

# DRIED BLOOD SPOT (DBS) TECHNICAL WORKING GROUP

## Terms of Reference

The WADA Dried Blood Spot (DBS) Technical Working Group [DBS WG] is a specific Working Group<sup>1</sup> created by the WADA Science & Medicine Department.

*These Terms of Reference (ToR) are approved by the WADA Director General, following consultation with the Senior Director, Science & Medicine.*

### **Background**

Since 2019, WADA has been leading a Collaborative Project with Anti-Doping Organizations (ADOs) and WADA-accredited Laboratories to develop DBS testing and to address some of its technical challenges. This collaboration led to the development of the Technical Document on DBS for Doping Control (TD2021DBS), which came into effect on 1 September 2021 and provides ADOs and Laboratories with specific requirements and procedures for DBS sample collection, transport, analysis and storage. This initial version of the TD DBS, and the revised TD2023DBS, specifically covers some requirements for Analytical Testing Procedures to be applied on DBS Samples for the detection of Non-Threshold Substances without Minimum Reporting Levels (MRL) only.

### **Purpose**

The purpose of this new DBS WG is to build on the work done within the frame of the DBS Collaborative Project for a wider and harmonized implementation of DBS testing in WADA-accredited Laboratories, and to provide expert advice, recommendations, and guidance to WADA Management with regards to the further development of DBS analysis. More specifically, the DBS WG will deliver recommendations on pre-analytical (e.g., equipment required) and analytical conditions, as well as minimum required laboratory performance and reporting criteria, in order to expand DBS analysis to a wider selection of prohibited substances and prohibited methods, including Non-Threshold Substances with MRL and the quantitative analysis of Threshold Substances.

It is forecast that the DBS WG will complete its mandate within a three-year period (i.e., from January 2024 to December 2026). It will deliver recommendations to WADA periodically during this timeframe. The necessary meeting timelines will be framed with this in mind.

There may be future work for this DBS WG, and it will be evaluated at the end of this current period.

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<sup>1</sup> WGs are created on an as-needed basis only, and generally with a defined mandate requiring deliverables within a set timeframe. Where the expected deliverables are not met, an extension of mandate is possible, however it is not expected that WGs continue indefinitely. If it is considered that their work should be ongoing in nature, whether WG should be elevated to an Expert Advisory Group would need to be determined.

## **Objectives/Key Activities**

The tasks of the DBS WG may include, but are not limited to:

- 1) Review the literature and other available information, including information from anti-doping laboratories, in the field of DBS in sport as well as in other relevant sectors;
- 2) Identify knowledge gaps and propose research agenda (including research objectives and funding allocation) to address gaps in knowledge and make recommendations to WADA Management. For example, recommend excretion studies if *in-vivo* data that are not available for defining laboratory compliance reporting criteria and analytical data evaluation;
- 3) Propose to WADA Management a Minimum DBS Testing Menu to be implemented across Laboratories (initially, on an optional basis), including the expansion of DBS analysis to more Non-Threshold Substances without MRL, as well as to Non-Threshold Substances with MRL and the quantification of Threshold Substances. This Minimum DBS Testing Menu should be gradually expanded as more data is collected and further progress is made on the implementation and harmonization of DBS testing programs;
- 4) Propose pre-analytical and analytical conditions, as well as minimum laboratory performance requirements [e.g., Minimum Required Performance Levels (MRPL)] and reporting criteria [e.g., MRL or Decision Limits (DLs)], for substances included in the DBS Testing Menu;
- 5) Support the preparation of Laboratory normative documents (e.g., Laboratory Guidelines and/or a Technical Document and/or Technical Letter(s) or Technical Note(s) to describe the expected requirements, which might include guidance on the validation of analytical testing procedures;
- 6) Advise on how DBS samples should be counted towards the minimum total number of samples required to be analyzed by Laboratories annually;
- 7) Provide recommendations on the development of a DBS External Quality Assessment Scheme (EQAS), including the identification of EQAS Samples Provider(s).

## **Reporting Structure**

The DBS WG reports to WADA Management and the Laboratory Expert Advisory Group (Lab EAG).

Where necessary or requested, the DBS WG will provide a report on matters pertinent to the Strategic Testing Expert Advisory Group (STEAG).

## **Membership/Composition**

The composition of the DBS WG shall not exceed a maximum of six to eight members however an exception may be applied if deemed necessary.

The WADA Director General, following consultation with the responsible Director in charge of DBS WG and the Chair of the WADA Lab EAG will appoint members to the DBS WG.

Members are selected on the basis of their relevant background and experience (e.g., expertise in the areas of laboratory DBS method development and validation and application to anti-doping analysis).

The membership of the DBS WG is published on the WADA website.

*If required, additional experts may be called upon on an ad-hoc basis for their contributions.*

Member terms<sup>2</sup> reflect the mandate of DBS WG, *i.e.*, until 31 December 2026. If the work of the DBS WG is not completed within the originally planned timeframe, and is extended, the composition and terms of members are reviewed to ensure their relevance remains.

### **Chair/Rapporteur**

The DBS WG Chair<sup>3</sup> is selected based on his/her proven record and expertise in laboratory DBS method development and validation and application to anti-doping analysis. When possible, the Chair will be also a member of the Lab EAG.

He/she shall act as the official reporter who is responsible for ensuring appropriate coordination with WADA Management and the Lab EAG for providing accurate and timely information on all relevant issues.

### **WADA Liaison**

The WADA Science & Medicine Department, and in particular the Senior Associate Director of Science & Medicine (Laboratories), will serve as the primary liaison between WADA and the DBS WG.

The Senior Associate Director of Science & Medicine (Laboratories) will be an observer<sup>4</sup> to the DBS WG in the sense that he will contribute to and bring expertise to support the work of the DBS WG but will not have a voting position. Additional WADA Science & Medicine staff may also participate in DBS WG meetings as WADA experts on particular subject matters and to provide general support to the group where required.

### **Meetings and Working Norms**

The DBS WG will meet in person, or virtually via video or teleconference (as determined by WADA) as many times as is necessary to complete its mandate.

The DBS WG normally operates on the basis of consensus and maintains as informal a manner as is possible or appropriate for the conduct of business. Consensus will be sought whenever possible. In the event of divergence of opinion or disagreement concerning recommendations, the absolute majority (determined by vote by hand) will rule. In the event of a tie, the Chair has the casting vote. There is presently no formal practice concerning a quorum. The Chair has the responsibility to determine if a quorum is present. Meeting notes will record any dissenting opinion on request.

The Chair may limit discussion of resurfacing issues by referring to previous recommendations or conclusions of previous discussions.

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<sup>2</sup> Should a member come from a WADA-accredited Laboratory whose accreditation is revoked during their term, such member's term on the DBS WG will cease immediately. If the Laboratory is suspended or under an Analytical Testing Restriction, subject to WADA's discretion, such member may continue on the DBS WG.

<sup>3</sup> There are occasions where WADA staff may chair a WG, e.g. when an external chair is not deemed to be practical.

<sup>4</sup> Unless they are appointed as the Chair of the WG.

Meeting notes of the DBS WG meetings, reports and correspondence relative to the group's work shall be retained at the WADA Headquarters.

### **Code of Ethics, Conflict of Interest, Confidentiality and Media**

All DBS WG members are required to sign a document upon their appointment and again annually, pursuant to which they undertake (i) to comply with the Code of Ethics adopted by the WADA Foundation Board (as amended from time to time); (ii) to comply with the Conflict of Interest policy adopted by the Foundation Board (as amended from time to time); (iii) to keep all matters related to WADA confidential; and (iv) to comply with the WADA Media Relations Policy issued by the Agency (as amended from time to time).

#### **A) Code of Ethics**

In November 2021, the Foundation Board approved a WADA Code of Ethics, which purpose is to establish clear ethical standards over the activities of WADA's Officials (as defined in Section 2 of the Code of Ethics) to allow WADA to achieve its mission and protect its core values. WADA and all its Officials undertake to disseminate the culture of ethics, loyalty, and integrity within their respective areas of competence.

#### **B) Conflict of Interest**

DBS WG members will be bound by the WADA Conflict of Interest policy. They will be required to annually complete and sign a Statement of Absence of Conflict of Interest in accordance with the policy, and to update such statement if and as necessary during the year.

#### **C) Confidentiality**

All DBS WG members are required to sign a Confidentiality Declaration upon appointment and again annually. This ensures all members reflect on the confidential nature of their WADA work and confirm their adherence to such confidentiality rules.

#### **D) Communications and Media**

All DBS WG members must read and comply with WADA's Media Relations policy. If a member should receive a request for an interview in relation to their role in WADA, or WADA's work in the fight against doping in sport, they should first consult with the WADA Head of Media Relations or (if absent), with the WADA Communications Director.

### **Budget and Financial Support**

WADA has budgeted for the DBS WG in 2024 (and as a three-year project, it will be included in WADA's annual budget when developed for 2025 and 2026). Should an extension of the mandate be required beyond 2026, additional budget may need to be approved prior to final confirmation of the group continuing.

WADA shall provide the necessary administrative and operational resources for meetings. WADA will cover certain expenses and compensate members for meetings in accordance with its applicable indemnity policy.

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It is acknowledged that some experts go above and beyond, including providing extensive advice throughout the year, outside of annual meetings. WADA offers a further indemnity to experts for such work carried out. The specific indemnity details are outlined in the “Overview of WADA Working Groups” document provided to Members on appointment.

**Effective Date**

The mandate of the WADA DBS WG will formally commence on 1 January 2024, and these ToR will therefore come into effect on such date.

These ToR are published on the WADA website.