



TBS/AFDC 11 (2269) DTZS/ISO 23511:2023

DRAFT TANZANIA STANDARD

Biotechnology - General requirements and considerations for cell line authentication

TANZANIA BUREAU OF STANDARDS

NATIONAL FOREWORD

The Tanzania Bureau of Standards is a statutory national standards body for Tanzania established under the Act.No.3 of 1975, amended by Act.No.2 of 2009.

This draft Tanzania Standard is being prepared by the Biotechnology Technical Committee, under supervision of Agriculture and Food Standards Divisional Committee (AFDC)

This draft Tanzania standard defines terms related to cell line authentication in the field of biotechnology. It describes the general principles, detection strategies and analytical methods for cell line authentication. It specifies requirements and key considerations for method selection, quality control parameters, data analysis and reporting.

This draft Tanzania standard is applicable to routine inspection of cell lines in culture and in storage in the fields of basic research, translational studies and product manufacturing. It is also applicable to cell line origin validation in academic and industrial laboratories, cell banks and manufacturing sites. It is primarily applicable to mammalian cells, including human cells.

This draft Tanzania standard does not apply to non-animal cells (e.g. microbial contamination, plant cells), nor to cells in complex matrices (e.g. tissues, organs, organoids, plants).

This draft Tanzania standard is identical to the ISO 23511:2023 Biotechnology - General requirements and considerations for cell line authentication, published by International Organization for Standardization.

TERMINOLOGY AND CONVENTIONS

This text of the international standards if found suitable, may be approved for application as a Tanzania Standard without deviations.

Some terminology and certain conventions are not identical with those used in Tanzania standards; attention is drawn especially to the following.

- 1) The comma has been used as a decimal marker for metric dimensions. In Tanzania standards, it is current practice to use a full point on the base line as the decimal marker.
- 2) Wherever the words “International Standard” appear, referring to this Standard they should read as “Tanzania Standard”.