
In vitro diagnostični delovni postopki z uporabo sekvenciranja naslednje generacije (NGS) - 1. del: Preiskava človeškega DNK (ISO/DIS 25379-1:2026)

In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 1: Human DNA examination (ISO/DIS 25379-1:2026)

Next-Generation-Sequencing(NGS)-Arbeitsabläufe für die In-vitro-Diagnostik - Teil 1: Untersuchung von menschlicher DNA (ISO/DIS 25379-1:2026)

Flux de travaux pour le diagnostic in vitro par séquençage de nouvelle génération (NGS) - Partie 1: Examen de l'ADN humain (ISO/DIS 25379-1:2026)

Ta slovenski standard je istoveten z: prEN ISO 25379-1

ICS:

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

oSIST prEN ISO 25379-1:2026**en,fr,de**

Sample Document

get full document from standards.iteh.ai



DRAFT International Standard

ISO/DIS 25379-1

In vitro diagnostic Next Generation Sequencing (NGS) workflows —

Part 1: Human DNA examination

*Flux de travaux pour le diagnostic in vitro par séquençage de
nouvelle génération (NGS) —*

Partie 1: Examen de l'ADN humain

ICS: 11.100.10

ISO/TC 212

Secretariat: **ANSI**

Voting begins on:
2026-09-16

Voting terminates on:
2026-12-09

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

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 25379-1:2026(en)

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

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

ISO/DIS 25379-1:2026(en)

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 General requirements	14
4.1 General	14
4.2 Examination design	15
4.3 Examination development	19
4.4 Examination performance verification and validation	20
4.5 Technical examination performance characteristics	25
5 Pre-examination processes for examination development	26
5.1 General	26
5.2 Human DNA isolation	27
5.2.1 General	27
5.2.2 Isolation from formalin fixed and paraffin embedded (FFPE) tissue	27
5.2.3 Isolation from fresh frozen tissue	27
5.2.4 Isolation from fine needle aspirates (FNA)	27
5.2.5 Isolation from whole blood	27
5.2.6 Isolation of circulating cell free DNA from plasma	28
5.2.7 Isolation of DNA from saliva	28
5.2.8 Isolation of cfDNA from other body fluids	28
5.3 DNA sample quality and quantity evaluation	28
6 Examination processes for examination development	29
6.1 Sequencing library preparation for examination development	29
6.1.1 General	29
6.1.2 Sequencing library preparation steps	30
6.1.3 Panels, exomes and whole genome sequencing	32
6.2 NGS equipment requirements and recommendations for examination development	34
6.2.1 General	34
6.2.2 Techniques	34
6.2.3 Sequencing quality control	35
6.3 Data analysis requirements for examination development	36
6.4 Quality control (QC) requirements for examination development	37
7 Requirements for the development of the examination reporting tool	37
7.1 General	37
7.2 Report attributes	38
7.3 Report content	38
8 Implementation of the <i>in vitro</i> diagnostic NGS workflow into routine practice	39
9 Reporting and interpretation of results	40
10 Quality assurance procedures	41
10.1 General	41
10.2 Performance monitoring, optimization of the examination and interlaboratory comparison	41
Annex A (normative) <i>in vitro</i> diagnostic NGS workflow for single-cell analyses	42
Annex B (informative) NGS workflow scheme for the examination of DNA	49
Bibliography	51

ISO/DIS 25379-1:2026(en)

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).

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 212, *Medical laboratories and in vitro diagnostic systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 25379 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 25379-1:2026(en)

Introduction

Molecular *in vitro* diagnostics has enabled significant progress in medicine. Further progress is expected by new technologies analysing profiles of nucleic acids, proteins, and metabolites in human tissues and body fluids. Next Generation Sequencing (NGS) takes a prominent place in the series of molecular techniques used for diagnostics. It facilitates sequence analysis of nucleic acids that can result in precise information for diagnosis and progression of diseases.

The NGS technique, however, has a very complex workflow that contains many steps. The target nucleic acids can originate from different sources (e.g. tissues, blood, and body fluids). The profiles of the isolated DNA or methylated DNA can change during specimen collection, transport, storage and processing (e.g. formalin fixation), making the outcome from diagnostics or research unreliable or even impossible because the subsequent analytical assay will not determine the situation in the patient, but an artificial profile generated during the pre-examination process. The available material can be small, the cells in a tissue can be dispersed heterogeneously (e.g. ratio of tumour to normal), the target nucleic acids can be circulating in blood or body fluids free of cells or in circulating cells (e.g. circulating tumour cells (CTCs)). For a successful and reliable sequencing result, a suitable strategy needs to be chosen for every case depending on the available material and disease conditions. Therefore, the NGS workflow can differ from case to case, and the NGS workflow steps need to be carefully considered and chosen to get a sound and reliable result to determine the best available treatment for the patient. In addition, sequencing platforms can differ in their technique (e.g. detection of a change in a current or fluorescence) and approach (e.g. panels, short-read sequencing, long-read sequencing) for sequence assessment. The bioinformatics analysis can differ in approach and ability to detect non-conformities and unreliable sequencing results. To enable such capabilities, NGS metadata needs to be collected during all workflow steps from the patient to the reporting. In addition, controls and added controls need to be analysed properly. In this way, non-conformities or detected unreliabilities can be reported to the patient and the treating physician. The reporting of diagnostic NGS results can differ in clarity and depth, which can lead to different interpretations.

Standardization of the entire NGS workflow from specimen collection to the reporting of the results to the patient and the treating physician is needed for the development of reliable NGS examinations.

This document draws upon previous work to standardize the steps for NGS examinations from tissues, blood and body fluids in what is referred to as the pre-examination phase (sample collection), the examination phase (library preparation, sequencing), and the post-examination phase (analysis and reporting).

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.

Sample Document

get full document from standards.iteh.ai

In vitro diagnostic Next Generation Sequencing (NGS) workflows —

Part 1: Human DNA examination

1 Scope

This document specifies requirements and gives recommendations for next generation sequencing (NGS) workflows for *in vitro* diagnostics and biomedical research. This document covers the pre-examination processes including human DNA (somatic and germline) isolation, sequencing library preparation, sequencing, sequence analysis and reporting of the examined sequences for diagnostic purposes from isolated DNA from, e.g. formalin-fixed and paraffin embedded tissues, fresh frozen tissues, fine needle aspirates (FNA), whole blood, circulating tumour cells (CTCs), exosomes and other extracellular vesicles, circulating cell free DNA from plasma, and DNA from saliva.

NOTE 1 Typical applications include, but are not limited to, NGS for oncology, pharmacogenomics and clinical genetics; approaches include panels (e.g. disease panels, exome panels, target gene panels and *in silico* panels), exome and whole genome sequencing, as well as certain epigenetic and certain single-cell analyses.

This document addresses *in vitro* diagnostic examinations including laboratory developed examinations and is applicable to medical laboratories, molecular pathology laboratories and molecular genetic laboratories, *in vitro* diagnostic developers and manufacturers, biobanks and institutions and organizations performing biomedical research or sequencing services.

This document is not applicable for *in situ* sequencing, DNA-mediated protein sequencing, forensic sequencing, sequencing of pathogens or microorganisms and microbiome analysis.

NOTE 2 International, national or regional regulations or requirements or multiples 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 7552-2, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 2: Isolated DNA*

ISO 18702, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for exosomes and other extracellular vesicles in venous whole blood — DNA, RNA and proteins*

ISO 18704, *Molecular in vitro diagnostic examinations — Requirements and recommendations for pre-examination processes for urine and other body fluids — Isolated cell-free DNA*

ISO 4307, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 15189:2022, *Medical laboratories — Requirements for quality and competence*

ISO/DIS 25379-1:2026(en)

ISO/IEC 17020:2012, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*

ISO 20166-3, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 3: Isolated DNA*

ISO 20184-3, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 3: Isolated DNA*

ISO 20186-2, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 2: Isolated genomic DNA*

ISO 20186-3, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 3: Isolated circulating cell free DNA from plasma*

ISO 20397-1:2022, *Biotechnology — Massively parallel sequencing — Part 1: Nucleic acid and library preparation*

ISO 20397-2, *Biotechnology — Massively parallel sequencing — Part 2: Quality evaluation of sequencing data*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189 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/>

3.1 aliquot

portion of a larger amount of homogenous material, assumed to be taken with negligible sampling error

Note 1 to entry: The term is usually applied to fluids. Tissues are heterogeneous and therefore cannot be aliquoted.

Note 2 to entry: The definition is derived from [1][2][3].

[SOURCE: ISO 20184-3:2021, 3.1, modified — Note 2 to entry was added.]

3.2 amplicon

specific DNA fragment produced by a DNA-amplification technology, such as the polymerase chain reaction (PCR)

[SOURCE: ISO 13495:2013, 3.3.1]

3.3 analyte

component represented in the name of a measurable quantity

Note 1 to entry: The term “analyte”, or the name of a substance or compound, is not to be confused with the term “measurand”, because analytes are not quantities.

EXAMPLE Amount of substance of glucose in plasma is a *measurand* (3.39), while glucose is the analyte.

[SOURCE: ISO 17511:2021, 3.1, modified — Note 1 and example were added]

ISO/DIS 25379-1:2026(en)

3.4

analytical accuracy

closeness of the agreement between the result of an *examination* (3.23) and a true property value

Note 1 to entry: For NGS-based examinations, accuracy represents the degree of concordance (or agreement) of results between a sequence obtained from the examination and the same sequence determined by a valid comparator method, or between a reference sample run on an NGS-based examination and the high confidence sequence of the reference.

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified – Original notes were deleted, Note 1 to entry was added; "analytical accuracy" replaces all old terms, "a measured quantity value" was replaced by "the result of an examination" and "quantity value of a measurand" was replaced by "property value".]

3.5

analytical sensitivity**sensitivity of a measurement procedure**

quotient of the change in a *measurement* (3.40) indication and the corresponding change in a value of a quantity being measured

Note 1 to entry: The sensitivity of a *measurement procedure* (3.41) can depend on the value of the quantity being measured.

Note 2 to entry: The change considered in the value of the quantity being measured only becomes useful when large compared with the resolution.

Note 3 to entry: The analytical sensitivity of a measuring system is the slope of the calibration curve.

Note 4 to entry: Analytical sensitivity is often confused with positive percentage agreement (*PPA*), because similar calculations are used for both the analytical sensitivity and the *PPA*. However, the term *PPA* instead of analytical sensitivity is only used, if a reference method is not available or not used. The *PPA* represents merely an estimation of the analytical sensitivity. *PPA* is applicable only to measurements of quantities that have the nature of a count.

[SOURCE: ISO/IEC Guide 99:2007, 4.12, modified — terms changed from "sensitivity of a measuring system /sensitivity" changed to "analytical sensitivity/sensitivity of a measurement procedure"; "an indication of a measuring system" replaced by "a measurement indication", "measuring system" replaced by "measurement procedure" in Note 1; new Note 3 and Note 4 were added.]

3.6

analytical specificity**selectivity of a measurement procedure**

capability of a measuring system, using a specified *measurement procedure* (3.41), to provide *measurement* (3.40) results for one or more *measurands* (3.39) which do not depend on each other nor on any other quantity in the system undergoing measurement

Note 1 to entry: Lack of analytical specificity is called analytical interference (see ISO 18113-1:2022, 3.2.2).

Note 2 to entry: Specificity of a *measurement procedure* (3.41) should not be confused with *diagnostic specificity* (3.14) (see ISO 18113-1:2022, 3.2.18).

Note 3 to entry: ISO/IEC Guide 99:2007 uses the term selectivity for this concept instead of specificity.

Note 4 to entry: Adapted from ISO/IEC Guide 99:2007, 4.13.

Note 5 to entry: Selectivity as used in metrology is a concept close to specificity as it is sometimes used in chemistry. "Specificity" of measurements has some risk of ambiguity with "clinical/diagnostic specificity".

Note 6 to entry: Analytical specificity is often confused with negative percentage agreement (*NPA*), because the same calculations are used for both the analytical specificity and the *NPA*. However, the term *NPA* instead of analytical specificity is only used, if a *reference method* (3.54) is not available or is not used. The *NPA* represents merely an estimation of the analytical specificity.

[SOURCE: ISO 18113-1:2022, 3.2.5, modified — Note 2 was deleted and Note 5 and 67 were added.]

ISO/DIS 25379-1:2026(en)

3.7

bioinformatics pipeline

suite of different bioinformatics tools that process the *next generation sequencing* (3.43) data

3.8

biomarker**molecular marker**

detectable and/or quantifiable molecule or group of molecules used to indicate a biological condition, state, identity or characteristic of an organism

[SOURCE: ISO 16577:2022, 3.4.28]

3.9

circulating cell free DNA**ccfDNA**

extracellular human DNA present in blood and plasma

Note 1 to entry: ccfDNA includes DNA present in vesicles such as exosomes.

[SOURCE: EN ISO 20186-3:2019, 3.5]

3.10

cell free DNA**cfDNA**

extracellular human DNA present in body liquids such as urine and plasma

Note 1 to entry: cfDNA can include DNA present in vesicles such as exosomes.

[SOURCE: ISO/DIS 18704, 3.8]

3.11

clinical accuracy**diagnostic accuracy**

extent of agreement between the outcome of the *examination* (3.23) and the target clinical condition

3.12

clinical performance

ability of an *examination* (3.23) to yield results that are correlated with a particular clinical condition, physiological or pathological state in accordance with the target population and intended use(r)

Note 1 to entry: Although sometimes referred to as diagnostic performance or *clinical validity* (3.16); clinical performance is the harmonized term endorsed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Devices Regulators Forum (IMDRF).

Note 2 to entry: Evaluation of clinical performance often relies on the outcome of other types of clinical *examinations* (3.23) to define “true positive or true negative” results.

3.13

clinical sensitivity**diagnostic sensitivity**

ability of an *in vitro* diagnostic *examination* (3.23) procedure to have positive results associated with a particular disease or condition

Note 1 to entry: Also defined as percent positivity in samples where the target marker is known to be present.

Note 2 to entry: Diagnostic sensitivity is expressed as a percentage (number fraction multiplied by 100), calculated as $100 \times \frac{\text{number of true positive values (TP)}}{\text{number of true positive values (TP)} + \text{number of false negative values (FN)}}$, or $100 \times \frac{\text{TP}}{\text{TP} + \text{FN}}$. This calculation is based on a study design where only one sample is taken from each subject.

Note 3 to entry: The target condition is defined by criteria independent of the examination procedure under consideration.

ISO/DIS 25379-1:2026(en)

Note 4 to entry: Clinical sensitivity is often confused with positive percentage agreement (*PPA*), because the same calculations are used for both the clinical sensitivity and the *PPA*. However, the term *PPA* instead of clinical sensitivity is only used, if a reference method is not available or is not used. The *PPA* represents merely an estimation of the clinical sensitivity.

[SOURCE: ISO 18113-1:2022, 3.2.17, modified — The term "clinical sensitivity" was added; second sentence in Note 1 was deleted; Note 4 was added.]

3.14

clinical specificity **diagnostic specificity**

ability of an *in vitro* diagnostic examination (3.23) procedure to have negative results associated with an absence of particular disease or condition

Note 1 to entry: Also defined as percent negativity in samples where the target marker is known to be absent. For information regarding description of the diagnostic performance characteristics of an IVD medical device, see Reference [4].

Note 2 to entry: Clinical specificity is expressed as a percentage (number fraction multiplied by 100), calculated as $100 \times \frac{\text{number of true negative values (TN)}}{\text{sum of the number of true negative plus the number of false positive values (FP)}}$, or $100 \times \frac{\text{TN}}{\text{TN} + \text{FP}}$. This calculation is based on a study design where only one sample is taken from each subject.

Note 3 to entry: The target condition is defined by criteria independent of the examination (3.23) procedure under consideration.

Note 4 to entry: Clinical specificity is often confused with negative percentage agreement (*NPA*), because the same calculations are used for both the clinical specificity and the *NPA*. However, the term *NPA* instead of clinical specificity is only used, if a *reference method* (3.54) is not available or is not used. The *NPA* represents merely an estimation of the clinical specificity.

[SOURCE: ISO 18113-1:2022, 3.2.18, modified — The term "clinical specificity" was added; Note 4 was added.]

3.15

clinical utility

ability of a screening or diagnostic examination (3.23) to prevent or ameliorate adverse health outcomes such as mortality, morbidity, or disability through the adoption of efficacious treatments conditioned on examination results

Note 1 to entry: Clinical utility can be part of scientific validity and *clinical performance* (3.12)[5][6].

[SOURCE: [6]]

3.16

clinical validity

predictive value of an examination (3.23) for a given clinical outcome

Note 1 to entry: Clinical validity is primarily determined by the *clinical sensitivity* (3.13) and *clinical specificity* (3.14) with which an examination identifies individuals with a defined clinical condition within a given population. The *clinical validity* (3.16) of a genetic examination is the likelihood that, e.g. cancer will develop in someone with a positive examination result.

3.17

closed system

non-modifiable system (by the user) provided by the vendor including all necessary components for the examination (3.23)

Note 1 to entry: Necessary components are hardware, software, procedures and reagents.

ISO/DIS 25379-1:2026(en)

3.18**Design of Experiments****DoE**

<NGS> structured, statistical approach for planning sequencing runs and experimental conditions in order to systematically evaluate the effects of key variables (e.g. library preparation methods, input nucleic acid quantity, sequencing depth, and indexing strategies) on sequencing quality, coverage, and downstream data interpretation

3.19**diagnosis**

identification of a disease from its signs and symptoms, where the diagnostic process can involve *examinations* (3.23) and tests for classification of an individual's condition into separate and distinct categories or subclasses that allow medical decisions about treatment and prognosis to be made

3.20**deoxyribonucleic acid****DNA**

polymer of deoxyribonucleotides occurring in a double-stranded (dsDNA) or single-stranded (ssDNA) form

3.21**DNA sequencing**

determining the order of nucleotide bases (e.g. adenine, guanine, cytosine and thymine) in a molecule of *DNA* (3.20)

Note 1 to entry: Sequence is generally described from the 5' end.

[SOURCE: ISO 17822:2020, 3.19, modified — Added e.g.]

3.22**epigenetics**

study of changes of genome usage without alterations in the underlying DNA sequence

[SOURCE: [7]]

3.23**examination****analytical test**

set of operations having the objective of determining the numerical value or characteristics of a property

Note 1 to entry: An examination can be the total of a number of activities, observations or measurements required to determine a value or characteristic.

Note 2 to entry: Laboratory examinations that determine a numerical value of a property are called "quantitative examinations"; those that determine the characteristics of a property are called "qualitative examinations".

Note 3 to entry: Laboratory examinations are also called "assays" or "tests".

Note 4 to entry: A "measurement procedure" or "measurement system" becomes an "examination" (also in complex terms like "examination procedure"), where nominal properties (e.g. DNA bases like G, A, T, C, or a set of terms for the types of leukocytes found in human blood) or ordinal quantities (e.g. a 5-value scale (0, 1, 2, 3, 4) for dip-stick reading (assessed using 1 = not elevated, 2 = doubtfully elevated, 3 = slightly elevated, 4 = elevated, 5 = strongly elevated)) are the results of a "detection" instead of a "measurement" (derived from ISO/DIS 15193).

[SOURCE: ISO 15189:2022, 3.8, modified — A new note 4 to entry was added. "analytical test" has been added as an alternative term.]

3.24**examination manufacturer****analytical test manufacturer**

entity that manufactures and/or produces measurement or detection systems, instruments, and reagents for a specific *examination* (3.23)

ISO/DIS 25379-1:2026(en)

3.25

examination performance
analytical test performance
analytical performance

ability of an *examination* (3.23) procedure to measure or detect a particular *analyte* (3.3)

Note 1 to entry: Analytical performance is determined from analytical performance studies used to assess the ability of an *in vitro* diagnostic examination procedure to measure or detect a particular analyte.

Note 2 to entry: Analytical performance includes such characteristics as analytical sensitivity, detection limit, analytical specificity (interference and cross-reactivity), trueness, precision and linearity.

[SOURCE: ISO 20186-3:2019, 3.11]

3.26

extracellular vesicle**EV**

particle naturally released from the cell that is delimited by a lipid bilayer and cannot replicate, i.e. does not contain a functional nucleus

EXAMPLE Exosomes, endosomes, oncosomes, apoptotic bodies.

[SOURCE: [8]]

3.27

fine needle aspirate**FNA**

specimen (3.67) withdrawn by a non-operative procedure that uses a thin, hollow-bore needle

[SOURCE: CEN/TS 17688-1:2021, 3.18^[49]]

3.28

formalin

saturated aqueous formaldehyde solution which at 100 % contains 37 % formaldehyde by mass (corresponding to 40 % by volume)

[SOURCE: ISO 20166-1:2018, 3.11]

3.29

guard band

interval between a tolerance limit and a corresponding acceptance limit

Note 1 to entry: The guard band includes the limits.

[SOURCE: ISO/IEC Guide 98-4:2012, 3.3.11]

3.30

***in vitro* diagnostic NGS workflow**

all activities required to generate the NGS examination result including the *pre-examination processes* (3.50), *examination* (3.23) and *post-examination processes* (3.49)

3.31

intended use**intended purpose**

objective regarding the application of a product, process or service as reflected in the specifications, instructions and information provided by the *examination manufacturer* (3.24)

Note 1 to entry: Intended use statements for IVD labelling can include two components: a description of the functionality of the IVD medical device (e.g. an immunochemical measurement procedure for the detection of analyte (3.1.4) “x” in serum or plasma), and a statement of the intended medical use of the examination results.

Note 2 to entry: The intended use can include the indications for use.