



SLOVENSKI STANDARD
oSIST prEN ISO 18113-4:2021

01-oktober-2021

In vitro diagnostični preskusni sistemi - Informacije proizvajalca (označevanje) - 4. del: Diagnostični reagenti in vitro za samopreskušanje (ISO/DIS 18113-4:2021)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO/DIS 18113-4:2021)

In-vitro-Diagnostika - Bereitstellung von Informationen durch den Hersteller - Teil 4: Reagenzien für in-vitro-diagnostische Untersuchungen zur Eigenanwendung (ISO/DIS 18113-4:2021)

Dispositifs médicaux de diagnostic in vitro - Informations fournies par le fabricant (étiquetage) - Partie 4: Réactifs de diagnostic in vitro pour auto-tests (ISO/DIS 18113-4:2021)

ITEH STANDARD PREVIEW
(standards.iteh.ai)

oSIST prEN ISO 18113-4:2021
<https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021>

Ta slovenski standard je istoveten z: prEN ISO 18113-4

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
-----------	---	----------------------------------

oSIST prEN ISO 18113-4:2021

en,fr,de

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN ISO 18113-4:2021](https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021)

<https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021>

DRAFT INTERNATIONAL STANDARD

ISO/DIS 18113-4

ISO/TC 212

Secretariat: ANSI

Voting begins on:
2021-08-02Voting terminates on:
2021-10-25

In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 4:

In vitro diagnostic reagents for self-testing

*Dispositifs médicaux de diagnostic in vitro — Informations fournies par le fabricant (étiquetage) —
Partie 4: Réactifs de diagnostic in vitro pour auto-tests*

ICS: 11.100.10

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN ISO 18113-4:2021](https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021)<https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021>

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING



Reference number
ISO/DIS 18113-4:2021(E)

© ISO 2021

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 18113-4:2021](https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021)

<https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

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.....	1
4.1 Essential requirements.....	1
4.2 Identification of kit components.....	2
4.3 Presentation of the instructions for use.....	2
5 Content of the outer container.....	2
5.1 Manufacturer.....	2
5.2 Identification of the IVD reagent.....	2
5.2.1 IVD reagent name.....	2
5.2.2 Batch code / lot number.....	2
5.2.3 Unique device identifier/identification (UDI).....	3
5.3 Contents.....	3
5.4 Intended use/Intended purpose.....	3
5.5 <i>in vitro</i> diagnostic use.....	3
5.6 Storage and handling conditions.....	4
5.7 Expiry date.....	4
5.8 Warnings and precautions.....	4
6 Content of the immediate container label.....	4
6.1 General provisions.....	4
6.1.1 Single container.....	4
6.1.2 Small label.....	5
6.2 Manufacturer.....	5
6.3 Identification of the IVD reagent.....	5
6.3.1 IVD reagent or component name.....	5
6.3.2 Batch code/lot number.....	5
6.3.3 Unique device identifier/identification (UDI).....	5
6.4 Contents.....	5
6.5 <i>in vitro</i> diagnostic use.....	5
6.6 Storage and handling conditions.....	5
6.7 Expiry date.....	5
6.8 Warnings and precautions.....	6
7 Content of the instructions for use.....	6
7.1 Manufacturer.....	6
7.2 Identification of the IVD reagent.....	6
7.3 Intended purpose/Intended Use.....	6
7.4 Principles of the method.....	6
7.5 Traceability of values assigned to calibrators and trueness-control materials.....	7
7.6 Components.....	7
7.7 Additional required equipment and / or materials.....	7
7.8 Storage and shelf life after first opening.....	8
7.9 Warnings and precautions.....	8
7.10 Primary sample collection, handling and storage.....	8
7.11 Procedure to obtain a result.....	8
7.12 Control procedure.....	9
7.13 Reading of test results.....	9
7.14 Interpretation of results.....	9
7.15 Performance characteristics.....	9
7.15.1 General.....	9

ISO/DIS 18113-4:2021(E)

7.15.2	Measuring interval	9
7.16	Biological reference intervals.....	9
7.17	Limitations of the procedure	10
7.18	Literature references	10
7.19	Document control.....	10
Bibliography	11

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[oSIST prEN ISO 18113-4:2021](https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021)

<https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021>

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

This second edition cancels and replaces the first edition (ISO 18113:2009), which has been technically revised.

The main changes compared to the previous edition are as follows:

- Updated text to reflect changes in regulations and provide examples for clarity
- Added information pertaining to UDI (Unique Device Identification)
- Updated the bibliography

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. Information marked as “NOTE” is for guidance in understanding or clarifying the associated requirement.

A list of all parts in the ISO 18113 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/DIS 18113-4:2021(E)

Introduction

Manufacturers of *in vitro* diagnostic (IVD) reagents for self-testing supply users with information to enable the safe use and expected performance of their devices. The type and level of detail varies according to the intended uses and country-specific regulations.

The International Medical Devices Regulatory Forum (IMDRF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions could allow patients earlier access to new technologies and treatments. This document provides a basis for the harmonization of labelling requirements for IVD reagents for self-testing.

This document is concerned solely with information supplied with IVD reagents, calibrators, and control materials intended for self-testing. It is intended to be used in conjunction with ISO 18113-1, which contains the general requirements for information supplied by the manufacturer and definitions of general labelling concepts.

This document is intended to support the essential labelling requirements of all the IMDRF [9] partners, as well as other countries that have enacted or plan to enact labelling regulations for IVD medical devices.

For IVD reagents, calibrators and/or control materials that are intended to be used as a system with an instrument provided by the same manufacturer, this document is also intended to be used together with ISO 18113-1 and ISO 18113-5.

iTeh STANDARD PREVIEW (standards.iteh.ai)

[oSIST prEN ISO 18113-4:2021](https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021)

<https://standards.iteh.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021>

In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 4:

In vitro diagnostic reagents for self-testing

1 Scope

This document specifies requirements for information supplied by the manufacturer of IVD reagents, calibrators, and controls intended for self-testing.

This document can also be applied to accessories.

This document applies to the labels for outer and immediate containers and to the instructions for use.

This document does not apply to:

- a) IVD instruments or equipment;
- b) IVD reagents for professional use.

2 Normative references

The following referenced documents are indispensable for the application 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 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18113-1, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18113-1 apply.

ISO and IEC maintain terminological 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/>

4 General

4.1 Essential requirements

The requirements of ISO 18113-1 apply. For the use of symbols, the requirements of ISO 15223-1 apply.

ISO/DIS 18113-4:2021(E)

ISO standards for specific IVD medical devices may also contain requirements for information supplied by the manufacturer.

EXAMPLES ISO 15197; ISO 17593.

4.2 Identification of kit components

In the case of a kit, each component shall be identified by name, letter, number, symbol, colour, or graphics in the same manner on all labels and in the instructions for use.

NOTE A unique device identifier/identification (UDI) is not required on the immediate label of kit components unless the component is a device in its own right.

4.3 Presentation of the instructions for use

4.3.1 The instructions for use shall be written or provided in a language that is easily understood and applied by a lay person, and where appropriate, supplemented with drawings and diagrams and/or video.

Some devices may require separate information for the healthcare professional.

4.3.2 The information supplied shall be sufficient to enable a lay person to use the IVD reagent safely and properly, to confirm that the device is operating or has operated as intended, to understand the IVD examination results and follow up actions and/or recommendations.

NOTE Recommendations for developing user instruction manuals for IVD medical devices used in home health care are found in Reference [10].

iTech STANDARD PREVIEW
(standards.itech.ai)

5 Content of the outer container

oSIST prEN ISO 18113-4:2021
<https://standards.itech.ai/catalog/standards/sist/1de02513-398b-43c7-94e2-26ce253a3459/osist-pren-iso-18113-4-2021>

5.1 Manufacturer

The name and address of the manufacturer shall be given. The address indicates a single point at which the manufacturer can be contacted, for example, street, number, city, postal code and country. If a full address is not practical, an abbreviated version may be sufficient provided the full address is included in the instructions for use.

If an Authorized Representative is acting on behalf of the manufacturer in the country/jurisdiction, the label shall also contain the address of the Authorized Representative if required by the regulatory authority having jurisdiction.

5.2 Identification of the IVD reagent

5.2.1 IVD reagent name

The name or trade name of the IVD reagent shall be given. This brand or trade name should allow its differentiation from other products of the same or similar type.

When the name does not uniquely identify the IVD reagent, an additional means of identification shall also be given.

EXAMPLES Catalogue number, commodity number.

5.2.2 Batch code / lot number

A batch code/lot number shall be given.