International Standard

ISO 18209-1

Biotechnology — Biobanking of parasites —

Part 1: Helminths

First edition
2024-04

Reference number
ISO 18209-1:2024(en)

© ISO 2024



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword ..... **v**
Introduction ..... **vi**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 General requirements **3**
4.1 General 3
4.2 Legal and ethical requirements 3
4.3 Health and safety 4
4.3.1 General 4
4.3.2 Chemical safety 4
4.3.3 Biosafety, biosafety levels and biorisk 4
4.3.4 Personal protective equipment (PPE) 5
5 Personnel **6**
6 Facilities **6**
6.1 General 6
6.2 Breeding facilities 6
6.3 Sample storage room 6
7 Critical equipment for parasite biobanking **7**
7.1 General 7
7.2 Calibration 7
7.3 Incubators 7
7.4 Refrigerators 7
7.5 Ultra-low temperature electrically powered storage 7
7.6 Liquid nitrogen storage system/liquid nitrogen supply 8
8 Process requirements **8**
8.1 General 8
8.2 Collection 8
8.2.1 Adult worms 8
8.2.2 Larvae 8
8.2.3 Eggs 9
8.3 Pre-treatment according to the preservation form of biological material 9
8.3.1 Immersion samples 9
8.3.2 Slide samples 9
8.3.3 Pre-treatment for freezing tissue and DNA, RNA, protein isolation 9
8.4 Characterization and identification 9
8.5 Preparation, preservation and storage 10
8.6 Distribution and disposal 10
8.7 Transport of helminths and associated data 10
9 Complaint management **11**
10 Management of information and data **11**
10.1 Information system requirements 11
10.1.1 General 11
10.1.2 Biological material identification and tracking system 11
10.1.3 Data management 11
10.1.4 Biobank accession number 12
10.1.5 Location 12
10.2 Inventory management 12
11 Quality control, validation and verification **12**
11.1 General 12

© ISO 2024 – All rights reserved

11.2 Contamination inspection of biological material accompanying QC 12
11.2.1 Immersion samples 12
11.2.2 Slide samples 12
11.2.3 DNA 12
11.2.4 RNA 12
11.2.5 Protein 13
12 Reporting **13**
Annex A (informative) **Process of helminths management** **14**
Annex B (informative) **Morphology analysis** **15**
Bibliography **17**

© ISO 2024 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

A list of all parts in the ISO 18209 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2024 – All rights reserved

Introduction

The biological industry has been using helminths to treat diseases such as Crohn's disease, ulcerative colitis, auto-immune disease like allergic asthma, and even incurable disease like cancer. The industry is also developing anthelmintic drugs and rapid infection diagnosis methods.

A biobank that can fulfil the role as a platform for collecting, storing and distributing parasitic resources is of urgent need.

This document supports processes that maintain animal welfare, as it is anchored in the principle of the three Rs: to "Replace, Reduce and Refine the use of animals"[20].

This document deals with the management and operation of the biobank: Helminth, which can safely manage and supply uncontaminated parasitic resources for the biological industry to develop treatment of autoimmune diseases, parasite infection diagnostic tests, and anthelmintics.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

© ISO 2024 – All rights reserved

Biotechnology — Biobanking of parasites —

Part 1: Helminths

1 Scope

This document provides requirements for the biobanking of helminths as parasitic resources including the collection, safeguarding, classification, proliferation, preservation, storage and distribution of helminths.

This document sets requirements for the quality of helminths and their associated data, the data collection, and safety management when handling the helminths as a source of human disease infection.

This document is applicable to all organizations performing biobanking with helminths used for research and development.

NOTE International, national or regional regulations or requirements, or multiple of them, can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15190:2020, *Medical laboratories — Requirements for safety*

ISO 20387:2018, *Biotechnology — Biobanking — General requirements for biobanking*

ISO 21710:2020, *Biotechnology — Specification on data management and publication in microbial resource centers*

ISO 24088-1, *Biotechnology — Biobanking of microorganisms — Part 1: Bacteria and archaea*

ISO 35001, *Biorisk management for laboratories and other related organisations*

ISO 45001:2018, *Occupational health and safety management systems — Requirements with guidance for use*

IEC 61010-1, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387 and ISO 24088-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

© ISO 2024 – All rights reserved

3.1
biobank
parasite resource bank
legal entity or part of a legal entity that performs biobanking of *parasites* (3.8)

[SOURCE: ISO 20387:2018, 3.5, modified — The accepted term "parasite resource bank" was added and the words "of parasites" were added to the definition.]

3.2
cyst
form in which *parasites* (3.8) are surrounded by resistant covers or membranes

3.3
final host
organism that nourishes a *parasite* (3.8), which undergoes a stage of reproduction from the final adult stage

3.4
helminth
relatively large multicellular invertebrate *parasites* (3.8)

Note 1 to entry: Helminth can be found in the gastrointestinal tract and other parts of the stomach as well as in other organs and parts of the body.

Note 2 to entry: Typical helminth include acanthocephalan, nematode and platyhelminth (monogenean, trematode, cestode).

3.5
host
organism that nourishes a *parasite* (3.8) and is either an *intermediate host* (3.6) or a *final host* (3.3)

3.6
intermediate host
organism that nourishes a *parasite* (3.8) during the larva stage

3.7
minimum dataset
MDS
collection of technical and scientific data digitized in specific fields of a database, which is necessary to distinguish unambiguously a particular biological material and provides a minimum amount of information available for each accession in a *biobank* (3.1)

[SOURCE: ISO 21710:2020, 3.15, modified — Note 1 to entry was deleted; in the definition, "microbial material" was replaced by "biological material" and "an MRC" was replaced by "a biobank".]

3.8
parasite
organism that temporarily or permanently resides in the body of another organism and receives the necessary nutrients therefrom

3.9
parasite life cycle
life history stage of the parasite
chain of consecutive life stages, in which the growth of *parasites* (3.8) is divided into eggs, larvae and adults

3.10
recommended data set
RDS
collection of data that includes useful information for an improved description of the functions and properties of a biological material

Note 1 to entry: This includes optional data fields for use by the *biobank* (3.1) in the catalogue, when available.

© ISO 2024 – All rights reserved

[SOURCE: ISO 24088-1:2022, 3.17, modified — In the definition, “microbial material” was replaced by “biological material”; in the note, “microbial biobank” was changed to “biobank”.]

3.11
room temperature
temperature in the range of 18 °C to 25 °C

Note 1 to entry: The definition is given for the purposes of this document. Local or national regulations can have different definitions.

[SOURCE: ISO 20186-1:2019, 3.23]

4 General requirements

4.1 General

The biobank shall meet the requirements described in ISO 20387, in addition to those in this document. ISO/TR 22758 can be used as additional reference for the implementation of ISO 20387.

Properly trained personnel shall carry out the sampling and identification of samples.

The biobank for helminths shall prepare, implement and document procedures for the preservation, identification, information provision, distribution, etc. of parasitic resources.

NOTE Annex A includes a visualization of the helminths management process within a biobank.

The biobank shall determine the optimal storage environment for its use, and ensure that sufficient equipment, facilities and funds should be secured to store parasitic samples until they are necessary.

The biobank shall establish an effective utilization plan for parasitic resources by defining the collection, pre-treatment, identification, preservation, storage and distribution of parasite resources and associated data.

The biobank shall define and document the scope of activities in accordance with this document. The biobank should insist on the suitability of this document only to the defined extent of banking activities.

4.2 Legal and ethical requirements

The collection of biological material from live animals shall comply with applicable animal welfare practice. The biobank shall be aware of and able to demonstrate compliance with applicable animal welfare requirements.

NOTE Additional guidance can be found in References [2] and [3].

National and international legislation can require the biobank to retain documented information. This can include:

— evidence of compliance with applicable health and safety requirements;

— parasite risk classification;

— quarantine requirements;

— intellectual property rights;

— international treaties;

— access and benefit-sharing including biological material and associated data access, exchange and transfer.

© ISO 2024 – All rights reserved