

TD2022LDOC version 1.0

Summary of Major Modifications

The *Technical Document* on Laboratory Documentation Packages, TD2022LDOC version 1.0, has been modified to include the following main changes:

- In the main body of the *TD*, a new Article 3.3.2 has been introduced to describe additional documentation requirements for Non-Threshold Substances with a *Minimum Reporting Level (MRL)*;
- In addition, in Article 3.3.3, clarification has been provided regarding documentation requirements for “B” *Sample* confirmations of exogenous and endogenous Threshold Substances;
- In Annex C: ERA, a new Article 2.2.3 has been added to describe documentation requirements for additional analyses related to the investigation of recombinant EPO (rEPO) findings, including the EPO testing of blood samples and the performance of DNA analyses (EPO gene sequencing).

The TD2022LDOC version 1.0 replaces the former TD2021LDOC version 1.0 and becomes effective on 1 January 2022.