27 September 2022

Strategic Testing Expert Advisory Group In-person Meeting

Summary of Outcomes and Recommendations

Dear Colleagues,

The World Anti-Doping Agency's (WADA's) Strategic Testing Expert Advisory Group (STEAG) met at the Sports Medicine Research and Testing Laboratory (SMRTL), a WADA-accredited laboratory in Salt Lake City, Utah, USA, on 10-11 August 2022 to discuss the following topics:

- A review of all the comments received in connection with the stakeholder consultation process that WADA initiated in June regarding the draft 2023 International Standard for Testing and Investigation (ISTI), which has since been approved by WADA's Executive Committee (ExCo) in September 2022 and will come into effect on 1 January 2023;
- Additional measures to confirm the identification of athletes, potential criteria for mandatory storage of samples involving high-level athletes from higher risk sports and proposals for enhancements in WADA's Anti-Doping Administration and Management System (ADAMS) to more accurately record samples in long-term storage;
- A review of the implementation of, and compliance with, the Technical Document for Sports Specific Analysis (TDSSA), including a comparison of Anti-Doping Organizations' (ADOs) implementation for the period 2016-2021; and
- Updates on new and existing areas of testing, including implementation of dried blood spot (DBS); and, latest developments on the steroidal module of Athlete Biological Passport (ABP) using venous blood samples (serum), as well as the endocrinological module of the ABP.

The main outcomes of the meeting and recommendations are outlined below:

1. Draft 2023 ISTI

A global consultation process was undertaken with stakeholders for the draft 2023 ISTI from 6 June 2022 to 11 July 2022 where over 120 comments were received from 23 stakeholders. All comments were closely reviewed by WADA and the STEAG. Following discussions at the STEAG meeting, the 2023 ISTI was finalized and a summary of the major changes proposed to the 2021 ISTI is outlined below:

a) **ISTI Definitions**: Some definitions contained within other International Standards, and which are referenced in the ISTI were corrected to align verbatim. One definition contained in the ISTI was removed following the removal of its single reference in the ISTI.
b) **Dried Blood Spot Samples**: Following the implementation of dried blood spot collection and analysis in the field for the first time in 2021, the procedures from the Technical Document TD2021DBS have been transferred to the ISTI. Dried blood spot is now referenced as a type of sample in addition to urine and

venous blood. This transfer also includes requirements around dried blood spot sample collection equipment and sample collection procedures which are documented in a new ISTI Annex J titled 'Collection, Storage and Transport of Dried Blood Spot Samples'.
The collection of dried blood spot samples is currently not mandatory, however if ADOs wish to collect such samples then the equipment and procedures around collection, storage and transport of samples included in the ISTI are mandatory.

c) **Athlete Whereabouts**: Greater clarity on the term 'Whereabouts Filing' and associated Code Article 2.4 consequences to confirm that this defined term only applies to athletes in a Registered Testing Pool and not to athletes in a Testing Pool.
d) **Sport Gender**: During a sample collection session the sport gender of the athlete shall be recorded in the relevant documentation rather than the gender of the athlete.
e) **Athletes who are Minors**: ISTI Annex B was revised to reflect the importance of safeguarding athletes who are minors. As such, there is now a requirement that a minimum of two sample collection personnel are assigned to a sample collection session involving a minor and that when an athlete that is a minor is in the doping control station, there shall always be two sample collection personnel present.
Additional language was also added recommending that the athlete who is a minor have a representative present with them throughout the sample collection session and that sample collection personnel will make reasonable efforts to assist the athlete to locate one. If a representative is unable to be located, a second sample collection personnel will accompany the athlete until a representative is located or until the athlete arrives at the doping control station.
It remains not mandatory for the athlete to have a representative present and the test will not be invalidated if one cannot be located.
f) **Venous Blood Collection**: With the addition of dried blood spots as a new type of sample, the word 'venous' has been added to reflect the difference between venipuncture collection of whole blood that is currently used for the athlete biological passport program and for the detection of a number of prohibited substances, and capillary collection of dried blood spots.
g) **Blood Stability Score – Athlete Biological Passport**: Amendments have been made to the blood stability score range to ensure that blood athlete biological passport samples arrive to a WADA accredited laboratory in a suitable condition for analysis. The changes are based on revised calculations that take into account the temperature in which the venous blood samples are transported to the laboratory, the time it takes for the venous blood sample from collection to its reception at the laboratory and a maximum of 12 hours between the reception and the analysis in the laboratory.
h) **Collection of Urine Samples in a Virtual Environment During a Pandemic**[1]: A new ISTI Annex K has been developed that permits a partial virtual collection of urine samples from an athlete during a pandemic where in-person notification is permitted but entry into the athlete's residence or training center is not permitted and therefore, conducting the in-person aspect of sample collection is not possible. The aim of the new ISTI Annex K is to replicate as close as possible a 'regular', in-person sample collection session using a secure video connection between the athlete and a doping control officer (it is important to note that the session is not recorded). The development of these procedures will ensure that sample collection during a pandemic can occur in a consistent and harmonized way, whilst maintaining the security of the sample and protecting the integrity of the sample collection process.
The implementation of a partial virtual sample collection program is not mandatory during a pandemic. However, for those ADOs that wish to do so and that have the ability to put in place the necessary IT systems and security, where the procedures meet the national data privacy requirements and the

[1] Please note that Annex K is not included in the 2023 ISTI that was approved by the WADA ExCo in September 2022 and that will come into effect on 1 January 2023. The discussion on this topic is ongoing and Annex K will be considered for inclusion in future versions of the ISTI.

International Standard for Protection of Privacy and Personal Information (ISPPPI) and where the national, regional and local rules of the pandemic permit such activity, then the implementation of the procedures in the ISTI Annex K are mandatory to follow.

- ***Outcome/Recommendation No 1:*** *WADA will submit the final version of the 2023 ISTI to the WADA ExCo for approval.*

2. Measures for the Identification of Athletes, Criteria for Mandatory Storage of samples and relevant ADAMS enhancements

Following a recommendation contained in WADA's Intelligence and Investigations Department (WADA I&I) October 2020 public report on weightlifting and a decision of the WADA Executive Committee in November 2021 to task the STEAG to consider measures to prevent and/or detect doppelgangers, the discussion focused on ways to enhance athlete identification at the time of sample collection and on mandating long-term storage of samples based on specific criteria involving high-level athletes from higher risk sports. WADA also provided an update on upcoming ADAMS enhancements to be built in ADAMS late in 2022/early 2023 that will provide ADOs the ability to record samples in long-term storage and run relevant reports. The STEAG will discuss this matter further at its next meeting planned for the first half of 2023.

- ***Outcome/Recommendation No 2:*** *The STEAG recommended that further evaluation of the following areas take place*:

  a) *A review of the various types of photo identification that athletes could provide to a doping control officer in an attempt to achieve greater global harmonization and validate their identity at the time of a test. The various types of photo identification could be ranked, and a 'level' type system assigned including where a combination of 'levels' of photo identification could be combined to satisfy athlete identification requirements.*
  b) *To further review the use of athlete photographs at the time of sample collection and linking the photo to a doping control form, as well as the impact this may have on the storage capacity of ADAMS for undertaking this type of procedure and any potential data privacy concerns.*
  c) *To further consider mandatory criteria that would require the long-term storage of samples by ADOs linked to the level of competition an athlete competes in and the risk of the sport in which they participate. These samples in long term storage could be used for further analysis as scientific methods are enhanced or for DNA analysis to confirm the identity of an athlete's sample if required.*

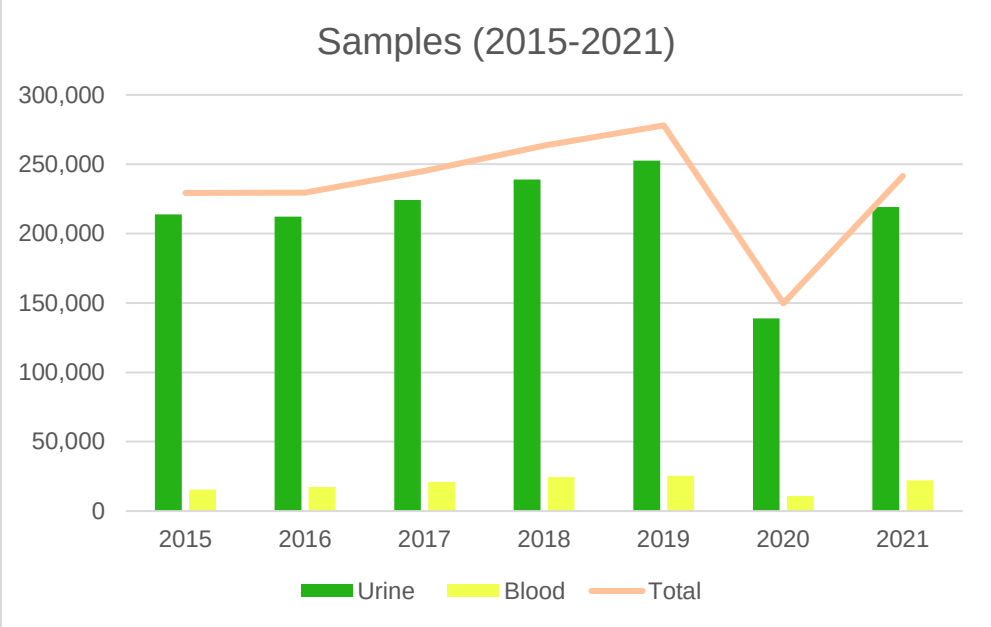
3. TDSSA

3.1 Implementation of and Compliance with the TDSSA

The EG reviewed the TDSSA data for the period 1 January 2015 – 30 June 2022 and identified trends of increasing ADO adoption and greater compliance with the TDSSA requirements since the introduction of WADA's compliance monitoring program. It was acknowledged that the majority of Tier 1 and Tier 2[2] National Anti-Doping Organizations (NADOs) and the applicable International Federations (IFs) have already incorporated the TDSSA requirements into their Test Distribution Plans (TDPs). WADA will continue to monitor ADO compliance with the TDSSA through its various compliance monitoring tools.

[2] Classification according to the International Standard for Code Compliance by Signatories Prioritization Policy.

Preliminary ADAMS testing data from the first part of 2022 shows similar testing activities to the year 2021 for the collection of urine and blood samples, and an increase for in-competition tests in comparison to the year 2021 due to the increased number of events in the first half of 2022.



A summary of TDSSA figures is outlined below for the period 1 January 2015 – 30 June 2022.

Erythropoietin Receptor Agonists (ERAs)

	# of Samples	# of Sports	# of TA[3]s	AAF[4]s
2022 (Jan-Jun)	26,096	101	205	18
2021	55,885	100	218	66
2020	37,792	102	197	32
2019	55,686	120	243	92
2018	52,747	118	229	77
2017	48,853	116	220	85
2016	46,710	108	212	66
2015	36,218	94	183	46

[3] Testing Authority
[4] Adverse Analytical Finding

Growth Hormone (GH)

	# of Samples	# of Sports	# of TAs	AAFs
2022 (Jan-Jun)	8,821	83	117	7
2021	19,453	85	130	5
2020	10,364	82	114	1
2019	24,183	103	150	5
2018	24,242	99	137	2
2017	20,482	90	124	0
2016	17,538	68	111	6
2015	13,264	74	103	4

Growth Hormone Releasing Factors (GHRFs)

	# of Samples	# of Sports	# of TAs	AAFs
2022 (Jan-Jun)	24,137	106	193	2
2021	56,639	104	221	11
2020	46,347	102	199	13
2019	66,990	126	234	26
2018	60,964	124	231	21
2017	57,869	119	218	19
2016	42,730	111	207	15
2015	21,654	88	145	14

3.2 Prohibited Substances in the TDSSA in 2023

The STEAG discussed the possibility to transition to mandatory testing of GHRFs in all urine samples; as a result such analysis would become part of standard analysis requested by ADOs instead of a TDSSA sport-specific requirement in the future. This would simplify the compliance with the TDSSA requirements and expand the number of analytes in the standard analysis in a urine sample, however, such transition should be at a low additional cost. The STEAG will liaise with ADOs and the WADA Laboratory Expert Group to explore if this option is feasible.

- ***Outcome/Recommendation No 3:*** *No new categories of specific analysis are proposed to be added to the TDSSA in 2023; however, the EG continues to monitor laboratory capacity and methodology developments. The possibility to add GHRFs analysis in the standard urine analysis will be explored further in the future.*

3.3 TDSSA Version 8.0

Following a request from the International Testing Agency (ITA), the cycling disciplines listed and in their respective MLAs are revised in the 2023 TDSSA version 8.0. The ITA submitted a proposal for these revised cycling disciplines and MLAs which was approved by the STEAG.

In addition, the TDSSA version 8 includes two disciplines (scooter and skate-cross) under the sport of roller sports (instead of skating), and revised disciplines for the sports of skiing and underwater sports. The three disciplines of the sport of para skiing have been moved to the non-IPC section of the TDSSA version 8 since the sport is now managed by the International Ski Federation instead of the International Paralympic Committee.

Finally, the TDSSA version 8 includes some minor improvements in its text to align it with the 2023 ISTI.

- ***Outcome/Recommendation No 4:*** *The revised TDSSA version 8 with a small number of minor amendments will be submitted for approval at the next WADA Executive Committee meeting on 23 September 2022. Upon approval, the final TDSSA v8 will be circulated to all stakeholders and is proposed to come into effect on 1 January 2023.*

4. Updates on new and existing Areas of Testing e.g. Dried Blood Spot, the Steroidal and the Endocrinological Module of the Athlete Biological Passport

4.1 Dried Blood Spot

Since the Technical Document TD2021DBS came into effect on 1 September 2021, more than 1700 dried blood spot samples have been collected by more than 10 ADOs. Dried blood spot testing is currently not mandatory for ADOs and laboratories, and the current scope of dried blood spot testing is restricted to the detection of non-threshold substances without Minimum Reporting Levels. As the DBS collaborative project is coming to an end, along with the terms of its DBS Steering Committee and Working Groups, WADA's Science department will be proposing a DBS Working Group that will focus on dried blood spot analysis. To complement this new group, the STEAG agreed to take on the responsibility of assisting with best practices on dried blood spot testing strategies. It was also suggested that a STEAG member participates in the new DBS Working Group to ensure effective cross-group communication and collaboration.

- ***Outcome/Recommendation No 5:*** *In case dried blood spot samples are collected in isolation (i.e., not in conjunction with a urine and/or a venous blood sample), they shall not be included in the calculation of the TDSSA MLAs. The STEAG will continue to monitor testing figures and the use of dried blood spot samples in relation to other types of samples. In addition, the STEAG will assist with the development of best practices on dried blood spot testing strategies and will liaise closely with the new DBS Working Group.*

4.2 Steroidal Module of the Athlete Biological Passport

WADA's ABP team provided an update on the new features of the Steroidal Module of the Athlete Biological Passport that will come into effect at the start of January 2023. The Steroidal Module will be applied not only on

urine samples but also venous blood samples (serum), the steroid Athlete Passport Management Unit (APMU) will manage both urine and blood steroid profiles and the Expert Panel will be the same for both sample types. This new method will not be mandatory to implement i.e., applied upon ADO's request and laboratory availability. It is anticipated that these new blood steroid markers will be particularly valuable in detecting abuse of testosterone and related compounds in females.

4.3 Endocrinological Module of the Athlete Biological Passport

The new features of the Endocrinological Module of the Athlete Biological Passport will also come into effect at the start of January 2023. This module will require a new APMU role and a new expert panel. Similarly, to the Steroidal Module of the Athlete Biological Passport for venous blood samples, this new method will also not be mandatory to implement i.e., upon ADO's request and laboratory availability. This new module aims to establish GH use through profiling of GH biomarkers over time, as well as to assist in targeting the GH isoform differential immunoassay on specific samples.

For both the Steroidal and Endocrinological Modules, the relevant International Standards and Technical Documents will be updated, Guidelines for steroid analysis in blood will be created, and a new update in ADAMS NextGen will be launched to facilitate these new features. These features will be discussed in more detail at the upcoming WADA ABP Symposium (12-14 October 2022, New Delhi) and more guidance will be provided via other channels (e.g., Q&As and webinars).

- ***Outcome/Recommendation No 6:*** *The STEAG will assist with the development of best practices on testing strategies for both the steroidal module (applied on venous blood samples) and the endocrinological module of the Athlete Biological Passport and will liaise closely with WADA's ABP team.*

We hope you find this update useful. Should you have any comments or questions regarding the above, please contact WADA at testing@wada-ama.org.

Thank you for your continued commitment to clean sport.

Yours sincerely,

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