SLOVENSKI STANDARD
oSIST prEN ISO 24051-2:2026

01-december-2026

Medicinski laboratoriji - 2. del: Digitalna patologija in analiza slik na podlagi umetne inteligence (UI) (ISO/DIS 24051-2:2026)

Medical laboratories - Part 2: Digital pathology and artificial intelligence (AI)-based image analysis (ISO/DIS 24051-2:2026)

Medizinische Laboratorien - Teil 2: Digitale Pathologie und auf künstlicher Intelligenz (KI) basierende Bildanalyse (ISO/DIS 24051-2:2026)

Laboratoires médicaux - Partie 2: Pathologie numérique et analyse d'images basée sur l'intelligence artificielle (IA) (ISO/DIS 24051-2:2026)

Sample Document
get full document from standards.iteh.ai

Ta slovenski standard je istoveten z: **prEN ISO 24051-2**

ICS:

11.100.01	Laboratorijska medicina na splošno	Laboratory medicine in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

oSIST prEN ISO 24051-2:2026 **en,fr,de**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

Sample Document

get full document from standards.iteh.ai

oSIST prEN ISO 24051-2:2026

DRAFT International Standard

ISO/DIS 24051-2

Medical laboratories —

Part 2: Digital pathology and artificial intelligence (AI)-based image analysis

ICS: 35.240.80; 11.100.01

Sample Document
get full document from standards.iteh.ai

ISO/TC **212**

Secretariat: **ANSI**

Voting begins on:
2026-10-23

Voting terminates on:
2027-01-15

This document has not been edited by the ISO Central Secretariat.

ISO/CEN PARALLEL PROCESSING

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS 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.

© ISO 2026

Reference number
ISO/DIS 24051-2:2026(en)

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

oSIST prEN ISO 24051-2:2026

Sample Document

get full document from standards.iteh.ai



COPYRIGHT PROTECTED DOCUMENT

© ISO 2026

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

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

oSIST prEN ISO 24051-2:2026

Contents

Page

Foreword ..... **v**
Introduction ..... **vi**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Overview on digital pathology and AI-based image analysis **10**
5 General requirements **10**
6 Pre-examination process (according to ISO 20166-4:2021) **11**
7 Digital image acquisition (slide scanning) **11**
7.1 General requirements for the scanner and workstation 11
7.1.1 General 11
7.1.2 Technical and performance characteristics 12
7.1.3 Manufacturers' instructions for users 14
7.2 Slide preparation requirements for digital image acquisition 14
7.2.1 General 14
7.2.2 Pre-scanning Quality Control - Evaluation of pre-examination artefacts 14
7.2.3 Measures to eliminate pre-examination artefacts 15
7.3 Slide scanning requirements 15
7.3.1 Calibration 15
7.3.2 Loading of slides 15
7.3.3 Selection of scanning mode/profile/parameters 15
7.3.4 Start of scanning process 16
7.3.5 Scanning quality control & corrective adjustments during scanning 16
7.3.6 Post-scanning quality control of digital images 16
7.3.7 Metadata refer to (data) provenance 16
8 Image/data management and viewing **16**
8.1 General 16
8.2 Image/data storing and archiving 16
8.3 Image/data viewing 17
8.3.1 Viewing process 17
8.3.2 Monitor parameters 17
8.3.3 Monitor validation and verification 18
8.3.4 Slide viewer 18
8.4 Image/data editing 20
8.5 Image/data sharing 20
8.6 Quality control 20
8.6.1 General 20
8.6.2 Pre-implementation 21
8.6.3 Implementation 21
8.6.4 Post-implementation 21
9 AI-based image analysis **22**
9.1 General 22
9.1.1 General 22
9.1.2 AI system description 22
9.2 Training, test and validation data 22
9.3 Al-based tool control 24
9.3.1 Human-machine interface 24
9.3.2 Human Oversight 24
9.4 Documentation 25
9.4.1 General 25
9.4.2 Manufacturers' instructions for users 25

Sample Document
det full document from standards.iteh.ai

© ISO 2026 – All rights reserved

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

oSIST prEN ISO 24051-2:2026

9.4.3 AI-based tool application(s) 26
9.4.4 Examination report for clinicians 26
9.4.5 Record keeping by the user 27
9.5 Quality control (by the user) 27
Annex A (informative) **Software-related standards** **29**
Bibliography **30**

Sample Document
get full document from standards.iteh.ai

© ISO 2026 – All rights reserved

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

oSIST prEN ISO 24051-2:2026

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/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.

Sample Document

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

A list of all parts in the ISO 24051 series can be found on the ISO website.

get full document from standards.iteh.ai

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 2026 – All rights reserved

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

oSIST prEN ISO 24051-2:2026

Introduction

Technological advances and the increased focus on precision medicine demanding precision diagnostics created a need for application of digital pathology and artificial intelligence (AI)-based image analysis.

Digital pathology using high-resolution digitized (whole slide) images of slide-mounted, stained tissue sections from e.g. surgical resection, biopsy or autopsy specimens, gained increasing relevance in the context of medical diagnostics and precision medicine. The stained, slide-mounted tissue sections can result from various in situ detection techniques, such as classical histological staining, (e.g. Hematoxylin & Eosin staining), histochemical techniques, immunohistochemical staining, and hybridization-based techniques).

The increasing application of digital pathology was enabled by the availability of slide scanners generating digital images with high resolution and information content comparable to classical light microscopes. The generation and processing of these digital (whole slide) images required the modification of diagnostic workflows and created the need for solutions (e.g. slide viewers/image viewers) to properly manage large image files and to present them via monitors (e.g. as part of a workstation) to the pathologists for histopathologic diagnosis making [1] [2] [3] [4].

The use of AI-based image analysis solutions allows computational analysis of image features and their quantitation. These features could be for example the detection and quantification of mitotic cells, of cells stained with a certain antibody, or of complex features such as tumour and stroma (e.g. for quantification of tumour cell content) or of specific tumour features, such as Gleason grade, or tumour-adipose feature [5] [6] [7] [8]. The result of the AI-based image analysis is typically presented to the pathologist as decision support for diagnosis making.

Digital pathology and AI-based image analysis can be applied in disease detection, diagnosis and prediction of prognosis. Furthermore, it supports the identification of the optimal treatment regimen based on patient profiles as well as the discovery of novel biomarkers and drug targets [1] [2] [9] [10] [11] [12]. The application of AI-based applications including machine learning (ML) and deep learning methods in context of pathology are often referred to as computational pathology.

Sample Document

The global digital pathology market was valued at USD 736 million in 2021 and is expected to grow at a Compound Annual Growth Rate (CAGR) of 13.2% for the period of 2021-2026. This is driven by rising incidence of cancer, global shortage of pathologists fostering the adoption of digital pathology, telepathology, and growing applications of digital pathology in drug development, complementary diagnostics and companion diagnostics. The immunohistochemistry sector (using stained tissue sections) is estimated to register the highest growth rate in the market sector for diagnostic application; the highest growth rate by end user is expected in the pharmaceutical and biopharmaceutical companies segment due to rising R&D investments [13] [14] [15].

Typically, digital pathology and AI-based image analysis for anatomical pathology examinations requires the following:

— Workflow adaptations for digital pathology and AI-based image analysis comprising the pre-examination workflow to generate slide-mounted sections from paraffin-embedded tissue (as defined in ISO 20166-4 [16]), the in situ detection applied to stain these slides (not covered in this standard), the preparation (e.g. cleaning) of slides for digitization, the acquisition of digital images (i.e. scanning), the storing, viewing, editing and sharing of images, the selection and application of AI-based image analysis solutions, and the evaluation and interpretation of the analysis result by the pathologist for anatomical pathology examinations.

— Medical devices for digital pathology that have been placed on the market typically comprise an image acquisition device (i.e. slide scanner) and a workstation (comprising hard- and software components) for slide viewing and pathological examination in combination referred to as whole slide imaging (WSI) system. This requires data storage and management solutions and may be used with and without application of AI-based image analysis in the context of computational pathology solutions. The US Food and Drug Administration (FDA) has published a guidance document and approved the first registrations of WSI equipment as medical devices in 2017 [11] [17].

These aspects will be covered within this document.

© ISO 2026 – All rights reserved

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

oSIST prEN ISO 24051-2:2026

The following will not be covered within this document:

— the in situ detection techniques;

— information on technical security and privacy requirements;

— general software-related issues (e.g. software lifecycle management, cybersecurity, interoperability with information management systems);

— diagnosis making by pathologists.

Some of these issues are addressed in other standards (for overview see Annex A).

Digital pathology together with AI-based analysis of digital images poses new requirements on the standardization of the entire workflow to obtain high-quality (whole slide) images and reproducible, qualitative and quantitative analysis results. Factors which can impact the quality of the image and the quality of the computational analysis result include, for example:

— pre-examination (pre-analytical) and examination (analytical) factors associated with the collection and processing of tissue specimens and production of stained slides (e.g. tissue fixation and processing, embedding, section quality [e.g. uniformity of section thickness], intactness, size, material and thickness of the slide, staining intensity and homogeneity, placing of the coverslip, air bubbles, dust, or markings on the slide [18];

— factors such as errors occurring during scanning e.g. bar code detection failure, focus failure, incomplete slide scanning (no detection of tissue or missing of tissue parts), improper stitching, line artefacts [18], or variable colour calibration and different settings of brightness, intensity disparity, and boundary intensity during scanning [19];

— factors associated with visualization of digitized images on monitors (e.g. colour calibration [19];

— factors associated with the AI-based analysis (e.g. wrong detection of features or “Clever Hans effect”, performance of an AI algorithm not demonstrated for features present on a whole slide image) [20]; and

— performance drift, which could arise due to minor differences in slide preparation protocols between sites or due to changes in preparation materials as they may change incrementally over time.

Sample Document
get full document from standards.iteh.ai

Therefore, a standardization of the entire digital pathology and AI-based image analysis workflow, and requirements and recommendations for the respective devices including the performance verification and validation are needed to secure the proper quality of the image and the AI-based analysis result to support anatomical pathology examinations.

This standard provides guidance for the use of digital pathology and AI-based image analysis and complements ISO/DIS 24051-1 [21].

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 2026 – All rights reserved

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

Sample Document

get full document from standards.iteh.ai

oSIST prEN ISO 24051-2:2026

Medical laboratories —

Part 2: Digital pathology and artificial intelligence (AI)-based image analysis

1 Scope

This document specifies requirements and gives recommendations for the digitalization of slide-mounted, stained sections, processing of digital whole slide images, and artificial intelligence (AI) based image analysis. This document focuses on sections from formalin-fixed paraffin-embedded (FFPE) tissues (derived e.g. from surgical resection, biopsy or autopsy). It is also applicable to paraffin-embedded tissue fixed by fixatives other than formalin.

This document is applicable to in vitro diagnostic examinations using digital pathology and AI-based image analysis performed by medical laboratories, in particular but not limited to anatomical pathology laboratories. It is also intended to be used by health institutions, in vitro diagnostics developers and manufacturers, and regulatory authorities.

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

Sample Document

2 Normative references

get full document from standards.iteh.ai

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 15189, *Medical laboratories — Requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189 as well as the following apply.

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

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

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

3.1
anatomic pathology
branch of laboratory medicine that examines tissue samples

[SOURCE: ISO/TS 23824:2024 [22], 3.1]

© ISO 2026 – All rights reserved

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026

oSIST prEN ISO 24051-2:2026

3.2
artificial intelligence
AI, noun
research and development of mechanisms and applications of AI systems

Note 1 to entry: A definition that better explains how AI differs from other laboratory software is that AI is "the capability of computational systems to perform tasks typically associated with human intelligence, such as learning, reasoning, problem-solving, perception, and decision-making."

Note 2 to entry: See Clause 4 for a description of the characteristics of AI that differ from other systems.

[SOURCE: ISO/IEC 22989:2022 [23], 3.1.3, modified - Notes added]

3.3
AI system, noun
artificial intelligence system
engineered system that generates outputs such as content, forecasts, recommendations or decisions for a given set of human-defined objectives

[SOURCE: ISO/IEC 22989:2022 [23], 3.1.4]

3.4
automatic
automation, noun
automated, noun
pertaining to a process or system that, under specified conditions, functions without human intervention

[SOURCE: ISO/IEC 2382:2015 [24], 2121282, modified — In the definition, "a process or equipment" has been replaced by "a process or system" and preferred terms of "automated" and "automation" are added; Notes to entry 1 and 2 have been removed.]

Sample Document
get full document from standards.iteh.ai

3.5
bias
systematic difference in treatment of certain objects, people or groups in comparison to others

Note 1 to entry: Treatment is any kind of action, including perception, observation, representation, prediction or decision.

[SOURCE: ISO/IEC TR 24027:2021 [25], 3.2.2]

3.6
control
purposeful action on or in a process to meet specified objectives

[SOURCE: IEC 61800-7-1:2015 [26], 3.2.6]

3.7
controllability
controllable, noun
property of an *AI system* (3.3) that allows a human or another external agent to intervene in the system's functioning

[SOURCE: ISO/IEC 22989:2022 [23], 3.5.6]

3.8
dataset(s)
collection of data with a shared format

EXAMPLE 1 Whole slide images of prostate tissue, each one labelled as being benign or malignant.

EXAMPLE 2 A collection of blood examination results from 10,000 patients with recorded clinical outcomes in a structured data format.

EXAMPLE 3 Numerical results for 1000 patients from a laboratory instrument.

© ISO 2026 – All rights reserved

oSIST prEN ISO 24051-2:2026 • https://standards.iteh.ai/catalog/standards/sist/1c09dd40-d251-4f7e-bf13-db87a23b490b/osist-pren-iso-24051-2-2026