excellent customer service to UKAD throughout the duration of the Contract
- 5.1.4 Reliable process for investigating delayed orders/faulty equipment
- 5.1.5 Clear and efficient process for ordering and shipping of equipment. This includes as short lead in times as possible, flexibility of orders (for e.g., the ability to split orders across multiple shipments) and efficient shipment into the UK (taking into consideration customs considerations). All equipment shipments will be to the UK, with the primary address for delivery being Sprint Logistics Ltd, A2 Parkway West, Cranford Lane, Heston. Middx TW5 9QA, United Kingdom.

5.2 A Bidder should be able provide test/training equipment and supporting training resources to be used for Doping Control Personnel training needs throughout the Contract.

6. Out of scope services

6.1 The list below provides a description of the services which will not fall within the scope of the appointed Supplier:

6.1.1 Dried Blood Spot collection equipment

6.1.2 Any other Sample collection equipment used in the drug detection industry (e.g., hair sampling)

6.1.3 Transportation equipment, for example data trackers

7. Annex 1: ISTI Annex C - Collection of Urine

ANNEX C - COLLECTION OF URINE SAMPLES

C.1 Objective

To collect an Athlete's urine Sample in a manner that ensures:

a) Consistency with relevant principles of internationally recognized standard precautions in healthcare settings so that the health and safety of the Athlete and Sample Collection Personnel are not compromised;

b) The Sample meets the Suitable Specific Gravity for Analysis and the Suitable Volume of Urine for Analysis. Failure of a Sample to meet these requirements in no way invalidates the suitability of the Sample for analysis. The determination of a Sample's suitability for analysis is the decision of the relevant Laboratory, in consultation with the Testing Authority for the Sample Collection Session in question.

[Comment to C.1 (b): The measurements taken in the field for Suitable Specific Gravity for Analysis and the Suitable Volume of Urine for Analysis are preliminary in nature, to assess whether the Sample meets the requirements for analysis. It is possible there could be discrepancies between the field readings and the final Laboratory readings due to the precision of the Laboratory equipment. The Laboratory reading will be considered final, and such discrepancies (if any) shall not constitute a basis for Athletes to seek to invalidate or otherwise challenge an Adverse Analytical Finding.]

c) the Sample has not been manipulated, substituted, contaminated or otherwise tampered with in anyway;

d) the Sample is clearly and accurately identified; and

e) the Sample is securely sealed in a Tamper Evident kit.

C.2 Scope

The collection of a urine Sample begins with ensuring the Athlete is informed of the Sample collection requirements and ends with discarding any residual urine remaining at the end of the Athlete's Sample Collection Session.

C.3 Responsibility

C.3.1 The DCO has the responsibility for ensuring that each Sample is properly collected, identified and sealed.

C.3.2 The DCO/Chaperone has the responsibility for directly witnessing the passing of the urine Sample.

C.4 Requirements

C.4.1 The DCO shall ensure that the Athlete is informed of the requirements of the Sample Collection Session, including any modifications as provided for in Annex A - Modifications for Athletes with Impairments and/or in Annex B - Modifications for Athletes who are Minors.

C.4.2 The DCO shall ensure that the Athlete is offered a choice of Sample collection vessels for collecting the Sample. If the nature of an Athlete's impairment requires that they must use additional or other equipment as provided for in Annex A - Modifications for Athletes with Impairments, the DCO shall inspect that equipment to ensure that it will not affect the integrity, identity or security of the Sample.

C.4.3 When the Athlete selects a collection vessel, and for selection of all other Sample Collection Equipment that directly holds the urine Sample, the DCO will instruct the Athlete to check that all seals on the selected equipment are intact and the equipment has not been tampered with. If the Athlete is not satisfied with the selected equipment, they may select another. If the Athlete is not satisfied with any of the equipment available for selection, this shall be recorded by the DCO. If the DCO does not agree with the Athlete that all of the equipment available for the selection is unsatisfactory, the DCO shall instruct the Athlete to proceed with the Sample Collection Session. If the DCO agrees with the Athlete that all of the equipment available for the selection is unsatisfactory, the DCO shall terminate the urine Sample collection, and this shall be recorded by the DCO.

C.4.4 The Athlete shall retain control of the collection vessel and any Sample provided until the Sample (or partial Sample) is sealed, unless assistance is required by reason of an Athlete's impairment as provided for in Annex A - Modifications for Athletes with Impairments. Additional assistance may be provided in exceptional circumstances to any Athlete by the Athlete's representative or Sample Collection Personnel during the Sample Collection Session where authorized by the Athlete and agreed to by the DCO.

C.4.5 The DCO/Chaperone who witnesses the passing of the Sample shall be of the same gender as the Athlete providing the Sample and where applicable, based on the gender of the Event the Athlete competed in.

C.4.6 The DCO/Chaperone shall, where practicable, ensure the Athlete thoroughly washes their hands with water only prior to the provision of the Sample or wears suitable (e.g., disposable) gloves during provision of the Sample.

C.4.7 The DCO/Chaperone and Athlete shall proceed to an area of privacy to collect a Sample.

C.4.8 The DCO/Chaperone shall ensure an unobstructed view of the Sample leaving the Athlete's body and shall continue to observe the Sample after provision until the Sample is securely sealed. In order to ensure a clear and unobstructed view of the passing of the Sample, the DCO/Chaperone shall instruct the Athlete to remove or adjust any clothing which restricts the DCO's/Chaperone's clear view of Sample provision.

C.4.9 The DCO/Chaperone shall ensure that urine passed by the Athlete is collected in the collection vessel to its maximum capacity and thereafter the Athlete is encouraged to fully empty their bladder into the toilet. The DCO shall verify, in full view of the Athlete, that the Suitable Volume of Urine for Analysis has been provided.

C.4.10 Where the volume of urine provided by the Athlete is insufficient, the DCO shall follow the partial Sample collection procedure set out in Annex E - Urine Samples – Insufficient Volume.

C.4.11 Once the volume of urine provided by the Athlete is sufficient, the DCO shall instruct the Athlete to select a Sample collection kit containing A and B bottles or containers in accordance with Annex C.4.3.

C.4.12 Once a Sample collection kit has been selected, the DCO and the Athlete shall check that all Sample code numbers match and that this code number is recorded accurately by the DCO on the Doping Control form. If the Athlete or DCO finds that the numbers are not the same, the DCO shall instruct the Athlete to choose another kit in accordance with Annex C.4.3. The DCO shall record the matter.

C.4.13 The Athlete shall pour the minimum Suitable Volume of Urine for Analysis into the B bottle or container (to a minimum of 30 mL), and then pour the remainder of the urine into the A bottle or container (to a minimum of 60 mL). The Suitable

Volume of Urine for Analysis shall be viewed as an absolute minimum. If more than the minimum Suitable Volume of Urine for Analysis has been provided, the DCO shall ensure that the Athlete fills the A bottle or container to capacity as per the recommendation of the equipment manufacturer. Should there still be urine remaining, the DCO shall ensure that the Athlete fills the B bottle or container to capacity as per the recommendation of the equipment manufacturer. The DCO shall instruct the Athlete to ensure that a small amount of urine is left in the collection vessel, explaining that this is to enable the DCO to test the residual urine in accordance with Annex C.4.15.

C.4.14 The Athlete shall then seal the A and B bottles or containers as directed by the DCO. The DCO shall check, in full view of the Athlete, that the bottles or containers have been properly sealed.

C.4.15 The DCO shall test the residual urine in the collection vessel to determine if the Sample has a Suitable Specific Gravity for Analysis. If the DCO's field reading indicates that the Sample does not have a Suitable Specific Gravity for Analysis, then the DCO shall follow Annex F - Urine Samples that do not meet the requirement for Suitable Specific Gravity for Analysis.

C.4.16 Urine should only be discarded when both the A and B bottles or containers have been sealed and the residual urine has been tested in accordance with Annex C.4.15.

C.4.17 The Athlete shall be given the option of witnessing the discarding of any residual urine that will not be sent for analysis.

8. Annex 2: ISTI Annex E – Urine Samples – Insufficient Volume

ANNEX E - URINE SAMPLES - INSUFFICIENT VOLUME

E.1 Objective

To ensure that where a Suitable Volume of Urine for Analysis is not provided, appropriate procedures are followed.

E.2 Scope

The procedure begins with informing the Athlete that the Sample that they have provided is not of Suitable Volume of Urine for Analysis and ends with the Athlete's provision of a Sample of sufficient volume.

E.3 Responsibility

The DCO has the responsibility for declaring the Sample volume insufficient and for collecting the additional Sample(s) to obtain a combined Sample of sufficient volume.

E.4 Requirements

E.4.1 If the Sample collected is of insufficient volume, the DCO shall inform the Athlete that a further Sample shall be collected to meet the Suitable Volume of Urine for Analysis requirements.

E.4.2 The DCO shall instruct the Athlete to select partial Sample Collection Equipment in accordance with Annex C.4.3.

E.4.3 The DCO shall then instruct the Athlete to open the relevant equipment, pour the insufficient Sample into the new container (unless the Sample Collection Authority's procedures permit retention of the insufficient Sample in the original collection vessel) and seal it using a partial Sample sealing system, as directed by the DCO. The DCO shall check, in full view of the Athlete, that the container (or original collection vessel, if applicable) has been properly sealed.

E.4.4 The DCO shall record the partial Sample number and the volume of the insufficient Sample on the Doping Control form and confirm its accuracy with the Athlete. The DCO shall retain control of the sealed partial Sample.

E.4.5 While waiting to provide an additional Sample, the Athlete shall remain under continuous observation and be given the opportunity to hydrate in accordance with Article 7.3.3.

E.4.6 When the Athlete is able to provide an additional Sample, the procedures for collection of the Sample shall be repeated as prescribed in Annex C - Collection of Urine Samples, until a sufficient volume of urine will be provided by combining the initial and additional Sample(s).

E.4.7 Following each Sample provided, the DCO and Athlete shall check the integrity of the seal(s) on the container(s) containing the previously provided partial Sample(s). Any irregularity with the integrity of the seal(s) will be recorded by the DCO and investigated according to Annex A - Review of a Possible Failure to Comply of the International Standard for Results Management. The DCO may request that an additional Sample is collected from the Athlete. A refusal to provide a further Sample if requested, where the minimum requirements for Sample collection volume are not met, shall be recorded by the DCO and dealt with as a potential Failure to Comply in accordance with the International Standard for Results Management.

E.4.8 The DCO shall then direct the Athlete to break the seal(s) and combine the Samples, ensuring that additional Samples are added in the order they were collected to the original partial Sample until, as a minimum, the requirement for Suitable Volume of Urine for Analysis is met.

E.4.9 The DCO and the Athlete shall then continue with Annex C.4.12 or Annex C.4.14 as appropriate.