South African Institute for Drug-Free Sport

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Bid Specification for the Procurement of Sample Collection Equipment

The South African Institute for Drug-Free Sport (SAIDS) is a Schedule 3A (of the Public Finance Management Act (PFMA)) Public Entity. SAIDS invites suitably qualified companies to submit proposals/quotations for the supply of sample collection equipment to the entity that meet the requirements of the International Standard for Testing and Investigations (ISTI for a period of five (5) years.

Globally, only four (4) companies who manufacture sample collection equipment for the purpose of drug-testing in sport meet the requirements of the ISTI viz., LockCon and Berlinger based in Switzerland, Versapak based in the United Kingdom and InnoVero based in the USA. SAIDS is a signatory to the UNESCO Convention and the World Anti-Doping Code (WADC), hence it is mandatory for SAIDS to use sample collection equipment manufacturing suppliers that meet the requirements of the ISTI. The successful bidder will be required comply with the standards and guidelines as set out by South Africa's National Treasury Regulations.

Sample collection equipment is defined in the ISTI as "A" and "B" bottles, kits or containers, collection vessels, tubes or other apparatus used to collect, hold or store the Sample (blood and urine) at any time during and after the Sample Collection Session that shall meet the requirements of Article 6.3.4. of the ISTI as listed below:

6.3.4 The Sample Collection Authority shall only use Sample Collection Equipment systems for urine and blood Samples which, at a minimum:

a) 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;

b) Have a Tamper-Evident sealing system;

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

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

e) 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;

f) Are constructed of a material and sealing system that will:

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

(ii) Can withstand temperatures of -80°C for urine and blood and -20°C for dried blood spots. Tests conducted to determine integrity under freezing conditions shall use the matrix or material that will be stored in the Sample bottles, containers or tubes i.e., urine, blood, or capillary blood applied on a dried blood spot absorbent Sample support (e.g., dried blood spot cellulose card or other equipment made of another material);

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

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

h) 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;

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

j) 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 or are compliant with the local and international regulations for the transport of dried blood spot Samples, if applicable;

k) Comply with local regulatory requirements for medical devices (for blood and dried blood spot Samples) where necessary, as well as any other applicable law or regulation;

l) Have been manufactured under the internationally recognized ISO 9001 certified standard which includes quality control management systems;

m) 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;

n) 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 b), f), g), h), i), j) and m) above;

o) 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 per n) above;

For Urine Sample Collection:

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

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

(i) the minimum volume of urine required in each A and B bottle or container as outlined in Annex C - Collection of Urine Samples;

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

(iii) the level of Suitable Volume of Urine for Analysis on the collection vessel.

r) 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 Venous Blood Sample Collection:

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

t) 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;

u) 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

[Comment to 6.3.4 (t) and (u): If specific tubes have been indicated in the applicable WADA International Standard, Technical Document or Guidelines, then the use of alternative tubes which meet similar criteria shall be validated with the involvement of the relevant Laboratory(ies) and approved by WADA prior to use for Sample collection.]

v) For the transport of blood Samples, ensure the storage and transport device and temperature data logger meet the requirements listed in Annex I - Collection, Storage and Transport of Blood Athlete Biological Passport Samples.

For Dried Blood Spot Sample Collection:

w) A dried blood spot absorbent Sample support (e.g., dried blood spot cellulose card) shall also be labelled if it is necessary to remove it from its container at the Laboratory to take an aliquot; and

x) Allow the collection, storage and secure transportation of dried blood spots on absorbent Sample support that can be sealed as distinct “A” and “B” Samples (Tamper Evident kit consisting of “A” and “B” containers/sub-containers and/or storage sleeves/packages/receptacles).

[Comment to 6.3.4 (x): Due to logistical reasons at the Laboratory, it is recommended to seal the "A" and "B" Samples in separate containers. Transporting and/or storing "A" and "B" Samples in the same container is however acceptable, provided that they are sealed as distinct "A" and "B" Samples.]

[**Comment to 6.3.4: It is strongly recommended that prior to the equipment being made commercially available to stakeholders, such equipment be distributed to the anti-doping community, which may include Athletes, Testing Authorities, Sample Collection Authorities, Sample Collection Personnel, and Laboratories to seek feedback and ensure the equipment is fit for purpose.]**

Notwithstanding the suppliers compliance with Article 6.3.4 of the ISTI, the following procedure will be followed to assess the bids:

First Phase

All the bids will be evaluated on functionality and will be limited to urine and venous blood collection equipment only. The following information is included in **Annexure A:**

1. The evaluation criteria for measuring functionality.
2. The weight of each criterion which will be equitable for all 16 criteria.
3. The applicable values and rating.

The minimum threshold for functionality will be 60%, hence if you do not score 60% for functionality based on **Annexure A**, you will not proceed to Phase 2.

SAIDS will use a minimum of three (3) SAIDS accredited Sample Collection Personnel (SCP) to evaluate the sample collection equipment based on Functionality and the variables and scores identified in **Annexure A**.

Second Phase

Only the qualifying bids i.e. those bids that have scored 60% and above will be evaluated in terms of the 80/20 preference points system, where the 80 points must be used for price only and the 20 points are used for specific goals which are geared towards Historically Disadvantaged Individuals (HDI) ownership and/ or for achieving the prescribed Reconstruction and Development (RDP) goals. Since none of the bidders meets the 20% for specific goals, a score of zero (0) will be given for this

and will only be measured on the 80% preference points system for pricing. **The guidance provided above replaces and prevails over the relevant guidelines contained in paragraphs 4.9 and 5.9 of the Supply Chain Management (SCM): A Guide to Accounting Officers/Authorities, paragraph 9 of Practice Note No. 3 of 2003 on the Appointment of Consultants dated 5 December 2003 and paragraph 2 of the SCM Circular dated 10 May 2005.**

The following must be included with the bid and couriered with the sample collection equipment:

1. Completed SBD 1 form (**Annexure B**).
2. Completed SBD 4 form (**Annexure C**).
3. A company profile.
4. A detailed catalogue or brochure of the available equipment.
5. Individual costs for standard urine collection test kit equipment, sample collection vessels, partial sample equipment, blood collection test kit equipment, dried blood spot equipment.
6. Packaged costs for standard urine collection test kit equipment, sample collection vessels, partial sample equipment, blood collection test kit equipment, dried blood spot equipment.
7. Additional costs related to individual branding.
8. Discounted rates and/or costs or package deals based on the procurement of increased quantities.

We require the above as well as six (6) samples of each of the **plastic** urine collection test kit equipment, sample collection vessels, partial sample equipment, **plastic** blood collection test kit equipment, dried blood spot equipment to be delivered via courier to the physical address below **before 17:00** on the **23rd January 2024**.

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You can address any questions and or queries you may have to Fahmy Galant at fahmy@saids.org.za

Based on an assessment of the bids submitted, a winning bidder will be selected for the supply of sample collection equipment. This procurement will be advertised on 20th December 2023 and will run for a minimum of twenty-one (21) days as per the requirement by National Treasury Regulations.

The contract with the selected supplier is for a period of five (5) years and is expected to commence on the 1st of April 2024 until 30th March 2029.