WORLD ANTI-DOPING AGENCY
play true

SUPPORTING DOCUMENT B

FREQUENTLY ASKED QUESTIONS (FAQs) ON THE Technical Document for Sport Specific Analysis (TDSSA)[1]

General

1. What is the TDSSA?

The TDSSA is a tool that is intended to assist *Anti-Doping Organizations (ADOs)* in achieving more intelligent and effective *Testing* programs for sports/disciplines by requiring a minimum level of analysis for *Prohibited Substances* and/or *Prohibited Methods* that are not currently part of the standard routine urine analysis menu.

The TDSSA – is mandated by Article 5.4.1 of the 2015 *World Anti-Doping Code* (WADC2015) which all signatories approved - is intended to further protect the clean *Athletes* by ensuring that the *Prohibited Substances* and/or *Prohibited Methods* within the scope of the TDSSA and other tools that support the detection of *Prohibited Substances* and/or identify the *Use* of *Prohibited Methods* such as the *Athlete Biological Passport* are subject to an appropriate and more consistent level of analysis and adoption by all *ADOs* that conduct *Testing* on those sports/disciplines.

2. When did the TDSSA become effective?

The TDSSA came into effect on 1 January 2015.

3. To whom does the TDSSA apply?

The TDSSA applies to all ADOs that authorize the collection of *Samples*. This includes International Federations (IFs), *National Anti-Doping Organizations (NADOs)*, Regional Anti-Doping Organizations (RADOs) and *Major Event Organizations (MEOs)*.

4. Which *Prohibited Substances* are within the scope of the TDSSA?

- Erythropoiesis Stimulating Agents (ESAs) (e.g. recombinant erythropoietins and their analogues);
- Human Growth Hormone (GH) and;
- Growth Hormone Releasing Factors (GHRFs) including Growth Hormone Releasing Hormone (GHRH) and its analogues, Growth Hormone Secretagogues (GHS) and Growth Hormone Releasing Peptides (GHRPs).

5. What was the process by which the Minimum Levels of Analysis (MLAs) were developed?

A drafting group of experts was appointed by *WADA* to develop the TDSSA with science, Laboratory, exercise physiology and anti-doping backgrounds, covering a number of stakeholder groups.

[1] The FAQs on the TDSSA is a supporting document to assist ADOs with the implementation of the TDSSA. Where the interpretation of any text within the FAQ is in contradiction with the TDSSA, the TDSSA shall prevail.

The expert group undertook an extensive consultation process with the IFs of Olympic, IOC Recognized and Non-IOC Recognized sports and sports disciplines, and evaluated the *Prohibited Substances* and/or *Prohibited Methods* within the scope of the TDSSA from a physiological risk and ergogenic benefit perspective. *WADA* also consulted with other *ADOs* including *National Anti-Doping* Organizations (*NADOs*) and *Major Event Organizations (MEOs)*.

The MLA requirements contained in Appendix 1 and 2 of the TDSSA are listed as a percentage (%) of total eligible Tests in each specific analysis category. These MLAs are based on a Physiological Risk Assessment that considered physiological demand and non-physiological factors in each sport/discipline, as well as *WADA* accredited Laboratory analytical capacity for the *Prohibited Substances* and/or *Prohibited Methods,* analyses conducted historically by *ADOs* and a relative physiological and non-physiological comparison of sports/disciplines within similar categories.

The input of the *ADOs*, particularly IFs who have direct expertise in their sport, was critical in determining the assessments described above.

6. Were factors other than physiological and non-physiological demand – such as financial gain, sport culture in a country, country performance, intelligence or gender considered when establishing the MLAs?

No, these factors should be considered by each *ADO* as part of the wider Risk Assessment that *ADO*s must conduct in accordance with Article 4.2 of the *International Standard* for *Testing* and *Investigations* (ISTI), which is an important step in the development of their Test Distribution Plan (TDP).

7. Is there a guideline to assist *ADOs* in conducting a Risk Assessment and to optimize the effectiveness of their *Testing* programs?

Yes. *WADA* developed a document titled "*Guidelines for Implementing an Effective Testing Program"* to assist *ADO*s with conducting the overall Risk Assessment and elements of their TDP. The Guideline focuses on the development of 'smart' *Testing* programs based on a more qualitative approach rather than strictly a quantitative one.

WADA prepared a Risk Assessment template which is available to ADOs since February 2017.

8. Is *WADA* monitoring *ADO* compliance with the TDSSA?

Yes, monitoring compliance with the TDSSA requirements began on 1 January 2016.

9. Is the TDSSA implementation part of the overall Code compliance process? If so, how will compliance with the TDSSA be monitored?

Yes. The TDSSA will be monitored and evaluated through *ADAMS.* A wider evaluation of ADOs' compliance with the TDSSA is being addressed through WADA's compliance and monitoring program and includes the review of the methods the *ADOs* applied to the implementation of the *Tests* to meet the MLAs as outlined in the ISTI Article 4.

10. How should the cost implications of the TDSSA be managed?

For those *ADOs* whose TDPs already exceed the MLAs, there will be no impact on their programs and they should continue with their current levels of analyses and not reduce them.

Those *ADOs* that are not currently conducting the required MLAs will need to review how they can optimize the use of existing resources within their anti-doping program or seek additional funding from their funding bodies.

Where additional funding is not available or the redistribution of resources/programs within an *ADO* is not possible, a reduction in Test numbers by the *ADO* may occur in order to reach the MLA. However, it should not reduce the Test numbers to a level where a program becomes ineffective.

11. What are the intended benefits of the TDSSA?

The TDSSA is intended to contribute to:

- Greater protection of the rights of clean *Athletes* within a sport/discipline through an increase in the level of analysis for *Prohibited Substances* and/or *Prohibited Methods* within the scope of the TDSSA and other tools that support the detection of *Prohibited Substances* and/or identify the Use of *Prohibited Methods* such as the *Athlete Biological Passport*, which enhances the risk of detection.

- Increased levels of deterrence from a greater range of sports/disciplines and *Athletes* being tested for *Prohibited Substances* and/or *Prohibited Methods* within the scope of the TDSSA and other tools that support the detection of Prohibited Substances and/or identify the Use of *Prohibited Method*s such as the *Athlete Biological Passport*.

- Increase the level of data sharing and use of intelligence in order to conduct more effective targeting of the population of A*thletes* to be tested for *Prohibited Substances* and/or *Prohibited Methods* within the scope of the TDSSA and other tools that support the detection of *Prohibited Substances* and/or identify the Use of *Prohibited Methods* such as the *Athlete Biological Passport*.

- An increase in the analytical capacity of Laboratories to implement and validate the methods to detect the TDSSA *Prohibited Substances* and/or *Prohibited Methods*.

12. What messages can *ADOs* take to their funding bodies when seeking additional resources to implement the requirements of the TDSSA?

- The TDSSA is a tool that provides greater protection to the clean *Athletes* by ensuring that the prohibited substances within its scope, which are not part of the standard routine urine analysis menu, are subject to an appropriate and consistent level of analysis.

- The TDSSA implementation will increase the deterrence effect.

- Article 23.3 of the WADC2015 (Implementation of Anti-Doping Programs) states:
  "Signatories shall devote sufficient resources in order to implement anti-doping programs in all areas that are compliant with the Code and the International Standards".

- The TDSSA is a mandatory level-two document of the WADC2015 that signatories are required to implement.

- The TDSSA will be part of *WADA*'s measurement of *ADO*s' Code compliance.

Implementing the TDSSA and Test Planning for NADOs and IFs

13. Which *Athletes* are subject to the TDSSA?

The TDSSA only applies to *National-Level* and *International-Level Athletes*, as defined by *NADOs* and IFs in their Anti-Doping Rules. *ADO*s may conduct additional analysis on other *Athletes* at any time but such Tests will not be counted towards achieving the required MLAs of the TDSSA. Further information on the definition of an *Athlete* can be found in the WADC2015 definitions and Article 4.3 of the *ISTI*.

14. Does an *Athlete* need to know what level of *Athlete* they are at the time of a Test?

No. The *Testing* Authority who authorized or requested the Test is responsible for putting in place a system to record the level of *Athlete* being Tested; as defined by the IF or NADO. This may be, in *ADAMS* or by other means.

If the Test is authorized by a NADO and conducted on an *Athlete* within the NADO's definition of *National-Level Athlete,* then the level of the *Athlete* should be "national". If the IF authorizes the Test on an *Athlete* within the IF's definition of *International-Level Athlete* and requests a NADO or other *Sample* collection service provider to conduct a Test on its behalf, then the *Athlete* should be recorded as "international". Tests conducted on *Athletes* outside of the IF's or NADO's definition of *Athlete* should be recorded as "other".

The level of *Athlete* does not prevent any *Athlete* being tested for all *Prohibited Substances* and/or Prohibited Methods on the *Prohibited List* at any time by any ADO that has jurisdiction to do so.

15. If an *Athlete* is subject to *Testing* by multiple *ADO*s, which *ADO* receives credit for the MLA?

In some situations, an *Athlete* may be subject to *Testing* under the authority of his or her IF, NADO or an *MEO*. Any MLA analyses conducted on an *Athlete* are counted towards meeting the MLA requirements based on who the *Testing* Authority was that requested the Test.

16. How should specific analysis of tests collected under the TDSSA be allocated between *Athletes*?

*ADO*s should make this decision as part of their risk assessment, TDP management and through utilizing available information (intelligence).

17. Should *NADOs* apply the MLAs in each sport that is listed separately on the TDSSA or only in those sports and disciplines that are part of the NADO's TDP?

The TDSSA is a sport/discipline specific document that relates to *International-Level* and *National-Level Athletes*. *NADOs* must comply on an individual basis with the TDSSA for every sport or discipline within their jurisdiction in which they plan to test as part of their TDP.

18. How should an *ADO* calculate the MLAs and apply them to its TDP?

A Test shall be the basis of the calculation of the MLA. One Test includes any number and type of *Samples* that may be collected from one *Athlete* during a *Sample* Collection Session.

Once an *ADO* has applied the number of Tests to a sport/discipline following its Risk Assessment, it then applies the MLA percentages to those Tests. Multiple analyses can be conducted on one *Sample*, whether it be blood or urine collected during one *Sample* Collection Session. The *Athletes* and *Samples* to which those analyses are applied are at the *ADO*'s discretion.

As an example, if an *ADO* plans to conduct 100 Tests in a sport or discipline and the MLAs are 60% for ESAs, 10% for GH and 10% for GHRFs, the minimum number of analyses an *ADO* should conduct is as follows:

- 60 ESAs analyses to be conducted in either urine or blood
- 10 GH analysis in blood (serum) and
- 10 GHRFs analysis in urine

*ADO*s can request multiple analyses on *Samples* collected during the same *Sample* Collection Session. In this example the absolute minimum number of *Sample* Collection Sessions or Tests could be 60. This is on the basis that GH and GHRFs analyses are performed on those *Athletes* who are also being tested for ESAs.

The remaining 40 Tests from the 100 Tests would then be subject to either the standard routine urine analysis or a greater level of analysis, which ADOs are encouraged to do.

The application of these analyses to *Athletes* subject to the TDSSA should be based on intelligence and identified risk factors particular to each *Athletes*' circumstances.

19. What should an *ADO* do if a sport or discipline, which has been allocated a small number of Tests has a MLA that results in the required number of analyses under the TDSSA being less than one?

In this situation, the *ADO* shall conduct a greater level of analysis than the calculation the TDSSA prescribes, which at a minimum should be one analysis. As an example, if a sport discipline is required to conduct 0.5 of an ESAs analysis because the actual number of Tests is 5 and the ESAs MLA is 10%, then the *ADO* will be required to conduct a minimum of 1 ESAs analysis.

In circumstances where the *ADO* has intelligence that the "1" analysis would be more effective if applied to a sport/discipline/*Athlete* of higher risk in their TDP, the *ADO* may transfer the "1" analysis from the lower risk sport/discipline to a higher risk sport/discipline.

20. What should an *ADO* do, if the MLA calculation of a sport or discipline results in a portion of a type of analysis e.g. 4.2?

Any portion of a type of analysis shall be required to be rounded up to the nearest whole analysis for calculation purposes. This situation will also be applicable to a number of *ADO*s who implement small *Testing* programs for a particular sport or discipline.

21. What sport /discipline should be applied to the Doping Control Form (DCF) for *Out-of-Competition Samples* collected from an *Athlete* who competes in a broad range of sport disciplines?

The *Athlete*'s discipline should be recorded as the one that has the highest MLA percentage.

22. If an *Athlete* competes in more than one discipline (as listed in the TDSSA) at an event, what MLA applies if they are different?

The discipline in which the *Athlete* competed and was selected for *Testing* should be the discipline to which the MLA applies.

23. Is it important that an *ADO* records the discipline of a sport on the DCF?

Yes. An *ADO*'s DCF must contain the discipline of a sport on the Laboratory copy of the DCF so that the Laboratory can assign a discipline to the sport when reporting the results and type of analysis. If the discipline is not provided, then the analysis statistics by sport and discipline will not be accurate for that *ADO*, which will affect the evaluation of the *ADO*'s implementation of the TDSSA.

ADOs that sub-contract out their *Sample* collection services should ensure that the *Sample* Collection Authority is made aware of these requirements.

24. Is it mandatory that an *ADO* record the level of *Athlete* on the *Doping Control* Form?

No. However, it is recommended that *ADOs* develop a system or utilize ADAMS to record the level of *Athlete,* for the purpose of monitoring their TDP progress and their compliance with the application of the MLAs to those defined *Athletes* only.

25. What if a sport does not have a discipline listed in the TDSSA?

Where the sport and discipline are listed the same in the TDSSA (e.g. Weightlifting/Weightlifting), they should be recorded in *ADAMS* and on the DCF this way.

26. Where a sport has the discipline listed as "All" in the TDSSA, how should the *ADO* apply the MLAs to the disciplines of that sport and how should the disciplines be listed in *ADAMS* and on the DCF?

In this case, the *ADO* has the discretion to distribute the MLAs across the disciplines of the sport equally or to those disciplines the *ADO* identifies as having the higher risk(s) to those *Prohibited Substances* and/or *Prohibited Methods* within the scope of the TDSSA. The actual discipline of the sport being tested should be recorded on the DCF and *ADAMS.*

27. How should *ADO*s advise the Laboratories of the type of analysis they require on a *Sample*?

*ADO*s must ensure that the type(s) of analysis required for each *Sample* is recorded at a minimum on the chain of custody documentation (or equivalent) shipped with the *Samples* to the Laboratory or via another system that the *ADO* has agreed with the Laboratory. This requires that clear instructions are provided to the *Doping Control Officer* who is authorized to collect the *Sample*(s).

In certain situations, an *ADO* may request further analysis of a *Sample* following the results of another *Sample* collected at the same or an earlier time. As an example, an *ADO* may collect an *ABP* blood *Sample* at the same time as a urine *Sample* and following the review of the profiles in the *ABP Sample* may request ESA analysis on the urine *Sample.* In such circumstances the *ADO* would have to notify the Laboratory of this request for further analysis (which may be by email). *ADOs* are reminded that *Samples* are routinely stored by Laboratories for a maximum of three

months in accordance with the requirements of the *International Standard* for Laboratories. Any further storage of samples must be negotiated with the applicable Laboratory and should be considered as part of an *ADO*s overall TDP strategy in term of what criteria should trigger the long-term storage of such samples.

As per the ISTI the type of analysis shall not to be recorded on the DCF.

28. How has *ADAMS* been modified to assist *ADO*s with the implementation of the TDSSA and to report accurate statistics so *ADO*s and *WADA* can monitor the implementation of the TDSSA?

WADA has made the following changes to *ADAMS* to support the implementation of the TDSSA.

- The disciplines of the sports listed in the TDSSA.
- The ability to record the level of *Athlete.*

In addition *WADA* has developed and published the **Reporting Guide to Monitor Testing** to assist *ADO*s in the monitoring of their TDSSA programs. All ADOs are encouraged to use this new Reporting Guide which can be found on WADA's website.

In early 2019, *ADAMS* will include a revised module, which will monitor the implementation of the TDSSA MLAs automatically.

29. In the case where an *ADO* collects *Samples* as a service provider for another *ADO*, which *ADO* is accountable for meeting the MLAs?

In such situations, the organization requesting the Tests, known as the *Testing* Authority, is responsible for ensuring it is meeting the required TDSSA MLAs.

Any such plans by the TA to conduct analyses under the TDSSA should be clearly outlined within a *Testing* service agreement. This situation also applies where a NADO who is the service provider wishes to conduct additional analysis on *Samples* (at its own cost) that it collects on behalf of an IF or *MEO* under Article 5.2.6 of the WADC2015. In such cases, if the sport/discipline contains MLAs in the TDSSA, the IF or *MEO* (as the TA) would receive credit for such analyses towards meeting their individual MLA requirements.

30. What if an *ADO* exceeds the MLAs?

The MLAs are minimums. *ADO*s are encouraged to exceed those minimums if their Risk Assessment or any other relevant information indicates they should do so.

31. Could the TDSSA lead to some *ADO*s just meeting the minimum percentages and not applying the Tests effectively?

The implementation of the TDSSA and meeting the MLAs is one part of achieving an effective *Testing* program. Whilst the decision of which *Athletes* are selected and the timing of such Tests is at the discretion of the *ADOs*, it is important that the decision-making process applied to such Tests is effective in deterring and detecting doping.

A wider evaluation of an *ADO*s compliance with the TDSSA will be addressed through *WADA*'s compliance and monitoring program and will include the review of the methods the *ADOs* applied to the implementation of the *Tests* to meet the MLAs as outlined in the ISTI.

32. How should *MEOs* implement the TDSSA for multi-sports events?

The priorities for *MEOs* when implementing the TDSSA into multi-sport events should be the incorporation of the MLA requirements into the TDP as early as possible. In doing so, the *MEO* should apply the majority of the MLAs in the *Out-of-Competition* period leading into the *Event* (this may include where the *MEO* has extended *Event* jurisdiction) and/or immediately upon arrival of *Athletes* within the country hosting the *Event* and prior to the competition starting. *MEOs* should attempt to obtain test history on high risk sports and disciplines from *NADOs* and IFs in advance of the *Event* so the application of TDSSA MLAs can be better targeted. It is also important that analysis for TDSSA MLAs is planned and targeted during the *In-Competition* period as well.

Implementation of an *ABP* haematological module

33. Is the *Athlete Biological Passport (ABP)* haematological module subject to the TDSSA?

The TDSSA is intended to ensure that the tools that support the detection of *Prohibited Substances* and/or identify the *Use* of *Prohibited Methods* such as the Athlete Biological Passport are subject to an appropriate level of analysis and adoption by all ADOs that conduct Testing in those sports/disciplines deemed at risk.

To further protect clean Athletes and enhance the global effectiveness of Testing programs, effective 1 January 2019 the implementation of an *ABP* haematological module for sports and disciplines with an ESAs MLA equal to or greater than 30% will be a mandatory component of compliance with the TDSSA.

As outlined in the TDSSA, it is strongly recommended that any sport or discipline with an ESAs MLA of 15% implements the *ABP* haematological module. Those sports or disciplines with an ESA MLA of 10% are encouraged to consider the benefits of implementing the *ABP* haematological module. When implementing the ABP haematological module for sports/disciplines with an ESAs MLA of 15% or less, ADOs are encouraged to apply the criteria as outlined in TDSSA Article 3.3.

Implementation of the *ABP* haematological module also enables *ADOs* to seek a reduction in the MLA percentage for ESAs of up to 50%, subject to meeting the criteria outlined in Article 6 of the TDSSA.

WADA will provide the necessary support required to *ADO*s in establishing *ABP* programs.

34. How does an ADO setup an *ABP* haematological module?

In order to setup an *ABP* haematological module, the mandatory aspects of its implementation are detailed in Annex K and L of the ISTI, and the Technical Document for Athlete Passport Management Units (TD2019APMU). For an *ADO* these elements include:

- Ensuring the collection and transportation of *ABP* blood *Samples* is carried out in accordance with Annex K of the ISTI.
- Appointing an APMU to manage the passport review process on behalf of the *ADO*. Starting from 1 January 2020, the use of a WADA approved APMU will become mandatory.

- Consulting with the APMU to establish a list of Experts who are qualified to comprise an Expert panel for the review of Passports according to section 6.0 of the TD2019APMU.

For further information on how to set up the implementation of an *ABP* haematological module, please contact athletepassport@wada-ama.org

35. Which are the new mandatory criteria for the implementation of an *ABP* haematological module, in order for it to comply with the TDSSA?

The implementation of the *ABP* haematological module shall include the following mandatory criteria;

- Apply to all *Athletes* from those sports/disciplines with an ESAs MLA of 30% or greater (as identified in the TDSSA) that are referenced in an *ADO's* TDP, and are part of the *ADO's* Registered Testing Pool (RTP);

- The program shall be compliant with all applicable *ABP* Technical Documents and International Standards, including the ISTI and TD2019APMU;

- At a minimum, an average of three blood ABP Tests shall be planned annually across all *Athletes* from those sports/disciplines with an ESAs MLA of 30% or greater who are part of the RTP of an *ADO* and therefore part of the *ADO's ABP* haematological module program; and

- The distribution of these Tests shall be carried out according to the status of the Athlete's Passport, as well as any intelligence the *ADO* may have access to and the recommendations of the APMU, so that *Athletes* with atypical/suspicious passports receive more Tests than those with normal passports.

ADOs will be required to report the details of their RTP to WADA through ADAMS.

36. When do these criteria come into effect?

These criteria will come into effect on 1 January 2019.

37. If I have 100 *Athletes* in my RTP, of which 25 are from sports/disciplines with an ESAs MLA of 30% or greater, how many *ABP* blood tests shall I conduct to comply with the mandatory criteria?

The *ADO* should plan on a minimum of 75 blood *ABP* tests for these 25 *Athletes*.

38. Our *ADO* includes *Athletes* from sports/disciplines with an ESAs MLA of 30% or greater in the RTP for deterrence purposes but cannot afford to test them three times. What shall we do?

The provision of whereabouts information by the *Athlete* is considered to be proportionate when this information is being used to direct appropriate levels of testing. Thus, the inclusion of *Athletes* in an RTP for deterrence purposes, where there is no intention to appropriately test the *Athlete*, is not recommended.

39. If an A*thlete* is in both an IF's and NADO's RTP how should we plan to meet the minimum number of ABP blood tests for *Athletes* in a sport or discipline with an ESAs MLA of 30% or greater?

ADOs are encouraged to collaborate on testing programs for *Athletes* that they have joint jurisdiction over to ensure they are conducted effectively. As per the minimum number of planned OOC tests for RTP *Athletes* can be shared between *ADOs*, the same principle applies to *ABP* blood tests.

Where *ADOs* collaborate and share *ABP* blood testing on the same RTP *Athlete*, the *ADO* should re-allocate testing resources for *ABP* blood testing by 1) increasing testing on *Athletes* with atypical/suspicious passports, 2) adding additional *Athletes* to the RTP from sports/disciplines with an ESA MLA of 30% or greater or 3) expanding *ABP* blood testing on other *Athletes*.

Upon WADA's request, ADOs should be in a position to provide justification on why the minimum level of *ABP* blood tests was not met.

40. If urine *Samples* are collected from a non-RTP *Athlete* in a sport or discipline with an ESAs MLA of 30% or greater, do *ABP* blood *Samples* need be collected from the same *Athlete*?

No, there is no requirement for ABP blood tests on non-RTP athletes in a sport or discipline with an ESAs MLA of 30% or greater. However, ADOs are encouraged to expand their pool of RTP athletes in these sports or disciplines.

41. When implementing an ESAs analysis program that is supported by an *ABP* haematological module, should any Target Tests be based solely on the review of blood profiles by an APMU?

An APMU plays a key role in reviewing blood profiles and guiding the *ADO* when *Target Testing* should be conducted. This is one reason why a reduction in ESA MLAs is available for those *ADOs* that are implementing an effective *ABP* program. However, there may be times when the *Athlete's* passport does not clearly reflect blood manipulation and therefore the *ADO* should also rely on other intelligence and risk factors to guide them with the targeting for ESAs.

42. When collecting an *ABP* haematological *Sample* should the *ADO* also collect a urine *Sample* during the same *Sample* Collection Session?

Yes, an *ADO* should collect a urine *Sample* during the same *Sample* Collection Session to enable the analysis of ESAs should the *Athlete's* passport be atypical. The benefit of collecting a urine *Sample* with an *ABP* haematological *Sample* is that if the *ABP Sample* is atypical an ESAs analysis can then be requested on the urine *Sample.* This is a much more efficient use of resources and intelligence. If there is no urine *Sample* to analyse, the window of opportunity to detect ESAs may be lost due to the time required to collect a follow up urine *Sample*.

43. What are the obligations of *MEOs* with regards to the implementation of an ABP haematological module on sports/disciplines with an ESAs MLA equal to 30% or greater?

Ideally, MEOs should collaborate with the respective IFs (as the passport custodian) for the sports/disciplines with an ESAs MLA equal to 30% or greater in advance of the Major Event to

determine whether the IF requires any *ABP* blood *Samples* to be collected on its *Athletes* who are participating in the Major Event. As *MEOs* cannot be passport custodians of *Athletes*, they should discuss, with the respective IFs in advance of the Major Event, to determine the number of *ABP* blood *Samples*, or the *Athletes* to be targeted, etc. related to the *ABP* haematological module. During the Major Event, the IF's APMU should review sample profiles and provide real time feedback on tests conducted by the MEO such as any follow up test recommendations or ESA analysis on blood or urine *Samples* taken. This information should be provided to the *MEO* through the IF. The *MEO* should take these recommendations into consideration when applying their TDP.

Application for a TDSSA reduction

44. Can the MLAs be reduced and, if so, what is the process for obtaining a reduction?

Yes, in accordance with Article 6.4.2 of the WADC2015, an *ADO* can apply to *WADA* for a reduction in the MLAs contained in the TDSSA. Further information on the criteria is located in Article 6 of the TDSSA. The application form can be found in Supporting Document A.

45. What criteria must be met in accordance with Article 6.4.2 of the WADC2015 in order to qualify for a reduction in MLAs?

WADA will consider a request for a reduction in MLAs by an *ADO* where such reduction would lead to a more intelligent *Testing* program than compliance with the prescribed MLAs alone. For example, the implementation of the haematological module of the *ABP* within the specific sport / discipline for which a reduction is being sought is considered a justifiable criterion for possible reduction given that it has the potential to be a more intelligent basis for directing ESAs.

An *ADO* may present a case for possible reduction based on other particular circumstances provided that the *ADO* demonstrates how the reduction of the MLA can support a more intelligent, effective and efficient use of available *Testing* resources. This includes but is not limited to: target testing based on recommendations from an APMU, the gathering and use of intelligence to inform *Testing* and conduct investigations, the sharing of *Testing* information with other *ADOs* or other sport specific, intelligent or innovative anti-doping strategies.

46. Does a robust and effective *ABP* haematological program of an *ADO* result in an automatic reduction of the ESAs MLAs?

No. *WADA* recognizes that the *ABP* haematological program is an important tool in implementing effective *Testing* programs for certain sports/disciplines. The TDSSA Expert Group considered whether a reduction of up to 50% in ESAs MLAs, which ADOs can apply for on the basis that they are implementing an effective *ABP* haematological program, should be automatic. It was agreed that ADOs must still apply for a reduction to the ESAs MLAs in accordance with Section 6 of the TDSSA and using Supporting Document A before such a reduction is approved by WADA. The application form process has been streamlined and is contained within Supporting Document A of the TDSSA.

***Prohibited Substances* within the scope of the TDSSA & *WADA* Accredited Laboratories**

47. Will GH and GHRFs have their own MLAs?

GH and GHRFs were originally combined together due to a lack of laboratory capacity to analyze for GHRFs which are detectable in urine (GH is only detectable in blood) at the time of developing the TDSSA back in 2014.

Combining GH and GHRFs into one MLA meant that a signatory could share the analysis of both these substances or do them all for one substance to meet the required MLAs. Effectively, ADOs could comply with the requirement without collecting and analyzing blood. While cost effective, this approach is limited in its effectiveness. The TDSSA Expert Group did however make a recommendation that it the analysis for GH/GHRFs be spread 50/50 recognizing the analytical limitations at the time.

The 2016 data showed that 75% of the analysis conducted was for GHRFs and 25% for GH.

The capacity of laboratories to analyze for GHRFs has increased significantly since the inception of the TDSSA and all WADA accredited laboratories have the GHRF method validated to conduct this analysis.

Since 1 January 2017, GH and GHRFs are subject to separate MLAs. The MLAs for GH and GHRFs are each the same as the combined GH/GHRF MLA that was previously attributed to the sport/discipline. For example, if the GH/GHRF combined MLA was 10% then it now becomes 10% for GH and 10% for GHRFs.

While the GHRFs MLAs are mandatory since 1 January 2017, compliance with the GH MLAs will be postponed until the endocrine module of the *ABP* is ready for implementation. *ADOs* are encouraged to continue to collect Samples for GH and attempt to meet the GH MLAs during this period.

48. Should *ADO*s stop testing for GH in 2019?

No. ADOs are strongly encouraged to continue their best efforts to conduct GH testing and meet the existing GH MLAs for those sports/disciplines listed in the TDSSA.

In situations where *Samples* are reported as atypical for GH, and/or where investigations indicate reliable intelligence on possible GH abuse, *ADOs* should target test the *Athlete* for GH analysis. In addition, *ADOs* are strongly encouraged to store the samples for future analysis and/or re-analysis when further technological advancements for GH analysis are available.

49. What are the analysis methods for GH?

There are two complementary methods for GH analysis: The Isoforms Differential Immunoassays (the GH Isoforms method) and the GH Biomarkers method.

The GH Isoforms method has been applied since the Athens Olympic Games 2004, commercial test kits have been available since 2008 and the method is now available at all WADA accredited Laboratories.

The second method (GH Biomarkers) was initially implemented during the 2012 London Olympic and Paralympic Games. Following the withdrawal from the market of one of its assays, the method had to undergo a process of re-validation of new component assays. The assays were revalidated in 2015 and the method is available in a number of accredited Laboratories.

These two GH analytical methods are complementary in nature: while the GH Isoforms method detects GH doping up to 24-48h after administration, the GH Biomarkers method, which measures changes in concentration levels of two main markers of GH biological action, namely IGF-1 and P-III-NP, may not detect GH in the initial phase of use but does at later times and for a longer period that the GH Isoforms method.

It is recommended that *ADO*s conduct both analytical methods when *Testing* for GH as they provide a greater ability to detect GH when applied together.

One analysis towards the minimum level requirement shall be counted irrespective of whether the GH Isoforms and/or the GH Biomarkers method is conducted on a blood *Sample* collected during a *Sample* Collection Session on an Athlete.

50. What is the permitted shipping time to a *WADA* accredited Laboratory for a blood *Sample* that will be analyzed for GH?

The *WADA* Technical Document – TD2015GH outlines that a blood *Sample* should be analyzed with the GH Isoforms method *at a WADA* accredited Laboratory within a maximum of 4 days from *Sample* collection. The equivalent period for a blood *Sample*, which will be analyzed with the GH Biomarkers method, is a maximum of 5 days.

51. What is the permitted shipping time to a WADA accredited Laboratory for an ABP blood Sample?

WADA has developed a Blood Stability Score (BSS) which can increase the shipping time of a blood ABP *Sample* to the Laboratory from 36h up to 60h based on the *Sample* being shipped in constant cooled conditions.

The integrity of the *Markers* used in the haematological module of the *ABP* is guaranteed when the Blood Stability Score (BSS) remains below 85, where the BSS is computed as

BSS = 3 * T + CAT

with CAT being the Collection to Analysis Time (in hours), and T the average Temperature (in degrees Celsius) measured by the data logger between *Sample* collection and analysis.
Within the framework of the BSS, the following table can be used by the DCO/BCO to estimate the maximal transport time to a Laboratory or WADA-Approved Laboratory for the ABP, called the Collection to Reception Time (CRT), for a given average temperature T:

T [°C]	CRT [h]
15	35
12	41
10	46
9	48
8	50
7	53
6	55
5	58
4	60

The DCO/BCO apply a conservative approach and rapidly transport the *Sample* to a Laboratory or WADA-Approved Laboratory for the ABP located close to the *Sample* collection site.

52. What are the different categories of GHRFs?

Growth hormone-releasing factors (GHRFs) are categorized into three different groups within the WADA Prohibited List including:

- Natural Growth Hormone-Releasing Hormone (GHRH), its peptides and nonpeptidyl analogs;
- Growth Hormone Secretagogues (GHS); and
- Synthetic Growth Hormone Releasing Peptides (GHRPs)

53. Will the TDSSA have a direct impact on *WADA* accredited Laboratories' capacity to analyze for those *Prohibited Substances* within the scope of the TDSSA?

All *WADA* accredited Laboratories can analyze for ESAs and GHRFs (GHS/GHRP – small peptides) in urine, and GH (isoforms method) in blood serum. A number of Laboratories can also analyze for GH using the biomarkers method and for GHRFs (GHRH – large peptides).

Where applicable, *WADA* will identify and encourage the expansion of the necessary capacity within those Laboratories where particular analytical methods are deemed a priority for surrounding regions to implement the TDSSA, and in doing so, attempt to minimize shipping time and costs.

54. How does an *ADO* know which *WADA* accredited Laboratory can test for the *Prohibited Substances* on the TDSSA?

As part of the 2015 *International Standard* for Laboratories (ISL), it is a requirement for Laboratories to publish the capacity and costs associated with their *Sample* analysis services. From 1 January 2015, *ADO*s are able to identify those *Prohibited Substances* or classes of *Prohibited Substances* that each Laboratory can analyze within *ADAMS*.
This information is only accessible to *ADO*s that have an *ADAMS* user agreement in place and is password-protected.

55. The TDSSA outlines that ESAs can be analyzed in urine or blood. Does this mean that an *ADO* has to collect a blood and urine *Sample* each time to conduct ESAs *Testing* or can an ADO decide for either blood or urine (and sometimes both)?

The *ADO* has the choice as to whether it wishes to analyze ESAs in either urine or blood. However, it is noted that the detection method for CERA is more effective in blood than urine. When Laboratories analyze for CERA in blood serum or plasma, they will also be applying methods, such as IEF-PAGE or SAR-PAGE, capable of detecting other ESAs in addition to CERA (recombinant EPOs, NESP, etc.).

One analysis towards the minimum level requirement shall be counted irrespective of whether a single or multiple ESAs analysis is conducted on a urine and/or blood *Sample* collected during a *Sample* Collection Session on the same *Athlete*.

56. What should an *ADO* do if they don't have the capacity i.e. *BCOs* to collect blood *Samples* or if they are unable to ship blood *Samples* to the nearest Laboratory within the required

shipping times due to distance or issues with the export or import into a country that hosts a WADA-accredited Laboratory of blood *Samples*?

If the *ADO* does not have trained Sample Collection Personnel to conduct blood testing, the *ADO* should put the necessary measures in place (recruitment of *BCOs*, training, etc.) to comply with the collection and analysis of blood *Samples* for GH MLAs and *ABP* as soon as possible.

If the *ADO* is unable to ship blood *Samples* to the nearest Laboratory within the required shipping times due to distance or issues with export or import into the country that hosts a WADA-accredited Laboratory of blood S*amples*, the ADO should contact *WADA* immediately and explain the particular circumstances on the matter. WADA will consider such situations to address the lack of blood collection capacity as part of its global strategy.

57. The original scope of the TDSSA included Haemoglobin Based Oxygen Carriers (HBOCs), Homologous Blood Transfusion (HBT) and Insulins. Why are these not included in the TDSSA?

HBOCs and HBT should be tested on a discretionary but targeted basis applying analytical knowledge gained from the implementation of an effective *ABP* program and non-analytical intelligence. On the basis of the relative performance benefit, as well as detection efficacy and health risks of these methods, they were removed from the scope of the TDSSA. This decision remains subject to review. However, this should not prevent any *ADO* to order such *Testing* based on experience and/or intelligence-based targeting.

Insulins have been known to be used in conjunction with other *Prohibited Substances* such as ESAs and GH and so *Testing* is recommended for those sports and disciplines that are at a high risk to both these *Prohibited Substances.*

HBOCs, HBT and Insulins all remain on the *Prohibited List* and are prohibited in all sports and disciplines.

58. Which *Samples* should be analyzed for HBOCs and HBT?

- HBOCs: any blood *Sample* collected (either for the *ABP* or for the detection of *Prohibited Substances* and/or *Methods* when an A and B *Sample* is collected) which shows plasma red coloration beyond reasonable hemolysis after centrifugation or sedimentation;
- HBT: any blood *Sample* collected (either for the *ABP* or for the detection of *Prohibited Substances* and/or *Methods* when an A and B *Sample* is collected) which shows a sudden increase of haemoglobin and/or reduction of the percentage of reticulocytes, or if there is a suspicion based on a high phthalates measurement.

59. Will any *Prohibited Substances* or *Prohibited Methods* that are included in the *WADA Prohibited List* be added to the TDSSA in the future or will these new *Prohibited Substances* or *Prohibited Methods* be part of the standard routine urine analysis?

Any *Prohibited Substance* or *Prohibited Method* that is added to the *Prohibited List* and has an approved analytical method may be subject to inclusion on the TDSSA as part of its ongoing review and development (if their analysis is not included in the standard routine urine analysis).

Note: *ADOs are encouraged to provide WADA with any further questions they may have on the TDSSA or its implementation.*