

## IUPAC Recommendations

Gunnar Nordin\*, René Dybkaer, Urban Forsum, Xavier Fuentes-Arderiu  
and Françoise Pontet†

# Vocabulary on nominal property, examination, and related concepts for clinical laboratory sciences (IFCC-IUPAC Recommendations 2017)

<https://doi.org/10.1515/pac-2011-0613>

Received June 29, 2011; accepted September 6, 2017

**Abstract:** Scientists of disciplines in clinical laboratory sciences have long worked on a common language for efficient and safe request of investigations, report of results, and communication of experience and scientific achievements. Widening the scope, most scientific disciplines, not only clinical laboratory sciences, rely to some extent on various examinations in addition to measurements. The ‘International vocabulary of metrology – Basic and general concepts and associated terms’ (VIM), is designed for metrology, the science of measurement. The aim of this vocabulary is to suggest definitions and explanations of concepts and a selection of terms related to nominal properties, *i.e.* properties that have no size.

**Keywords:** concept; examination; kind-of-nominal-property; nominal property; term; vocabulary.

## CONTENTS

1. INTRODUCTION .....	914
1.1. Conventions .....	914
1.2. Scope.....	915
2. BASIC CONCEPTS RELATED TO ‘EXAMINATION’ .....	915
3. CONCEPTS RELATED TO ‘EXAMINATION RESULT’ .....	921
4. EXAMINATION STANDARDS AND REFERENCE EXAMINATION PROCEDURES .....	929
5. ALPHABETICAL INDEX OF TERMS .....	932
MEMBERSHIP OF SPONSORING BODIES .....	934
ACKNOWLEDGMENTS .....	934
ABBREVIATIONS .....	934
REFERENCES .....	934

**Article note:** This document was prepared in the frame of IUPAC Project # 2004-023-1-700, extended 2008-019-1-700.

**Supplementary information available online:** In the online version of this article, located at <https://doi.org/10.1515/pac-2011-0613>, hyperlinks connect related terms and entries, allowing for direct navigation between them.

†Deceased 2013.

\*Corresponding author: Gunnar Nordin, Equalis, Uppsala, Sweden, e-mail: [gunnar.nordin@equalis.se](mailto:gunnar.nordin@equalis.se)

René Dybkaer: Department of Standardization in Laboratory Medicine, H:S Frederiksberg Hospital, Copenhagen University Hospital, Frederiksberg, Denmark

Urban Forsum: Division of Clinical Microbiology, Faculty of Medicine, Linköpings Universitet, Linköping, Sweden

Xavier Fuentes-Arderiu: Clinical Laboratory Sciences Consulting, Barcelona, Catalonia, Spain

 © 2018 IUPAC & De Gruyter. This work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License. For more information, please visit: <http://creativecommons.org/licenses/by-nc-nd/4.0/>

Brought to you by | Linköping University Library  
Authenticated

Download Date | 5/23/18 11:27 AM

# 1 Introduction

In a world of increased communication of examination results mediated by information technology, there is a need for a common vocabulary.

The International vocabulary of metrology – Basic and general concepts and associated terms (VIM) deals with metrology, defined as the science of measurement and its application [1]. According to VIM in 2.1, note 1, “Measurement does not apply to nominal properties,” so they cannot be a subject for metrology. However, most scientific disciplines, not only clinical laboratory sciences, also rely – some predominantly – on the description of properties without size. Typical cases can be found in several recommendations and technical reports in *Pure and Applied Chemistry (PAC)* authored by the Committee-Subcommittee on Nomenclature for Properties and Units (C-SC-NPU) [2–6] that rely heavily on kinds-of-nominal-property, such as ‘taxon’ or ‘sequence variation’. Some of these concepts have been covered earlier [7], but a vocabulary on nominal property should be useful in the development of the 4<sup>th</sup> edition of the VIM.

It is believed that concepts for non-measurable properties should be useful for practitioners and the scientific community in disciplines such as general chemistry, health science, clinical laboratory sciences, biology, engineering, biochemistry, food science, forensic medicine, molecular biology, environmental science, and physics.

The starting point and basis of this work have been the VIM, the definitions of which have been widely applied or adapted to nominal properties. However, a few concepts have different definitions from those given in VIM.

It should be noted that this vocabulary deals exclusively with nominal properties, *i.e.* with values that have no size, and not with ordinal quantities, including binary ordinal quantities, such as those with “no/yes” or “0/1” values that can be ordered by size. The meaning of a nominal property value is given in the examination procedure.

The authors have a clinical laboratory sciences background, including several specialties. The examples, therefore, deal mostly with this discipline.

An earlier version of this document has been published [8]. Under the reviewing process for the present publication in *PAC*, many valuable comments have been received, notably from Jean Schwob. Professor Emil Bashkansky has provided helpful input to the discussions on statistics for nominal property values. Compared to the earlier version, the number of defined concepts has been reduced. Several basic concepts are now used as non-defined ‘primitives’, hopefully without reducing the understanding by laboratory practitioners. The term “examination” has been used instead of “nominal examination”. Several of the remaining definitions have been corrected and improved.

The term “magnitude” as generally used by VIM has raised some discussion. In this document, the term has been replaced by “size” throughout.

## 1.1 Conventions

### Terminology Rules

The definitions and terms given in this vocabulary, and their formats, comply as far as possible with the rules of terminology outlined in ISO 704:2009 [9], ISO 10871:2000 [10], and ISO 10241-1:2011 [11]. In particular, the substitution principle applies; that is, it is possible in any definition to replace a term referring to a concept defined elsewhere in this vocabulary by the definition corresponding to that term without introducing contradiction or circularity.

### Format

The format of terminological entries in this document is as follows:

**Entry number (bold) term (bold)**  
definition

EXAMPLE 1

EXAMPLE 2

Note to example(s):

Note 1 to entry:

Note 2 to entry:

[SOURCE:]

**Document structure**

The concepts have been divided into three sections: Basic concepts related to ‘examination’ (Section 2), Concepts related to ‘examination result’ (Section 3) and ‘Examination standards and reference examination procedures’ (Section 4).

**Quotation marks**

In this document, single quotation marks (‘...’) surround a term representing a concept, unless the term is in italics. Double quotation marks (“...”) are used when only the term is considered, or for a quotation.

**Curly brackets**

The possible values in a set are separated by commas and surrounded by curly brackets, {*a, b, c, ...*}.

**Italic font**

Terms for concepts defined elsewhere in the document are printed in italic font followed by parenthetical entry number at the first appearance in an entry. Taxonomic terms in Latin, *i.e.* for genera, species, and subspecies, are also given in italics.

**1.2 Scope**

As previously stated, this vocabulary is written by clinical laboratory scientists and will be presented to JCGM-WG2 for its work towards a fourth edition of the VIM. Like VIM, it uses some general concepts without definition. These primitives include ‘aspect’, ‘body’, ‘classification’, ‘code’, ‘component’, ‘device’, ‘equivalence’, ‘indication’, ‘instrument’, ‘material’, ‘object’, ‘phenomenon’, ‘property’, ‘reference’, ‘set’, ‘size’, ‘substance’, ‘system’, and ‘verification’.

This document encompasses a limited scientific field. Experts with other scientific backgrounds than the clinical laboratory are invited to consider the applicability of this vocabulary to activities in their domains.

**2 Basic concepts related to ‘examination’****2.1 nominal property**

property of a phenomenon, body, or substance, where the property has no size

EXAMPLE 1 Colour at a specified lighting of a given leaf of a plant.

EXAMPLE 2 Sequence variation of nucleotides of a given gene.

EXAMPLE 3 *Taxon* (2.4) of a bacterium in a given sample of urine.

EXAMPLE 4 Shape of the nucleus of a given white blood cell.

Note 1 to entry: The concept ‘nominal property’ is defined as the opposite of ‘quantity’, *i.e.* the former concept lacks the essential characteristic of ‘size’ (or ‘magnitude’). In such cases, ISO 704:2009-6.5.4 allows a ‘negative definition’ [9].

- Note 2 to entry: The term “attribute” has sometimes been used to designate ‘nominal property’, but not here.
- Note 3 to entry: The term “qualitative property” is also used, but not here as it is ambiguous because ‘ordinal quantity’ is often included under that term.
- Note 4 to entry: ‘Nominal property’ is sometimes termed “nameable property”, but not here.

## 2.2 kind-of-nominal-property

defining aspect, common to mutually comparable *nominal properties* (2.1)

- EXAMPLE 1 Colour at a specified lighting.
- EXAMPLE 2 Sequence variation.
- EXAMPLE 3 *Taxon* (2.4).
- EXAMPLE 4 Shape.

Note to entry: ‘Kind-of-nominal-property’ is sometimes termed “attribute”, but not here.

[SOURCE: The definition of this concept is analogous to that of ‘kind of quantity’ in VIM 1.2.]

## 2.3 category

*Kind-of-nominal-property* (2.2) indicating a class among *nominal properties* (2.1) ordered according to *nominal property values* (3.1) of a specified *nominal property value set* (3.2) without relation to size

- EXAMPLE Blood type A is a nominal property value within the blood group system ABO where the nominal property value set is {A, B, AB, O}.

## 2.4 taxon

*category* (2.3) indicating a class of organisms within a recognized hierarchically structured *nominal property value set* (3.2)

- EXAMPLE In the system ‘Blood’ with the component ‘*Staphylococcus*’, the application of the *kind-of-nominal-property* (2.2) ‘*taxon*’ could give the *nominal property values* (3.1) ‘species *Staphylococcus aureus*, species *Staphylococcus lugdunensis*, and *Coagulase negative staphylococci* (CNS)’. The value set comprises all species and groups of *Staphylococcus* that the procedure can identify.

Note to entry: Taxonomy is the science of classification and its applications, usually regarding organisms.

## 2.5 dedicated kind-of-nominal-property

*kind-of-nominal-property* (2.2) with a sort of system and any pertinent sort(s) of component(s)

- EXAMPLE 1 The colour of the fluid within the central channel of the spinal cord of any person. The colour might be affected by a cerebral haemorrhage.

EXAMPLE 2 The sequence variation of nucleotides of the gene CYP2D6 in DNA from any person. CYP2D6 is a gene coding for one of the enzymes within the cytochrome P450 oxidase system, *e.g.* affecting drug metabolism.

EXAMPLE 3 The *taxon* (2.4) of the bacterium in a sample of expectoration from any person.

EXAMPLE 4 The typical shape of the nuclei in monocytes (a type of leukocyte) in a sample of blood from any person. The morphology of cells is studied under microscope after fixation and staining of a thin blood film.

Note to examples: The dedicated kinds-of-nominal-property above correspond to EXAMPLES 1 – 4 of kind-of-nominal-property.

Note 1 to entry: A dedicated kind-of-nominal-property is not specified to any individual person, in contrast to an individual nominal property, and it cannot have a *nominal property value* (3.1).

Note 2 to entry: In clinical laboratory report forms, dedicated kind-of-nominal-properties may be described according to an internationally recommended NPU syntax from IFCC-IUPAC [12]. The syntax is System(specification)–Component(specification); kind-of-property(specification). The last “specification” might contain information on the *examination procedure* (2.12) or the *nominal property value set* (3.2) The initial capital for System and for Component is mandatory.

Examples of the NPU syntax

Blood–Plasma; colour({milky, red, yellow}).

Erythrocytes(Blood)–Erythrocyte antigen; blood group({A, B, AB, O}).

For EXAMPLES 1 – 4N under the definition above, individual nominal properties can be written as follows (omitting patient identity and time but including the nominal property value for clarity):

1. Patient–Spinal fluid; colour(visual) = reddish
2. DNA(Leukocytes)–CYP2D6 gene; sequence variation(allele specific PCR) = \*1/\*3
3. Expectoration–Bacterium; taxon(Phadebact coagglutination test) = *Mycobacterium tuberculosis*.
4. Monocytes(Blood)–Nuclei; shape = oval

Note 3 to entry: The patient’s name (or other identifier), location, and date and time of obtaining the sample of the system under consideration shall always be given in the clinical laboratory report.

[SOURCE: The definition of this concept is analogous to that of ‘dedicated kind-of-property’ [7].]

## 2.6 examination

process of experimentally obtaining one or more *nominal property values* (3.1) that can reasonably be attributed to a *nominal property* (2.1)

EXAMPLE 1 Examination of genotype by, *e.g.* allele specific PCR or melting point analysis.

EXAMPLE 2 Erythrocyte antigen examined by agglutination reactions with known antibodies.

Note 1 to entry: The outcome of an examination is an *examination result* (3.4).

Note 2 to entry: The activity of examination essentially consists in comparing the property considered, *i.e.* the *examinand* (2.7) by way of an *examining system* (2.8), with the property

of a ‘reference’ of similar nature. Such a reference may be personal and subjective, such as a person’s memory of a colour, or the reference may be objective, such as a *nominal reference material* (4.2).

[SOURCE: The definition of this concept is analogous to that of ‘measurement’ in VIM, 2.1.]

## 2.7 examinand

*nominal property* (2.1) intended to be examined

EXAMPLE 1 Morphology of cells in blood.

EXAMPLE 2 The *taxon* (2.4) of *Entamoeba* in faeces.

Note 1 to entry: The *nominal property value* (3.1) of an examinand may be different from that of the property actually being examined due to changes of the system bearing the property during the *examination* (2.6).

Note 2 to entry: The *examined value* (3.5) may be obtained indirectly through examinations of other nominal properties, giving the examined value by using an algorithm which may involve measurement results and *examination results* (3.4).

[SOURCE: The definition for this concept is analogous to that of ‘measurand’ in VIM, 2.3.]

## 2.8 examining system

set of one or more devices, including any reagent and supply, assembled and adapted to give information used to generate *examined values* (3.5) from a *nominal property value set* (3.2)

EXAMPLE 1 Selective culture medium for the identification of *Candida albicans* in a biological fluid.

EXAMPLE 2 Chromatograph and mass spectrometer for the identification of mass/charge ratios of molecules.

EXAMPLE 3 Instrument used for running a polymerase chain reaction (PCR) followed by restriction fragment length polymorphism (RFLP) for the identification of a genotype.

Note to entry: A human eye may be an essential element of an examining system.

[SOURCE: The definition of this concept is analogous to that of ‘measuring system’ in VIM, 3.2.]

## 2.9 influence nominal property

*nominal property* (2.1) that, in an *examination* (2.6), does not affect the nominal property that is actually examined, but affects the relation between the *nominal indication* (2.13) on the *examining system* (2.8) and the *examination result* (3.4)

EXAMPLE Contaminating microbiological species may influence the nominal indication of a nominal property related to the examined species.

Note to entry: A quantity might also influence a nominal property.

[SOURCE: The definition of this concept is analogous to that of ‘influence quantity’ in VIM, 2.52.]

## 2.10 examination principle

phenomenon serving as a basis of an *examination* (2.6)

EXAMPLE 1 Selective amplification of a DNA sequence to compare for equivalence with a target sequence.

EXAMPLE 2 Comparison of spectral properties of a component with properties of known substances.

Note to entry: The phenomenon can be of a physical, chemical, or biological nature.

[SOURCE: The definition of this concept is analogous to that of ‘measurement principle’ in VIM, 2.4.]

## 2.11 examination method

generic description of a logical organization of operations used in an *examination* (2.6)

EXAMPLE 1 Polymerase chain reaction (PCR)-restriction fragment length polymorphism (RFLP).

EXAMPLE 2 Infra-red spectrometry.

Note to entry: The laconic description in an examination method is insufficient to allow an examination with prescribed *examination uncertainty* (3.9), but aids in formulating one or more *examination procedures* (2.12).

[SOURCE: The definition of this concept is analogous to that of ‘measurement method’ in VIM, 2.5.]

## 2.12 examination procedure

detailed description of an *examination* (2.6) according to one or more *examination principles* (2.10) and to a given *examination method* (2.11) and any decision algorithm necessary to obtain an *examination result* (3.4)

EXAMPLE Working instructions, or “standard operating procedure”, at laboratory A to examine a sample for a possible mutation in the gene for haemochromatosis (HFE).

Note 1 to entry: An examination procedure specifies the *dedicated kind-of-nominal-property* (2.5) involved, any sampling, *examining system* (2.8), *nominal reference material(s)* (4.2) needed, and the *nominal property value set* (3.2) used. The examination procedure also specifies how many *examined values* (3.5) that are necessary to obtain an examination result and how to estimate the expected *examination uncertainty* (3.9).

Note 2 to entry: The information presented in an examination procedure is intended to be operational and should be sufficient for a trained operator to perform an examination satisfactorily.

Note 3 to entry: An examination procedure can include a statement concerning a *target examination uncertainty* (3.18).

[SOURCE: The definition of this concept and notes 2 and 3 to the entry are inspired by those of ‘measurement procedure’ in VIM, 2.6.]

### 2.13 nominal indication

*nominal property value* (3.1) provided by an *examining system* (2.8)

[SOURCE: The definition is modified from VIM, 4.1.]

### 2.14 blank nominal indication

*nominal indication* (2.13) obtained from an object similar to the one under investigation, except that the *nominal property* (2.1) of interest is supposed not to be present, or is not contributing to the nominal indication

EXAMPLE                      Nominal indication obtained by examining a serum containing immunoglobulins, but no HLA-antibodies, when the component searched for is HLA-antibodies [13].

Note 1 to entry:              A blank nominal indication shall not be confused with a quantity value below a detection limit.

Note 2 to entry:              A blank nominal indication is necessary for quality assessment in some *examination procedures* (2.12).

Note 3 to entry:              A blank nominal indication, when the examination procedure is expected to produce a *nominal property value* (3.1), is an erroneous nominal property value.

Note 4 to entry:              The concept is often termed “negative control”, but not here.

[SOURCE: The definition of this concept is analogous to that of ‘blank indication’ in VIM, 4.2.]

### 2.15 repeatability condition of examination

condition of *examination* (2.6) out of a set of conditions that includes the same *examination procedure* (2.12), same operators, same *examining system* (2.8), same operating conditions, same location, and replicate examinations on the same or similar objects over a short period of time

[SOURCE: The definition of this concept is analogous to that of ‘repeatability condition of measurement’ in VIM, 2.20.]

### 2.16 intermediate precision condition of examination

condition of *examination* (2.6) out of a set of conditions that includes the same *examination procedure* (2.12), same location, and replicate examinations on the same or similar objects over an extended period of time, but may include other conditions involving changes

[SOURCE: The definition of this concept is analogous to that of ‘intermediate precision condition of measurements’ in VIM, 2.22.]

### 2.17 reproducibility condition of examination

condition of *examination* (2.6) out of a set of conditions that includes different locations, operators, *examining systems* (2.8), and replicate examinations on the same or similar objects

Note to entry: The different examining systems may use different *examination procedures* (2.12).

[SOURCE: The definition of this concept is analogous to that of ‘reproducibility condition of measurement’ in VIM, 2.24.]

### 3 Concepts related to ‘examination result’

#### 3.1 nominal property value

feature common to equivalent individual *nominal properties* (2.1)

EXAMPLE 1 ‘Yellow’ is a nominal property value for a nominal property of the *kind-of-nominal-property* (2.2) ‘colour’ of a given Urine as system. There is no separate component.

EXAMPLE 2 ‘\*1/\*3’ is a nominal property value for a nominal property of the kind-of-nominal-property ‘sequence variation’ of the CYP2D6 gene in a given ‘DNA’ as system. The allele ‘\*1’ is related to normal enzyme activity while the allele ‘\*3’ is related to decreased enzyme activity.

EXAMPLE 3 The species *Mycobacterium tuberculosis* is a nominal property value for a nominal property of the kind-of-nominal-property *taxon* (2.4) of the component *Mycobacterium* in a given ‘Expectoration’ as system. Infectious diseases might be caused by several different species of *Mycobacterium*. The species can be examined in a sample from an expectoration.

EXAMPLE 4 ‘Oval’ is a nominal property value for a nominal property with of kind-of-nominal-property ‘shape’ of the component ‘Leukocyte nucleus’ in a given Blood as system. This shape is typical of immature forms of monocytes, such as promonocytes,

Note 1 to entry: Nominal property values can be words, alphanumerical codes, symbols, etc, but cannot enter into algebraic equations and is not related to a quantity dimension or a measurement unit.

Note 2 to entry: A nominal property value can consist of a set of items.  
Example: The colours of the national flag of Switzerland are red and white.

Note 3 to entry: The term “nominal quantity value” and its short form “nominal value” are used, for example in VIM 4.6, to indicate a concept concerning rounded or approximate quantity values. The term “nominal indication interval” is used in VIM 4.4 to indicate a concept concerning rounded or approximate extreme indications.

[SOURCE: The first part of Note 1 to entry is from VIM, 1.30, Note 1.]

#### 3.2 nominal property value set

set of possible *nominal property values* (3.1) for *nominal properties* (2.1) of a given *kind-of-nominal-property* (2.2)

EXAMPLE 1 {milky, red, yellow} can be a nominal property value set for nominal properties with the kind-of-nominal-property ‘colour’.

EXAMPLE 2 {A, B, AB, O} can be a nominal property value set of four nominal property values for nominal properties with the kind-of-nominal-property ‘blood group’.

Note to entry: A ‘nominal property value set’ can be ordered by convention, for example in alphabetic order of words, or alphanumerical codes identifying nominal property values, or an order reflecting a classification, but neither of these is an ordering by size.

EXAMPLE 3 Nominal property value sets that are ordered by other means than size, *e.g.* numbering of chromosomes and alphabetical list of country codes.

### 3.3 reference nominal property value

*nominal property value* (3.1) used as a basis for comparison with nominal property values of *nominal properties* (2.1) of the same *kind-of-nominal-property* (2.2)

Note to entry: A reference nominal property value can be a *true nominal property value* (3.6) of an *examinand* (2.7), in which case it is unknown, or a *conventional nominal property value* (3.7), in which case it is known.

[SOURCE: The definition and note of this concept are analogous to those of ‘reference quantity value’ in VIM, 5.18.]

### 3.4 examination result

set of *nominal property values* (3.1) being attributed to an *examinand* (2.7) together with any other available relevant information

EXAMPLE The gene for hemochromatosis (HFE) is examined for a possible mutation at c.187 from C to G. The result is C/C. If the probability of having an examination result that deviates from a *conventional nominal property value* (3.7) is close to zero, then the *examination uncertainty* (3.9) is considered negligible.

Note 1 to entry: An ‘examination result’ sometimes contains “relevant information“ about the set of nominal property values, such that some may be more representative of the *examinand* than others.

Note 2 to entry: ‘Examination result’ should not be confused with *nominal property value set* (3.2).

Note 3 to entry: An ‘examination result’ may be expressed as a single *examined value* (3.5) and an examination uncertainty. If there is no dispersion of nominal property values attributed to the *examinand* or if the examination uncertainty is considered to be negligible for a specified purpose, the examination result may be expressed as a single *examined value*.

[SOURCE: The definition and the first parts of Notes 1 and 2 for this concept are analogous to those of ‘measurement result’ in VIM, 2.9.]

### 3.5 examined value

*nominal property value* (3.1) representing an *examination result* (3.4)

Note to entry: The term “observed value“ is sometimes used for ‘examined value’, but not here.

[SOURCE: The definition of this concept is analogous to that of ‘measured quantity value’ in VIM, 2.10.]

### 3.6 true nominal property value

*nominal property value* (3.1) consistent with the definition of a *nominal property* (2.1)

[SOURCE: The definition of this concept is analogous to that of ‘true quantity value’ in VIM, 2.11.]

### 3.7 conventional nominal property value

*nominal property value* (3.1) attributed by agreement to a *nominal property* (2.1) for a given purpose

EXAMPLE ‘Red’ for ‘Blood(oxygenated)—Blood; colour’

[SOURCE: The definition of this concept is analogous to that of ‘conventional quantity value’ in VIM, 2.12.]

### 3.8 examination trueness

fraction of *examined values* (3.5) identical to one or more *reference nominal property values* (3.3) among all the examined values provided

EXAMPLE The reference nominal property value is ‘B’. The *nominal property value set* (3.2) of all possible values is {A, B}. For nine of 10 *examinations* (2.6) the examined value is ‘B’. The examination trueness is therefore 0.9 (90 %).

Note 1 to entry: Each examined value is either equivalent, or non-equivalent, to the reference nominal property value.

Note 2 to entry: The examination trueness, in contrast to measurement trueness (VIM, 2.14), is a quantity, and is complementary to *examination uncertainty* (3.9).

### 3.9 examination uncertainty

fraction of *examined values* (3.5) that is different from a *reference nominal property value* (3.3) among all the examined values provided

EXAMPLE 1: The reference nominal property value is ‘B’. The *nominal property value set* (3.2) of all possible nominal property values is {A, B}. For one of 10 *examinations* (2.6) the examined value differs from ‘B’. The examination uncertainty is therefore 0.1 (10 %).

EXAMPLE 2: A patient suffers from a urinary tract infection. The *examination result* (3.4) from the *examination procedure* (2.12) is growth of bacteria of the species *E. coli* in a sample of urine with 20 % examination uncertainty. With knowledge and experience from the examination procedure it can be concluded that there is some probability that the true species of bacteria could be instead a *Salmonella* or *Shigella* species, while the probability that the reference nominal property value is some other species of bacteria is very low.

Note 1 to entry: Examination uncertainty is a quantity that is complementary to *examination trueness* (3.8).

Note 2 to entry: Examination uncertainty is a part of an examination result.

- Note 3 to entry: With exception of the situation where the examination uncertainty is zero, some examined values differ from the reference nominal property value. In a comment to the examination result, the laboratory can provide information about other possible *nominal property values* (3.1), based on the information available.
- Note 4 to entry: The definition of this concept is not analogous to that of ‘measurement uncertainty’ in VIM, 2.26.

### 3.10 examination error

disagreement between an *examined value* (3.5) and a *reference nominal property value* (3.3)

EXAMPLE 1 The reference nominal property value is ‘red’ and the examined value is ‘pink’.  
Narrative expression: The examined value disagrees with the reference nominal property value, so that an examination error is present.

EXAMPLE 2 The reference nominal property value is ‘BCD’ and the examined value is ‘BCD’.  
Narrative expression: The examined value agrees with the reference nominal property value, so there is no examination error.

- Note 1 to entry: An examination error is either present or absent.
- Note 2 to entry: Examination error is associated with an examined value, but not with an *examining system* (2.8).
- Note 3 to entry: Examination error should not be confused with production error or mistake.

[SOURCE: Note 3 is analogous to that of ‘measurement error’ in VIM, 2.16, note 2.]

### 3.11 examination accuracy

closeness of agreement between an *examined value* (3.5) and a *true nominal property value* (3.6) of an *examinand* (2.7)

EXAMPLE The true nominal property value is ‘A’, the first examined value is ‘B’, and the second examined value is ‘A’.  
Narrative expression: The first examined value is inaccurate, and the second examined value is accurate.

- Note to entry: Examination accuracy is a feature of an individual examined value, but not of an *examining system* (2.8).

[SOURCE: The definition for this concept is inspired by that of ‘measurement accuracy’ in VIM, 2.13.]

### 3.12 examination precision

closeness of agreement between *nominal indications* (2.13) on an *examining system* (2.8) or *examined values* (3.5) obtained by replicate *examinations* (2.6) on the same or similar objects under specified examination conditions

- Note 1 to entry: Examination precision can be expressed numerically by measures of dispersion of examined values such as Index of Qualitative Variation (IQV) [14] and the Shannon’s

entropy [15], under specified examination conditions. IQV varies between 0 (no dispersion, all examined values in a single class) and 1 (two or more classes with identical frequency). Shannon's entropy varies between 0 (no dispersion, that is all examined values belong to a single category) and a maximum value equal to the logarithm (on basis 2) of the number of all categories.

## EXAMPLE

Examinations of a *nominal property* (2.1) were done with three different examining systems, used with respective specified *examination procedures* (2.12) under the same specified conditions. The *nominal property value set* (3.2) is {A, B, C, and D}. The frequency distribution of the examined values for examining systems 1, 2, and 3 were:

Possible examined values	Examined values		
	Examining system 1	Examining system 2	Examining system 3
A	8	6	6
B	1	2	4
C		1	
D	1	1	
Total number of examined values	10	10	10

In the example above the dispersion is lowest for Examining system 1, so that it has the lowest values for IQV and entropy. According to entropy, examination of system 2 has the highest degree of dispersion (data in four categories), while Examining system 3 has the greatest dispersion according to IQV. Methods have also been suggested for the investigation of differences in homogeneity of dispersion between groups [16].

- Note 2 to entry: A proportion distribution of a set of examined values describes proportions of data belonging to every possible *nominal property value* (3.1).
- Note 3 to entry: 'Specified examination conditions' can, for example, be *repeatability condition of examination* (2.15), *intermediate precision condition of examination* (2.16), or *reproducibility condition of examination* (2.17).
- Note 4 to entry: Examination precision is used to define *examination repeatability* (3.13), *intermediate examination precision* (3.14), and *examination reproducibility* (3.15).
- Note 5 to entry: Examination precision is a feature of an examining system used with a specified examination procedure.

[SOURCE: The definition and Notes 4 and 5 for this concept are analogous to those of 'measurement precision' in VIM, 2.15.]

### 3.13 examination repeatability

*examination precision* (3.12) under *repeatability condition of examination* (2.15)

- Note 1 to entry: Examination repeatability is a quantity.
- Note 2 to entry: Examination repeatability is a feature of an *examining system* (2.8) used with a specified *examination procedure* (2.12).

[SOURCE: The definition of this concept is analogous to that of 'measurement repeatability' in VIM, 2.21.]

### 3.14 intermediate examination precision

*examination precision* (3.12) under *intermediate precision condition of examination* (2.16)

Note 1 to entry: Intermediate examination precision is a quantity.

Note 2 to entry: Intermediate examination precision is a feature of an *examining system* (2.8) used with a specified *examination procedure* (2.12).

[SOURCE: The definition of this concept is analogous to that of ‘intermediate measurement precision’ in VIM, 2.23.]

### 3.15 examination reproducibility

*examination precision* (3.12) under *reproducibility condition of examination* (2.17)

Note 1 to entry: Examination reproducibility is a quantity.

Note 2 to entry: Examination reproducibility is a feature of a set of *examined values* (3.5).

[SOURCE: The definition of this concept is analogous to that of ‘measurement reproducibility’ in VIM, 2.25.]

### 3.16 systematic examination error

fraction of *examined values* (3.5) with *examination error* (3.10) that in replicate *examinations* (2.6) remains constant or varies in a predictable manner

EXAMPLE The *reference nominal property value* (3.3) is ‘B’. The following number of examined values were obtained in one set of examinations: 8 times ‘B’, 9 times ‘C’, 8 times ‘D’, 4 times ‘E’. In another set the following values were obtained: 16 times ‘B’, 9 times ‘C’, and 4 times ‘E’.

Narrative expression: The systematic examination error is that ‘C’ and ‘E’ are found in replicate examinations and neither represents a reference nominal property value.

Note 1 to entry: Systematic examination errors for examined values are quantities.

Note 2 to entry: The systematic examination error for examined values can be expressed for a set of examined values as *examination bias* (3.17).

Note 3 to entry: Systematic examination error is a feature of an *examining system* (2.8) used with a specified *examination procedure* (2.12).

[SOURCE: The definition of this concept is inspired by that of ‘systematic measurement error’ in VIM, 2.17.]

### 3.17 examination bias

estimate of a *systematic examination error* (3.16)

EXAMPLE 53 *examined values* (3.5) were obtained with a *reference examination procedure* (4.4), 106 were obtained by Examination procedure 1 and with Examination procedure 2. Examination procedure 1 resulted in examined values with the same proportion distribution as for the Reference examination procedure, and the examined values have thus no examination bias. The 106 examined values with Examination procedure 2 have

a different distribution compared to that of the *reference nominal property values* (3.3), and the examined values thus have an examination bias.

Possible examination values	Examined values		
	Reference examination procedure	Examination procedure 1	Examination procedure 2
A	21	42	2
B			40
C	18	36	2
D			36
E	12	24	10
F			5
G	2	4	11
Total number of examined values	53	106	106

One estimate of examination bias for *nominal properties* (2.1) is the Bhattacharyya distance [17], which measures the similarity of two nominal data sets. It equals zero when two proportion distributions are identical as is the case when comparing Examination procedure 1 and Reference examination procedure. There is an examination bias between Examination procedure 2 and Reference examination procedure, because the proportion distributions are different.

Note 1 to entry: Examination bias is a quantity.

Note 2 to entry: If the proportion distributions of the reference nominal property values and the examined values are the same, there is no examination bias for the *examining system* (2.8). If the distributions differ there is an examination bias.

Note 3 to entry: In some publications on analytical chemistry, ‘examination bias’ is termed “lack of reliability“, but this is not recommended here.

[SOURCE: The definition of this concept is analogous to that of ‘measurement bias’ in VIM, 2.18.]

### 3.18 target examination uncertainty

*examination uncertainty* (3.9) specified as an acceptable fraction and decided on the basis of the intended use of *examination results* (3.4)

Note to entry: Target examination uncertainty is a quantity.

[SOURCE: The definition of this concept is analogous to that of ‘target measurement uncertainty’ in VIM, 2.34.]

### 3.19 nominal property value coverage set

subset of the *nominal property value set* (3.2) containing the *true nominal property value(s)* (3.6) of an *examinand* (2.7) with a stated probability, based on the information available

EXAMPLE A nominal property value coverage set for ‘Urine(midstream)—Bacterium; taxon’ could be {*Escherichia coli*, *Staphylococcus epidermidis*} as specified in Bergey’s manual.

[SOURCE: The definition of this concept is analogous to that of ‘coverage interval’ in VIM, 2.36.]

### 3.20 nominal property value coverage probability

probability that the set of *true nominal property values* (3.6) of an *examinand* (2.7) is contained within a specified *nominal property value coverage set* (3.19)

EXAMPLE            The nominal property value coverage probability that the bacteria in the urine belongs to the species *Escherichia coli* and *Staphylococcus epidermidis* is more than 95 %.

[SOURCE: The definition of this concept is analogous to that of ‘coverage probability’ in VIM, 2.37.]

### 3.21 examination traceability

property of an *examination result* (3.4) whereby it can be related to a reference through a documented unbroken chain of *examination calibrations* (4.3), each contributing to the *examination uncertainty* (3.9)

Note to entry:        An ISO Technical report (TR 79:2015) [18] characterizes reference materials for “qualitative properties”.

[SOURCE: The definition of this concept is analogous to that of ‘metrological traceability’ in VIM, 2.41.]

### 3.22 examinational comparability of examination results

comparability of *examination results* (3.4), for *nominal properties* (2.1) of a given *kind-of-nominal-property* (2.2), that are examined and traceable to the same reference

EXAMPLE            Examination results for the colours of two different biological fluids are comparable when they are both traceable to the same colour chart.

[SOURCE: The term and definition of this concept are analogous to those of ‘metrological comparability’ in VIM, 2.46.]

### 3.23 examinational compatibility of examination results

property of a set of *examination results* (3.4) for a specified *examinand* (2.7) of a given *kind-of-nominal-property* (2.2) that have overlapping *nominal property value sets* (3.2)

EXAMPLE            Let the nominal property value set for ‘Patient—Urine; colour(proc.)’ be {red, dark red}.  
‘Red’ is a compatible examination result because it is contained within the nominal property value set. ‘Black’ and ‘white’ are not compatible as they do not belong to the nominal property value set.

Note 1 to entry:        Two compatible examination results can be identical.

Note 2 to entry:        The definition of this concept is not analogous to that of ‘metrological compatibility of measurement results’ in VIM, 2.47.

## 4 Examination standards and reference examination procedures

### 4.1 examination standard

realization of the definition of a given *nominal property* (2.1), with stated *nominal property value* (3.1) and associated *examination uncertainty* (3.9), used as a reference

EXAMPLE            A given *examined value* (3.5) for a bacterial *taxon* (2.4) can be compared for equivalence with the stated nominal property value of an examination standard in the form of typical bacteria of the species.

Note to entry:      A ‘realization of the definition of a given nominal property’ can be provided by an *examining system* (2.8) or a *nominal reference material* (4.2).

[SOURCE: The definition and note of this concept are analogous to those of ‘measurement standard’ in VIM, 5.1.]

### 4.2 nominal reference material

material, sufficiently homogeneous and stable with reference to a specified *nominal property* (2.1), that has been established to be fit for its intended use in an *examination* (2.6)

EXAMPLE 1            Colour chart with one or more specified colours.

EXAMPLE 2            DNA compound containing a specified nucleotide sequence.

Note to entry:      Nominal reference materials with or without assigned *reference nominal property values* (3.3) can be used for control of *examination precision* (3.12), whereas only nominal reference materials with assigned reference nominal property values can be used for the control of *examination calibration* (4.3) or evaluation of *examination trueness* (3.8).

[SOURCE: The definition of this concept and related examples are analogous to those of ‘reference material’ in VIM, 5.13, where the superordinate concept of both nominal reference material and measurement reference material is defined.]

### 4.3 examination calibration

process that confers to one or more persons or to a device the capacity to provide *nominal property values* (3.1) from specified *examinations* (2.6) after having examined one or more *examination standards* (4.1)

EXAMPLE            Identifying a bird after having studied certified pictures and sounds.

Note to entry:      Examination calibration differs from that of calibration in VIM3 2.39, because in examination calibration there is no explicit mention of ‘nominal indication’ and ‘examination uncertainty’.

### 4.4 reference examination procedure

*examination procedure* (2.12) accepted as providing *examination results* (3.4) fit for their intended use in assessing *examination trueness* (3.8) of *examined values* (3.5) obtained from other examination procedures

for *nominal properties* (2.1) of the same *kind-of-nominal-property* (2.2), in *examination calibration* (4.3), or in characterizing *nominal reference materials* (4.2)

- EXAMPLE 1            A reference examination procedure provided by a perfume firm to identify smells.  
 EXAMPLE 2            The official examination procedure for car technical control (involving both measurements and nominal *examination* (2.6)).

[SOURCE: The definition of this concept is analogous to that of ‘reference measurement procedure’ in VIM, 2.7.]

#### 4.5 primary reference examination procedure

*reference examination procedure* (4.4) used to obtain an *examination result* (3.4) without relation to an *examination standard* (4.1) for a *nominal property* (2.1) of the same *kind-of-nominal-property* (2.2)

[SOURCE: The definition of this concept is analogous to that of ‘primary reference measurement procedure’ in VIM, 2.8.]

#### 4.6 international examination standard

*examination standard* (4.1) recognized by signatories to an international agreement and intended to serve worldwide

- EXAMPLE            The WHO 1<sup>st</sup> international genetic reference panel for Factor V Leiden, Human gDNA: 03/254, 03/260, 03/248 [19].

[SOURCE: The definition of this concept is analogous to that of ‘international measurement standard’ in VIM, 5.2.]

#### 4.7 national examination standard

*examination standard* (4.1) recognized by national authority to serve in a state or economy as the basis for assigning *nominal property values* (3.1) to other examination standards for the same *kind-of-nominal-property* (2.2)

- EXAMPLE            The *examinand* (2.7) ‘HLA specific allo-antibodies in human blood plasma’ is detected and identified according to a nationally agreed *examination procedure* (2.12) and *nominal reference material* (4.2).

[SOURCE: The definition of this concept is analogous to that of ‘national measurement standard’ in VIM, 5.3.]

#### 4.8 primary examination standard

*examination standard* (4.1) established using a *primary reference examination procedure* (4.5), or created as an artefact, chosen by convention

[SOURCE: The definition of this concept is analogous to that of ‘primary measurement standard’ in VIM, 5.4.]

## 4.9 secondary examination standard

*examination standard* (4.1) established through *examination calibration* (4.3) with respect to a *primary examination standard* (4.8) for a *nominal property* (2.1) of the same *kind-of-nominal-property* (2.2)

[SOURCE: The definition of this concept is analogous to that of ‘secondary measurement standard’ in VIM, 5.5.]

## 4.10 reference examination standard

*examination standard* (4.1) designated for the *examination calibration* (4.3) of other examination standards for *nominal properties* (2.1) of a given *kind-of-nominal-property* (2.2) in a given organization or at a given location

[SOURCE: The definition of this concept is analogous to that of ‘reference measurement standard’ in VIM, 5.6.]

## 4.11 working examination standard

*examination standard* (4.1) that is used routinely to calibrate or verify *examining systems* (2.8)

Note to entry: A working examination standard is usually calibrated with respect to a *reference examination standard* (4.10).

[SOURCE: The definition and note for this concept are analogous to those of ‘working measurement standard’ in VIM, 5.7.]

## 4.12 travelling examination standard

*examination standard* (4.1), sometimes of special construction, intended for transport between different locations

[SOURCE: The definition of this concept is analogous to that of ‘travelling measurement standard’ in VIM, 5.8.]

## 4.13 transfer examination device

device used as an intermediary to compare *examination standards* (4.1)

Note to entry: Sometimes, examination standards are used as transfer examination devices.

[SOURCE: The definition and note for this concept are analogous to those of ‘transfer measurement device’ in VIM, 5.9.]

## 4.14 intrinsic examination standard

*examination standard* (4.1) based on a reproducible *nominal property* (2.1) of a phenomenon or substance

EXAMPLE For tri-dimensional shape, a crystal obtained from a solution of a pure compound.

Note to entry: A *nominal property value* (3.1) of an intrinsic examination standard is assigned by consensus and does not need to be established by relating it to another examination standard of the same type.

[SOURCE: The definition and note for this concept are analogous to those of ‘intrinsic measurement standard’ in VIM, 5.10.]

#### 4.15 conservation of an examination standard

set of operations necessary to preserve the examinational properties of an *examination standard* (4.1) within stated limits

Note to entry: Conservation of an examination standard commonly includes periodic verification of predefined *nominal properties* (2.1) or *examination calibration* (4.3), storage under suitable conditions, and specified care in use.

[SOURCE: The definition and note for this concept are analogous to ‘conservation of a measurement standard’ in VIM, 5.11.]

#### 4.16 examination calibrator

*examination standard* (4.1) used in *examination calibration* (4.3)

[SOURCE: The definition of this concept is analogous to that of ‘calibrator’ in VIM, 5.12.]

#### 4.17 certified nominal reference material

*nominal reference material* (4.2) accompanied by documentation issued by an authoritative body and providing one or more specified *nominal property values* (3.1) with *examination uncertainty* (3.9) and *examination traceability* (3.21), using valid *examination procedures* (2.12)

[SOURCE: The definition of this concept is analogous to that of ‘certified reference material’ in VIM, 5.14.]

## 5 Alphabetical index of terms

blank nominal indication # 2.14  
 category # 2.3  
 certified nominal reference material # 4.17  
 conservation of an examination standard # 4.15  
 conventional nominal property value # 3.7  
 dedicated kind-of-nominal-property # 2.5  
 examinand # 2.7  
 examination # 2.6

examination accuracy # 3.11  
examination bias # 3.17  
examination calibration # 4.3  
examination calibrator # 4.16  
examination error # 3.10  
examination method # 2.11  
examination precision # 3.12  
examination principle # 2.10  
examination procedure # 2.12  
examination repeatability # 3.13  
examination reproducibility # 3.15  
examination result # 3.4  
examination standard # 4.1  
examination traceability # 3.21  
examination trueness # 3.8  
examination uncertainty # 3.9  
examinational comparability of examination results # 3.22  
examinational compatibility of examination results # 3.23  
examined value # 3.5  
examining system # 2.8  
influence nominal property # 2.9  
intermediate examination precision # 3.14  
intermediate precision condition of examination # 2.16  
international examination standard # 4.6  
intrinsic examination standard # 4.14  
kind-of-nominal-property # 2.2  
national examination standard # 4.7  
nominal indication # 2.13  
nominal property # 2.1  
nominal property value # 3.1  
nominal property value coverage probability # 3.20  
nominal property value coverage set # 3.19  
nominal property value set # 3.2  
nominal reference material # 4.2  
primary examination standard # 4.8  
primary reference examination procedure # 4.5  
reference examination procedure # 4.4  
reference examination standard # 4.10  
reference nominal property value # 3.3  
repeatability condition of examination # 2.15  
reproducibility condition of examination # 2.17  
secondary examination standard # 4.9  
systematic examination error # 3.16  
target examination uncertainty # 3.18  
taxon # 2.4  
transfer examination device # 4.13  
travelling examination standard # 4.12  
true nominal property value # 3.6  
working examination standard # 4.11

## Membership of sponsoring bodies

**The combined membership of the IFCC Committee on Nomenclature, Properties and Units during the preparation of these recommendations (2004 – 2016) was as follows:**

*Chairpersons:* U Forsum (Sweden), F Pontet (France); R Flatman (Australia)

*Members:* I Bruunshuus Petersen (Denmark); R Flatman (Australia); U Forsum (Sweden); X Fuentes-Arderiu (Spain); J Ihalainen (Finland); A Jabor (Czechia), D Karlsson (Sweden); Wolf R Külpmann; U Magdal Petersen (Denmark); G Nordin (Sweden); P Soares de Araujo (Brazil), and K Toska (Norway).

*Consultant:* R Dybkaer (Denmark)

**The combined membership of the IUPAC SubCommittee on Nomenclature, Properties and Units (SC-NPU) during the preparation of these recommendations (2004 – 2016) was as follows:**

*Chairpersons:* U Forsum (Sweden), F Pontet (France); R Flatman (Australia)

*Secretaries:* P Soares de Araujo (Brazil), G Nordin (Sweden), Ulla Magdal Petersen (Denmark)

*Members:* I Bruunshuus Petersen (Denmark); R Dybkaer (Denmark); G Férard (France); R Flatman (Australia); U Forsum (Sweden); X Fuentes-Arderiu (Spain); J Gleditsch (Norway); G Hill (Canada); J Ihalainen (Finland); H Møller Johannessen (Denmark), D Kang (Japan); D Karlsson (Sweden); Wolf R Külpmann (Germany); U Magdal Petersen (Denmark); CJ McDonald (USA); G Nordin (Sweden); F Pontet (France); G Schadow (USA); P Soares de Araujo (Brazil), and Anders Thor (Sweden).

**Acknowledgments:** The authors acknowledge that a former chairman of C-SC-NPU, Professor Robert Zender, made the first working draft, which provided ideas and parts for the present text.

## Abbreviations

BIPM	Bureau International des Poids et Mesures
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine*
IUPAC	International Union of Pure and Applied Chemistry
JCGM	Joint Committee for Guides in Metrology
VIM	International vocabulary of metrology – Basic and general concepts and associated terms
WHO	World Health Organization

\*Formerly: International Federation of Clinical Chemistry

## References

- [1] BIPM International vocabulary of metrology – Basic and general concepts and associated terms (VIM), 3rd edition (2012), also known as ISO/IEC Guide 99; [http://www.bipm.org/utils/common/documents/jcgm/JCGM\\_200\\_2012.pdf](http://www.bipm.org/utils/common/documents/jcgm/JCGM_200_2012.pdf) (accessed 2017-08-14).
- [2] H. Olesen, A. Giewercman, D. M. de Kretser, D. Mortimer, H. Oshima, P. Troen. *Pure Appl. Chem.* **69**, 2621 (1997).
- [3] H. Olesen, D. Cowan, R. De La Torre, I. Bruunshuus, M. Rohde, D. Kenny. *Pure Appl. Chem.* **72**, 479 (2000).
- [4] U. Forsum, H. Olesen, W. Frederiksen, B. Persson. *Pure Appl. Chem.* **72**, 555 (2000).
- [5] K. Varming, U. Forsum, I. Bruunshuus, H. Olesen. *Pure Appl. Chem.* **75**, 1477 (2003).
- [6] P. Soares de Araujo, B. Zingales, P. Alía-Ramos, A. Blanco-Font, X. Fuentes-Arderiu, C. Mannhalter, K. Varming, S. Bojesen, I. Bruunshuus, H. Olesen. *Pure Appl. Chem.* **76**, 1799 (2004).
- [7] R. Dybkaer. An Ontology on Property for physical, chemical, and biological systems (2009); <http://ontology.iupac.org/> (accessed 2017-08-14).
- [8] G. Nordin, R. Dybkaer, U. Forsum, X. Fuentes-Arderiu, G. Schadow, F. Pontet. *Clin. Chem. Lab. Med.* **48**, 1553 (2010).
- [9] ISO 704:2009, Terminology work – Principles and methods.

- [10] ISO 1087-1:2000, Terminology work – Vocabulary – Part 1: Theory and application.
- [11] ISO 10241-1:2011, Terminological entries in standards – Part 1: General requirement and examples of presentation.
- [12] G. Férard, R. Dybkaer, X. Fuentes-Arderiu. International Union of Pure and Applied Chemistry, and International Federation of Clinical Chemistry and Laboratory Medicine – Compendium of terminology and nomenclature of properties in clinical laboratory sciences: Recommendations 2016 – Cambridge, UK: The Royal Society of Chemistry (2017).
- [13] National Institute for Biological Standards and Control (NIBSC) CE Marked Material Anti-HLA Control NIBSC code: 10/142; <http://www.nibsc.org/documents/ifu/10-142.pdf> (accessed 2017-08-14).
- [14] J. P. Gibbs, D. L. Poston, Jr. *Soc. Forces* **53**, 468 (1975).
- [15] C. E. Shannon. *Bell Sys. Tech. J.* **27**, 379 and 623 (1948).
- [16] R. J. Light, B. H. Margolin. *J. Am. Stat. Assoc.* **71**, 534 (1971).
- [17] A. Bhattacharyya. *Bull. Calcutta Math. Soc.* **35**, 99 (1943).
- [18] ISO/TR 79: 2015, Reference materials – Examples of reference materials for qualitative properties.
- [19] National Institute for Biological Standards and Control (NIBSC) WHO Reference Reagent Factor V Leiden, Human gDNA 1st International Genetic Reference Panel NIBSC code: 04/224 (<http://www.nibsc.org/documents/ifu/04-224.pdf>) (accessed 2017-08-14).