

## 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 clarifies 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  $u_{c\_Max}$  is the relative  $u_{c\_Max}$  (%) applied to  $\underline{T}$ .

#### 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.