
**Molecular biomarker analysis —
Terms and definitions**

Analyse moléculaire de biomarqueurs — Termes et définitions

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 34, *Food products*, Subcommittee SC 16, *Horizontal methods for molecular biomarker analysis*.

Molecular biomarker analysis — Terms and definitions

1 Scope

This International Standard gives the definition of terms used in the International Standards published in the frame of ISO/TC 34/SC 16.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13495, *Foodstuffs — Principles of selection and criteria of validation for varietal identification methods using specific nucleic acid*

ISO/IEC Guide 99, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 13495, ISO/IEC Guide 99 and the following apply.

3.1

absolute error

result of a measurement minus a true value of the measurand

3.2

accordance

similarity of consistent results from a qualitative method (i.e. both positive or both negative) from identical samples analyzed in the same laboratory in repeatability conditions

3.3

accuracy

accuracy of measurement

measurement accuracy

closeness of agreement between a measured quantity value and a true quantity value of a measurand

Note 1 to entry: The concept “measurement accuracy” is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.

Note 2 to entry: The term “measurement accuracy” should not be used for measurement trueness and the term measurement precision should not be used for “measurement accuracy”, which, however, is related to both these concepts.

Note 3 to entry: “Measurement accuracy” is sometimes understood as closeness of agreement between measured quantity values that are being attributed to the measurand.

[SOURCE: ISO/IEC Guide 99:2007, 2.13]

3.4

allele

one of several alternate forms of a gene which occur at the same locus on homologous chromosomes and which become separated during meiosis and can be recombined following fusion of gametes

3.5

allele competition

competitive phenomenon that results in the preferential amplification of one allelic sequence over another in a heterozygous or mixed sample during the application of nucleic acid amplification technologies such as PCR

[SOURCE: ISO 13495:2013, 3.6.1, modified]

3.6

allele frequency

frequency at which an allele appears on a specific locus in a population

[SOURCE: ISO 13495:2013, 3.6.2, modified]

3.7

amplicon

DNA sequence produced by a DNA-amplification technology, such as the PCR technique

[SOURCE: ISO 13495:2013, 3.3.1, modified]

3.8

analyte

component of a system to be analyzed

Note 1 to entry: AOI is Analyte of Interest.

3.9

annealing

pairing of complementary single strands of nucleic acids to form a double-stranded molecule

3.10

antibody

protein (immunoglobulin) produced and secreted by B lymphocytes in response to a molecule recognised as foreign (antigen) and which is capable of binding to that specific antigen

Note 1 to entry: Immunoglobulin is the common synonym for antibody.

3.11

antibody selectivity

ability of an antibody to specifically bind to an antigenic determinant (epitope) but not to other similar structures on that or other antigens

3.12

antigen

substance that is recognized as foreign by the immune system and elicits an immune response through stimulating antibody production

3.13

applicability

analytes, matrices, and concentrations for which an analytical approach may be used satisfactorily

3.14

applicability range

range of quantification

range of linearity

dynamic range

upper and lower limits of quantification as expressed by a set of reference materials (or dilutions) with a suitable level of precision and accuracy

3.15

background

intrinsic level of signal resulting from the instruments, reagents and consumables used in the reaction

3.16**baseline**

level of detection or the point at which a reaction reaches fluorescence or signal intensity above the background level

3.17**bias**

measurement bias

estimate of a systematic measurement error

[SOURCE: ISO/IEC Guide 99:2007, 2.18]

3.18**biotechnology-derived trait**

see *genetically engineered organism* (3.73)

3.19**blocking reagent**

compound used to saturate the residual unspecific binding sites

3.20**calibration**

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties, and in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

Note 1 to entry: A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table. In some cases, it may consist of an additive or multiplicative correction of the indication with associated measurement uncertainty.

Note 2 to entry: Calibration should not be confused with adjustment of a measuring system, often mistakenly called “self-calibration”, nor with verification of calibration.

[SOURCE: ISO/IEC Guide 99:2007, 2.39, modified]

3.21**certified reference material**

CRM

reference material, accompanied by documentation issued by an authoritative body and providing one or more specified property values with associated uncertainties and traceability, using valid procedures

EXAMPLE Human serum with assigned quantity value for the concentration of cholesterol and associated measurement uncertainty stated in an accompanying certificate, used as a calibrator or measurement trueness control material.

Note 1 to entry: Documentation is given in the form of a “certificate” (see ISO/IEC Guide 30).

Note 2 to entry: Procedures for the production and certification of certified reference materials are given, e.g. in ISO Guide 34 and ISO Guide 35.

Note 3 to entry: In this definition, “uncertainty” covers both “measurement uncertainty” and “uncertainty associated with the value of the nominal property”, such as for identity and sequence. “Traceability” covers both “metrological traceability of a value” and “traceability of a nominal property value”.

Note 4 to entry: ISO/REMCO has an analogous definition (Accred. Qual. Assur.:2006) but uses the modifiers “metrological” and “metrologically” to refer to both quantity and nominal property.

[SOURCE: ISO/IEC Guide 99:2007, 5:14, modified]

3.22

clone

population of cells, generated by asexual reproduction, that are genetically identical and direct descendants of a parent cell, derived from a single cell

3.23

collaborative trial

see *interlaboratory study* (3.84)

3.24

complementary sequence

complementarity is a property shared between two nucleic acid sequences, such that when they are aligned antiparallel to each other, the nucleotide bases at each position will be complementary

3.25

concordance

similarity or agreement of results (i.e. both positive or both negative) from identical samples that are analysed in two different laboratories in terms of qualitative analysis

3.26

construct-specific detection method

targets a specific combination of inserted DNA sequences (such as genes, promoters, terminators or other genetic elements of interest) unique to biotechnology-derived organisms

3.27

conventional quantity value

conventional value of a quantity

conventional value

attributed by agreement to a quantity for a given purpose

EXAMPLE 1 Standard acceleration of free fall (formerly called “standard acceleration due to gravity”), $g_n = 9,806\,65\text{ m}\cdot\text{s}^{-2}$.

EXAMPLE 2 Conventional quantity value of the Josephson constant, $K_{J-90} = 483\,597,9\text{ GHz V}^{-1}$.

EXAMPLE 3 Conventional quantity value of a given mass standard, $m = 100,003\,47\text{ g}$.

Note 1 to entry: The term “conventional true quantity” is sometimes used for the concept but its use is discouraged.

Note 2 to entry: Sometimes, a conventional quantity value is an estimate of a true quantity value.

Note 3 to entry: A conventional quantity value is generally accepted as being associated with a suitably small measurement uncertainty, which might be effectively considered to be zero.

[SOURCE: ISO/IEC Guide 99:2007, 2.12, modified]

3.28

copy number

number of molecules (copies) of a DNA sequence

3.29

critical value

value of the net concentration or amount, the exceeding of which leads, for a given error probability, α , to the decision that the concentration or amount of the analyte in the analysed material is larger than that in the blank material:

$$\Pr(\hat{L} > L_c | L = 0) \leq \alpha$$

where

$\hat{L}$ is the estimated value;

L is the expectation or true value;

L_C is the critical value.

Note 1 to entry: The definition of critical value is important for defining the Limit of Detection (LOD). The critical value L_C is estimated by $L_C = t_{1-\alpha, \nu} s_0$, where $t_{1-\alpha, \nu}$ is Student's- t , based on ν degrees of freedom for a one-sided confidence interval of $1-\alpha$ and s_0 is the sample standard deviation.

If L is normally distributed with known variance, i.e. $\nu = \infty$ with the default α of 0,05, $L_C = 1,645s_0$. A result falling below the L_C triggering the decision "not detected" should not be construed as demonstrating analyte absence.

3.30

cross-reactivity

degree to which binding occurs between an antibody and antigenic determinants which are not the analyte of primary interest

3.31

cultivar

group of cultivated plants which may be clearly defined by morphological, physical, cytological, chemical or other characteristics and which, after sexual or asexual reproduction, keeps its distinct character

Note 1 to entry: The concept of "cultivar" is essentially different from the concept of the botanical variety "varietas", in that "cultivar" is an infraspecific division resulting from controlled selection, even if empirical; "varietas" is an infraspecific division resulting from natural selection. The terms "cultivar" and "variety" (in the sense of cultivated variety) are equivalent. In translations or adaptations of botanical nomenclature for particular uses, the terms "cultivar" or "variety" (or their equivalents in other languages) may be used in text.

3.32

cycle threshold

C_t

in real-time quantitative PCR, the cycle at which the fluorescence from the reaction crosses a specified threshold level at which the signal can be distinguished from background levels

3.33

denaturation

process of partial or total alteration of the native structure of a macromolecule resulting from the loss of tertiary and/or secondary structure that is a consequence of the disruption of stabilizing weak bonds

EXAMPLE Denaturation can occur when proteins and nucleic acids are subjected to elevated temperature, extremes of pH, non-physiological concentrations of salt, organic solvents, urea or other chemical agents.

3.34

denaturation of protein

physical and/or chemical treatment which destroys or modifies the structural, functional, enzymatic, or antigenic properties of the protein of interest

3.35

denatured DNA

DNA that has been converted from double-stranded to a single-stranded form by a denaturation process such as heating

3.36

deoxyribonuclease/ribonuclease

DNase/RNase

enzyme that catalyses the hydrolytic cleavage of deoxyribonucleic acid/ribonucleic acid that may produce a single nucleotide residue by cleavage at the end of the chain or a polynucleotide by cleavage at a position within the chain

3.37

deoxyribonuclease/ribonuclease inhibitor

substance that either fully or partially blocks deoxyribonuclease/ribonuclease activity

3.38

deoxyribonucleic acid

DNA

polymer of deoxyribonucleotides occurring in double strand (dsDNA) or single strand (ssDNA) form that is the carrier of genetic information, encoded in the sequence of bases (nitrogen containing ring compounds that are either purines or pyrimidines), and is present in chromosomes and chromosomal material of cell organelles as well as in plasmids and in viruses

3.39

deoxyribonucleotide triphosphate

dNTP

generic term referring to a deoxyribonucleotide that includes: deoxyadenosine nucleotide triphosphate (dATP), deoxycytidine nucleotide triphosphate (dCTP), deoxyguanosine nucleotide triphosphate (dGTP), deoxythymidine nucleotide triphosphate (dTTP) and deoxyuridine nucleotide triphosphate (dUTP)

3.40

detection assay

procedure or method that is used to identify the presence of traits, microorganisms, pests or other analytes in a biological sample

3.41

detection limit

limit of detection

measured quantity value, obtained by a given measurement procedure, for which the probability of falsely claiming the absence of a component in a material is β , given a probability α of falsely claiming its presence

Note 1 to entry: IUPAC recommends default values for α and β equal to 0,05.

Note 2 to entry: The abbreviation LOD is sometimes used.

Note 3 to entry: The term “sensitivity” is discouraged for this concept.

[SOURCE: ISO/IEC Guide 99:2007, 4.18, modified]

3.42

detection of PCR product

act of noting or discovering the existence of a PCR product by visualizing a fluorescent band (i.e. ethidium bromide staining) on an agarose gel or with fluorescent probes in real-time PCR applications or other approaches

3.43

dip stick test

see *lateral flow membrane assay* ([3.90](#))

3.44

DNA extraction

sample treatment for the liberation and separation of DNA from other cellular components

3.45

DNA polymerase

enzyme that synthesizes DNA by catalysing the addition of deoxyribonucleotide residues to the free 3'-hydroxyl end of a DNA molecular chain, starting from a mixture of the appropriate triphosphorylated bases

3.46**DNA probe**

short sequence of DNA labelled isotopically or chemically that is used for the detection of a complementary nucleotide sequence

3.47**DNA purification**

see *nucleic acid purification* ([3.125](#))

3.48**DNA sequencer**

gene sequencer

genetic analyser

apparatus used for determining the arrangement of the nucleotide bases (adenine, guanine, cytosine, and thymine) in a molecule of DNA

3.49**DNA target**

see *target sequence* ([3.203](#))

3.50**electrophoresis**

technique used for separating, identifying, and purifying molecules (e.g. plasmid DNA, DNA fragments resulting from digestion, RNA, protein, and PCR products) based upon the differential movement of charged particles through a matrix when subjected to an electric field

[SOURCE: ISO 13495:2013, 3.4.1, modified]

3.51**endogenous DNA sequence**

defined reference DNA sequence native to a corresponding taxon

Note 1 to entry: The endogenous DNA sequence can be used to determine the quantity of genome equivalents of the target taxon if the sequence is present in a constant copy number and does not show allelic variation among cultivars of the target taxon.

3.52**end-point PCR**

method where the amplicons are detected at the end of the PCR reaction, typically by gel electrophoresis and the amplified product is visualized with a fluorescent dye

3.53**environment control**

control used to demonstrate that no contamination from the environment was introduced to test samples

3.54**enzyme linked immunosorbent assay**

ELISA

in vitro assay used for qualitative, semi-quantitative, or quantitative purposes that combines enzyme-linked antibodies and a substrate to form a coloured or a fluorescence emitting reaction product

Note 1 to entry: Because of the presence of an antibody-linked enzyme, a colourless substrate can rapidly be converted into a coloured product or a non-fluorescent substrate into an intensely fluorescent product.

3.55**error**

error of measurement

measurement error

measured quantity value minus a reference quantity value

Note 1 to entry: The concept of “measurement error” can be used both

- a) when there is a single reference quantity value to refer to, which occurs if a calibration is made by means of a measurement standard with a measured quantity value having a negligible measurement uncertainty or if a conventional quantity value is given, in which case the measurement error is known, and
- b) if a measurand is supposed to be represented by a unique true quantity value or a set of true quantity values of negligible range, in which case the measurement error is not known.

Note 2 to entry: Measurement error should not be confused with production error or mistake.

[SOURCE: ISO/IEC Guide 99:2007, 2.16]

3.56

event

transgene construct and its unique site of insertion into a genome

3.57

event-specific method

detection method that targets DNA sequences at the integration site unique to a specific transformation event

3.58

exonuclease

enzyme that hydrolyses (cleaves) terminal phosphodiester bonds of a nucleic acid

3.59

expanded measurement uncertainty

expanded uncertainty

product of a combined standard measurement uncertainty and a factor larger than the number one

Note 1 to entry: The factor depends upon the type of probability distribution of the output quantity in a measurement model and on the selected coverage probability.

Note 2 to entry: The term factor in this definition refers to a coverage factor.

Note 3 to entry: Expanded measurement uncertainty is termed "overall uncertainty" in Recommendation INC-1 (1980), paragraph 5 (see ISO/IEC Guide 98-3) and simply "uncertainty" in IEC documents.

3.60

external amplification control

spiked amplification control

DNA added to an aliquot of the extracted nucleic acid in a defined amount or copy number serving as a control for amplification in nucleic acid-based reactions

3.61

extraction blank control

reagent blank

negative control reaction generated by performing all required steps in an extraction procedure except for the addition of the test portion

EXAMPLE By substitution of water for the test portion.

Note 1 to entry: This control is used to demonstrate the absence of contamination during extraction.

3.62

false negative

error of failing to reject a null hypothesis when it is in fact not true

3.63

false negative rate

probability that a known positive test sample has been classified as negative by the method

Note 1 to entry: The false negative rate is the number of misclassified known positives divided by the total number of positive test samples.

$$\% \text{ false negative results} = \left(\frac{\# \text{ of misclassified known positive samples total}}{\# \text{ of positive test results (including misclassified)}} \right) \times 100$$

3.64**false positive**

error of rejecting a null hypothesis when it is actually true

3.65**false positive rate**

probability that a known negative test sample has been classified as positive by the method

Note 1 to entry: The false positive rate is the number of misclassified known negatives divided by the total number of negative test samples.

$$\% \text{ false positive results} = \left(\frac{\# \text{ of misclassified known negative samples total}}{\# \text{ of negative test results (including misclassified)}} \right) \times 100$$

3.66**fitness for purpose**

applicability of a prescribed method or the degree to which data produced by a measurement process enables a user to make technically and administratively correct decisions for a stated purpose

3.67**fluorescence resonance energy transfer**

FRET

distance dependent energy transfer from a donor molecule to an acceptor molecule resulting in enhanced fluorescence of the acceptor molecule after excitation with electromagnetic radiation of a defined wave length

3.68**fluorescent probe**

oligonucleotide or oligonucleotide analogue of defined sequence coupled with one or more fluorescent molecules emitting a fluorescent signal after specific hybridization to the target nucleic acid sequence which can be detected by the specific equipment

3.69**fluorophore**

molecule with a functional group that absorbs energy of a specific wavelength and re-emits energy at a different (but equally specific) wavelength dependent on both the fluorophore and the chemical environment

3.70**forward flow**

principle of material/sample handling applied to ensure that laboratory samples, raw and processed test portions remain physically segregated during the entire procedure

3.71**genetic engineering**

genetic modification

selective, deliberate alteration of genes (genetic material) by means of recombinant DNA technology

3.72**genetically engineered content**

GE content

measured value that identifies and quantifies levels of genetically engineered (GE) traits or GE-derived material in a product

Note 1 to entry: Generally, the GE content is estimated by analyte detection, identification and quantification.

3.73

genetically engineered organism

GEO

genetically modified organism

GMO

organism in which the genetic material has been changed through modern biotechnology in a way that does not occur naturally by multiplication and/or natural recombination

3.74

good laboratory practice

set of rules and regulations issued by an authoritative body or standards organization, or generally agreed upon best practices for laboratory operation, that establishes broad methodological guidelines for procedures and record keeping

3.75

HorRat

ratio of the reproducibility relative standard deviation to that calculated from the Horwitz equation

Note 1 to entry: Predicted relative standard deviation $(PRSD)_R = 2C^{-0,15}$

$$HorRat_R = RSD_R / PRSD_R$$

$$HorRat_r = RSD_r / PRSD_R$$

Note 2 to entry: If applied to within-laboratory studies, the normal range of HorRat(r) is 0,30 – 1,30.

Note 3 to entry: To check proper calculation of PRSDR, a C of 10^{-6} should give a PRSDR of 16 %. C is concentration expressed as a mass fraction (both numerator and denominator expressed in the same units). The HorRat is indicative of method performance for a large majority of methods in chemistry. Normal values lie between 0,50 and 2,00.

3.76

hot-start PCR

method that uses a thermostable DNA polymerase enzyme which becomes activated at a specific temperature through an initial heating step to reduce non-specific amplification

3.77

hybridization

non-covalent sequence-specific interaction of two complementary nucleic acid sequences (either RNA and/or DNA) under an appropriate set of reaction conditions to give a double-stranded molecule

3.78

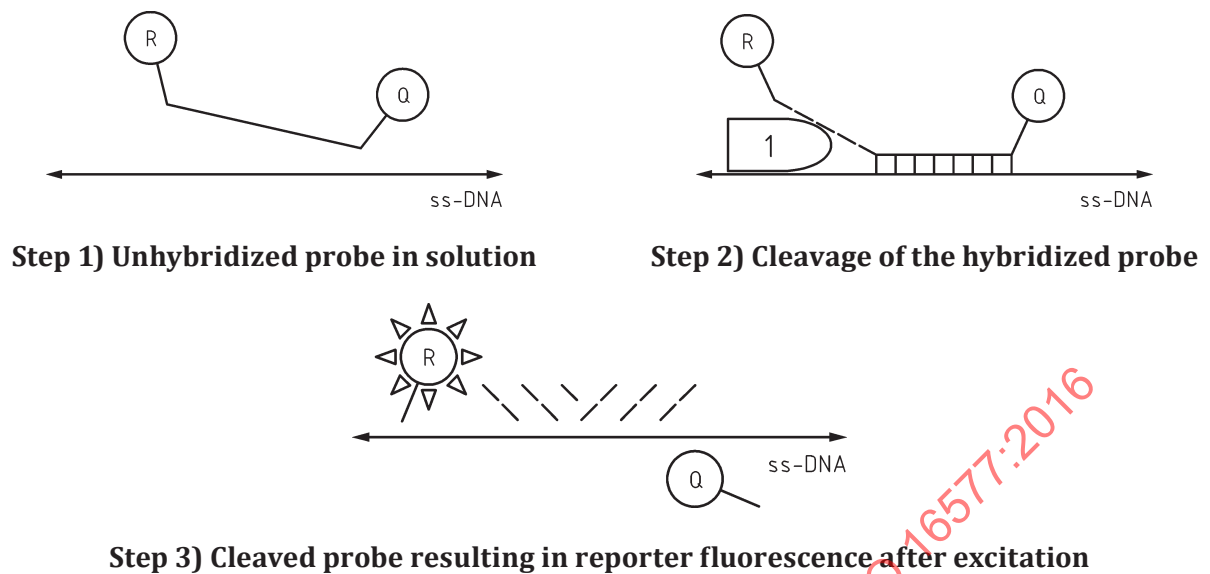
hybridization probe

fragment of DNA/RNA of variable length which is used to detect the presence of nucleotide sequences (the target) that are complementary to the nucleotide sequence in the probe

3.79

hydrolysis probe

fluorescent probe coupled with two fluorescent molecules which are separated by enzyme activity during the amplification process

**Key**

- 1 enzyme
 Q quenching molecule
 R fluorescent molecule

Figure 1 — Hydrolysis probe schematic**3.80****identification assay**

procedure or method that is used to identify a single organism, trait, analyte, or pest at a specified taxonomic level

Note 1 to entry: See also *detection assay* (3.40).

3.81**identity preservation**

process or system of maintaining the segregation and documenting the identity of a product

3.82**inhibition control**

sample that enables the analyst to check that there has been no inhibition affecting the results of a DNA amplification assay

Note 1 to entry: This amplicon may or may not be different from the target fragment. An inhibition control makes it possible to unambiguously interpret a negative result (highlighting the false negatives obtained in the presence of inhibitors). There are two possible types of inhibition control:

- internal inhibition control: amplicon acting as an internal control and obtained during the amplification reaction of the target fragment by adding DNA and/or primers. This amplicon is clearly different from the target fragment;
- external inhibition control: amplicon acting as an external control, obtained through a separate amplification reaction to that of the target fragment (i.e. in a different reaction tube).

3.83**integration-border region**

junction region where one element originates from the host organism and the other originates from the DNA introduced during transformation

3.84

interlaboratory study

study where laboratories measure a quantity in one or more “identical” portions of homogeneous, stable materials under documented conditions, the results of which are compiled

Note 1 to entry: The larger the number of participating laboratories, the greater the confidence that can be placed in the resulting estimates of the statistical parameters. The IUPAC-1987 protocol requires a minimum of eight laboratories for method performance studies (*Pure & Appl. Chem.*, 66, 1903–1911 (1994), p.1906, Clause 2). Guidelines for performing collaborative trials are elaborated in ISO 5725-2 and the ISO/AOAC/IUPAC harmonized protocol.

3.85

endogenous amplification control

gene sequence naturally present in template DNA (e.g. housekeeping gene with known copy #/genome) that is amplified to check the quality and yield of a DNA extract.

3.86

intralaboratory study

study performed within a single laboratory

3.87

junction region

DNA sequence encompassing two consecutive sequences

EXAMPLE A promoter and the coding region of a gene.

3.88

laboratory performance study

laboratory proficiency study

study involving one or more measurements by a group of laboratories on one or more homogeneous, stable, test samples by the method selected or used by each laboratory in which the reported results are compared with those from other laboratories or with the known or assigned reference values, usually with the objective of improving laboratory performance

Note 1 to entry: Laboratory performance studies can be used to support laboratory accreditation of laboratories or to audit performance. If a study is conducted by an organization with some type of management control over the participating laboratories (organizational, accreditation, regulatory or contractual), the method may be specified or the selection may be limited to a list of approved or equivalent methods. In such situations, a single test sample is insufficient to judge performance. A laboratory performance study may be used to select a method of analysis that will be used in a method performance study. If all laboratories or a sufficiently large subgroup of laboratories use the same method, the study may also be interpreted as a method performance study, provided that the test samples cover the range of concentration of the analyte. Laboratories of a single organization with independent facilities, instruments, and calibration materials, are treated as different laboratories.

3.89

laboratory sample

sample or subsample(s) received by the laboratory

3.90

lateral flow membrane assay

lateral flow device

LFD

lateral flow strip

LFS

immunoassay in which antibodies are bound in specific zones on a porous membrane of one or more layers, where a liquid sample is applied to one end of the membrane and drawn through the reagent zones by capillary action, usually assisted by an absorbent at the opposite end of the membrane

Note 1 to entry: Typically, a coloured “control line” close to the absorbent pad indicates whether the test performed successfully. Results of the test are indicated by the presence or absence of one or more additional test lines that are expected between the point of sample application and the “control line”.

Note 2 to entry: Immunoassay is the most common form but other biorecognition particles have also been used.

3.91

limit of quantification

LOQ

determination limit

lowest concentration or content of the *AOI* (3.8) per defined amount of matrix that can be measured with reasonable statistical certainty consistently under the experimental conditions specified in the method

Note 1 to entry: Generally expressed in terms of the signal or measurement (true) value that will produce estimates having a specified relative standard deviation (RSD).

3.92

linearity

ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quantity of analyte to be determined in the laboratory sample

3.93

living modified organism

LMO

living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology

Note 1 to entry: Common LMOs include agricultural crops that have been genetically modified for greater productivity or for resistance to pests or diseases.

3.94

loop mediated isothermal amplification

LAMP

strategy for achieving isothermal DNA amplification by utilizing two or three uniquely designed primer sets and a polymerase with high strand displacement activity

3.95

material certification study

interlaboratory study that assigns a reference value ("true value") to a quantity (concentration or property) in the test material, usually with a stated uncertainty

Note 1 to entry: A material certification study often utilizes selected reference laboratories to analyse a candidate reference material by a method(s) judged most likely to provide the least-biased estimates of concentration (or of a characteristic property) and the smallest associated uncertainty.

3.96

matrix

all relevant components of a sample inclusive of analyte

3.97

measurand

quantity intended to be measured

Note 1 to entry: The specification of a measurand requires knowledge of the kind of quantity, description of the state of the phenomenon, body, or substance carrying the quantity, including any relevant component, and the chemical entities involved.

Note 2 to entry: In the second edition of the VIM and in IEC 60050-300:2001, the measurand is defined as the "quantity subject to measurement".

Note 3 to entry: The measurement, including the measuring system and the conditions under which the measurement is carried out, might change the phenomenon, body, or substance such that the quantity being measured may differ from the measurand as defined. In this case, adequate correction is necessary.

EXAMPLE 1 The potential difference between the terminals of a battery may decrease when using a voltmeter with a significant internal conductance to perform the measurement. The open-circuit potential difference can be calculated from the internal resistances of the battery and the voltmeter.

EXAMPLE 2 The length of a steel rod in equilibrium with the ambient Celsius temperature of 23 °C will be different from the length at the specified temperature of 20 °C, which is the measurand. In this case, a correction is necessary.

Note 4 to entry: In chemistry, “analyte”, or the name of a substance or compound, are terms sometimes used for “measurand”. This usage is erroneous because these terms do not refer to quantities.

[SOURCE: ISO/IEC Guide 99:2007, 2.3]

3.98

measurement method

method of measurement

generic description of a logical organization of operations used in a measurement

Note 1 to entry: Measurement methods may be qualified in various ways such as

- substitution measurement method,
- differential measurement method,
- null measurement method, or
- direct measurement method, and
- indirect measurement method.

See IEC 60050-300:2001.

[SOURCE: ISO/IEC Guide 99:2007, 2.5, modified]

3.99

measurement precision

precision

closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

Note 1 to entry: Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

Note 2 to entry: The “specified conditions” can be, for example, repeatability conditions of measurement, intermediate precision conditions of measurement or reproducibility conditions of measurement (see ISO 5725-3).

Note 3 to entry: Measurement precision is used to define measurement repeatability, intermediate measurement precision and measurement reproducibility.

Note 4 to entry: Sometimes, “measurement precision” is erroneously used to mean measurement accuracy.

[SOURCE: ISO/IEC Guide 99:2007, 2.15]

3.100

measurement procedure

detailed description of a measurement according to one or more measurement principles and to a given measurement method, based on a measurement model and including any calculation to obtain a measurement result

Note 1 to entry: A measurement procedure is usually documented in sufficient detail to enable an operator to perform a measurement.

Note 2 to entry: A measurement procedure can include a statement concerning a target measurement uncertainty.

[SOURCE: ISO/IEC Guide 99:2007, 2.6, modified]

3.101**measurement repeatability**

repeatability

measurement precision under a set of repeatability conditions of measurement

Note 1 to entry: See [3.167](#).

[SOURCE: ISO/IEC Guide 99:2007, 2.21]

3.102**measurement reproducibility**

reproducibility

measurement precision under reproducibility conditions of measurement

Note 1 to entry: See [3.174](#).

[SOURCE: ISO/IEC Guide 99:2007, 2.25, modified]

3.103**measurement result**

result of measurement

set of quantity values being attributed to a measurand together with any other available relevant information

Note 1 to entry: A measurement result generally contains “relevant information” about the set of quantity values, such that some may be more representative of the measurand than others. This may be expressed in the form of a probability density function (PDF).

Note 2 to entry: A measurement result is generally expressed as a single measured quantity value and a measurement uncertainty. If the measurement uncertainty is considered to be negligible for some purpose, the measurement result may be expressed as a single measured quantity value. In many fields, this is the common way of expressing a measurement result.

Note 3 to entry: In the traditional literature and in the previous edition of the VIM, measurement result was defined as a value attributed to a measurand and explained to mean an indication, or an uncorrected result, or a corrected result, according to the context.

[SOURCE: ISO/IEC Guide 99:2007, 2.9]

3.104**measurement standard**

etalon

realization of the definition of a given quantity, with stated quantity value and associated measurement uncertainty, used as a reference

EXAMPLE 1 1 kg mass measurement standard with an associated standard measurement uncertainty of 3 µg.

EXAMPLE 2 100 Ω measurement standard resistor with an associated standard measurement uncertainty of 1 µΩ.

EXAMPLE 3 Caesium frequency standard with a relative standard measurement uncertainty of 2×10^{-15} .

EXAMPLE 4 Hydrogen reference electrode with an assigned quantity value of 7,072 and an associated standard measurement uncertainty of 0,006.

EXAMPLE 5 Set of reference solutions of cortisol in human serum having a certified quantity value with measurement uncertainty for each solution.

EXAMPLE 6 Reference material providing quantity values with measurement uncertainties for the mass concentration of each of ten different proteins.

Note 1 to entry: A “realization of the definition of a given quantity” can be provided by a measuring system, a material measure, or a reference material.

Note 2 to entry: A measurement standard is frequently used as a reference in establishing measured quantity values and associated measurement uncertainties for other quantities of the same kind, thereby establishing metrological traceability through calibration of other measurement standards, measuring instruments, or measuring systems.

Note 3 to entry: The term “realization” is used here in the most general meaning. It denotes three procedures of “realization”. The first one consists in the physical realization of the measurement unit from its definition and is realization *sensu stricto*. The second, termed “reproduction”, consists not in realizing the measurement unit from its definition but in setting up a highly reproducible measurement standard based on a physical phenomenon, as it happens, e.g. in case of use of frequency-stabilized lasers to establish a measurement standard for the meter, of the Josephson effect for the volt or of the quantum Hall effect for the ohm. The third procedure consists in adopting a material measure as a measurement standard. It occurs in the case of the measurement standard of 1 kg.

Note 4 to entry: A standard measurement uncertainty associated with a measurement standard is always a component of the combined standard measurement uncertainty (see ISO/IEC Guide 98-3:2008, 2.3.4) in a measurement result obtained using the measurement standard. Frequently, this component is small compared with other components of the combined standard measurement uncertainty.

Note 5 to entry: Quantity value and measurement uncertainty shall be determined at the time when the measurement standard is used.

Note 6 to entry: Several quantities of the same kind or of different kinds may be realized in one device which is commonly also called a measurement standard.

Note 7 to entry: The word “embodiment” is sometimes used in the English language instead of “realization”.

Note 8 to entry: In science and technology, the English word “standard” is used with at least two different meanings: as a specification, technical recommendation, or similar normative document (in French “norme”) and as a measurement standard (in French “étalon”). This vocabulary is concerned solely with the second meaning.

Note 9 to entry: The term “measurement standard” is sometimes used to denote other metrological tools, e.g. “software measurement standard” (see ISO 5436-2).

[SOURCE: ISO/IEC Guide 99:2007, 5.1]

3.105

measurement trueness

trueness of measurement

trueness

closeness of agreement between the average value of an infinite number of replicate measured quantity values and a reference quantity value

Note 1 to entry: Measurement trueness is not a quantity and thus cannot be expressed numerically but measures for closeness of agreement are given in the ISO 5725 series.

Note 2 to entry: Measurement trueness is inversely related to systematic measurement error but is not related to random measurement error.

Note 3 to entry: Measurement accuracy should not be used for “measurement trueness” and vice versa.

Note 4 to entry: The measure of trueness is usually expressed in terms of bias. Trueness has sometimes been referred to as “accuracy of the mean”.

[SOURCE: ISO/IEC Guide 99:2007, 2.14, modified]

3.106**measurement uncertainty**

uncertainty of measurement

uncertainty

non-negative parameter characterizing the dispersion of the quantity values attributed to a measurand based on the information used

Note 1 to entry: Measurement uncertainty includes components arising from systematic effects, such as components associated with corrections and the assigned quantity values of measurement standards, as well as the definitional uncertainty. Sometimes, estimated systematic effects are not corrected for but, instead, associated measurement uncertainty components are incorporated.

Note 2 to entry: The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.

Note 3 to entry: Measurement uncertainty comprises, in general, many components. Some of these may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from series of measurements and can be characterized by standard deviations. The other components, which may be evaluated by Type B evaluation of measurement uncertainty, can also be characterized by standard deviations, evaluated from probability density functions based on experience or other information.

Note 4 to entry: In general, for a given set of information, it is understood that the measurement uncertainty is associated with a stated quality value attributed to the measurand. A modification of this value results in a modification of the associated uncertainty.

[SOURCE: ISO/IEC Guide 99:2007, 2.26]

3.107**melting curve**

analysis describing the dissociation characteristics of double-stranded DNA observed during heating

Note 1 to entry: The information gathered can be used to infer the presence and identity of single-nucleotide polymorphisms. Temperatures of dissociation (defined as 50 % dissociation) may be revealed at peaks in a plot of the negative first derivative of the melting curve.

3.108**melting temperature** T_m

temperature at which 50 % of double-stranded DNA helices are dissociated since a DNA helix melts in a temperature range rather than at one very specific temperature

3.109**method performance study**

interlaboratory study in which all laboratories follow the same written protocol, use the same test method to measure quantity in sets of identical test samples, and the reported results are used to estimate the performance characteristics of the method

Note 1 to entry: See *interlaboratory study* (3.84).

[SOURCE: Codex CAC/GL 72-2009]

3.110**metrological traceability**

property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

Note 1 to entry: For this definition, a “reference” can be a definition of a measurement unit through its practical realization or a measurement procedure including the measurement unit for a non-ordinal quantity or a measurement standard.

Note 2 to entry: Metrological traceability requires an established calibration hierarchy.

Note 3 to entry: Specification of the reference shall include the time at which this reference was used in establishing the calibration hierarchy, along with any other relevant metrological information about the reference, such as when the first calibration in the calibration hierarchy was performed.

Note 4 to entry: For measurements with more than one input quantity in the measurement model, each of the input quantity values should itself be metrologically traceable and the calibration hierarchy involved may form a branched structure or a network. The effort involved in establishing metrological traceability for each input quantity value should be commensurate with its relative contribution to the measurement result.

Note 5 to entry: Metrological traceability of a measurement result does not ensure that the measurement uncertainty is adequate for a given purpose or that there is an absence of mistakes.

Note 6 to entry: A comparison between two measurement standards may be viewed as a calibration if the comparison is used to check and, if necessary, correct the quantity value and measurement uncertainty attributed to one of the measurement standards.

Note 7 to entry: The ILAC considers the elements for confirming metrological traceability to be an unbroken metrological traceability chain to an international measurement standard or a national measurement standard, a documented measurement uncertainty, a documented measurement procedure, accredited technical competence, metrological traceability to the SI, and calibration intervals (see ILAC P-10:2002).

Note 8 to entry: The abbreviated term “traceability” is sometimes used to mean “metrological traceability”, as well as other concepts, such as “sample traceability” or “document traceability” or “instrument traceability” or “material traceability”, where the history (“trace”) of an item is meant. Therefore, the full term of “metrological traceability” is preferred if there is any risk of confusion.

[SOURCE: ISO/IEC Guide 99:2007, 2.41]

3.111 microsatellite

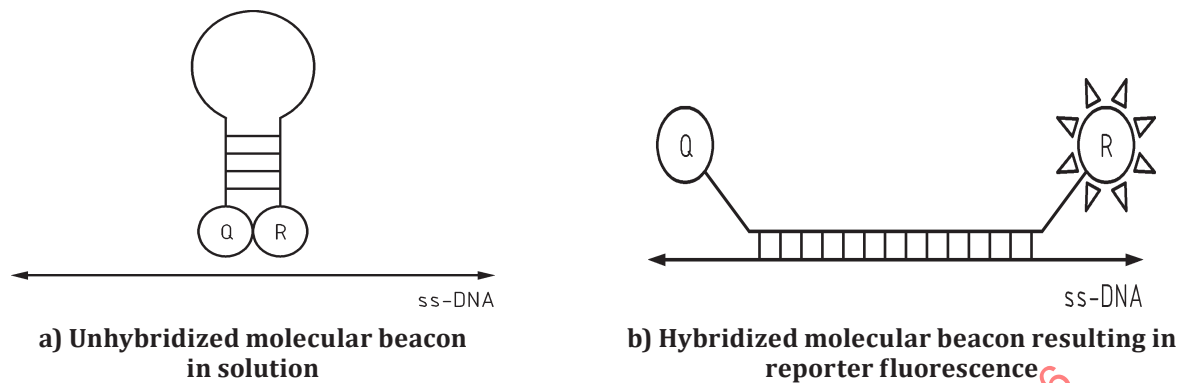
repetitive DNA elements, also known as simple sequence repeats (SSR), consisting of short in tandem repeat motifs of one to a few nucleotides that tend to occur in non-coding DNA of eukaryotic genomes and that are sometimes referred to as variable number of tandem repeats (VNTRs)

3.112 modern biotechnology

in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) technologies or fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection

3.113 molecular beacon

fluorescent probe that consists of three different parts: the central component is complementary to the target nucleic acid sequence, whereas the 5′- and the 3′- components are complementary to each other; the reporter is attached to one arm of the molecule; and the end of the other arm carries a quencher

**Key**

Q quenching molecule
 R fluorescent molecule

Figure 2 — Molecular beacon schematic

3.114 molecular biomarker

detectable and/or quantifiable molecule or group of molecules used to indicate a biological condition, state, identity or characteristic or an organism, e.g. but not limited to, nucleic acid sequences, proteins, small molecules such as metabolites and other molecules such as lipids and polysaccharides

3.115 monoclonal antibody

antibody produced from a single hybridoma clone and directed to a single antigen determinant

3.116 monomorphic locus

genome region that presents only one form, i.e. is not polymorphic in a specific population or collection of varieties

3.117 multiplex PCR

PCR technique that employs multiple pairs of primers combined simultaneously within a single reaction mixture to produce multiple amplicons

3.118 negative DNA target control

well-characterized DNA preparation material that does not contain target nucleic acid

3.119 negative process control

recognized reference sample lacking target analyte and that should be put through the same process steps as the test samples

3.120 nested PCR

specific PCR technique in which a second PCR is used to amplify a DNA sequence within an amplicon produced during a first PCR run

3.121 nicking enzyme amplification reaction

NEAR

isothermal method for exponential *in vitro* DNA amplification

3.122

non-specific DNA staining

method of staining DNA products, typically used following electrophoresis, that is independent of the DNA sequence

3.123

northern blotting

transfer of RNA fragments separated in electrophoretic gels to membrane filters for detection of specific sequences complementary to a labelled DNA or RNA probe

3.124

nucleic acid extraction

sample treatment for liberation of target nucleic acid

Note 1 to entry: Nucleic acid extraction could be DNA or RNA extraction.

3.125

nucleic acid purification

procedure or process involving sequential steps used to separate DNA and/or RNA from other components in a sample

Note 1 to entry: A highly purified DNA or RNA sample contains negligible observable or measurable effects attributable to inhibitors during the polymerase chain reaction.

3.126

nucleic acid sequence based amplification

NASBA

isothermal transcription-based *in-vitro* nucleic acid amplification process that involves the concomitant action of an RNA-directed DNA polymerase, a ribonuclease, and a DNA-directed RNA polymerase to synthesize large quantities of sequence-specific RNA and DNA molecules

3.127

nucleoside

glycosidic compound consisting of a purine or pyrimidine base and a pentose (ribose or deoxyribose)

3.128

nucleotide

subunit of DNA or RNA composed of a base (purine or pyrimidine), a pentose (ribose or deoxyribose), and a phosphate group

3.129

null allele

mutant copy of a gene that completely lacks that gene's normal function

Note 1 to entry: In the context of PCR, a null allele is a sequence variant that precludes PCR amplification of a particular target, resulting in the absence of detectable PCR product.

3.130

optical detection system

photosensitive element on thermal cyclers (for example) necessary for detecting fluorescence signals

3.131

outlier

member of a set of values which is inconsistent with other members of that set as determined by statistical analysis

3.132

passive reference dye

fluorescent molecules present in the reaction mix used to normalize the signal and may be coupled with nucleic acid sequences or other molecules not taking part in the reaction

3.133**pathogen**

pathogenic organisms

sub-category of the definition of pest with specific focus on a micro-organism causing disease which is detected or identified predominantly by using molecular diagnostic procedure development

[SOURCE: International Standards for Phytosanitary Measures No 3, Guidelines for the Export, Shipment, Import, and Release of Biological Control Agents and Other Beneficial Organisms (IPPC 2005)]

3.134**PCR**

see *polymerase chain reaction* ([3.148](#))

3.135**PCR-ELISA**

immunoenzymatic method for detecting amplicons in liquid phase after they have been captured on a solid surface, such as in microplate wells

3.136**PCR inhibition control**

see *inhibition control* ([3.82](#))

3.137**PCR master mix**

mixture of the reagents required for PCR but excluding DNA template and controls

3.138**PCR product**

DNA molecule/fragment produced by PCR amplification

3.139**PCR quality DNA**

DNA template of sufficient length, chemical purity, and structural integrity enabling PCR amplification

3.140**PCR reagent control**

containing all the amplification reagents except the extracted test sample template DNA

Note 1 to entry: This control is used to demonstrate the absence of contaminating nucleic acids in the reagents. Instead of the template DNA, for example, a corresponding volume of nucleic acid free water is added to the reaction.

3.141**PCR target sequence**

specific region of DNA that becomes selectively amplified during PCR-based detection, identification and/or quantification

Note 1 to entry: The PCR target sequence is characterized by being located between the primers, and in the case of real-time PCR, may include the probe hybridization site.

3.142**percent error**

relative error expressed as a percentage

3.143**pest**

species, strain or biotype of plant, animal or pathogenic agent injurious to the host organism

[SOURCE: International Standards for Phytosanitary Measures No 5, Glossary of Phytosanitary terms (IPPC 2010)]

3.144

plant molecular farming

PMF

use of plants in agriculture for the production of compounds (pharmaceuticals, diagnostic products, vaccines, biologics, industrial chemicals, biodegradable plastics, etc.)

3.145

plant with novel trait

PNT

plant to which a unique (novel) trait has been added by classical breeding or genetic engineering

3.146

plasmid

stable, independently replicating DNA molecule in bacterial cells that is not part of the chromosomal DNA

3.147

polyclonal antibody

mixture of antibodies capable of reacting specifically with a certain immunogenic substance

3.148

polymerase chain reaction

PCR

in vitro enzymatic technique to increase the number of copies of a specific DNA fragment by several orders of magnitude

[SOURCE: ISO 13495:2013, 3.3.4, modified]

3.149

polymorphic locus

genetic locus with two or more alleles

Note 1 to entry: It is this genetic variation that is exploited by SSR and SNP markers.

3.150

positive DNA target control

positive PCR control

any reliable source of well-characterized positive sample material, containing intact target nucleic acid sequences for PCR

Note 1 to entry: Reference DNA or DNA extracted from a certified reference material is generally used to demonstrate that PCR reagents are working as intended.

3.151

positive process control

well-characterized reference sample containing a detectable amount of an analyte

Note 1 to entry: The positive process control goes through exactly the same process steps as the test samples.

3.152

practicability

ease of operations, in terms of sample throughput and costs, to achieve the required performance criteria and thereby meet the specified purpose

3.153

primer

strand of nucleic acid sequence that serves as a starting point for DNA synthesis

[SOURCE: ISO 13495:2013, 3.153]

3.154**primer extension**

enzymatic reaction that synthesizes a new DNA strand by adding a deoxyribonucleotide to the 3' end of the primer sequence

3.155**probe**

see *DNA probe* (3.46)

3.156**qualitative method**

method of analysis that yields a binary result

3.157**quality assurance**

planned and systematic actions necessary to provide adequate confidence that analytical results will satisfy given requirements for quality

3.158**quantitative analysis**

analyses in which the amount or concentration of an analyte may be determined and expressed as a numerical value in appropriate units

3.159**quantitative method**

analytical method by which amount or concentration of an analyte may be determined and expressed as a numerical value in appropriate units

3.160**quencher**

molecule which acts as an energy acceptor and quenches the fluorescence signal of the reporter molecule

3.161**rational method of analysis**

method that determines identifiable chemical(s) or analyte(s) for which there may be several equivalent methods of analysis available

3.162**real-time PCR**

enzymatic procedure which combines the *in vitro* amplification of specific DNA segments with the detection of specific PCR products during the amplification process

Note 1 to entry: While the PCR reaction is producing copies of the relevant DNA sequence, the fluorescent marker becomes un-quenched at the same time, so it fluoresces in direct proportion to the amount of DNA present (which can theoretically be back-calculated to infer the original amount of that particular DNA present in a sample prior to initiation of PCR).

3.163**recovery**

recovery factor

proportion of the amount of analyte, present in, added to, or present in and added to the analytical portion of the test material, which is presented for measurement following extraction from the matrix

3.164**reference material**

reference sample

material or substance, one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials

3.165

reference quantity value

reference value

quantity value used as a basis for comparison with values of quantities of the same kind

Note 1 to entry: A reference quantity value can be a true quantity value of a measurand, in which case it is unknown, or a conventional quantity value, in which case it is known.

Note 2 to entry: A reference quantity value with associated measurement uncertainty is usually provided with reference to

- a) a material, e.g. a certified reference material,
- b) a device, e.g. a stabilized laser,
- c) a reference measurement procedure, and
- d) a comparison of measurement standards.

[SOURCE: ISO/IEC Guide 99:2007, 5.18]

3.166

relative error

absolute error divided by the magnitude of the true (best accepted) value

3.167

repeatability condition of measurement

repeatability condition

condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time

Note 1 to entry: A condition of measurement is a repeatability condition only with respect to a specified set of repeatability conditions.

Note 2 to entry: In chemistry, the term “intra-serial precision condition of measurement” is sometimes used to designate this concept.

[SOURCE: ISO/IEC Guide 99:2007, 2.20]

3.168

repeatability limit

value less than or equal to which the absolute difference between two test results obtained under repeatability conditions may be expected to be within a probability of 95 %

Note 1 to entry: The symbol used is r .

Note 2 to entry: When examining two single test results obtained under repeatability conditions, the comparison should be made with the repeatability limit $r = 2,8 s_r$.

3.169

repeatability standard deviation

standard deviation of test results or measurement results obtained under repeatability conditions

Note 1 to entry: It is a measure of the dispersion of the distribution of test or measurement results under repeatability conditions. Similarly, “repeatability variance” and “repeatability coefficient of variation” can be defined and used as measures of the dispersion of test or measurement results under repeatability conditions.

3.170

repeatability relative standard deviation

RSD_r is calculated by dividing the repeatability standard deviation by the mean

Note 1 to entry: Relative standard deviation (RSD) is a useful measure of precision in quantitative studies and reflects precision under repeatability conditions. The RSD is also known as coefficient of variation.

3.171**repeat region**

genomic region in which a particular DNA or RNA sequence occurs in multiple copies

[SOURCE: ISO 13495:2013, 3.6.5]

3.172**reporter gene**

gene used to facilitate detection of gene expression, as determined by a specific regulatory sequence

3.173**reporter molecule**

fluorescent molecule used to detect the hybridization of specific probes by excitation with electromagnetic radiation of an appropriate wavelength

3.174**reproducibility condition of measurement**

reproducibility condition

condition of measurement, out of a set of conditions that includes different locations, operators, measuring systems, and replicate measurements on the same or similar objects

Note 1 to entry: The different measuring systems may use different measurement procedures.

Note 2 to entry: A specification should give the conditions changed and unchanged, to the extent practical.

[SOURCE: ISO/IEC Guide 99:2007, 2.24]

3.175**reproducibility limit**

value less than or equal to which the absolute difference between two test results obtained under *reproducibility conditions* ([3.174](#)) may be expected to be with a probability of 95 %

3.176**reproducibility standard deviation**

standard deviation of test results or measurement results obtained under reproducibility conditions

Note 1 to entry: It is a measure of the dispersion of the distribution of test or measurement results under reproducibility conditions. Similarly, "reproducibility variance" and "reproducibility coefficient of variation" can be defined and used as measures of the dispersion of test or measurement results under reproducibility conditions.

3.177**restriction endonucleases**

class of enzymes that cleave (i.e. restrict) DNA at specific and unique internal location(s) along its length

3.178**restriction fragment length polymorphism**

RFLP

nucleotide difference in homologous DNA sequences that can be detected by the presence of fragments of different lengths after digestion of the DNA samples with specific restriction endonucleases

Note 1 to entry: RFLP, as a molecular marker, is specific to a single probe/restriction enzyme combination.

3.179**reverse transcriptase**

class of RNA-directed DNA polymerase enzymes, which allow for the synthesis of DNA (complementary to the RNA) using suitable primers and reaction conditions

3.180**reverse transcription**

process of making DNA from an RNA template, using the enzymatic activity of a reverse transcriptase associated with one or more oligonucleotide primers under a suitable set of conditions

3.181

reverse transcription PCR

RT-PCR

process by which an RNA strand is first reverse transcribed into its DNA complement (complementary DNA or cDNA) using reverse transcriptase and the resulting cDNA is amplified using traditional or real-time PCR

3.182

ribonucleic acid

RNA

polymer of nucleotides that consist of a nucleobase (adenine, guanine, thymine, or uracil), a ribose sugar, and a phosphate group

Note 1 to entry: Synthesis of proteins in cells is directed by genetic information carried in the sequence of nucleotides in a class of RNA known as messenger RNA (mRNA).

3.183

RNA extraction

separation of RNA from the other cellular components in a test sample

3.184

robustness

ruggedness

measure of the capacity of an analytical procedure to remain unaffected by small variations in method parameters and provides an indication of the method's reliability during normal usage

3.185

sample

small portion or quantity, taken from a population or lot that is ideally a representative selection of the whole

3.186

screening method

broad-spectrum procedure that rapidly and reliably identifies a large number of negative (or positive) test samples and restricts the number of test samples requiring the application of a more rigorous and specific method

[SOURCE: ISO 24276:2006, 3.1.24, modified]

3.187

selectivity of a measuring system

selectivity

property of a measuring system, used with a specified measurement procedure, whereby it provides measured quantity values for one or more measurands such that the values of each measurand are independent of other measurands or other quantities in the phenomenon, body, or substance being investigated

EXAMPLE 1 Capability of a measuring system including a mass spectrometer to measure the ion current ratio generated by two specified compounds without disturbance by other specified sources of electric current.

EXAMPLE 2 Capability of a measuring system to measure the power of a signal component at a given frequency without being disturbed by signal components or other signals at other frequencies.

EXAMPLE 3 Capability of a receiver to discriminate between a wanted signal and unwanted signals, often having frequencies slightly different from the frequency of the wanted signal.

EXAMPLE 4 Capability of a measuring system for ionizing radiation to respond to a given radiation to be measured in the presence of concomitant radiation.

EXAMPLE 5 Capability of a measuring system to measure the amount-of-substance concentration of creatininium in blood plasma by a Jaffé procedure without being influenced by the glucose, urate, ketone, and protein concentrations.