
In vitro diagnostični delovni postopki z uporabo sekvenciranja naslednje generacije (NGS) - 2. del: Preiskava človeškega RNK (ISO/DIS 25379-2:2026)

In vitro diagnostic Next Generation Sequencing (NGS) workflows - Part 2: Human RNA examination (ISO/DIS 25379-2:2026)

Next-Generation-Sequencing (NGS)-Arbeitsabläufe für die In-vitro-Diagnostik - Teil 2: Untersuchung von menschlicher RNA (ISO/DIS 25379-2:2026)

Flux de travaux pour le diagnostic in vitro par séquençage de nouvelle génération (NGS) - Partie 2: Examen de l'ARN humain (ISO/DIS 25379-2:2026)

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ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
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ISO/DIS 25379-2

In vitro diagnostic Next Generation Sequencing (NGS) workflows —

Part 2: Human RNA examination

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

Partie 2: Examen de l'ARN humain

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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

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Foreword

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This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems*.

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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 RNA 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. whole transcriptome, 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. 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.

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In vitro diagnostic Next Generation Sequencing (NGS) workflows —

Part 2: Human RNA 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 RNA isolation, sequencing library preparation, sequencing, sequence analysis and reporting of the examined sequences for diagnostic purposes from isolated RNA 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, and circulating cell free RNA from plasma.

NOTE 1 Typical applications include, but are not limited to, NGS for oncology and clinical genetics, 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 as well as institutions and organizations performing biomedical research or sequencing services.

This document is not applicable for *in situ* 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 7552-1, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for circulating tumor cells (CTCs) in venous whole blood — Part 1: Isolated RNA*

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 18703, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Isolated circulating cell free RNA from plasma*

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

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 20166-1, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 1: Isolated RNA*

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ISO 20184-1:2018, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 1: Isolated RNA*

ISO 20186-1, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 1: Isolated cellular RNA*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

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]

3.4 analytical accuracy

closeness of the agreement between the result of an *examination* (3.21) 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”.]

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3.5

analytical sensitivity**sensitivity of a measurement procedure**

quotient of the change in a measurement 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 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 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* (3.40)

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* (3.40) should not be confused with diagnostic specificity (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 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 5 and 6 were added.]

3.7

bioinformatics pipeline

suite of different bioinformatics tools that process the NGS 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 or an organism

[SOURCE: ISO 16577:2022, 3.4.28]

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3.9

circulating cell free RNA

ccfRNA

extracellular human RNA ([3.65](#)) present in blood and plasma

Note 1 to entry: ccfRNA includes RNA present in vesicles such as exosomes.

3.10

clinical accuracy

diagnostic accuracy

extent of agreement between the outcome of the *examination* ([3.21](#)) and the target clinical condition

3.11

clinical performance

ability of an *examination* ([3.21](#)) 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; 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 to define “true positive or true negative” results.

3.12

clinical sensitivity

diagnostic sensitivity

ability of an *in vitro* diagnostic examination 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 $100 \times \frac{\text{number of true positive values (TP)}}{\text{sum of the number of true positive values (TP) plus the number of false negative values (FN)}}$, 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.

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.]

3.13

clinical specificity

diagnostic specificity

ability of an *in vitro* diagnostic examination 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.

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

3.14

clinical utility

ability of a screening or diagnostic examination 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* (3.11)^[5],^[6].

[SOURCE: ^[6]]

3.15

clinical validity

predictive value of an *examination* (3.21) for a given clinical outcome

Note 1 to entry: Clinical validity is primarily determined by the *clinical sensitivity* (3.12) and *clinical specificity* (3.13) with which an examination identifies individuals with a defined clinical condition within a given population. The clinical validity of a genetic examination is the likelihood that, e.g. cancer will develop in someone with a positive examination result.

3.16

closed system

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

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

3.17

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

3.18

deoxyribonuclease**DNase**

enzyme that catalyzes the degradation of *DNA* (3.19) into smaller components

[SOURCE: ISO 20186-3:2019, 3.9]

3.19

deoxyribonucleic acid**DNA**

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

3.20

diagnosis

identification of a disease from its signs and symptoms, where the diagnostic process can involve *examinations* (3.21) 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

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3.21**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 — The term "analytical test" was added; note 1 was added.]

3.22**examination manufacturer
analytical test manufacturer**

entity that manufactures and/or produces measurement or detection systems, instruments, and reagents for a specific *examination* ([3.21](#))

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

ability of an examination 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* ([3.3](#)).

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]

3.24**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: [\[7\]](#)]

3.25**fine needle aspirate****FNA**

specimen ([3.72](#)) withdrawn by a non-operative procedure that uses a thin, hollow-bore needle

[SOURCE: CEN/TS 17688-1:2021, 3.18^[60]]

3.26**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]

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3.27

fraser

detection enhancement method of aberrant splicing events in RNA-seq data [\[13\]](#)

3.28

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]

3.29

in vitro diagnostic NGS workflow

all activities required to generate the NGS examination result including the *pre-examination processes* ([3.50](#)), *examination* ([3.21](#)) and *post-examination processes* ([3.49](#))

3.30

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* ([3.22](#))

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* ([3.3](#)) “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.

Note 3 to entry: The intended purpose indicates the object to be detected/measured, the examination's function (screening, monitoring, diagnosis, prognosis, companion diagnostic), if the examination is automated, specific information to be provided as a component of the device (to determine physiological/pathological state, clinical condition or predisposition, prediction to treatment response/reaction or monitoring of a therapy or non-proprietary name of the medicinal product for companion test; safety to recipients), if the examination results are qualitative or quantitative, the type of specimen required, and the intended population.

Note 4 to entry: The intended purpose directly drives the level of the performance evaluation, the examination methodology, the hardware and software, the examination limitations, positive controls, risk to health (e.g. diagnostic use or screening; consequences of false negatives (FN) or false positives (FP)), the number of samples, and the types of samples.

[SOURCE: ISO 18113-1:2022(en), 3.1.37, modified — Eliminated circularity and repetition in the definition; two Notes to entry added; “the IVD manufacturer” is replaced with “examination manufacturer”; “supplied” is replaced with “provided”.]

3.31

intermediate precision**intermediate measurement precision**

measurement precision under a set of *intermediate precision conditions of measurement* ([3.32](#))

Note 1 to entry: Relevant statistical terms are given in ISO 5725-3:1994.

[SOURCE: ISO/IEC Guide 99:2007, 2.23]

3.32

intermediate precision condition of measurement**intermediate precision condition**

condition of *measurement* ([3.40](#)), out of a set of conditions that includes the same *measurement procedure* ([3.41](#)), same location, and replicate measurements on the same or similar objects over an extended period of time, but can include other conditions involving changes

Note 1 to entry: The changes can include new calibrations, calibrators, operators, and measuring systems.