TD2021DL

Summary of Major Modifications

The Technical Document on Decision Limits for the confirmatory quantification of Threshold Substances by Chromatography – based Analytical Methods, TD2021DL, has been aligned with the 2021 World Anti-Doping Code (Code) and the recently approved 2021 International Standard for Laboratories (ISL); and, the other International Standards, which are set to come into force on 1 January 2021.

The main changes in the TD2021DL include:

- Formatting as well as updating of terms and definitions, where relevant;
- Footnotes have been inserted as Comments where relevant in the main text;
- Title has been updated to better reflect that the scope of the document has been redirected towards the confirmatory quantification of exogenous Threshold Substances analyzed by chromatography-based Analytical Methods;
- The different sections in this document have been reorganized to facilitate the reading and interpretation.

Article 1.0 Introduction

- The objective of the document has been redirected towards the confirmatory quantification of exogenous Threshold Substances analyzed by chromatography-based Analytical Methods and Table 1 has been updated accordingly;
- Table 1 in this section to clarify the targets of this document (hCG was removed and was referred to TD CG/LH);
- The Decision Limits (DLs) and Threshold (T) are expressed to three (3) significant figures, instead of two (2) in the previous version.

Article 2.0 Target Analytes

- This new section details the instructions for each class of substances and replaces the footnotes previously included below Table 1;
- For morphine, a reference to Technical Letter 22 (Ethylmorphine) was included.

Article 3.0 Threshold (T) and Decision Limit (DL)

- It was clarified by adding Equation 3 that $u_{c,\text{Max}}$ is the relative $u_{c,\text{Max}}$ (%) applied to $T$.

Article 4.0 Maximum Levels of Measurement Uncertainty

- Table 1 was moved from this section to the introduction of the document.
Article 5.0 Adjustment of the DL for the Urine Specific Gravity (SG)

- This new section was created to detail the instructions for the adjustment of the DL when the SG is greater than 1.018 as described in the previous version;
- It was specified that the adjusted DL will be expressed truncated to three (3) significant figures.

Article 6.0 Reporting

- The quantitative result must now be reported as the mean from triplicate determinations, truncated to three (3) significant figures;
- Any reference to the Laboratory Documentation Package was removed since this information is provided in TD LDOC.

Article 7.0 Interpretation Examples

- The examples were updated based on the new reporting rule from section 6.0 and carboxy-THC was provided as an example to replace morphine.

ANNEX A

1. Estimating Measurement Uncertainty (MU)

- This section was reworded, when necessary, for clarification;
- The equations were reformatted and rewritten, when necessary, for clarification;
- Equations were added to explain the difference between external bias ($B_{ext}$) and the root mean square of the bias ($RMS_{bias}$);
- The section on method validation was completely removed since it is detailed in a separate document.

2. Verification of Measurement Uncertainty

- This section on the $E_n$ score is now more detailed to clarify the interpretation.

ANNEX B

- This section was created to provide the Laboratories with the values of the adjusted DLs (for SG greater than 1.018) truncated to three (3) significant figures.

The TD2021DL replaces the former TD2019DL version 2.0 and becomes effective on 1 April 2021.