WORLD ANTI-DOPING AGENCY

TD2017DL

Summary of Major Modifications

The Technical Document on Decision Limits for the Confirmatory Quantification of Threshold Substances has undergone a revision by WADA's Laboratory Expert Group (LabEG).

The new version of the document, TD2017DL, includes the following main modifications:

Table 1

i) The Decision Limit (DL) for glycerol has been rounded up to 5.4 mg/mL;

ii) A DL at 5 IU/L has been established for human Chorionic Gonadotrophin (hCG);

iii) footnote b. It has been specified that the values of $u_{c\ Max}$ are expressed to 2 significant figures.

iv) footnote c. The formula for adjusting the Threshold and the DL when the specific gravity (SG) of the Sample is greater than 1.020 has been further developed and instructions are provided on the expression of the adjusted DL;

v) footnote d. Further guidance is provided on the reporting of exogenous Threshold Substances when detected in conjunction with a prohibited diuretic or other masking agent. This is further expanded in footnote 1. at the bottom of the page;

vi) footnote f. It is clarified that the decision about whether a cathine finding (when detected in the presence of pseudoephedrine at concentrations below the DL), constitutes an Anti-doping Rule Violation shall be made during the results management process.

vii) footnote h. It is clarified that a finding for Morphine at a urinary concentration greater than the DL shall be reported as an AAF, but that the Laboratory shall comment in the Test Report on whether the morphine finding may have resulted from the administration of a permitted substance such as codeine (when applicable). The decision about whether this finding constitutes an Anti-doping Rule Violation shall be made during the results management process.

viii) footnote i. It is explained that for endogenous Threshold Substances, for which the Threshold value has been established based on reference population statistics, the population Threshold established already incorporates the uncertainty of the measurements and, therefore, the Threshold constitutes the DL.

It is specified in the Note on page 3 that Human Growth Hormone (hGH) is also defined as a Threshold Substance and reference is made to the applicable Technical Document on human Growth Hormone Isoform Differential Immunoassays for Doping Control Analyses (TDGH) [2] and the WADA Guidelines on human Growth Hormone Biomarkers Test for Doping Control Analyses.

Section 2. Setting Decision Limit for Threshold Substances

Clarification was made regarding the specific case when a value is found in a *Sample* above the T value, but lower than the DL. It was added that "the Laboratory shall report this result as "Negative" and include a recommendation (e.g. in the opinion section of the Test Report) for the Result Management Authority to consider this result within its future "target and intelligence" test planning. This result shall not constitute an *AAF* regardless of the value of MU the Laboratory reports for the result".

Section 3. Reporting

3.1 Test Report

- With the purpose of further harmonizing reporting among WADA-accredited laboratories, important modifications have been made on the reporting of quantification results for Threshold Substances:

  "The confirmed concentration of a Threshold Substance in a Sample shall be reported in ADAMS (and/or Laboratory Test Report) as the mean value from triplicate determinations, rounded down (truncated) to the same number of decimal places as the applicable DL". Examples are provided for the reporting of concentrations of different Threshold Substances.

- It is now specified that the laboratory shall report the relative u_c (expressed as %) which is associated with a result at levels close to the Threshold value, as determined during the Confirmation Procedure method validation.

- An example is provided on how to report the quantification results in a Test Report in accordance with the reporting rules established in this Technical Document.

3.2 Laboratory Documentation Package

Requirements are provided for reporting of quantification parameters in the Laboratory Documentation Package, including:

- If an adjustment for SG is necessary, the SG of the Sample, the adjusted Threshold and resulting adjusted DL shall be provided;

- A statement that the relative u_c (%) for results at the Threshold does not exceed the maximum permissible relative $u_{c\ Max}$ (%) in Table 1 of TD2017DL or applicable Technical Document or Guidelines;

- The Laboratory result for the Threshold Substance in the Sample (units) with the u_c associated with the result. Generally this is provided by reporting the expanded uncertainty $U_{95\%}$ (units) and expressed as x ± $U_{95\%}$.

Interpretation examples on the reporting of quantitative results are provided.