TD2026DBS

Summary of Major Modifications

This document summarizes the modifications in the *Technical Document* (*TD*) on Dried Blood Spots (DBS) for *Doping Control* - Requirements and Procedures for Analytical *Testing* and *Sample* Storage. TD2026DBS has been revised to improve the formatting and structure, to clarify the DBS *Sample* Analytical Testing and storage requirements, and to introduce the Minimum DBS *Testing* Menu for Non-Threshold Substances without *Minimum Reporting Levels* (*MRL*).

The following main modifications are included:

1.0 Introduction and Scope

The reference to DBS *Samples* being "blood samples by definition" has been removed.

The reference to the ISL has been removed since the currently effective ISL 2021 does not specifically cover DBS in its general requirements for the Analytical *Testing* and storage of *Samples*.

The description of what is a DBS *Sample* has been reworded.

2.0 Analytical *Testing* of DBS *Samples*

2.1 DBS Collection Device Requirements

This Article has been added to include a description of the DBS Collection Device requirements. In addition, the Comment to Article 2.1 has been added to clarify the number of Initial *Testing* Procedures (ITPs) that *Testing* Authorities (TAs) may request on a single DBS Collection Device, based on the applicable *Sample* preparation/extraction protocols.

2.2 Acceptance of DBS *Samples* for Analysis

This article has been modified to clarify that DBS *Samples* shall not be accepted for analysis if the Laboratory does not have an Analytical *Testing* Procedure validated for the DBS Collection Device received.

2.2.1 DBS *Samples* with Irregularities

This Article has been modified to include additional examples of what should be considered irregularity for DBS *Samples* specifically, and the steps that Laboratories shall follow when irregularities are identified.

3.0 Initial Storage of DBS *Samples* and Aliquoting for Analysis.

This Article has been modified to include requirements for the initial storage of DBS *Samples* and aliquoting for analysis, which will ensure the stability and integrity of the *Sample*.

Articles 3.a-c include requirements for DBS "A" and "B" *Sample* storage and describe how to store a DBS "B" *Sample* during the "A" *Sample* analysis if the "B" *Sample* is in the same container as the "A" *Sample*.

The section regarding the aliquoting of DBS *Samples* has been simplified and an explanation of what is considered a DBS *Sample*'s Aliquot has been introduced in a footnote.

4.0 Selection and Validation of Analytical *Testing* Procedures

This Article has been modified with the addition of Article 4.a, which provides guidance to the Laboratories on the validation and implementation of the Minimum DBS *Testing* Menu for all relevant Analytical *Testing* Procedures and target Analytes – as described in the Annex A of this *TD*.

Article 4.b,c describes how to prepare calibrators, Quality Control (QC) samples and other types of reference samples when DBS samples are not available, clarifying that the Laboratory should avoid spiking the Reference Materials (RMs) directly on the sample absorbent support.

Article 4.d clarifies that Selectivity should be assessed with the use of capillary blood and not venous blood, when possible.

Article 4.f lists the conditions (changes in DBS *Sample* support or preparation workflow) that will trigger as a minimum a partial revalidation of the Analytical *Testing* Procedure, including the relevant validation parameters to be reassessed.

A footnote was added to clarify that Laboratories are not required to validate the Test Methods on multiple DBS Collection Devices/*Sample* supports.

5.0 *Sample* Analysis

5.1 "A" CP

This Article has been modified to remove the possibility for a Laboratory to punch or cut out the new "A" Aliquot needed for the Confirmation Procedure (CP) from the same spot/pebble as the one used for the ITP, when the spot/pebble volume is above 20 µL. In addition, it now clarifies that, independently of the volume of the spot/pebble, the same spot/pebble as the one used for the ITP cannot be used for the "A" CP.

5.2 "B" CP

This Article has been added to clarify that for the "B" CP, a new aliquot shall be obtained from the designated "B" spot(s)/pebble(s)

6.0 Storage of DBS *Samples*

6.1 Short-term Storage of DBS *Samples*

This Article now changes the minimum period of storage of DBS *Samples* from three (3) to six (6) months.

6.2 Long-term Storage of DBS *Samples*

This Article explains that all costs associated with long-term storage (i.e., beyond the six (6) months established for the short-term storage) shall be borne by the *ADO* that requested the long-term storage.

7.0 References

Reference citations have been added to the document.

ANNEX A –Minimum DBS *Testing* Menu

This a completely new Annex describing the different submenus and relative Minimum Required Performance Levels (MRPLs) included in the Minimum DBS *Testing* Menu for Non-Threshold Substances without *MRL*, i.e., Multi Class Substances, Steroid Esters, Small Peptides and Erythropoietin Receptor Agonists (ERAs).