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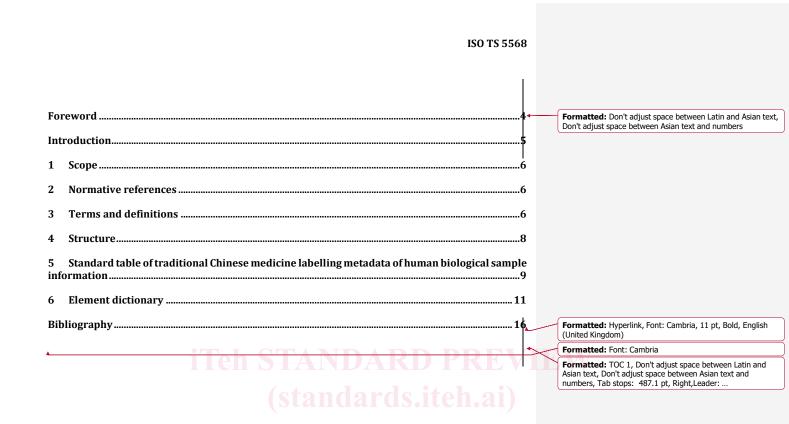
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ISO/PRF TS 5568

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Contents



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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with ISO/TC 249, *Traditional Chinese medicine*.

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Introduction

Biobanks play an integral role in research and precision medicine by acquiring, processing, storing, and distributing high-quality, clinically annotated biological material. There are a lot of mature biobanks that can be utilized in Europe and <u>USAthe US</u>. The construction of bio-sample databases for traditional Chinese medicine (TCM) is still evolving. Such databases imitate the labelling methods used in biomedicine samples. Information loss and ambiguity is unavoidable in these systems because of inconsistent content of labelling information for samples. For example, loss of TCM syndrome and physique information. There is no unified semantic information framework for labelling sample information, especially for clinical information of bio-samples in the TCM field. This lack of framework affects the effectiveness, safety and efficiency of data exchange and sharing between different organizations and databases and researchers.

While related western medical biological sample information base was built 30 years ago, which is experienced in the labelling of biological samples and formed a relatively perfect labelling framework. Especially, the standards for collecting, preserving, transporting and destroying physical samples, including organ tissues and body fluids, tends to be mature.

The establishment of a unified semantic classification framework for clinical information labelling of TCM biological samples will greatly

- ___improve the completeness, accuracy and safety of clinical information labelling of TCM biological* samples,
- ____establish a communication platform for basic research and clinical research of TCM, and _____
- ____lay a solid foundation for future information sharing and use.

At the same time, it can enhance the level of international scientific and technological cooperation of TCM γ and promote the modernization of TCM.

This document defines the metadata within the field of TCM sample labelling to address these problems.

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TECHNICAL SPECIFICATION

ISO/DTS 5568:2022(E)

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labellingLabelling metadata of human biological sample information		Formatted: zzSTDTitle, Space After: 0 pt, Line spacing: single, No page break before
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This document provides the definition of defines the metadata elements to accurately and consistency label clinical information in traditional Chinese medicine human biological samples.		Formatted: No bullets or numbering, Don't adjust space between Latin and Asian text, Don't adjust space between Asian text and numbers
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biological sample, specimen,		Formatted
discrete portion of a body fluid (e.g. blood, urine, saliva), breath, hair or tissue taken from the human	1*	Formatted: Font: Cambria, 11 pt, Not Bold
body, which is assumed to represent the whole patient, to support the assessment, diagnosis, treatment	· · · · · · · · · · · · · · · · · · ·	Formatted: Font: (Default) Cambria
mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms.		Formatted
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Note 1 to entry: Human biological samples obtained to support the clinical application of biomedical products of human origin are out of this scope.

[SOURCE: ISO/TS 22583:2019, 2.12, modified, "for POCT" removed, added "to support the assessment, diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms," original notes removed, Note 1 to entry added]

3.4

biological sample bank biobank

legal entity or part of a legal entity that performs *biobanking* (3.12).

Note 1 to entry: Biobanking means process of acquisitioning and storing, together with some or all of the / activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data

[SOURCE: ISO 20387;2018, 3.5, modified preferred Preferred term changed to "biological sample bank," note added]".]

3.5

clinical information

information about a person, relevant to his or hertheir health or healthcare

3.6 labelling

process of applying a classification, name or data to describe a sample

Note 1 to entry: <u>In this document the labelling_labelling of information includes health information, disease</u> information and treatment information of samples related to <u>TCM-traditional Chinese medicine</u>, <u>Accurate and</u> comprehensive labelling is beneficial for <u>identificationidentification</u>, use, storage and <u>retrievalofretrieval of</u> samples.

3.7

traditional Chinese medicine

TCM

traditional medicine that originated in china, and is characterized by holism and treatment based on pattern identification/syndrome differentiation

[SOURCE: ISO/TS 17948:2014, 2.2]

3.8

metadata element
resource property name that can be used in metadata and that can be given a value

Note 1 to entry: A metadata element is referred to as metadata attribute in other communities.

[SOURCE: JSO 24622-1:2015, 2.12], modified — Example deleted.]

3.9

metadata entity, set of metadata elements (3.8) describing the same aspect of data

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