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Clinical laboratory testing and *in vitro* diagnostic test systems — *In vitro* diagnostic medical devices for professional use — Summary of regulatory requirements for information supplied by the manufacturer

Essais cliniques de laboratoire et systèmes d'essai de diagnostic in vitro — Dispositifs de diagnostic médical in vitro à usage professionnel — Résumé des exigences de régulation pour les informations fournies par le fabricant

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Contents

Page

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 18112 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

Introduction

This Technical Report summarizes the current labelling requirements of Canada, the EU, Japan and the US for *in vitro* diagnostic (IVD) medical devices for professional use. It also includes, for comparison, proposed guidance from the Global Harmonization Task Force (GHTF) and recommendations from the *In vitro* Diagnostic Device Working Group of the Australian National Coordinating Committee for Therapeutic Goods. This technical report is intended for use in identifying gaps between existing CEN documents and country regulations, and the best solution for these gaps; it is one of a multi-part series of documents that is described in ISO/TC 212 New Work Item Proposal N96-Rev.1.

This summary provides regulatory authorities, manufacturers and users of IVD medical devices with an opportunity to compare existing and proposed labelling requirements from a cross-section of the regulated world, so significant differences can be recognized and addressed. A preliminary summary has been provided to the GHTF for use in identifying opportunities for harmonizing IVD labelling requirements. This report was prepared to assist ISO/TC 212 in developing international standards to support the harmonization efforts.

While significant benefits from harmonized labelling requirements are anticipated, this Technical Report does not evaluate the merits of one regulatory approach over another. Rather, it presents existing requirements factually, so organizations charged with developing harmonized regulations and standards can decide which requirements are essential for promoting safe and effective IVD medical devices.

This summary is only a snapshot in time, while the regulatory environment is dynamic and changing. Australia and Japan are developing new regulatory frameworks for IVD medical devices. The United States is revisiting its position on graphical symbols. European countries continue to debate which languages are necessary on limited label space.

Manufacturers are cautioned that this Technical Report does not substitute for official published labelling requirements. Although efforts were made to verify the accuracy of the information at this point in time, regulatory requirements are subject to interpretation and change. Specific guidance may be in place in some countries that interprets, explains, clarifies, amplifies or even modifies the requirements. Manufacturers are responsible for knowing, understanding and complying with the official regulatory requirements in each country in which their product is sold.

Clinical laboratory testing and *in vitro* diagnostic test systems — *In vitro* diagnostic medical devices for professional use — Summary of regulatory requirements for information supplied by the manufacturer

1 Scope

This Technical Report summarizes regulatory requirements and associated guidance for information supplied by the manufacturer with IVD medical devices intended for professional use.

Information supplied by the manufacturer includes labels on the outer and immediate container as well as instructions for use.

Current labelling regulations and regulatory guidance from Canada, the European Union, Japan and the United States are included.

Labelling guidance from the Global Harmonization Task Force and proposed labelling regulations from Australia are included for comparison.

IVD medical devices for self-testing are excluded.

2 Labelling requirements

EN 375:2001 and EN 591:2001 are harmonized European standards for reagents and instruments, respectively. These standards have been proposed as the basis for the international labelling standards being developed by TC 212, and therefore are used as the basis for comparison in this report.

The labelling requirements from the countries surveyed are presented in Annex A, which is organized in a table format to facilitate comparison of requirements and identification of key commonalities and differences. The source documents are listed in the Bibliography.

The first column in the table lists the requirements of EN 375 and EN 591 in approximately the order that they appear in the Standards. Subsequent columns present the corresponding regulatory requirements. Where a regulatory requirement was identified that did not correspond to a specific requirement in the standard, an additional row was entered at an appropriate place in the table.

For some topics, comparison may not be straightforward because the source documents are organized in different ways. The CEN standards are organized by location of the required information (i.e. outer packaging, inner packaging, accompanying documentation). Some regulations are organized by the type of information required; some specify where the information must be placed, while others allow the manufacturer to determine the most suitable location.

3 Commonalities in required information supplied by the manufacturer

The following information is required or allowed by all of the regulations and regulatory proposals surveyed:

— Device name.

— Batch code or serial number.

— Expiry date for reagents.

— Intended purpose or intended use.

— Specified storage conditions or environmental conditions.

— Container contents (e.g. mass, volume, number of tests) for reagents.

— Instructions for use, which must be supplied with the device, when required.

— Statement that the device is for *in vitro* use.

— Description of the test procedure.

— Calculation of results.

— Warnings, precautions, and limitations of the device.

Exemptions are allowed for immediate-container labels that cannot accommodate the entire list of required information.

4 Differences in required information supplied by the manufacturer

Requirements for the following topics differed significantly across the regulations surveyed.

4.1 Definition of *in vitro* diagnostic medical device

A harmonized definition of medical device, including *in vitro* diagnostic medical device, has been proposed by the GHTF, but has not yet been adopted by the participating countries.

The European Union, the United States and Canada consider calibrators and control materials to be IVD medical devices and must be labelled as such.

In Japan, IVD regulations do not apply to calibrators and control materials, unless they are part of a kit.

Accessories are IVD medical devices, according to EU definition, only when they are specifically intended for diagnostic use by their manufacturer.

4.2 Definitions of label and labelling

GHTF defines a label as information provided upon the medical device itself or on its packaging.

Australian, EU, Japanese and U.S. definitions and/or common usage are consistent with the GHTF definition.

The Canadian Food and Drugs Act defines label to include “any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package,” i.e. what GHTF and other countries inclusively term “labelling” and what the EU terms “information supplied by the manufacturer.

4.3 Instructions for use

All countries require instructions for use unless the device can be used safely and effectively without them. Specific requirements differ in detail and flexibility.

GHTF guidance states that labelling content, format, and location should be appropriate to the device and its intended purpose, e.g. in a leaflet, packaging insert or other means supplied with one or multiple devices.

Australia and the U.S. also allow instructions for use to accompany the device, with “accompany” being interpreted liberally. The U.S. Federal Food, Drug and Cosmetic Act states that “accompanying” means more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. as well as labelling that is brought together with the device after shipment or delivery for shipment in interstate commerce.

Canadian Medical Devices Regulations state that directions for use are required, unless directions are not required to use the device safely and effectively. Draft guidance from Health Canada states that package inserts are essential for most IVDs.

The EU IVD Medical Device Directive states that instructions for use must accompany or be included in the packaging of one or more devices, except that in duly justified and exceptional cases instructions for use are not needed if the device can be used properly and safely without them. “Accompany” is not defined and has been interpreted differently by member states.

Japanese regulations require instructions for use with each device.

4.4 Labelling media

GHTF guidance states that instructions for use may be presented on a display screen incorporated into the device, via internet access to the manufacturer’s web site, or on magnetic or optical media, as well as printed documents, with the information targeted to the anticipated user population.

Current requirements and practices vary considerably.

Electronic labelling is not prohibited or otherwise mentioned in Australian, Canadian regulations, nor in the IVD Medical Device Directive.

The US authorizes, by statute, the use of electronic labelling, rather than the traditional paper labelling by distributors of prescription devices that are to be used within the confines of a health care facility, so long as they afford users the opportunity to request the labelling in paper form and promptly provide such labelling to requestors without additional cost.

The U.S. also permits manufacturers to provide instructions for IVD systems, including consumable reagents, in user manuals. Most countries have adopted similar policies regarding user manuals.

The EN labelling standards allow the use of separate manuals and alternative media (e.g. electronic labelling) for instructions for use.

Japan requires written instructions in hard-copy format, while a draft Guidance Document from Health Canada states that package inserts are essential for most IVDDs.

4.5 Manufacturer, distributor, importer, exporter, authorized representative

The U.S. requires that the name and place of business of manufacturer, packer, or distributor appear on the label for, or the labelling accompanying each product.

The EU IVD Medical Device Directive states the manufacturer is the legally responsible entity and requires the manufacturer’s name on the labels. If the manufacturer is outside the EU, its “Authorized Representative” must also be identified in the labelling.

Australia and Japan require the importer to be identified. Australia also requires the Australian exporter to be identified, if applicable.

Differences exist in the location where this information must be placed, e.g. outer package label and/or instructions for use.

4.6 Microbiological state

All regulations require a sterility designation for sterile products. The IVD Medical Device Directive requires an additional statement describing the microbiological state or state of cleanliness, where necessary for proper performance.

4.7 Language and country-specific requirements

The GHTF recommends that country-specific requirements and languages be limited to those essential for the safe and effective use of the device.

Australia and Japan require all information to be in English and Japanese, respectively.

Canada prefers both English and French, but accepts either one if a translation is readily available in the other language.

The EU allows each country to decide whether to require its national language, taking into account the principle of proportionality, whether harmonized symbols can be used, and the intended user. Some countries accept one of the major European languages as sufficient for professional use devices.

The United States requires English, except in its territories and the Commonwealth of Puerto Rico where the predominant language may be used. If any labelling appears in a foreign language, all of the required information must appear in that language.

4.8 Graphical symbols

The GHTF supports the use of internationally recognized symbols to replace wording on labels and labelling where the meaning is unambiguous.

Australia, Canada and the EU IVD Medical Device Directive are consistent with the GHTF position.

The U.S. and Japan presently require explanatory wording to appear in association with the symbol. However, a recent draft guidance document from FDA states that 25 symbols from ISO 15223 and EN 980 have been recognized as symbols that may be used on labels without explanatory wording for professional use devices.

4.9 Expiry date

The IVD Medical Device Directive requires the use of the ISO 8601 date format, i.e. CCYY-MM-DD.

Other countries allow any date format that is unambiguous.

As an alternative to an expiry date, the US allows the label to state an observable indication of stability or a simple method by which the user can confirm stability.

4.10 Reactive ingredients

The U.S. requires a list of reactive ingredients, as well as their concentrations, on the outer and immediate containers, and in the instructions for use. In the case that the immediate container is too small, the reactive ingredients may appear in the outer-container labelling only. Metric system units are encouraged.

In the EU and Canada, it is sufficient to list the reactive ingredients and their concentrations in the instructions for use.

Japan allows reactive ingredients and their concentrations to be listed in the instructions for use, but also requires the ingredient name on the outer container.

4.11 Small-sized label exemption

All countries allow for the possibility that the label space on small containers will not accommodate all of the required information. However, requirements vary as to what details on a small-sized label may be eliminated or placed elsewhere.

Furthermore, the US Food Drug and Cosmetic Act considers a product misbranded when any required information is omitted from a label if any of the label space is occupied by non-required information. Thus the small-label exemption does not apply if any information required by another country is on the label, such as a CE Mark or name of the authorized representative, unless it is also required by US law.

4.12 *In vitro* (diagnostic) use

Particular requirements vary. Some regulations allow use of a symbol to indicate the reagent is for *in vitro* diagnostic use. Others require specific wording. The EU specifies "*in vitro* use" as an alternative to the symbol the U.S. and Canada specify "*in vitro* diagnostic use." The U.S. FDA has announced plans to accept the international IVD symbol.

4.13 Danger warnings (e.g. chemical, biological, radioactive hazards)

Particular requirements for warning users of hazardous substances vary from country to country.

In the EU, Directives on classification, packaging and labelling of dangerous substances and dangerous preparations require standardized symbols and specific risk and safety phrases in product labelling. Compliance with the labelling requirements of these Directives is mandated by the IVD Medical Device Directive.

In the U.S., compliance with the Federal Hazardous Substances Control Act is specifically required by the IVD labelling regulations. The manufacturer is additionally required to state other warnings appropriate to the hazard presented by the product. In Australia, Canada, the EU and the U.S., (Material) Safety Data Sheets may also be required unless all information required by occupational safety laws is included in the product labelling.

Canada and Japan require appropriate hazard warning phrases/statements or symbols. Japan requires specific language in a specific format for poisonous or powerful reagents.

NOTE This report does not attempt to include all danger/hazard warning requirements. Compulsory labelling requirements may also be found in other national and local regulations.

4.14 Components of human or animal origin

Disclosure of materials from human and animal sources is required by some countries, regardless of whether a hazard is known to exist. Compulsory labelling may also be required by worker protection regulations.

4.15 Reagent preparation and storage

The U.S. specifies that storage instructions for reconstituted or mixed product are required on the container label. If the label is too small, the storage instructions may be included in labelling accompanying the product.

In other countries, these instructions may be placed in the instructions for use.

4.16 Units of measure

The EU requires numerical values to be given in legal units, which means SI units of measure (ISO 1000).

The U.S. Food Drug and Cosmetic Act encourages the use of SI units for reagent ingredients. However, US IVD labelling regulations require quantity, proportion, concentration or activity to be stated in the system generally used and recognized by the intended user.

Australian, Canadian and Japanese labelling regulations are silent regarding units.

4.17 Analytical performance characteristics

All countries require a description of expected performance and provide examples of typical characteristics that might be included.

Significant differences exist in the definitions of some common performance characteristics, such as accuracy, precision, trueness, and sensitivity. Most of these terms are not defined in the labelling regulations, but may be defined in laboratory regulations or national standards that influence the terms used by manufacturers in labelling. It will be necessary to standardize these terms for labelling to be interpreted consistently worldwide.

Accuracy: In US laboratory regulations (CLIA ’88) and in the EU IVD Medical Device Directive, accuracy is used to describe two different concepts: (1) agreement of the average of a large series of replicate measurements with the true value, and (2) agreement of an individual measurement result with the true value.

In international standards, including European harmonized standards, the first is termed “trueness,” a measure of systematic bias; the second is termed “accuracy,” which includes the effects of imprecision as well as bias on a test result. Many countries have adopted the terminology used in international standards.

Precision: In international standards, precision is described as repeatability (precision in highly controlled conditions, where all possible variables are held constant), intermediate precision (where some variables are controlled and some are allowed to vary), and reproducibility (precision in uncontrolled conditions, where all variables are allowed to vary). Included in the international definition of precision is a requirement that the conditions must be stipulated.

In laboratory medicine, these precision terms are roughly equivalent to “within-run,” “within lab”, and “lab to lab,” precision, respectively.

The concept of precision defined in VIM:1993 has been superseded by newer definitions in ISO 3534 and ISO 5725. Although the VIM definition of reproducibility is incorrect, it is still cited in some CEN standards.

Sensitivity: In international standards, sensitivity is used to describe the ability of an IVD assay to determine small changes in concentration throughout the range. In laboratory medicine, sensitivity is generally used to mean the least amount of analyte in a sample that can be detected (i.e. limit of detection).

4.18 Metrological traceability

The EU requires information on the metrological traceability of calibrator and trueness control values. The Australian proposal contains a similar requirement. Traceability of patients’ results is not required.

Draft FDA guidance on calibration and quality control labelling states that FDA currently requires information on calibration procedures performed and whenever possible encourages traceability of device performance to a reference method or material (i.e. a statement indicating the basis for the calibration).

Canada and Japan do not require traceability information.

4.19 Diagnostic performance characteristics

GHTF guidance states the labelling may include diagnostic performance characteristics, such as sensitivity and specificity related to the percentage of true negative and true positive values.

Canada and the EU require information on diagnostic performance characteristics.

Draft guidance from the U.S. FDA requests information when a device is compared to a “true” diagnostic state.

Australia and Japan have no requirements for diagnostic performance characteristics.

4.20 Predicate device (an existing legally marketed medical device)

The U.S. and Japan require data showing comparison to an existing, legally marketed device.

Other regulations do not have such a requirement, apart from the EU requirement to describe traceability to a higher order reference measurement procedure/material, if one is available.

4.21 Reference intervals

While GHTF guidance only states that device labelling may contain reference intervals, all five regulatory schemes and the EN standards require reference intervals along with descriptions of the reference populations.

In the EN standards, the requirement for reference intervals is qualified by “if known.”

Canada and the US also require detailed information about how the ranges were established.

The EU is explicit that the values must be in SI units. The other countries are silent on units.

4.22 User quality control

Australia, Canada, the EU and the US require that manufacturers provide users with quality control information in the instructions for use. Australia and the EU call this “internal” quality control.

Australia and the EU also require “specific validation procedures.”

The U.S. requires details of the kinds of quality control procedures and materials required by users, including information on satisfactory limits of performance, as well as descriptions of any controls that are integral components of the device (also called “internal” quality controls).

In Japan, establishing quality control procedures is solely the responsibility of the Laboratory.

The GHTF has not taken a position on providing quality control information.

4.23 Change notification

Although not addressed explicitly in labelling regulations, a requirement to update labelling when performance characteristics or instructions for use change is included in the European labelling standards.

Manufacturers are generally required by manufacturing regulations and international quality system standards (e.g. ISO 13485) to inform users of significant changes in device performance and/or instructions for use.

4.24 Limitations

Each regulatory scheme requires disclosure of certain limitations; the requirements differ in limitations of what, and the details that must be disclosed.

GHTF guidance simply states the labelling should bear “any limitations.”

Australia and the EU require a description of the “limitations of the method.”

Canada specifies “test limitations”. The draft guidance from Health Canada says the Limitations section should include requirements for personnel qualification and limitations affecting test result interpretation.

Japan requires disclosure of limitations related to the specimen.

The U.S. specifies “limitations of the procedure.” The US considers requirements for further testing with more sensitive/specific methods as limitations.

4.25 Instrument requirements

In general, the requirements in EN 591 and Japanese regulations are more specific regarding instrumentation than those of the other countries.

Some significant differences are

— Only Japan, the EU and the U.S. require environmental specifications and installation instructions.

— Only Australia, the EU and GHTF guidance require verification of proper installation.

— Only Australia, Canada and the EU require labelling to state whether any particular training is required.

— Japan, the EU, the U.S. and GHTF require checking the function of the IVD instrument.

— All but Canada require mention of the nature and frequency of the maintenance needed to ensure that the IVD operates properly and safely; and any necessary sterilization, decontamination or disinfection.

— All but Australia and Canada require cleaning instructions, if applicable.

— Only Japan and the CEN standards mention the frequency of replacing consumables and parts.

— Only U.S. and CEN request servicing information.

Only Australia, the EU and the GHTF guidance mention requirements regarding electromagnetic emission and immunity.

Annex A
(informative)

Labelling requirements of countries surveyed

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
1	Primary documents	EN 375:2001, Information supplied by the manufacturer with *in vitro* diagnostic reagents for professional use *[10]* [b] EN 591:2001, Instructions for use for *in vitro* diagnostic instruments for professional use *[11]*	Proposal for a New Regulatory Framework for *In vitro* Diagnostic Devices, National Coordinating Committee for Therapeutic Goods *In vitro* Diagnostic Device Working Group, March 2003 *[1]*	Canadian Medical Devices Regulations, Food and Drugs Act, May 1998 *[5]* Health Canada - Health Products and Food Branch, Guidance for the Labelling of *In vitro* Diagnostic Devices – DRAFT, January 22, 2003 *[4]*	Directive 98/79/ EC of the European Parliament and the Council of 27 October 1998 on *in vitro* diagnostic medical devices *[8]*	Pharmaceutical Affairs Law (JAPAN 2003) and related documents *[24]*	U.S. Federal Food, drug, and Cosmetic Act *[36, 37]* U.S. Code of Federal Regulations, Title 21 *[27-33]* FDA Guidance Documents for Industry and FDA Staff *[39-43]*	Labelling for Medical Devices (including *In vitro* Diagnostic Devices), March 1, 2002 (Proposed) *[16]*
2	Scope							
3	Scope	These standards specify the requirements for a) the information supplied by the manufacturer of *in vitro* diagnostic reagents including reagent products, calibrators, control materials and kits for professional use, which hereafter are called IVD reagents. *[10, §1]* b) the contents of instructions for use for *in vitro* diagnostic instruments including apparatus, equipment, calibrators and control materials for professional use, hereafter called IVD instruments. This standard is not applicable to field	A national and uniform system of control over therapeutic goods supplied to the Australian market, or exported, – including IVDs – to ensure the quality, safety, efficacy and timely availability of products used in the diagnosis, curing, prevention or alleviation of disease, ailment, defect or injury.	Regulations apply to a) the sale and advertisement for sale of a medical device, and b) the importation of a medical device … These Regulations also apply to an *in vitro* diagnostic product that is a drug or that contains a drug, as if the product were an *in vitro* diagnostic device.	This Directive shall apply to *in vitro* diagnostic medical devices and their accessories. For the purposes of this Directive, accessories shall be treated as *in vitro* diagnostic medical devices in their own right. Both *in vitro* diagnostic medical devices and accessories shall hereinafter be termed devices. *[7, Article 1, 1]*	IVD reagents and IVD instruments shall be included. Buffers, traditional staining solution, diluent, calibrators or control materials that are not a part of a kit are not applied.	Labelling for *in vitro* diagnostic products *[31, Sec. 809.10]*	Reagents, calibrators, sample-collection devices, control materials, and related instruments or apparatus. Accessories intended specifically by manufacturers to be used together with a "parent" medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF guidance as applies to the medical device itself. *[13]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
		repair instructions *[11, §1]* These standards can also be applied to accessories.						
4	**Normative references**							
5	Normative references	ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units [10, §2; 11, §2]*	NA		*Other Directives cited as noted below, e.g. for hazard warning and disposal requirements.*		*Other acts and regulations cited as noted below, e.g. for communication of hazard warnings.*	
6	**Terms and definitions**							
7	Accessory	NA	A product required in the performance of a particular test or required for use with a particular IVD, e.g. a software program that is used to run an analyser.		An article which, whilst not being an *in vitro* diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose. Invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen within the meaning of Directive 93/42/EEC shall not be considered to be accessories to *in vitro* diagnostic medical devices; *[8, Article 1, 2(c)*			Accessories intended specifically by manufacturers to be used together with a "parent" medical device to enable that medical device to achieve its intended purpose, should be subject to the same GHTF guidance as applies to the medical device itself. *[13, §5.0 NOTE 3]*
8	Accuracy	The closeness of agreement between a test result and the accepted reference value. NOTE The term accuracy, when applied to a set of test			*Used throughout Directive 98/79/EC, as "trueness"*		*U.S. clinical laboratories use "accuracy" to mean "trueness" [35]*	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
		results, involves a combination of random components and a common systematic error or bias component. *[19, §3.11]*						
9	Active ingredient	Constituent that participates in the reaction used to measure or detect the analyte *[10, §3.1]*						
10	Analyte specific reagents	NA					Antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents which, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. *[44, § 864.4020(a)]* NOTE In simple terms, an analyte specific reagent is the active ingredient of an in-house test. *[40]*	
11	Authorized representative	NA			Any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
					regard to the latter's obligations under this Directive; *[8, Article 1, 2(g)]*			
12	Bar code	NA		A unique bar code in the symbology of the Universal Product Code (UPC), the Health Industry Business Communications Council (HIBCC) or the European Article Number (EAN), assigned to a medical device by the manufacturer				
13	Batch (lot)	Defined amount of material, either starting material, intermediate or finished product which is uniform in its properties and has been produced in one process or series of processes. *[10, §3.2]*	A quantity of product that is a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and b) made in one cycle of manufacture and, in the case of a product that is sterilized or freeze-dried, sterilized or freeze-dried in one cycle.				One or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. *[33, Sec. 820.3 (m)]*	
14	Batch code (lot number)	Code that is a distinctive combination of numbers and/or letters which specifically identifies a batch and permits its manufacturing history to be traced *[10, §3.3]*		Control number: a unique series of letter, numbers or symbols, or any combination of these, that is assigned to a medical device by the manufacturer and from which a history of the manufacturer, packaging, labelling and distribution of a unit, lot or batch of the device can be determined.			*Control number*: any distinctive symbols, such as a distinctive combination of letters or numbers, or both, from which the history of the manufacturing, packaging, labelling, and distribution of a unit, lot, or batch of finished devices can be determined. *[33, Sec. 820.3 (d)]*	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
15	Calibrator	Substance, material or article intended by its manufacturer to be used to establish the measurement relationships of an *in vitro* diagnostic medical device *[10, §3.4]*			Any substance, material or article intended by their manufacturer either to establish measurement relationships … in conjunction with the intended use of that device. *[8, Article 1, 3]*			
16	Component	NA					Any raw material, substance, piece, part, software, firmware, labelling, or assembly which is intended to be included as part of the finished, packaged, and labelled device. *[33, Sec. 820.3(c)]*	
17	Control material	Substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an *in vitro* diagnostic medical device *[10, §3.5]*			Any substance, material or article intended by their manufacturer … to verify the performance characteristics of a device in conjunction with the intended use of that device. *[8, Article 1, 3.]*			
18	Custom-made device	NA		A medical device, other than a mass-produced medical device, that a) is manufactured in accordance with a health care professional's written direction giving its design characteristics; b) differs from medical devices generally available for sale or from a dispenser; and c) is i) for the sole use			A device that necessarily deviates from devices generally available or from an applicable performance standard or premaket approval requirement in order to comply with the order of an individual physician or dentist; is not generally available to, or generally used by, other physicians or dentists; is not generally available in finished form for purchase or	Device for use by a single individual that has been manufactured according to a written prescription or pattern (i.e. it is custom-made). *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
				of a particular patient of that professional, or ii) for use by that professional to meet special needs arising in the course of his or her practice.			for dispensing upon prescription; is not offered for commercial distribution through labelling or advertising; and is intended for use by an individual patient named in the order of a physician or dentist, and is to be made in a specific form for that patient, or is intended to meet the special needs of the physician or dentist in the course of professional practice. *[32, §3]*	
19	Dangerous substances				Chemical elements and their compounds in the natural state or obtained by any production process, which are explosive, oxidizing, flammable, toxic, harmful, corrosive, irritant, sensitizing, carcinogenic, mutagenic, or are toxic for reproduction; or dangerous for the environment, including any additive necessary to preserve the stability of the products and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition; *[6, Article 2.1/2.2]*			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
20	Dangerous preparations				Mixtures or solutions, composed of two or more substances, which are explosive, oxidizing, flammable, toxic, harmful, corrosive, irritant, sensitizing, carcinogenic, mutagenic, or are toxic for reproduction; or dangerous for the environment. *[6, Article 2.1/2.2]*			
21	Dating period	NA					The period beyond which the product cannot be expected beyond reasonable doubt to yield its specific results. *[27, Sec. 600.3 (l)]*	
22	Device for performance evaluation	NA			Any device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises; *[8, Article 1, 2(e)]*		Investigational device means a device, including a transitional device, that is the object of an investigation. *[32, Sec. 812.3 (g)]*	
23	Expiry date	Date up to which product performance is assured by the manufacturer based on the stability of the IVD reagent *[10, §3.6]*			The labelling should indicate the date until which the device or one of its components can be used with complete safety; *[8, Article 20]*		The calendar month and year, and where applicable, the day and hour, that the dating period ends. *[27, Sec. 600.3 (m)]*	
24	Follow-up therapeutic procedure		A secondary medical procedure carried out following a positive result from an IVD, with the purpose of confirming a diagnosis and/or deciding on an appropriate course of treatment.					

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
25	General purpose reagent						Chemical reagent that has general laboratory application, that is used to collect, prepare, and examine specimens from the human body for diagnostic purposes, and that is not labelled or otherwise intended for a specific diagnostic application … when combined with or used in conjunction with an appropriate analyte specific reagent (ASR) and other general purpose reagents, is part of a diagnostic test procedure or system constituting a finished *in vitro* diagnostic (IVD) test. *[44, § 864.4010(a)]*	
26	Graphical symbol	Visually perceptible figure with a particular meaning used to transmit information independently of language *[17]*					“Symbols” … refers to the use of graphical symbols without equivalent accompanying text. *[39]*	
27	Health care professional	NA		A person who is entitled under the laws of a province to provide health services in the province				
28	Home use IVD	NA	An IVD supplied to lay persons, for use or interpretation in diagnosing, monitoring or identifying risk factors for a condition or state; or for collecting a sample for analysis in a testing facility.		Device for self-testing: any device intended by the manufacturer to be able to be used by lay persons in a home environment; *[8, Article 1, 2(d)]*			Device for self-administration: Any device intended by the manufacturer to be able to be used by lay persons in a non-clinical environment. *[12]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
29	Identifier	NA		A unique series of letters or numbers or any combination of these or a bar code that is assigned to a medical device by the manufacturer and that identifies it and distinguishes from similar devices				
30	Immediate container (primary container)	Packaging which protects the contents from contamination and/or other effects of the external environment NOTE Examples are a sealed vial, ampoule or bottle, a foiled pouch, or a sealed plastics bag containing e.g. culture media, microtitration plates or coated tubes. *[10, §3.7]*						
31	*In vitro* diagnostic instrument (IVD instrument)	*In vitro* diagnostic medical device which is an instrument, apparatus or equipment NOTE In some cases a particular IVD instrument, as defined for use in human medicine, may serve also in veterinary medicine. *[11, §3.5]*						

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
32	*In vitro* diagnostic medical device	NA	Any therapeutic device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination (with other diagnostic goods for *in vitro* use), intended by the manufacturer to be used *in vitro* for the examination of specimens (including blood and tissue donations) derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state or a congenital abnormality or to determine safety and compatibility with a potential recipient.	*In vitro* diagnostic device (IVDD) A medical device that is intended to be used *in vitro* for the examination of specimens taken from the body.	Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state, or concerning a congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. Includes specimen receptacles. Excludes products for general laboratory use unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination; *[8, Article 1, 2(b)]*		*In vitro* diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in Sec. 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to Sec. 351 of the Public Health Service Act. *[31, Sec. 8093 (a)]*	A device for *in vitro* examination includes, for example, reagents, calibrators, sample collection devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some *in vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations. *[13, §5.0 NOTE 1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
33	*In vitro* diagnostic reagent (IVD reagent)	*In vitro* diagnostic medical device which is a reagent, reagent product, calibrator, control material or kit NOTE In some cases a particular IVD reagent, as defined for use in human medicine, may serve also in veterinary medicine. *[10, §3.9]*				IVD reagents exclude buffers, traditional staining solution, diluent, calibrators and control materials if not a part of kit. *[25]*		
34	Indication		The intended use of an *in vitro* diagnostic device (IVD).					
35	Information supplied by the manufacturer	NA			This information comprises the data on the label and in the instructions for use			
36	In-house test		A test that is developed *de novo*, or modified from a published source, or modified or adapted from any other source, within the confines or scope of a laboratory; and validated for use within that laboratory only, and is not supplied for use outside that laboratory					
37	Inner packaging		Generally defined as the labelling found immediately on the IVD or if applicable, on each individual component of a kit.					

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
38	Insert document	NA				For reagents, a document provided with the reagent(s) containing specific information in a defined format. For instruments, a document provided with an IVD instrument or corresponding parts or consumables, comprising 8 pages of A4 size bearing indispensable but brief information for proper and safe use.*[25]* This document will hereafter be abbreviated as DOCI.	A document provided with the reagent(s) containing specific information in a defined format.	
39	Instructions for use (instrument)	Information supplied by the manufacturer with an IVD instrument concerning the proper use and the safe and correct operation, maintenance and basic trouble-shooting of the IVD instrument *[11, §3.3]*	For an IVD, can generally be defined as the documentation that accompanies an IVD …	Directions for use: full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects.		Supplemental information to DOCI supplied by the manufacturer with an IVD instrument. This document will hereafter be abbreviated as DOCM. The manufacturer shall provide DOCM and/or maintenance manual if an insert document is not sufficient to provide the necessary information. *[25]*		Information provided by the manufacturer to inform the device user of the products proper use and of any precautions to be taken. *[16]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
40	Instructions for use (reagents)	Information supplied by the manufacturer with an IVD reagent concerning the safe and proper use of the IVD reagent *[45, §3.9]*	For an IVD, can generally be defined as the documentation that accompanies an IVD …	Directions for use: full information as to the procedures recommended for achieving the optimum performance of the device, and includes cautions, warnings, contra-indications and possible adverse effects.		Supplemental information to an insert document supplied by the manufacturer with an IVD reagent. *[25]*		Information provided by the manufacturer to inform the device user of the products proper use and of any precautions to be taken. *[16]*
41	Instrument		A machine or piece of equipment that automates a particular assay process, either by bringing samples and reagents together and measuring the result, or by measuring other qualities or parameters in the samples being tested.					
42	Intended use/intended purpose	NA		Intended purpose: The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use/or in promotional material *[3]*	The use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use and/or in promotional materials; *[8, Article 1, 2(h)]*		The objective intent of the persons legally responsible for the labelling of devices. The intent is determined by such persons, expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labelling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labelled nor advertised. *[29, Sect. 801.4]*	The objective intent of the manufacturer or other legal entity, or person, under whose name the device is placed on the market, in respect of the application and performance of the device, as indicated in the labelling and/or promotional material. *[16]* The objective intent of the manufacturer regarding the use of a product, process or service as reflected in the specifications, instructions and information provided by the manufacturer. *[12]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
43	Quality control	Operational techniques and activities at the point of use that are used to fulfil requirements for quality of services NOTE Internal quality control comprises all steps of activity for production of results from collection of sample and measurement of a measurable quantity to reporting of result of measurement. *[10, §3.8]*						
44	Kit	Set of components (reagents and/or other materials) packaged together *[10, §3.10]*	An *in vitro* diagnostic device that consists of a collection of reagents and/or components, or any combination of these, intended for use in the conduct of a specific test.	Test kit: an *in vitro* diagnostic device that consists of reagents or articles, or any combination of these, and that is intended to be used to conduct a specific test.				
45	Kit component	*In vitro* diagnostic medical device intended to be part of a kit NOTE Typical kit components are e.g. antibody solutions, buffer solutions, calibrators or control materials. *[10, §3.11]*						

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
46	Label	Printed, written or graphic information placed on a container *[10, §3.12]*	A display of printed information on or attached to the goods, or on or attached to a container or primary pack in which the goods are supplied, or supplied with such a container or pack.	The LABEL as defined in the Food and Drugs Act includes any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package.			A display of written, printed, or graphic matter upon the immediate container of any article... The term “immediate container” does not include package liners. *[36, Sec. 201(k)]*	Information provided upon the medical device itself. Where physical constraints prevent this happening, this term includes information provided on the packaging of each unit or on the packaging of multiple devices. *[16]*
47	Labelling	NA	For IVDs, includes, but is not limited to, individual IVD labels, outer packaging and the instructions for use. Instructions for use are commonly provided in the form of a package insert.	Labelling for IVDDs includes, but is not limited to, the immediate device container label, the reagent/component label and package insert. *[4, §3.1]*			All labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. The term “accompanying” is interpreted liberally [see NOTE 2 for examples of intent]. *[36, Sec. 201(m)]*	An inclusive term to describe the label, instructions for use, maintenance instructions, packaging insert and other information associated with the device. *[16]*
48	Manufacturer	The manufacturer is the entity which has taken legal responsibility for the IVD reagent./instrument *[10, §3.1.2 NOTE]* *[11, §5.3 NOTE]*	The person who is responsible for the design, production, packaging and labelling of the device before it is supplied under the persons name, whether or not it is the person, or another person acting on the persons behalf, who carries out those operations. OR the person who, with a view to supplying the device under the persons name, does one or more of the following using ready-made products a) assembles the device;	A person who sells a medical device under their own name, or under a trade-mark, design, trade name or other name or mark owned or controlled by the person, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.	The natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party. The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-	The natural or legal person who has approved for manufacturing approved IVD. The approval requires qualification of facilities, production and/or quality management, and of such person.	Any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabelling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
			b) packages the device; c) processes the device; d) fully refurbishes the device; e) labels the device.		made products and/or assigns to them their intended purpose as devices with a view to their being placed on the market under his own name. This subparagraph does not apply to the person who, while not a manufacturer within the meaning of the first subparagraph, assembles or adapts devices already on the market to their intended purpose for an individual patient; *[8, Article 1, 2(f)]*		performing these functions. *[33, Sec. 820.3 (o)]*	
49	Material safety data sheet (MSDS)	NA		A document on which words, figures or symbols disclosing the information referred to in subparagraphs 13(a)(i) to (v) [regarding a hazardous chemical] may be written, printed or otherwise expressed; *[46, §11.(1)]*			written or printed material concerning a hazardous chemical which is prepared in accordance with 29 CFR 1910.1200 (g) *[34, Sec. 1910.1200 (c)]*	
50	Medical device	NA	Therapeutic device Therapeutic goods consist of instruments, apparatus, appliances, materials or other articles (whether for use alone or in combination), together with any accessories or software required for their proper functioning, which do not achieve their principal intended action by pharmacological, chemical, immunological or metabolic means. However, they may be assisted in their function by pharmacological, chemical, immunological	Any article, instrument, apparatus or contrivance, including any component, part or accessory thereof. A device within the meaning of the Act, but does not include any device that is intended for use in relation to animals.	Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation		An instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is 1) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, or	Harmonized definition of the term “medical device” *[13]* “Medical device” means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
			or metabolic means. This definition applies to goods or components of goods that are represented in any way to be for therapeutic use, or that are likely to be taken to be for therapeutic use, because of the way in which they are presented or for any other reason. Therapeutic use means use in, or in connection with — preventing, diagnosing, curing or alleviating a disease, ailment defect or injury in persons or animals; or — influencing, inhibiting or modifying a physiological process in persons or animals; or — testing the susceptibility of persons or animals to a disease or ailment; or — influencing, controlling or preventing conception in persons; or — testing for pregnancy in persons; or — the replacement or modification of parts of the anatomy in persons or animals. *[2]*		or compensation for an injury or handicap, — investigation, replacement or modification of the anatomy or of a physiological process, — control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means; *[8, Article 1, 2(a)]*		2) intended to affect the structure or any function of the body of man. *[36, Sec. 201(h)]*	purpose(s) of — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of or compensation for an injury, — investigation, replacement, modification, or support of the anatomy or of a physiological process, — supporting or sustaining life, — control of conception, — disinfection of medical devices, — providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. *[13, §5.0]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
51	Medical device family	NA		A group of medical devices that are made by the same manufacturer, that differ only in shape, colour, flavour or size, that have the same design and manufacturing process and that have the same intended use. *[5, Part 1, Sec. 1.]*				
52	Medical device group	NA		A medical device comprising a collection of medical devices, such as a procedure pack or tray, that is sold under a single name. *[5, Part 1, Sec. 1.]*				
53	Medical device group family	NA		A collection of medical device groups that are made by the same manufacturer, that have the same generic name specifying their intended use, and that differ only in the number and combination of products that comprise each group. *[5, Part 1, Sec. 1.]*				
54	Name (device/ product)	NA		In respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices.		Device or product name which is stated on the approval form.	Proper name, as applied to a product: the name designated in the license for use upon each package of the product. *[27, Sec. 600.3 (k)]*	
55	Near patient *in vitro* diagnostic device	NA		An IVDD that is intended for use outside a laboratory, for testing at home or at the point of care, such as a pharmacy, a health care professional's office or at the bedside				

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
56	Outer container (sales packaging)	Material used in the packaging of the immediate container(s) of (an) IVD reagent(s) consisting of a single entity or an assembly of different or identical components *[10, §3.13]*	Can generally be defined as the box, carton, etc., in which the IVD is presented. IVDs are usually removed from their outer packaging prior to use.					
57	Performance evaluation (of an *in vitro* diagnostic device)	An investigation of the performance of an *in vitro* diagnostic medical device based upon data already available, scientific literature and/or performance evaluation studies. *[48]*					Investigation is a clinical investigation or research involving one or more subjects to determine the safety and/or effectiveness of a device. *[32, Sec. 812.3 (h)]*	A premarket study of a medical device intended for the *in vitro* examination of specimens derived from the human body, undertaken in specialist laboratories for medical analysis or in other appropriate environments, outside the manufacturer's own premises, in order to demonstrate the device conforms to all relevant Essential Principles for Safety and Performance *[16]*
58	Precautions	NA		[Statements that] alert the user to the special care or procedures necessary for the safe and effective use of the IVDD.			Statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. [ANSI Z535.4-1998] It may also be used to alert against unsafe practices. This includes the special care necessary for the safe and effective use of the device and the	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
							care necessary to avoid damage to a device that may occur as a result of use or misuse. NOTE The distinction between warnings and precautions is a matter of degree of likelihood and seriousness of the hazard. *[49]*	
59	Predicate device	NA	A device that has been previously evaluated and is currently listed or registered on the ARTG. *[2]*				A legally marketed device(s) to which equivalence is drawn, [which must be] a device that was legally marketed prior to May 28, 1976 (preamendments device), or a device which has been reclassified from Class III to Class II or I. *[50, Sec. 807.92]*	
60	Product	NA					Components, manufacturing materials, in-process devices, finished devices, and returned devices. *[33, Sec. 820.3 (r)]*	
61	Professional use	Use by personnel who have received special education and training with regard to procedures utilizing *in vitro* diagnostic medical devices *[10, §3.14]*						

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
62	Reagent		A solution of highly specific biological or chemical substances that is able to react with target substances in samples being tested, and to give a product that can be measured (as in a quantitative assay) or seen (as in a qualitative assay).					
63	Reagent product (reagent carrier)	Product in which the reagents are fixed to or included in a carrier Examples: reagent strips, slides, discs and sticks. *[10, §3.15]*						
64	Shelf life	Period until expiry date *[10, §3.16]*						
65	Specimen	Biological material which is obtained in order to detect or to measure one or more quantities *[10, §3.17]*						The discrete portion of a body fluid or tissue taken for examination, study, or analysis of one or more quantity or characteristic to determine the character of the whole. *[12]*
66	Specimen receptacles	NA			those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of *in vitro* diagnostic examination *[8, Article 1, 2(b)]*			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
67	Sponsor		a) a person who exports, or arranges the exportation of, the goods from Australia; OR b) a person who imports, or arranges for the importation of, the goods into Australia; OR c) a person, who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who 1) exports, imports or manufactures the goods; OR 2) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in Australia.					
68	Stability	Ability of an IVD reagent when kept under specified conditions, to retain throughout the shelf						

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
		life its properties and/or performance within limits specified by the manufacturer *[10, §3.18]*						
69	System	NA	A term often used to refer to the reagents, instruments and accessories required to perform a given test.	A medical device comprising a number of components or parts intended to be used together to fulfil some or all of the device's intended functions, and that is sold under a single name.				
70	Therapeutic use		Use in or in connection with a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or b) influencing, inhibiting or modifying a physiological process in persons or animals; or c) testing the susceptibility of persons or animals to a disease or ailment; or d) influencing, controlling or preventing conception in persons, or e) testing for pregnancy in persons, or f) the replacement or modification of parts of the anatomy in persons or animals.					

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
71	Trueness	Closeness of agreement between the average value obtained from a large series of test results and an accepted reference value [ISO 3534-1] *[10, §3.19]*			Directive 98/79/EC uses "accuracy" synonymously with "trueness", whereas the term "accuracy" includes both "trueness" and "precision," according to ISO 3534-1 and ISO 5725-1. *[10, §3.19 NOTE]*		*US clinical laboratories use "accuracy" to mean "trueness" [35]*	
72	Warnings	NA		[Statements that] alert the user to potential serious adverse reactions and safety hazards that can occur in the proper use, or misuse, of an IVDD.			A warning alerts the reader about a situation which, if not avoided, could result in death or serious injury. [ANSI Z535.4-1998] It may also describe potential serious adverse reactions and safety hazards. The designation of a hazard alert as a "warning" is reserved for the most significant problems. NOTE The distinction between warnings and precautions is a matter of degree of likelihood and seriousness of the hazard. *[49]*	
73	**Labelling principles and general requirements**							
74	Purpose of labelling		[Provide] information needed to use the IVD safely, taking account of the training and knowledge of potential users, and *[1, Appendix B.8.1 c)]*		[Provide] the information needed to use it safely and properly, taking account of the training and knowledge of the potential users. *[8, Annex I.B.8.1]*	To provide necessary information to laboratory personnel for the proper use of IVD devices and to ensure the safety of patients. *[25]*		Labelling serves to communicate safety- and performance-related information to users of medical devices and/or patients as well as to identify individual devices. Such information may appear on the device

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
								itself, on packaging (or as a packaging insert), or as instructions for use. *[16, §5.1]*
75	Format and content		The format, content and location of the information must be appropriate for the IVD and its intended use. *[1, Appendix B.8.3]*	The label information must be presented in a format most likely to be understood by the expected user. *[4, §4]* The information required for a package insert may be presented in a different format than that indicated in 3.2.1 to 3.2.10 of this guideline. *[4, §*3.2]		Format, contents and their order on the labelling are precisely defined and required. *[25]*		The format, content and location of labelling should be appropriate to the particular device and its intended purpose. *[16, §5.1]*
76	Location		As far as practicable and appropriate, the information needed to use the IVD safely and properly must be set out on the IVD itself or, if full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with the IVD. *[1, Appendix B.8.4]*	Package inserts are essential for most IVDDS. The requirements for a package insert indicated in this section of the guideline apply to the majority of TEST KITS for all classes of IVDDS.	As far as practicable and appropriate, the information needed to use the device safely and properly must be set out on the device itself and/or, where appropriate, on the sales packaging. If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. *[8, Annex 1.B.8.1.]*	Item to be labelled on the outer container or the outer wrapper. If the outer container is not transparent and the items on the label of the immediate container are not clearly visible, those labelled items must also be placed on the outer container or the outer wrapper. *[25]*	Sec. 201(k) of the act provides that "a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper." *[31, Sec. 809.10(a)]*	As far as it is practical and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and /or on the packaging for each unit, and/or on the packaging of multiple devices. If individual packaging of each unit is not practicable, the information should be set out in the leaflet, packaging insert or other means supplied with one or multiple devices. *[16, §5.1,]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
77	Multiple devices							Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient and appropriate to provide with them only a single copy of the instructions for use. In these circumstances the device user should have access to further copies upon request. *[16, §5.1]*
78	Instructions for use	Instructions for use are essential to enable the safe and proper operation of IVD instruments. *[11, §2]*	Instructions for use must accompany or be included in the packaging of all IVDs, unless it can be justified that no such instructions for use are needed because the IVD can be used properly and safely without them. *[1, Appendix B.8.7]*	The label must indicate the directions for use, unless directions are not required for the device to be used safely and effectively; *[5, Part 1, Sec. 21. (1) (i)]*	Instructions for use must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases no such instructions for use are needed for a device if it can be used properly and safely without them. *[8, Annex 1.B.8.1.]*			Instructions may not be needed or may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the manufacturer without any such instructions. *[16, §5.1]*
79	Media and means of delivery			It is recognized that the extent of the information required in the package insert may depend upon the complexity and safety considerations of the test. *[4, §3.2.3]*				Labelling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, downloaded from the manufacturer's Web Site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
80	Essential information		All IVDs must be accompanied by information identifying the IVD; the manufacturer's name or trade name and address; information needed to use the IVD safely, taking account of the training and knowledge of potential users, and where applicable, information allowing the sponsor of the device to be identified. *[1, Appendix B.8]*					
81	User comprehension	The wording shall be readily understandable. *[11, §4]*		The required Labelling information must be conspicuous and clear enough to read as well as intended to last for the life of the device. Test marketing of the device labelling may be required in some cases. *[4, §4]*			Any word, statement, or other information required to appear on the label or labelling must be placed prominently with such conspicuousness and in such terms as to render it "likely to be read and understood by the ordinary individual under customary conditions of purchase and use". Information required by the FDCA to appear on the label or labelling will be deemed to lack the requisite prominence if [see NOTE 3 for details]: *[37]* Lack of prominence of required label statements for medical devices may be due to use of label space for non-required information, including any representation in a foreign language. *[29, Sect. 801.15*	Instructions for use should be written in terms readily understood by the intended user. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
82	Country-specific requirements							Country-specific requirements for labelling text, content, or the format of labels or labelling should be kept to the minimum and, where they currently exist, eliminated as the opportunity arises. *[16, §5.1]*
83	Language requirements	Label: Requirements concerning the language(s) of the country in which the IVD reagent is distributed shall be met. *[10, §4.1.1]* Instructions for use: Languages shall be used in accordance with the requirements of the countries in which the IVD reagent is distributed. *[10, §5.1]* Languages shall be used in accordance with the requirements of the country(ies) in which the IVD instrument is distributed. *[11, §5.1]*	The information must be provided in English, and may also be provided in any other language. *[1, Appendix B.8.2 a) b)]*	Devices sold in Canada must be labelled in both official languages where it is reasonable and prudent to do so. As a minimum, the device must be labelled in either English or French; other languages are permitted. If it is not economically reasonable nor necessary to supply the DIRECTIONS FOR USE in both official languages at the time and point of sale for every device, the DIRECTIONS FOR USE must be readily available in the other official language at the request of the purchaser. *[4, §6]*	Member States may require the information to be supplied pursuant to Annex I, part B, Sec. 8 to be in their official language(s) when a device reaches the final user. In the application of this provision, Member States shall take into account the principle of proportionality and, in particular: a) whether the information can be supplied by harmonized symbols or recognized codes or other measures; b) the type of user anticipated for the device. *[8, Article 4.4]*	Shall be in Japanese. *[25]*	All required words, statements, and other information shall appear in English, or Spanish in Puerto Rico, or the predominant language of the Territory. *[29, Sect. 801.15 (c)(1)]* If the labelling contains any representation in a foreign language, all required words, statements, and other information on the label or labelling shall appear on the labelling in the foreign language. *[29, Sect. 801.15 (3)]*	Taking into consideration the type of user anticipated for the device, national language requirements should be kept to a minimum. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
84	Graphical symbols	The label for an immediate container shall give the information specified in EN375, §4.2.2 to 4.2.10 in legible characters and/or symbols. *[10, §4.2.1]* Information which is a … symbol does not require to be expressed in multiple languages. *[10, §4.1.1]* If symbols and identification colours used on labels do not conform to European or International Standards, such symbols and identification colours shall be explained in the instructions for use. *[10, §5.1]* Any graphical symbols used on the IVD instrument shall be explained in the instructions for use, if no European or International Standards exist to which the symbols used conform. NOTE Any graphical symbols used on the IVD instrument should be explained and/or the relevant European or International Standards should be given. *[11, §5.2]*	Required information may take the form of symbols as appropriate: *[1, Appendix B.8.5]*		Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device. *[8, Annex I.B.8.2]*		FDA has recognized 25 symbols for IVD devices for professional use from ISO 15223 and EN 980. Although some provisions of *21 CFR. 809.10* and 21 CFR 610 and 660 specify particular labelling language, as a matter of enforcement discretion, FDA does not intend to object to the use of [specified] symbols without accompanying text. *[39]* A product is misbranded “if it does not bear such symbols from the uniform system for identification of devices prescribed under Sec. 510(e) as the Secretary by regulation requires” *[37, Sec.502(o)]*	The use of internationally recognized (i.e. standardized) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the device user, e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided with the device. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
85	**Outer container label (EN 375, §4.1)**							
86	Required information	The label for an outer container shall give the information specified in EN375, §4.1.2 to 4.1.10. *[10, §4.1.1]*	IVD labelling must bear the following particulars, which may take the form of symbols as appropriate: *[1, Appendix B.8.5]* For information that might appear on the outer packaging of an IVD includes, but not limited to: — name of the IVD; — manufacturer's name and address, and/or sponsor's name and address — batch/ lot number; — catalogue number; — components listing, in the case of a kit-type IVD that encompasses many different reagents and/or pieces of equipment; — storage instructions, and — expiry date (based on the component with the shortest shelf life), etc. *[1, Part D, §8.2]*	All IVDDs must have a LABEL which provides the information specified in Sec. 21 Subsection (1) Paragraphs (a) to (j) of the Medical Devices Regulations. *[4, §3.1]* *No specific reference to outer container label*	The label must bear the following particulars which may take the form of symbols as appropriate: *[8, Annex 1.B.8.4.]*	Requirements for the Outer Container Label are given below. *[25]*	The label for an *in vitro* diagnostic product shall state the following information, except where such information is not applicable, or as otherwise specified in a standard for a particular product class or as provided in paragraph (e) of this Sec. *[31, Sec. 809.10(a)]*	The labelling should bear the following particulars [specified below]. *[16, §5.2]*
87	Language	Requirements concerning the language(s) of the country in which the IVD reagent is distributed shall be met. *[10, §4.1.1]*	The information must be provided in English, and may also be provided in any other language. *[1, Appendix B.8.2 a) b)]*	Devices sold in Canada must be labelled in both official languages where it is reasonable and prudent to do so. As a minimum, the device must be labelled in either English or French; DIRECTIONS FOR USE must be readily available	Member States may require the information to be in their official language(s) when a device reaches the final user. Provided that safe and correct use of the device is ensured, Member States may authorize the	Shall be in Japanese. *[25]*	All words, statements, and other information required by or under authority of the act to appear on the label or labelling shall appear thereon in the English language, except the predominant language may be substituted for English	Taking into consideration the type of user anticipated for the device, national language requirements should be kept to a minimum. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
				in the other official language at the request of the purchaser. *[4, §6]*	information referred to in the first subparagraph to be in one or more other official Community language(s). *[8, Article 4.4]*		in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, *[29, Sect. 801.15 (c)(1)]* If the label contains any representation in a foreign language, all required information shall also appear in the foreign language. *[29, Sect. 801.15 (2)]*	
88	Graphical symbols	Information which is a proper name, address or symbol does not require to be expressed in multiple languages. *[10, §4.1.1]*	IVD labelling … may take the form of symbols as appropriate: *[1, Appendix B.8.5]*		Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device. *[8, Annex I.B.8.2.]*	Letter(s) appeared on graphical symbols shall be in Japanese. *[25]*	A product is misbranded "if it does not bear such symbols from the uniform system for identification of devices prescribed under Sec. 510(e) as the Secretary by regulation requires" *[37, Sect .502 (o)]* FDA has recognized 25 symbols for IVD devices for professional use from ISO 15223 and EN 980. *[39]*	The use of internationally recognized (i.e. standardized) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the device user, e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided with the device. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
89	Manufacturer identification	The name and address of the manufacturer shall be given. *[10, §4.1.2]*	IVD labelling must bear the manufacturer's name, or trade name and address; *[1, Appendix B.8.5 a)]*	** The label must indicate the name and address of the manufacturer; *[5, Part 1, Sec. 21. (1) (b)]*	The label must bear the name or trade name and address of the manufacturer. *[8, Annex I.B.8.4(a)]* If the product contains dangerous preparations, the label must bear the name, full address and telephone number of the person established in the Community who is responsible for placing the preparation on the market, whether it be the manufacturer, the importer or the distributor; *[6, Article 10, Sec. 2.2]*	Registered name and address of the manufacturer for domestic products. *[25]*	The label of a device in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor. *[29, Sect. 801.1 (a)]; [31, Sec. 809.10(a)(8)]* NOTE "Manufacturer" symbol may be used in place of the statement "Manufactured by_____" *[39]* *For additional details, see NOTE 1*	The labelling should bear … the name or trade name and address of the manufacturer and, if appropriate, a phone number and/or fax number and/or website address to obtain technical assistance. *[16, §5.2]*
90	Importer/ exporter/ authorized representative identification	The name and address of the authorized representative shall also be given when this is a legal requirement. *[10, §4.1.2]*	All IVDs must be accompanied by information, where applicable, allowing the sponsor of the device to be identified. *[1, Appendix B.8.1 d)]*		For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorized representative of the manufacturer; *[8, Annex I.B.8.4(a)]*	For imported products, the name and address of the importer shall be given. *[25]*	The "Authorized representative" symbol may be used as long as the use of this symbol does not violate other U.S. labelling requirements. For example, if the symbol interferes with the communication of information required by U.S. law, the device could be misbranded under Sec. 502(c) of the Act. *[39]*	The labelling should bear … for imported devices, the label, or the outer packaging, or instructions for use, may be required to contain in addition, the name and address of either the importer established within the importing country/region or of an authorized representative of the manufacturer established within the importing country/region. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
91	Device name/ identification	The product name shall be given. When the name does not uniquely identify the product, an additional means of identification shall also be given. *[10, §4.1.3]*	IVD labelling must bear sufficient information to enable the user to identify the IVD, or if relevant, the contents of the package; *[1, Appendix B.8.5 c)]*	The label must indicate the name of the device; *[5, Part 1, Sec. 21. (1) (a)]* The label must indicate the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family; *[5, Part 1, Sec. 21. (1) (c)]*	The label must bear the details strictly necessary for the user to uniquely identify the device and the contents of the packaging; *[8, Annex I.B.8.4(b)]* Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. *[8, Annex I.B.8.6.]*	In Principle, a single proprietary name should be assigned to a single product. Where more than one brand name is to be given to a single product for some appropriate reason, the material in support of this should accompany the approval application. Since this may not be approved depending on the reason given, an official in charge should be consulted, if necessary, before an application is submitted. *[25]*	The label shall state the proprietary name and established name (common or usual name), if any. *[31, Sec. 809.10(a)(1)]* For a reagent, a declaration of the established name (common or usual name), if any. *[31, Sec. 809.10 (a) (3)]* *Proper name, as applied to a product, means the name designated in the license for use upon each package of the product. (Applies to licensed Biologic assays only)* *[27, Sec. 600.3]*	The labelling should bear … sufficient details for the user to identify the device … *[16, §5.2]*
92	Micro-biological state	If necessary for proper performance of the IVD reagent, the microbiological state or state of cleanliness, e.g. “microbiologically controlled” or “sterile”, shall be given. *[10, §4.1.4]*	IVD labelling must bear, where appropriate, the word "STERILE", and information about the method that was used to sterilise the device; *[1, Appendix B.8.5 d)]*	The label must include the word “Sterile”, if the manufacturer intends the device to be sold in a sterile condition; *[5, Part 1, Sect. 21. (1) (f)]*	The label must bear where appropriate, the word “STERILE” or a statement indicating any special microbiological state or state of cleanliness; *[8, Annex I.B.8.4(c)]*	Not required. *[25]*		The labelling should *where applicable* bear an indication that the device is sterile and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
93	Batch code/ device traceability	A batch code shall be given. NOTE The graphical symbol as given in EN 980 should be used. *[10, §4.1.5]*	IVD labelling must bear the batch code, lot number or serial number of the IVD; *[1, Appendix B.8.5 e)]*	The Immediate container label must include a CONTROL NUMBER is required for Class III and IV IVDDs, in order to determine the complete manufacturing history of the product. It is standard convention for most IVDD kits or kit components to indicate a lot number. *[4, §3.3.8]*	The label must bear the batch code, preceded by the word "LOT", or the serial number; *[8, Annex I.B.8.4 (d)*]	A batch code shall be given. *[25]*	The label shall state a lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product. *[31, Sec. 809.10(a)(9)]*	The labelling should bear an indication of the batch code/lot number (e.g. on single-use disposable devices or reagents) … and to allow appropriate actions to trace and recall the devices and detachable components, *[16, §5.2]*
94	Batch code – kit traceability	If a kit contains different components bearing different batch codes, the batch code given on the outer container shall enable the individual product histories to be traced from the manufacturer's production file. *[10, §4.1.5]*	Wherever reasonable and practicable, IVD labelling must bear identification by batch number, of all of the IVD's components, so as to allow all appropriate action to detect any potential risk posed by the components. *[1, Appendix B.8.6]*	If it is a multiple-unit product, the CONTROL NUMBER should permit tracing the identity of the individual units. *[4, §3.3.8]*	Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. *[8, Annex I.B.8.6.]*		If it is a multiple-unit product, the lot or control number shall permit tracing the identity of the individual units. *[31, Sec. 809.10(a)(9)(i)]* For multiple-unit products which require the use of included units together as a system, all units should bear the same lot or control number, if appropriate, or other suitable uniform identification should be used. *[31, Sec. 809.10(a)(9)(iii)]*	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
95	Expiry date	An expiry date based upon the stated storage instructions shall be given. The label of the outer container shall give the expiry date of the component having the earliest expiry date or an earlier date if appropriate. NOTE 1 The graphical symbol as given in EN 980 should be used. *[10, §4.1.6]*	IVD labelling must bear, if applicable, an indication of the date by which the IVD or any of its components should be used, in safety, without degradation of performance; *[1, Appendix B.8.5 f)]*	The Immediate container label must include an Expiration date based upon the component of the IVDD having the shortest projected useful life. Expiration dates are required for the unopened IVDD or its components (reagents, calibrators, quality control materials, etc.) and for the opened IVDD or its components if different from the unopened IVDD *[4, §3.3.6]*	The label must bear, if necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order; *[8, Annex I.B.8.4 (e)]*	An expiry date based upon the stated storage instructions shall be given. *[25]*	For a reagent, the label shall state a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following: a) An expiration date based upon the stated storage instructions. b) A statement of an observable indication of an alteration of the product, e.g. turbidity, colour change, precipitate, beyond its appropriate standards. c) Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards. *[31, Sec.809.10(a)(6)]*	The labelling should bear an indication of the date until which the device may safely be used (i.e. put into service), … (e.g. on single-use disposable devices or reagents) where this is relevant. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
96	Date format	This shall be expressed as the year, the month, and, where relevant, the day in that order. In the case of year and month this means that the expiry date is the last day of the month indicated. The label of the outer container shall give the expiry date of the component having the earliest expiry date or an earlier date if appropriate. NOTE 2 The format for the expiry date should be either "CCYY-MM-DD" or "CCYY-MM". *[10, §4.1.6]*	[Must be] … expressed in a way that clearly identifies the month and year; *[1, Appendix B.8.5 f)]*		[Must be] … expressed as the year, the month and, where relevant, the day, in that order; *[8, Annex I.B.8.4 (e)]*	The approved period for use is to be recorded to month units. *[25]*		[Must be] … expressed at least as the year and month *[16, §5.2]*
97	Contents – quantities	The content in terms of e.g. mass, volume, volume after reconstitution and/or the number of measurements shall be given. *[10, §4.1.7]*	Might appear on outer package labels. *[1 Part D:, §8.2]*	If more than a single determination may be performed using the product, any statement of the number of tests must be consistent with instructions for use and amount of material provided. *[4, §3.3.3]*	The label must bear the details strictly necessary for the user to uniquely identify the device and the contents of the packaging; *[8, Annex I.B.8.4 (b)]*	Weight, volume or number of units and other physical parameters of contents	For a reagent, the label shall state a declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. *[31, Sec. 809.10(a)(7)]* If more than a single determination may be performed using the product, any statement of the number of tests shall be consistent with instructions for use and amount of material provided. *[31, Sec. 809.10(a)(7)]*	The labelling should bear sufficient details for the user to identify the device or, where relevant, the contents of any packaging. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
98	Contents – units						The use of metric designations is encouraged, wherever appropriate. *[31, Sec. 809.10(a)(7)]*	
99	Contents – kit components	In the case of a kit the components shall be designated in the same way as on the immediate containers as specified in EN375, §4.2.3. *[10, §4.1.7]*		(Immediate container) label must list kit contents, including quantities, descriptions, volumes, number of tests, etc. *[4, §3.3.3]*				*See above.*
100	Additional materials/ accessories	Information on additional materials, e.g. accessories, may be given on the label and/or in the instructions for use where practicable and appropriate. *[10, §4.1.7]*				*Not required on the outer container.*		
101	Intended use	Where appropriate, the intended purpose shall be given. EXAMPLES: Measurement of glucose concentration in serum; measurement of thromboplastin time. *[10, §4.1.8]*	IVD labelling must bear the intended purpose of the IVD *[1, Appendix B.8.5 b)]* IVD labelling must bear the kind of sample with which the IVD is intended to be used (if not obvious) *[1, Appendix B.8.5 b)]*	Unless self-evident to the intended user, the label must indicate the medical conditions, purposes and uses for which the device is manufactured, sold or represented, *[5, Part 1, Sec. 21. (1) (h)]*	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label. *[8, Annex I.B.8.5]*	*Not required on the outer container.*	The label shall state the intended use or uses of the product. *[31, Sec. 809.10(a)(2)]*	The labelling should bear the intended purpose, user and patient population of the device where these are not obvious. *For* in vitro *diagnostic medical devices,* the labelling should bear additional directions/ instructions for the proper use of *in vitro* diagnostic medical devices which may include: Intended use (e.g. monitoring, screening or diagnostic) … *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
102	*In vitro* (diagnostic) use	Additionally the *in vitro* use of the reagent shall be indicated. NOTE A graphical symbol for *in vitro* diagnostic medical device should be used. *[10, §4.1.8]*		*No specific reference to outer container label. Required on immediate container label.*	Where appropriate, the label must bear a statement indicating the *in vitro* use of the device; *[8, Annex I.B.8.4 (g)]*	The *in vitro* diagnostic use of the reagent shall be indicated.	The label shall include a statement "For *In vitro* Diagnostic Use" and any other limiting statements appropriate to the intended use of the product. *[31, Sec. 809.10(a)(4)]* Note "IVD" in a box symbol may be used in place of "For *In vitro* Diagnostic Use" *[39]*	… including an indication that it is for *in vitro* diagnostic use. *[16, §5.2]*
103	Storage and handling – general information	The storage conditions necessary to assure the stability of the product in the unopened state shall be indicated. Recommended storage temperature intervals shall be given. Other conditions that affect stability, e.g. light or humidity, shall be mentioned. Any other particular measures to be taken in the handling of the product shall be given (e. g "treat as fragile"). *[10, §4.1.9]*	IVD labelling must bear any particular storage and/or handling conditions; *[1, Appendix B.8.5 g)]*	The label must indicate any special storage conditions applicable to the device. *[5, Part 1, Sec. 21. (1) (j)*] Indicate the storage conditions necessary to ensure the stability of the product in the unopened state for both device and individual reagents. Recommended storage temperature intervals and other conditions for storage such as light, humidity, etc. should be stated. *[4, §3.2.7]*	The label must bear any particular storage and/or handling conditions; *[8, Annex I.B.8.4 (h)]*	The storage conditions necessary to assure the stability of the product in the unopened state shall be indicated. Recommended storage temperature intervals shall be given. Other conditions that affect stability, e.g. light or humidity should be mentioned.	For a reagent, the label shall state appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. NOTE The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in Sec. 211.166 of this chapter. *[31, Sec. 809.10(a)(5)]*	The labelling should bear any special storage and handling conditions at the appropriate packaging level. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
104	Warnings and precautions	If an IVD reagent is considered dangerous (e.g. chemical, radioactive or biological risk), the outer container shall be labelled with the appropriate danger symbol(s). If in the case of chemical hazards the IVD reagent is not accompanied with instructions for use giving appropriate risk and safety phrases, these phrases shall be given on the label of the outer container. NOTE For chemical hazards labelling see Directive 93/72/EC. *[10, §4.1.10]*	IVD labelling must bear any warnings, restrictions or precautions that should be taken, in relation to the use of the IVD; *[1, Appendix B.8.5 i)]*	Indicate appropriate warnings and precautionary statements for the safe and effective use of the IVDD. *[4, §3.2.5.2]*	The label must bear appropriate warnings and/or precautions to take, which may take the form of symbols; *[8, Annex I.B.8.4 (j)]* In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC and Directive 88/379/EEC shall apply. *[8, Annex I.B.8.3.]* The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use. *[8, Annex I.B.8.3.]* Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use. *[8, Annex I.B.8.3.]*	If an IVD is subjected to as dangerous, the outer container shall be labelled with the appropriate danger symbol.	The label shall include a statement of warnings or precautions for users as established in the regulations contained in 16 CFR part 1500 and any other warnings appropriate to the hazard presented by the product; *[31, Sec. 809.10(a)(4)]* A statement of warnings or precautions for users as established in the regulations contained in 16 CFR Part 1500 and any other warnings appropriate to the hazard presented by the product; *[31, Sec. 809.10(a)(4)]*	The labelling should bear any warnings, precautions, limitations or contraindications. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
105	Storage instructions – after reconstitution/ mixing			For products requiring further manipulation, such as reconstitution and/or mixing before use and with storage in the original bottle, the reagent label must include appropriate storage instructions for the reconstituted or mixed product. *[4, §3.4.4]*			For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product which is to be stored in the original container. The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in 211.166 of this chapter. *[31, Sec. 809.10(a)(5)]*	
106	Specific labelling statements		IVD labelling must bear, if applicable, the words "FOR EXPORT ONLY." *[1, Appendix B.8.5 k)]*		The CE marking of conformity must also appear on the sales packaging. The CE marking shall be accompanied by the identification number of the notified body … *[8, Article16.2]*	The Japanese approval number should be given on the package insert. Where the product carries no package insert, the number should be indicated in the container or wrapper.		

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
107	**Immediate container label (EN 375, §4.2)**							
108	Required information	The label for an immediate container shall give the information specified in EN375, §4.2.2 to 4.2.10 in legible characters and/or symbols. *[10, §4.2.1]*	IVD labelling must bear the following particulars, which may take the form of symbols as appropriate: *[1, Appendix B.8.5]* Information that might appear on inner packaging includes but is not limited to: — name of reagent; — contents, e.g. the quantity of product within a particular vial, etc.; — batch/lot number, and — expiration date, etc. *[1, Part D, §8.3]*	Immediate container label requirements are indicated below. *[4, §3.3]*	The label must bear the following particulars which may take the form of symbols as appropriate: *[8, Annex I.B.8.4.]*	The following items should be labelled on the immediate container or the immediate wrapper, except in those cases excluded from the requirement by a separate ordinance. (Details omitted) Labelling of kits (sets): For *in vitro* diagnostics kits approved as a single reagent product, each container in the kit shall be considered as an immediate container.	The [immediate container] label shall state the following information *[31, Sec. 809.10(a)]* If the presence of this information on the immediate container will interfere with the test, the information may appear on the outside container or wrapper rather than on the immediate container label. *[31, Sec. 809.10(a)(10)(ii)]*	See General Principles regarding required labelling information; location must be appropriate
109	Limited label space	If the available space is too small for this purpose, the information may be reduced to EN375, §4.2.2, 4.2.3, 4.2.5, 4.2.6 and 4.2.10. *[10, §4.2.1]*	If full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with the IVD. *[1, Appendix B.8.4]*	Where a package is too small to display all the information in accordance with Sec. 21, the directions for use shall accompany the device but need not be set out on the outside of the package or be visible under normal conditions of sale *[5, Part 1, Sec. 22.2]*	If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices. *[8, Annex I.B.8.1.]*	In the case of immediate containers too small to accommodate a label with sufficient space to bear all such information, information indicated with an asterisk * may be omitted or abbreviated (except powerful or poisonous reagent name) on the immediate container or wrapper, but shall be labelled on the outer container. (Details omitted)	In the case of immediate containers too small or otherwise unable to accommodate a label with sufficient space to bear all such information and which are packaged within an outer container from which they are removed for use, the information required by paragraphs (a) (2), (3), (4), (5), (6) (ii), (iii) and (7) of this Sec. may appear in the outer container labelling only. *[31, Sec. 809.10(a)(10)(i)]*	See General Principles regarding location of required labelling information.

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
110	Graphical symbols	The label for an immediate container shall give the information specified in EN375, §4.2.2 to 4.2.10 in legible characters and/or symbols. *[10, §4.2.1]*	IVD labelling … may take the form of symbols as appropriate: *[1, Appendix B.8.5]*		Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device. *[8, Annex I.B.8.2.]*		A product is misbranded "if it does not bear such symbols from the uniform system for identification of devices prescribed under Sec. 510(e) as the Secretary by regulation requires" *[FD&C 502(o)]* FDA has recognized 25 symbols for IVD devices for professional use from ISO 15223 and EN 980. Although some provisions of [*21 CFR. 809.10* and 21 CFR 610 and 660] specify particular labelling language, as a matter of enforcement discretion, FDA does not intend to object to the use of [specified] symbols without accompanying text *[39]*	The use of internationally recognized (i.e. standardized) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the device user, e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided with the device. *[16, §5.1]*
111	Languages	Information consisting of proper names and symbols does not require expression in multiple languages. *[10, §4.2.1]*	The information must be provided in English, and may also be provided in any other language. *[1, Appendix B.8.2 a) b).]*	… information shall, as a minimum, be in either English or French *[5, Part 1. Sec. 23(1)]* ..where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser *[5, Part 1. Sec. 23(2)]*	Member States may require the information to be supplied pursuant to Annex I, part B, Sec. 8 to be in their official language(s) when a device reaches the final user. Provided that safe and correct use of the device is ensured, Member States may authorize the information referred to in the first subparagraph to be in one or more other official Community language(s).	Shall be in Japanese	All words, statements, and other information required by or under authority of the act to appear on the label or labelling shall appear thereon in the English language, provided, however, that in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the	*See General Principles.*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
				Directions for use in respect of a medical device that is sold at a self-service display shall, as a minimum, be in both English and French *[5, Part 1. Sec. 23(3)]*	In the application of this provision, Member States shall take into account the principle of proportionality and, in particular: a) whether the information can be supplied by harmonized symbols or recognized codes or other measures; b) the type of user anticipated for the device. *[8, Article 4.4]*		predominant language may be substituted for English. *[29, Sect. 801.15 (c)(1)]* If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language. *[29, Sect. 801.15 (2)]*	
112	Immediate container is also the outer container	If the immediate container is also the outer container, the requirements for the label as specified in EN375, §4.1 apply. *[10, §4.2.1]*						See General Principles regarding the location of required labelling information.
113	Manufacturer identification	The name of the manufacturer shall be given. Alternatively, an unequivocal trade name or logo is sufficient. *[10, §4.2.2]*	IVD labelling must bear the manufacturer's name, or trade name and address; *[1, Appendix B.8.5 a)]*	** The label must indicate the name and address of the manufacturer; *[5, Part 1, Sec. 21. (1) (b)]* the Immediate container label and the reagent label must indicate the Name and address of the manufacturer *[4, §3.3.7 and §3.4.6]*	The label must bear the name or trade name and address of the manufacturer. *[8, Annex I.B.8.4(a).]*	Name and address of manufacturer or importer. For approved reagents of foreign manufacture, the name and the country of residence of the applicant receiving approval for foreign manufacture are to be recorded, along with the name and address of the domestic caretaker.	The label shall state the name and place of business of manufacturer, packer, or distributor. *[31, Sec. 809.10(a)(8)]* *Must appear on immediate container label per 31, Sec. 809.10(a)(10)(i)* NOTE "Manufacturer" symbol may be used in place of the statement "Manufactured by_____" *[39]*	The labelling should bear the name or trade name and address of the manufacturer and, if appropriate, a phone number and/or fax number and/or website address to obtain technical assistance. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
114	Device name and/or identification	The name shall ensure proper identification to the user of the product. *[10, §4.2.3]*	IVD labelling must bear sufficient information to enable the user to identify the IVD; *[1, Appendix B.8.5 c)]*	The label must indicate the name of the device; *[5, Part 1, Sec. 21. (1) (a)]* Name of the IVDD is required on the Immediate container label *[4, §3.3.1]* The label must indicate the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family; *[5, Part 1, Sec. 21. (1) (c)]* The identifier or catalogue number of the IVDD is required on the Immediate container label. *[4, §3.3.9]*	The label must bear the details strictly necessary for the user to uniquely identify the device and the contents of the packaging; *[8, Annex I.B.8.4(b)]*	Name (the name designated by the Japanese Pharmacopoeia (JP) for reagents listed in the JP; the generic name for reagents not listed in the JP, or the approved brand name if reagents are not listed in the JP and no generic name exists. The name designated by JP shall accompany the words JP.	The label shall state the proprietary name and established name (common or usual name), if any. *[31, Sec. 809.10(a)(1)]* *Required on immediate container label per [31, Sec. 809.10(a)(10)(i)*	The labelling should bear sufficient details for the user to identify the device or, where relevant, the contents of any packaging. *[16, §5.2]*
115	Kit components	Additionally, in a kit each component shall be identified by name, letter, number, symbol, colour or graphics in the same manner as described in the instructions for use or on the outer container. *[10, §4.2.3]*	Wherever reasonable and practicable, IVD labelling must bear identification by batch number, of all of the IVD's components, so as to allow all appropriate action to detect any potential risk posed by the components. *[1, Appendix B.8.6]*	For reagents to be used within a single kit, the reagent label must indicate the name of the reagent and the name of the IVDD. For multipurpose reagents which can be used with a number of kits, the name of the reagent on the label should be sufficient. *[4, §3.4.1]* For reagents to be used within a single kit, the reagent label must indicate the identifier or catalogue number of the reagent, where applicable. *[4, §3.4.8]*	Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. *[8, Annex I.B.8.6.]*			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
116	Microbio-logical state	If necessary for proper performance of the IVD reagent, the microbiological state or state of cleanliness, e.g "microbiologically controlled" or "sterile", shall be given. *[10, §4.2.4]*	IVD labelling must bear, where appropriate, the word "STERILE", and information about the method that was used to sterilize the device; *[1, Appendix B.8.5 d)]*	The label must include the word "Sterile", if the manufacturer intends the device to be sold in a sterile condition; *[5, Part 1, Sec. 21. (1) (f)]*	The label must bear, where appropriate, the word "STERILE" or a statement indicating any special microbiological state or state of cleanliness; *[8, Annex I.B.8.4(c)]*	Not required		The labelling should *where applicable* bear an indication that the device is sterile and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization. *[16, §5.2]*
117	Batch code	A batch code shall be given. NOTE The graphical symbol as given in EN 980 should be used. *[10, §4.2.5]*	IVD labelling must bear the batch code, lot number or serial number of the IVD; *[1, Appendix B.8.5 e)]*	The Immediate container label must include a CONTROL NUMBER is required for Class III and IV IVDDs, in order to determine the complete manufacturing history of the product. It is standard convention for most IVDD kits or kit components to indicate a lot number. If it is a multiple unit product, the CONTROL NUMBER should permit tracing the identity of the individual units. *[4, §3.3.8]*	The label must bear the batch code, preceded by the word "LOT", or the serial number; *[8, Annex I.B.8.4 (d)]* Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. *[8, Annex I.B.8.6.]*	*Manufacturing number or manufacturing symbol	The label shall state a lot or control number, identified as such, from which it is possible to determine the complete manufacturing history of the product. *[31, Sec. 809.10(a)(9)]* If it is a multiple-unit product, the lot or control number shall permit tracing the identity of the individual units. *[31, Sec. 809.10(a)(9)(i)]* *Required on immediate container label per [31, Sec. 809.10(a)(10)(i).*	The labelling should bear an indication of either the batch code/lot number (e.g. on single-use disposable devices or reagents) or the serial number (e.g. on electrically-powered medical devices), where relevant, and to allow appropriate actions to trace and recall the devices and detachable components, *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
118	Expiry date	An expiry date based upon the stated storage instructions shall be given. NOTE 1 The graphical symbol as given in EN 980 should be used. *[10, §4.2.6]*	IVD labelling must bear, if applicable, an indication of the date by which the IVD or any of its components should be used, in safety, without degradation of performance *[1, Appendix B.8.5 f)]*	The Immediate container label must include an Expiration date based upon the component of the IVDD having the shortest projected useful life. Expiration dates are required for the unopened IVDD or its components (reagents, calibrators, quality control materials, etc.) and for the opened IVDD or its components if different from the unopened IVDD *[4, §3.3.6]*	The label must bear, if necessary, an indication of the date by which the device or part of it should be used, in safety, without degradation of performance, *[8, Annex I.B.8.4 (e)]*	*An expiration date based upon the stated storage instructions.	For a reagent, the label shall state a means by which the user may be assured that the product meets appropriate standards of identity, strength, quality and purity at the time of use. This shall be provided, both for the product as provided and for any resultant reconstituted or mixed product, by including on the label one or more of the following: (i) An expiration date based upon the stated storage instructions. *[31, Sec. 809.10(a)(6)]* *Required on immediate container label per [31, Sec. 809.10(a)(10)(i).*	The labelling should bear an indication of the date until which the device may safely be used (i.e. put into service), (e.g. on single-use disposable devices or reagents) where this is relevant. *[16, §5.2]*
119	Date format	This shall be expressed as the year, the month, and, where relevant, the day in that order. In the case of year and month this means that the expiry date is the last day of the month indicated. NOTE 2 The format for the expiry date should be either “CCYY-MM-DD" or "CCYY-MM". *[10, §4.2.6]*	… expressed in a way that clearly identifies the month and year *[1, Appendix B.8.5 f)]*	The Immediate container label must include an Expiration date based upon the component of the IVDD having the shortest projected useful life. Expiration dates are required for the unopened IVDD or its components (reagents, calibrators, quality control materials, etc.) and for the opened IVDD or its components if different from the unopened IVDD *[4, §3.3.6]*	… expressed as the year, the month and, where relevant, the day, in that order; *[8, Annex I.B.8.4 (e)]*	The expiration date shall be given by month units.		… expressed at least as the year and month. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
120	Alternatives to expiry date						A statement of an observable indication of an alteration of the product, e.g. turbidity, colour change, precipitate, beyond its appropriate standards. *[31, Sec. 809.10(a)(6)(ii)]* Instructions for a simple method by which the user can reasonably determine that the product meets its appropriate standards. *[31, Sec. 809.10(a)(6)(iii)]*	
121	Contents – quantities	The content in terms of e.g. mass, volume, volume after reconstitution … shall be given. *[10, §4.2.7]*	Might appear on inner package labels. *[1, Part D, §8.3]*	If the contents are not readily apparent, the label must indicate what the package contains, expressed in terms appropriate to the device, such as the size, net weight, length, volume or number of units; *[5, Part 1, Sec. 21. (1) (e)]* The description of a component should include the Contents in terms of quantity (e.g. number of vials, if applicable), mass and/or volume or concentration. *[4, §3.2.5.1(a)]*	The details strictly necessary for the user to uniquely identify the device and the contents of the packaging; *[8, Annex I.B.8.4.(b)]*	Weight, volume or number of units and other physical parameters of contents	For a reagent, the label shall state a declaration of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these or other terms which accurately reflect the contents of the package. The use of metric designations is encouraged, wherever appropriate. *[31, Sec. 809.10(a)(7)]*	The labelling should bear sufficient details for the user to identify … where relevant, the contents of any packaging. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
122	Contents – reactive ingredients	NA		For reagents, indicate the Quantity, proportion, concentration or activity of each reactive ingredient. *(This information may be in a package insert) [4, §3.2.5.1(a)]*		For reagent not in the JP, names of active ingredients (generic name where applicable) and content (an outline of the chemical entity and manufacturing method where the active ingredients are unknown) NOTE It is preferred to have this information but not a requirement for the immediate container.	For a reagent, the label shall state the quantity, proportion or concentration of each reactive ingredient; *[31, Sec. 809.10(a)(3)]*	
123	Contents – biological materials	NA		For biological reagents, indicate the source and measure of activity. *(This information may be in a package insert) [4, §3.2.5.1(a)]*			For a reagent derived from biological material, the label shall state the source and a measure of its activity. *[31, Sec. 809.10(a)(3)]*	
124	Contents – other ingredients	NA		For reagents, include a statement indicating the presence of catalytic or non-reactive ingredients, such as buffers, preservatives or stabilizers, where this information is needed for the safe and effective use of the test. *(This information may be in a package insert) [4, §3.2.5.1(a)]*				

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
125	Contents – units	NA					The quantity, proportion, concentration, or activity shall be stated in the system generally used and recognized by the intended user, e.g. metric, international units, etc. *[31, Sec. 809.10(a)(3)]*	
126	Contents – number of measure-ments	The content in terms of … the number of measurements shall be given. *[10, §4.2.7]*		The description of a component should specify the maximum number of tests that can be performed with stated contents. *[4, §3.2.5.1(a)]* … any statement of the number of tests on the reagent label should be consistent with instructions for use and amount of material provided. *[4, §3.4.2]*			If more than a single determination may be performed using the product, any statement of the number of tests shall be consistent with instructions for use and amount of material provided. *[31, Sec. 809.10(a)(7)]*	
127	Intended purpose	NA *[10, §4.2.8]*	IVD labelling must bear the intended purpose of the IVD *[1, Appendix B.8.5 b)]* IVD labelling must bear the kind of sample with which the IVD is intended to be used (if not obvious) *[1, Appendix B.8.5 b)]*	Unless self-evident to the intended user, the label must indicate the medical conditions, purposes and uses for which the device is manufactured, sold or represented, *[5, Part 1, Sec. 21. (1) (h)]* Intended use is required on the Immediate container label. NOTE *An example is provided. [4, §3.3.2]*	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label. *[8, Annex I.B.8.5.]*		The label shall state the intended use or uses of the product. *[31, Sec. 809.10(a)(2)]*	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
128	*In vitro* use	The *in vitro* use of the reagent shall be indicated. NOTE A graphical symbol for *in vitro* diagnostic medical device should be used. *[10, §4.2.8]*		The Immediate container label must include the statement "For *In vitro* Diagnostic Use" for all IVDDs *[4, §3.3.4]*	Where appropriate, the label must bear a statement indicating the *in vitro* use of the device; *[8, Annex I.B.8.4 (g)]*	The "*in vitro* diagnostic use" label. When this labelling is displayed on the outer box, it needs not be placed on the immediate container.	The label shall include a statement "For *In vitro* Diagnostic Use" and any other limiting statements appropriate to the intended use of the product. *[31, Sec. 809.10(a)(4)]* NOTE "IVD" in a box symbol may be used in place of "For *In vitro* Diagnostic Use" *[39]*	*For in vitro diagnostic medical devices,* the labelling should bear additional directions/ instructions … including an indication that it is for *in vitro* diagnostic use. *[16, §5.2]*
129	Not for donor screening.	NA		For Class IV IVDDs not intended for donor screening, the Immediate container label must indicate "Not for donor screening" on the device immediate-container label and package insert. *[4, §3.3.2 Note:]*				
130	Storage and handling - unopened container	The storage conditions necessary to assure the stability of the product in the unopened state shall be indicated. Recommended storage temperature intervals shall be given (examples given) Any other particular measures to be taken in the handling of the product shall be given (e. g "treat as fragile"). *[10, §4.2.9]*	IVD labelling must bear any particular storage and/or handling conditions; *[1, Appendix B.8.5 g)]*	The label must indicate any special storage conditions applicable to the device. *[5, Part 1, Sec. 21. (1) (j)]* Indicate the storage conditions necessary to ensure the stability of the product in the unopened state for both device and individual reagents. Recommended storage temperature intervals and other conditions for storage such as light, humidity, etc. should be stated. *[4, §3.2.7]*	the label must bear any particular storage and/or handling conditions; *[8, Annex I.B.8.4 (h)]*	Not regulated but heavily recommended by the administrative guidance.	For a reagent, the label shall state appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. NOTE The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those	The labelling should bear any special storage or handling conditions at the appropriate packaging level. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
							described in Sec. 211.166 of this chapter. *[31, Sec. 809.10(a)(5)]*	
131	Storage – after reconstitution/ mixing		IVD labelling must bear any particular storage and/or handling conditions; *[1, Appendix B.8.5 g)]*	For products requiring further manipulation, such as reconstitution and/or mixing before use and with storage in the original bottle, the reagent label must include appropriate storage instructions for the reconstituted or mixed product. *[4, §3.4.4]*	The label must bear any particular storage and/or handling conditions; *[8, Annex I.B.8.4 (h)]*	Not regulated but heavily recommended by the administrative guidance.	For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product which is to be stored in the original container. NOTE The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in Sec. 211.166 of this chapter. *[31, Sec. 809.10(a)(5)]*	The labelling should bear any special storage or handling conditions at the appropriate packaging level. *[16, §5.2]*
132	Operating instructions	NA	IVD labelling must bear any particular operating instructions; *[1, Appendix B.8.5 h)]*	Specific operating instructions are required on the Immediate container label (where applicable). *[4, §3.3.10]*	The label must bear where applicable, any particular operating instructions; *[8, Annex I.B.8.4 (i)]*			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
133	Warnings and precautions	If an IVD reagent is considered dangerous (e.g. chemical, radioactive or biological risk) the immediate container shall be labelled with the appropriate danger symbol(s). NOTE For chemical hazards labelling see [Council Directive 67/548/EEC] on laws…relating to classification, packaging and labelling of dangerous substances (91/325/EEC…) *[10, §4.2.10]*	IVD labelling must bear any warnings, restrictions or precautions that should be taken, in relation to the use of the IVD; *[1, Appendix B.8.5 i)]*	The Immediate container label must indicate warnings or precautions for users appropriate to the IVDD/ reagent. For IVDDs/reagents containing potentially infectious agents, whether inactivated or not, the IVDD/ reagent label must indicate a statement to the effect: "Handle the reagent as though capable of transmitting infection." *[4, §3.3.4 and, §3.4.3]* An IVDD containing explosive material or components is required to have the following information on the LABEL: — The identity of the material or the components. — The nature of the potential hazard. — The precautions that should be taken during handling, storage or disposal of the device in order to avoid an explosion. *[4, §7]* For products containers originating from a laboratory supply house, that are intended to be used solely in a laboratory and are of a capacity of less than 10 kg, the labels must include: — product identifier — reference to MSDS	The label must bear appropriate warnings and/or precautions to take, which may take the form of symbols; *[8, Annex I.B.8.4 (j)]* In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC (2) and Directive 88/379/EEC (3) shall apply. *[8, Annex I.B.8.3.]* NOTE *Annex I B.8.4.(j) contains the citations for the Directives relating to classification, packaging, and labelling of dangerous preparations.*	The immediate container or the immediate wrapper shall be labelled with the product name and the word "Poisonous in white letters on a black background with a white border in the case of poisonous reagents, and with the name of the product and the word "Powerful" in red letters on a white background with a red border in the case of powerful reagents In case where *in vitro* diagnostics are a kit, this format shall also apply to the names of the constituent reagents.	The label shall include a statement of warnings or precautions for users as established in the regulations contained in 16 CFR part 1500 [Federal Hazardous Substances Act Regulations] and any other warnings appropriate to the hazard presented by the product; *[31, Sec. 809.10(a)(4)]*	The labelling should bear any warnings, precautions, limitations or contraindications. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
				— risk phrases — precautionary measures — first aid measures See Reference [47]				
134	**Instructions for use — Reagents (EN 375, §5)**							
135	Requirement for instructions for use	IVD reagents shall be accompanied by instructions for use. These instructions may alternatively be given on the outer container or in an operational manual which, together with the instructions for use of an instrument or of other parts of the analytical system, allow the user to safely and properly carry out the procedure. If an IVD reagent is not accompanied by detailed instructions, the information given shall make reference to the correct version of instructions provided in another manner. *[10, §5.1]*		Most IVDDs will require DIRECTIONS FOR USE. The required information may be presented in a package insert … *[4, §3.2.5]* Package inserts are essential for most IVDDS. *[4, §3.2]*	Each device must be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users. *[8, Annex I.B.8.1.]* Instructions for use must accompany or be included in the packaging of one or more devices. *[8, Annex I.B.8.1.]*	Detailed instruction shall accompany with IVD reagent. (Example: the user must have the correct insert with the correct lot number of reagents, but it is flexible whether or not each package must contain a package insert) Necessary instructions may alternatively be given on the outer or immediate container.	Labelling accompanying each product, e.g. a package insert, shall state in one place the following information in the format and order specified below, except where such information is not applicable, or as specified in a standard for a particular product class *[31, Sec. 809.10(b)]* The term “accompanying” is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. “Accompanying” also includes labelling that is brought together with the device after shipment or delivery for shipment in interstate commerce. *[36, Sec. 201(m)]*	The format, content and location of labelling should be appropriate to the particular device and its intended purpose. As far as it is practical and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and /or on the packaging for each unit, and/or on the packaging of multiple devices. If individual packaging of each unit is not practicable, the information should be set out in the leaflet, packaging insert or other means supplied with one or multiple devices. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
136	Exceptions	NA		The label must indicate the directions for use, unless directions are not required for the device to be used safely and effectively; *[5, Part 1, Sec. 21. (1) (i)]*	In duly justified and exceptional cases, no such instructions for use are needed for a device if it can be used properly and safely without them. *[8, Annex I.B.8.1.]*		The labelling for a reagent intended for use as a replacement in a diagnostic system may be limited to that information necessary to identify the reagent adequately and to describe its proper use in the system. *[31, Sec. 809.10(b)]*	Instructions may not be needed or may be abbreviated for devices of low or moderate risk if they can be used safely and as intended by the manufacturer without any such instructions. Where the manufacturer supplies multiple devices to a single user and/or location, it may be sufficient and appropriate to provide with them only a single copy of the instructions for use. In these circumstances the device user should have access to further copies upon request. *[16, §5.1]*
137	Alternative media and means of delivery	Complete instructions for use may be supplied as part of the built-in software of a dedicated analytical system or by electronic means. Parts of the instructions for use can be given in a coded format, e.g. barcode or chip, and be explained in the manual of the analytical system. NOTE Immediate access of the user to the complete instructions for use can be ensured by means of an electronic				The instructions shall be provided in a hard copy format.		Labelling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, downloaded from the manufacturer's Web Site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
		databank (Internet) or a free of charge return telefax system (polling). *[10, §5.1]*						
138	Graphical symbols	If symbols and identification colours used on labels do not conform to European or International Standards, such symbols and identification colours shall be explained in the instructions for use. *[10, §5.1]*	Required information may take the form of symbols as appropriate: *[1, Appendix B.8.5]*		Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device. *[8, Annex I.B.8.2.]*	Letter(s) appeared on graphical symbols shall be in Japanese.	FDA has recognized 25 symbols for IVD devices for professional use from ISO 15223 and EN 980. Although some provisions of *21* CFR 809.10 and 21 CFR 610 and 660 specify particular labelling language, as a matter of enforcement discretion, FDA does not intend to object to the use of [specified] symbols without accompanying text. *[39]* A product is misbranded "if it does not bear such symbols from the uniform system for identification of devices prescribed under Sec. 510(e) as the Secretary by regulation requires" *[37, Sect. 502(o)]*	The use of internationally recognized (i.e. standardized) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the symbol is not obvious to the device user, e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided with the device. *[16, §5.1, March 1, 2002]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
139	Languages	Languages shall be used in accordance with the requirements of the countries in which the IVD reagent is distributed. *[10, §5.1]*	The information must be provided in English, and may also be provided in any other language. *[1, Appendix B.8.2 a) b).]*	Devices sold in Canada must be labelled in both official languages where it is reasonable and prudent to do so. As a minimum, the device must be labelled in either English or French; other languages are permitted. If it is not economically reasonable nor necessary to supply the DIRECTIONS FOR USE in both official languages at the time and point of sale for every device, the DIRECTIONS FOR USE must be readily available in the other official language at the request of the purchaser. *[4, §6]*	Member States may require the information to be supplied pursuant to Annex I, part B, Sec. 8 to be in their official language(s) when a device reaches the final user. In the application of this provision, Member States shall take into account the principle of proportionality and, in particular: a) whether the information can be supplied by harmonized symbols or recognized codes or other measures; b) the type of user anticipated for the device. *[8, Article 4.4]*	Shall be in Japanese.	All required words, statements, and other information shall appear in English, or Spanish in Puerto Rico, or the predominant language of the Territory. *[29, Sect. 801.15 (c)(1)]* If the labelling contains any representation in a foreign language, all required words, statements, and other information on the label or labelling shall appear on the labelling in the foreign language. *[29, Sect. 801.15 (3)]*	Taking into consideration the type of user anticipated for the device, national language requirements should be kept to a minimum. *[16, §5.1]*
140	Required information	However, the minimum information provided together with the IVD reagent shall cover all aspects of safe handling and storage prior to its use. *[10, §5.1]*	The documentation that accompanies an IVD generally provides information such as the following (although not limited to): — the IVD's intended use; — the nature of the test, e.g. what marker the test or reagent is to used to detect, and in general, whether the particular assay is qualitative or quantitative; — appropriate directions for use, including how to calculate and interpret results;	Most IVDDs will require DIRECTIONS FOR USE. The required information may be presented in a package insert in a format different from that indicated in Sec. 3.2.5. For example, warnings and precautions may be indicated under a separate heading. Components of a TEST KIT may be indicated in a table format along with instructions for preparation and use, storage conditions, stability information, warnings and precautions, etc. *[4, §3.2.5]*	Where appropriate, the instructions for use must contain the following particulars (identified below): *[8, Annex I.B.8.7.]*		Labelling accompanying each product, e.g. a package insert, shall state in one place the following information in the format and order specified below, except where such information is not applicable, or as specified in a standard for a particular product class *[31, Sec. 809.10(b)]* The term "accompanying" is interpreted liberally to mean more than physical association with the product. It	As far as it is practical and appropriate, the information needed to identify and use the device safely should be provided on the device itself, and/or on the packaging for each unit, and/or on the packaging of multiple devices. If individual packaging of each unit is not practicable, the information should be set out in the leaflet, packaging insert or other means supplied with one or multiple devices. *[16, §5.1]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
			— specific contraindications; — storage information; — warning statements etc. *[1, Part D, §8.1]* Where appropriate, the instructions for use must contain the following particulars [specified below]: *[1, Appendix B.8.8]*	The information required for a package insert may be presented in a different format than that indicated in 3.2.1 to 3.2.10 of this guideline. *[4, §3.2]* The following information should be included [in the package insert]: *[4, §3.2.3]*			extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. "Accompanying" also includes labelling that is brought together with the device after shipment or delivery for shipment in interstate commerce. *[36, Sec. 201(m)]*	The format, content and location of labelling should be appropriate to the particular device and its intended purpose. *[16, §5.1]*
141	Manufacturer	The name and address of the manufacturer shall be given. NOTE The manufacturer is the entity which has taken legal responsibility for the IVD reagent. *[10, §5.2]*	Instructions for use must contain the manufacturer's name, or trade name and address; *[1, Appendix B.8.8 a)]*	The label must indicate the name and address of the manufacturer; *[5, Part 1, Sec. 21. (1) (b)]* The name and mailing address of the manufacturer is required. *[4, §3.2.2]*	Each device must be accompanied by the information needed to identify the manufacturer. *[8, Annex I.B.8.1 required by Article 8.7 (a)]*	Registered name of the manufacturer for domestic products or those of importer for imported products shall be given.	Labelling shall include: Name and place of business of manufacturer, packer, or distributor. *[31, Sec. 809.10(b)(14)]* The "Manufacturer" symbol may be used in place of the statement "Manufactured by_____" *[39]*	The labelling should bear the name or trade name and address of the manufacturer and, if appropriate, a phone number and/or fax number and/or website address to obtain technical assistance. *[16, §5.2]*
142	Authorized representative /importer/ distributor	The name and address of the authorized representative shall also be given when this is a legal requirement. *[10, §5.2]*	All IVDs must be accompanied by information, where applicable, allowing the sponsor of the device to be identified. *[1, Appendix B.8.1 d)]*		For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorized representative of the manufacturer; *[8, Annex I.B.8.4(a).]*	Address of the importer shall be given, if applicable.	The "Authorized representative" symbol as long as the use of this symbol does not violate other U.S. labelling requirements. For example, if the symbol interferes with the communication of information required by U.S. law, the device could be misbranded under Sec. 502(c) of the Act. *[39]*	The labelling should bear for imported devices, the label, or the outer packaging, or instructions for use, may be required to contain in addition, the name and address of either the importer established within the importing country/region or of an authorized representative of the manufacturer established within the importing country/region. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
143	Device name/ identifier	The product name as specified in 4.2.3 shall be given. *[10, §5.3]* When the name does not uniquely identify the product, an additional means of identification shall also be given. *[10, §5.3]*	All IVDs must be accompanied by the following information: a) information identifying the IVD *[1, Appendix B.8.1 a)]*	The label must indicate the name of the device; *[5, Part 1, Sec. 21. (1) (a)]* … including the identifier of any medical device that is part of a system, test kit, medical device group, family or group family; *[5, Part 1, Sec. 21. (1) (c)]* The name of the IVDD on the label should enable the user to identify the device and distinguish it from other similar devices. *[4, §3.2.1]* The description of a component should include the Name of the component. *[4, §3.2.5.1(a)]* The identifier or catalogue number should be indicated on the package insert. *[4, §3.2.8]*	The label must bear the details strictly necessary for the user to uniquely identify the device and the contents of the packaging; *[8, Annex I.B.8.4(b); required by Article 8.7 (a)]* Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. *[8, Annex I.B.8.6.]*	Indicate the approved brand name of the product An identifying mark to the brand name in such a manner that it will not be taken as part of the brand name may be given.	The labelling must indicate: The proprietary name and established name, i.e. common or usual name, if any. *[31, Sec. 809.10(b)(1)]* Reagent labelling shall include: A declaration of the established name (common or usual name), if any. *[31, Sec. 809.10(b)(5)(i)]*	The labelling should bear sufficient details for the user to identify the device or, where relevant, the contents of any packaging. *[16, §5.2]*
144	Mark of conformity	NA			The CE marking of conformity must appear in a visible, legible, and indelible form on the device, where practical and appropriate, and on the instructions for use. The CE marking shall be accompanied by the identification number of the notified body… *[8, Article16.2]*			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
145	Microbio-logical state	If necessary for the proper performance of the IVD reagent, the microbiological state or state of cleanliness, e.g. microbiologically controlled or sterile, shall be given. *[10, §5.4]*	For a sterile IVD, Instructions for use must contain the word "STERILE", and information about the method that was used to sterilize the device; *[1, Appendix B.8.8 j)]*	The Medical Devices Regulations requires the word Sterile, if the manufacturer intends the device or components to be sold in a sterile condition. *[4, §*3.2.5.2]	The label must bear where appropriate, the word "STERILE" or a statement indicating any special microbiological state or state of cleanliness; *[8, Annex I.B.8.4(c); required by Article 8.7 (a)]*			The labelling should *where applicable* bear an indication that the device is sterile and necessary instructions in the event of damage to sterile packaging and, where appropriate, description of methods of re-sterilization. *[16, §5.2]*
146	Intended purpose	The intended purpose shall be given. EXAMPLES: Measurement of glucose concentration in serum; measurement of thromboplastin time. *[10, §5.5]*	Instructions for use must contain the intended purpose of the IVD; *[1, Appendix B.8.8 b)]*	The package insert should clearly indicate intended use(s) and indications for use of the IVDD. The following information should be included: [see NOTE 4] *[4, §3.2.3]*	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label. *[8, Annex I.B.8.5.]*	State accurately the indication (purpose of use) approved.	The labelling must indicate: The intended use or uses of the product and the type of procedure, e.g. qualitative or quantitative. *[31, Sec. 809.10(b)(2)]*	The labelling should bear the intended purpose, user and patient population of the device where these are not obvious. Labelling should bear additional directions/ instructions for proper use of the devices which may include: Intended use (e.g. monitoring, screening or diagnostic) including an indication for *in vitro* diagnostic use. *[16, §5.2]*
147	*In vitro* use	NA		For all classes of IVDDs, indicate the statement: For *in vitro* diagnostic use. *[4, §3.2.5.2]*		State "*In vitro* diagnostic" in Japanese on the upper left corner or some other appropriate place of the package insert. For a radiopharmaceutical, state "*In vitro* diagnostic (radioactive)." Or it may be "*In vitro* radiopharmaceuticals."	Reagent labelling shall include: a statement "For *In vitro* Diagnostic Use" and any other limiting statements appropriate to the intended use of the product. *[31, Sec. 809.10(b)(5)(ii)]* NOTE "IVD" in a box symbol may be used in place of "For *In vitro* Diagnostic Use" *[39]*	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
148	Warnings and precautions	If a danger or hazard (e. g chemical, radioactive or biological) is associated with an IVD reagent or with its use, any special warnings and precautions shall be stated. *[10, §5.6]*	A detailed description of the procedure to be followed should include any contra-indications, warnings, restrictions, or precautions that may apply in relation to the use of the IVD; *[1, Appendix B.8.8 o)]* Instructions for use must contain any undesirable side effects caused by the use of the device; *[1, Appendix B.8.8 b)]*	Indicate appropriate warnings and precautionary statements for the safe and effective use of the IVDD. The use of international symbols and signal words such as “warning” and “caution” are effective in alerting the user to a hazard. *[4, §3.2.5.2]* The description of a component should include appropriate warnings and precautions. This information can also be provided in a separate Sec. of the package insert. *[4, §3.2.5.1(a)]*	In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC (2) and Directive 88/379/EEC (3) shall apply. Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use. *[8, Annex I.B.8.3.]*	For the user, provide necessary information about the use of the product (including safety information on the operating procedure), including biological hazard. Legal category (per the Japan classification system). When the reagents comprising a kit are poisonous, powerful, etc., the marks signifying such categories should be put to the names of the reagents involved in the “Entity” Sec. of the package insert. For *in vitro* diagnostics using immunoreaction, include such cautions as “Since non-specific reaction may occur in the serum from patients with auto-immune disease, the test results should be interpreted on the basis of overall consideration of other tests, clinical symptoms, etc.”	Reagent labelling shall include: A statement of warnings or precautions for users as established in the regulations contained in 16 CFR part 1500 and any other warnings appropriate to the hazard presented by the product; *[31, Sec. 809.10(b)(5)(ii)]*	The labelling should bear any warnings, precautions, limitations or contraindications. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
149	Warnings and precautions - chemical hazards	NOTE For chemical hazards provisions, see [Council Directives 67/548/EEC, 1999/45/EC and 1993/72/EC] The information to be reported on the safety data sheet according to EU Directive 91/155/EEC can be included in this Sec. of the instructions for use. *[10, §5.6]* *See also ISO 11014-1 Safety data sheet for chemical products: Part 1: Content and order of Sections*	*Material Safety Data Sheet (MSDS) may also be required.*	In addition to the requirements referred to in the Medical Devices Regulation, an IVDD containing explosive material or components is required to have the following information on the LABEL: — identity of the material or the components. — nature of the potential hazard. — precautions that should be taken during handling, storage or disposal of the device in order to avoid an explosion. *[4, §7]* *Material Safety Data Sheet (MSDS) may also be required. See 46, §13(a) and §14(a)].*	The provisions of the aforementioned Directives on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use. *[8, Annex I.B.8.3.]*	*Safety data sheet is not required.*	*Material Safety Data Sheet (MSDS) may also be required. See 34, §1910.1200 (g) for MSDS requirements.*	
150	Warnings and precautions - biological hazards	Where an IVD reagent includes substances of human or animal origin, a warning shall be given concerning their potentially infectious nature taking into account the risk posed by the nature or amount of the substances. *[10, §5.6]*		Biological Hazards: IVDDs containing material of human or animal origin are required to have a statement to the effect: "CAUTION: the device contains material of human or animal origin and should be handled as a potential carrier and transmitter of disease." For IVDDs containing potentially infectious agents, see NOTE 5 for additional details. *[4, §3.2.5.2]*	Where the device includes substances of human or animal origin, attention must be drawn to their potential infectious nature; *[8, Annex I.B.8.7 (s)]*	Indicate precautions to protect the user against hazards (e.g. for the product derived from human blood, precautions against HBV, HIV or HCV etc.)		The labelling should bear any medicinal substances or biological material incorporated into the device as an integral part of the device.

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
151	Warnings and precautions - environmental influences	NA	Instructions for use must contain precautions to be taken as regards to exposure environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; *[1, Appendix B.8.8 v)]*		Instructions for use must contain the precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; *[8, Annex I.B.8.7 (r)]*			The labelling should bear where applicable information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment). *[16, §5.2]*
152	Warnings and precautions - reasonably anticipated misuse	Possible risks resulting from misuse which may be reasonably anticipated shall also be indicated. *[10, §5.6]*		Warnings alert the user to potential serious adverse reactions and safety hazards that can occur in the proper use, or misuse, of an IVDD. *[4, §3.2.5.2]*				
153	Warnings and precautions - safe handling and disposal	If appropriate, information on the safe handling and disposal of materials used shall be given. *[10, §5.6]*	Instructions for use must contain precautions to be taken against any special, unusual risks related to the use of disposal of the IVD including special protective measures where the IVD includes substances of human or animal origin; *[1, Appendix B.8.8 w)]*	Indicate appropriate decontamination and disposal procedures of used or expired kits and/or reagents. Disposal of all specimens and kit components must comply with all applicable waste disposal requirements. NOTE Decontamination and disposal information may also be provided in the "Warnings and precautions" Sec. of the package insert. *[4, §3.2.5.9]*	Instructions for use must contain information about safe waste disposal; *[8, Annex I.B.8.7 (n)]* Instructions for use must contain the precautions to be taken against any special, unusual risks related to the use or disposal of the device; including special protective measures *[8, Annex I.B.8.7 (s)]*	When sodium azide or a mercury compound is used as the preservative, indicate cautions about their disposal.		iv) Precautions to be taken against any special, unusual risks related to the disposal of the device.

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
154	Composition	The nature and amount or concentration of the active ingredients in the IVD reagents shall be given as well as information on other ingredients that may influence the measurement (e. g. stabilizers, type of organism, host system). *[10, §5.7]*	Instructions for use must contain the composition of the IVD, including a list of all apparatus or components, and all reagents or reagent products by nature, amount or concentration of active ingredient(s); *[1, Appendix B.8.8 c)]*	The description of a component should include the Contents in terms of quantity (e.g. number of vials, if applicable), mass and/or volume or concentration. *[4, §3.2.5.1(a)]* For reagents, indicate the Quantity, proportion, concentration or activity of each reactive ingredient. *[4, §3.2.5.1(a)]* For biological reagents, indicate the source and measure of activity. *[4, §3.2.5.1(a)]* For reagents, include a statement indicating the presence of catalytic or non-reactive ingredients, such as buffers, preservatives or stabilizers, where this information is needed for the safe and effective use of the test. *[4, §3.2.5.1(a)]* The description of a component should specify the maximum number of tests that can be performed with stated contents. *[4, §3.2.5.1(a)]*	Instructions for use must contain the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit *[8, Annex I.B.8.7 (b)]* Instructions for use must contain the composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit *[8, Annex I.B.8.7 (b)]* The instructions for use must also contain a statement, where appropriate, that the device contains other ingredients which might influence the measurement; *[8, Annex I.B.8.7 (b)]*	Name and quantities of the ingredients involved in the basic reaction shall be given. Name of the poisonous or powerful reagent shall be given in such a manner as required. Name of other ingredients may be given if possible. For non-synthetic ingredients, indicate their origin (bacterial strain, animal species, organ, etc.) potency and other pertinent details. For the reference standard (including the standard for calibration), give the rationale, potency and other pertinent details. Packing Unit Example: 6 bottles of total protein reagent in one package.	Reagent labelling shall state: quantity, proportion or concentration or each reactive ingredient; *[31, Sec. 809.10(b)(5)(i)]* Reagent labelling shall state: for biological material, the source and a measure of its activity. *[31, Sec. 809.10(b)(5)(i)]* Reagent labelling shall include: A statement indicating the presence of and characterizing any catalytic or non-reactive ingredients, e.g. buffers, preservatives, stabilizers. *[31, Sec. 809.10(b)(5)(i)]*	The labelling should bear sufficient details for the user to identify the device or, where relevant, the contents of any packaging. *For* in vitro *diagnostic medical devices,* the labelling should bear additional directions/ instructions for the proper use of *in vitro* diagnostic medical devices which may include: Reagent description and any limitation (e.g. use with a dedicated instrument only). *[16, §5.2]*
155	Kit component identification	In the case of a kit, the components shall be designated in the same way as on the immediate containers as specified in EN375, §4.2.3. *[10, §5.7]*	See above.			The name of each constituent reagent for example, fractionating reagent, enzyme reagent, solvent, standard solution, may be given.		See above.

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
156	Units	When possible, quantities shall be expressed in units according to ISO 1000. *[10, §5.7]*			When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181 EEC. *[8, Annex I B.4.2.]*		The quantity, proportion, concentration or activity shall be stated in the system generally used and recognized by the intended user, e.g. metric, international units, etc. *[31, Sec. 809.10(b)(5)(i)]*	
157	Storage and stability – unopened reagents	NA		The label must indicate any special storage conditions applicable to the device. *[5, Part 1, Sec. 21. (1) (j)]* The description of a component should include — storage instructions for both opened and unopened reagents. NOTE This information can also be provided in a separate section of the package insert. — information regarding possible deterioration of the reagent, i.e. indicators of reagent, calibrator or quality control material deterioration, where applicable. *[4, §3.2.5.1(a)]* See also NOTE 6.	*Required on container labels.*		Reagent labelling shall include: appropriate storage instructions adequate to protect the stability of the product. When applicable, these instructions shall include such information as conditions of temperature, light, humidity, and other pertinent factors. NOTE The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in Sec. 211.166 of this chapter. *[31, Sec. 809.10(b)(5)(iv)]*	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
158	Storage and stability after opening, including working reagents	The storage conditions and shelf life following the first opening of the immediate container, together with the storage conditions and stability of working reagents shall be given, if different from those stated in EN375, §4.1.6, 4.1.9, 4.2.6 and 4.2.9. *[10, §5.8]*	Instructions for use must contain the storage conditions and shelf life following the first opening of the primary container, *[1, Appendix B.8.8 d)]* contain the storage conditions and stability of working reagents; *[1, Appendix B.8.8 d)]*	Indicate storage conditions as outlined above for opened or reconstituted/mixed reagents. *[4, §3.2.7]* Expiration dates are also required for the opened IVDD or its components if different from the unopened IVDD. *[4, §3.3.6]*	Instructions for use must contain the storage conditions and shelf life following the first opening of the primary container, *[8, Annex I.B.8.7 (c)]* Instructions for use must contain the storage conditions and stability of working reagents; *[8, Annex I.B.8.7 (c)]*	No requirements on the shelf life following the first opening of the immediate container. The storage conditions and expiration dates after preparation shall be documented for prepared or reconstituted reagents.	For products requiring manipulation, such as reconstitution and/or mixing before use, appropriate storage instructions shall be provided for the reconstituted or mixed product. NOTE The basis for such instructions shall be determined by reliable, meaningful, and specific test methods such as those described in Sec. 211.166 of this chapter. *[31, Sec. 809.10(b)(5)(iv)]*	
159	Materials and equipment required/ provided	Any special equipment required for proper performance and/or safe use but not necessarily provided shall be listed; Information necessary to enable that special equipment to be identified for proper use shall be given. *[10, §5.9]*	Instructions for use must contain an indication of any special equipment required including information necessary for the identification of that special equipment for proper use of the IVD; *[1, Appendix B.8.8 e)]* if the IVD must be used in combination with, installed with, or connected to other IVDs or equipment in order to operate as required, the instructions for use must contain sufficient details of its characteristics to identify the correct IVD or equipment to use in order to obtain a safe and proper combination; *[1, Appendix B.8.8 f)]*	The package insert should indicate if the IVDD must be used in combination with or installed with or connected to other medical devices or equipment. *[4, §3.2.3]* Indicate any dedicated instruments/equipment/ software. Include the following: — Name of instrument. — Model number(s)/ version number(s). — Brief description of use or function, performance characteristics/ specifications, warnings and precautions, limitations, etc. *[4, §3.2.5.1(c)]* See also NOTE 7.	Instructions for use must contain an indication of any special equipment required including information necessary for the identification of that special equipment for proper use; *[8, Annex I.B.8.7 (e)]* if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination; *[8, Annex I.B.8.7 (m)]*	Any equipment required by not provided shall be listed. The generic name of the measuring equipment shall be given, if appropriate.	Labelling shall include: A list of all materials provided, e.g. reagents, instruments and equipment, with instructions for their use. *[31, Sec. 809.10(b)(8)(i)]* Labelling shall include: A list of all materials required but not provided. Include such details as sizes, numbers, types, and quality. *[31, Sec. 809.10(b)(8)(ii)]*	If the device is to be installed with or connected to other medical devices or equipment, or with dedicated software, in order to operate as required for its intended use, the labelling should bear sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
160	Single-use reagents	NA						The labelling should bear an indication, where applicable, that the device has been specified by the manufacturer for single use only. *[16, §5.2]*
161	Specimen	The type of specimen to be used and any special conditions of collection, pretreatment and, if necessary, storage conditions as well as instructions for the preparation of the patient shall be given. *[10, §5.10]*	Instructions for use must contain the type of specimen (sample) to be used with the IVD, including any special conditions of collection, pre-treatment and, if necessary, storage conditions; *[1, Appendix B.8.8 m)]* the instructions for use must contain, where necessary, instructions for the preparation of the patient; *[1, Appendix B.8.8 n)]*	Indicate the following: Description of the specimen. Criteria for acceptance or rejection of samples. Patient preparation, precautions and procedure for specimen collection (e.g. removal of particulate matter by centrifugation, etc.). Additives and preservatives to be added to the specimen, to preserve the integrity of the specimen. Storage and handling requirements. *[4, §3.2.5.3]*	Instructions for use must contain the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient; *[8, Annex I.B.8.7 (f)]*	On the basis of domestic and foreign published reports or in-house data on the *in vitro* diagnostic in question, indicate the factors such as mentioned below that may influence measurement and relevant precautions in operation: a) Nature of test specimen and method of its collection, b) Interfering substances, etc.	Labelling shall include: Specimen collection and preparation for analysis, including a description of: Special precautions regarding specimen collection including special preparation of the patient as it bears on the validity of the test. *[31, Sec. 809.10(b)(7)(i)]* Labelling shall include: Additives, preservatives, etc., necessary to maintain the integrity of the specimen. *[31, Sec. 809.10(b)(7)(ii)]* Labelling shall include: Recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen. *[31, Sec. 809.10(b)(7)(iv)]*	The labelling should bear additional directions/ instructions for the proper use of *in vitro* diagnostic medical devices which may include: Specimen type, collection, handling and preparation. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
162	Measurement procedure	A detailed description of the procedure to be followed, which can be clearly understood by the operator, shall be provided. *[10, §5.11]*	Instructions for use must contain a detailed description of the procedure to be followed in using the IVD, including; *[1, Appendix B.8.8 o)]*	For the test method: Instructions for use must provide complete information relevant to the safe and effective use of the IVDD. The following should be included: — Description of the required amounts of reagents, samples, and controls; incubation schedules, temperature, wavelengths used for measurement, and other relevant environmental conditions under which the device is to be used. — Sample selection and handling. — Performance/ turnaround time. — Stability of the final reaction product. *[4, §3.2.5.4 (a)]*	Instructions for use must contain a detailed description of the procedure to be followed in using the device; *[8, Annex I.B.8.7 (g)]* Instructions for use must contain the measurement procedure to be followed with the device including as appropriate: *[8, Annex I.B.8.7 (h)]* The measurement procedure must include, as appropriate, an indication whether any particular training is required; *[8, Annex 1.B.8.7 (h)]*	Describe the operating procedure in detail on the basis of the administration dosage approved.	Labelling shall include: A step-by-step outline of recommended procedures from reception of the specimen to obtaining results. List any points that may be useful in improving precision and accuracy. *[31, Sec. 809.10(b)(8)]* Labelling shall include: A description of the amounts of reagents necessary, times required for specific steps, proper temperatures, wavelengths, etc. *[31, Sec. 809.10(b)(8)(iii)]* Labelling shall include: A statement describing the stability of the final reaction material to be measured and the time within which it shall be measured to assure accurate results. *[31, Sec. 809.10(b)(8)(iv)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the assay procedure including calculations and interpretation of results. Instructions for use should be written in terms readily understood by the intended user. *[16, §5.1]*
163	Calibration procedure	NA	A detailed description of the procedure to be followed should include information about the use of available reference measurement procedures and materials by the user, *[1, Appendix B.8.8 o)]*	The following should be included: — Calibration information: controls, reference samples, blanks, preparation of standard curve, indication of the maximum and minimum levels of detection, etc.	Instructions for use must contain details of the calibration needed to ensure that the device operates properly and safely; *[8, Annex I.B.8.7 (n)]* The measurement procedure must include, as appropriate, information about the use		Labelling shall include: Details of calibration: Identify reference material. Describe preparation of reference sample(s), use of blanks, preparation of the standard curve, etc. The description of the range of	The labelling should bear details of the calibration needed to ensure that the device operates properly and safely during its intended life. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
					of available reference measurement procedures and materials by the user, *[8, Annex 1.B.8.7 (h)]*		calibration should include the highest and the lowest values measurable by the procedure. *[31, Sec. 809.10(b)(8)(v)]*	
164	Principle of the method	Information on the principle of the method indicating the type of reaction (e.g. chemical, microbiological or immunochemical) and a description of the indicator or detection system shall be given. *[10, §5.12.1]*	A detailed description of the procedure to be followed should include the principle of the method, *[1, Appendix B.8.8 o)]*	The package insert should indicate the technology of the IVDD (e.g. ELISA, chromatographic, etc.). *[4, §3.2.3]* Indicate a brief summary and explanation of the test and how it works, including the clinical benefits and limitations of the test with respect to intended use. Describe the technique(s) and reactions (biological, chemical, microbiological, immunochemical, etc.) used, citing literature references where appropriate. The summary should include descriptions of the types of antibodies and antigens used in the test, (e.g. synthetic peptide, monoclonal, recombinant, etc.), and purification methods. *[4, §3.2.4]*	The measurement procedure must include, as appropriate, the principle of the method, *[8, Annex I.B.8.7 (h)]*	The measuring method (measuring principle) with the *in vitro* diagnostic in question shall be given. Characteristics of the method with the diagnostic in question may be given.	The labelling must indicate: Summary and explanation of the test. Include a short history of the methodology, with pertinent references and a balanced statement of the special merits and limitations of this method or product. If the product labelling refers to any other procedure, appropriate literature citations shall be included and the labelling shall explain the nature of any differences from the original and their effect on the results. *[31, Sec. 809.10(b)(3)]* The labelling must indicate: The chemical, physical, physiological, or biological principles of the procedure. Explain concisely, with chemical reactions and techniques involved, if applicable. *[31, Sec. 809.10(b)(4)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the scientific test principle. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
165	Performance characteristics	The specific analytical performance characteristics (e.g. analytical sensitivity, analytical specificity, trueness, repeatability, reproducibility, limits of detection and measurement interval), shall be described *[10, §5.12.2]*	A detailed description of the procedure to be followed should include the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range), *[1, Appendix B.8.8 o)]*	The label must include the performance specifications of the device if those specifications are necessary for proper use; *[5, Part 1, Sec. 21. (1) (h)]* The Performance characteristics Sec. must include a summary of data from clinical trials upon which the performance of the test is based. Performance characteristics such as sensitivity, specificity, predictive values, reproducibility, repeatability, stability, limits of detection and measurement range, earliest clinical detection in comparison with tests of reference, etc., are required. Indicate 95 % confidence intervals where appropriate. *[4, §3.2.6]* Indicate the maximum and minimum levels of detection, etc. *[4, §3.2.5.4 (a)]*	Instructions for use must contain the performances referred to in Sec. 3 of part A: [analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer.] *[8, Annex I.B.8.7 (d)]* The measurement procedure must include, as appropriate, the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, *[8, Annex I.B.8.7 (h)]*	Indicate performance of the *in vitro* diagnostic in question (sensitivity, specificity, repeatability and range of measurement), where sensitivity is the analytical sensitivity, minimum distance of distinguishable quantities, analytical specificity expressed in general by correlation over existing procedure, and repeatability, within run repeatability. For sensitivity, specificity and repeatability, it may be possible just to indicate the specifications for performance given in the specifications and testing methods column of the approval application form. Indicate the range of measurement on the basis of domestic and foreign published reports or in-house data on the *in vitro* diagnostic in question.	Include, as appropriate, information describing specific performance characteristics, such as accuracy, precision, specificity, and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the specific performance characteristics are based. *[31, Sec. 809.10(b)(12)]* All package inserts for laboratory tests should clearly explain how performance has been deduced or determined. Estimates of sensitivity, specificity, and ROC (Receiver Operating Characteristic) Curves, along with confidence intervals are appropriate measures of performance and may be presented in labelling. *[41]* The description of the range of calibration should include the highest and the lowest values measurable by the procedure. *[31, Sec. 809.10(b)(8)(v)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the analytical performance characteristics, such as sensitivity, specificity, accuracy (trueness and precision). *[16, §5.2]*

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166	Interferents	… information needed for the detection of known relevant interferents shall be described *[10, §5.12.2]*	A detailed description of the procedure to be followed should include information needed for the control of known relevant interferences, *[1, Appendix B.8.8 o)]*	Indicate any known interferences. *[4, §3.2.5.3]*	The specific analytical performance characteristics must include the information needed for the control of known relevant interferences), *[8, Annex I.B.8.7 (h)]*	On the basis of domestic and foreign published reports or in-house data on the *in vitro* diagnostic in question, indicate the factors such as mentioned below that may influence measurement and relevant precautions in operation: a) Nature of test specimen and method of its collection b) Interfering substances, etc.	Labelling shall include: Known interfering substances. *[31, Sec. 809.10(b)(7)(iii)]* State known extrinsic factors or interfering substances affecting results. *[31, Sec. 809.10(b)(10)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear information on interfering substances that may affect the performance of the assay. *[16, §5.2]*
167	Comparison to predicate IVD medical device	NA				Indicate the data on correlation with an existing approved *in vitro* diagnostic (indicate its name, manufacturer (importer)) or a standard measuring method (indicate its name). Comparison with an existing product should be made only when the product is in widespread use and sufficiently objective comparative data are available.	In cases where a candidate device is being compared to a predicate, the predicate and conditions under which it is performed should be defined. Conditions of use include operator experience, clinical laboratory facility or other test setting, controls applied, specimen acceptance criteria, etc. A test that has been characterized to a predicate but has not been compared to "true" diagnostic states should be labelled WITHOUT sensitivity or specificity claims. Relative performance may be described in terms of agreement, co-positivity and co-negativity, or using other similar terms. *[41]*	

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168	Limitations of the method.	The limitations of the method shall be described. *[10, §5.12.2]*	A detailed description of the procedure to be followed should include limitations of the method *[1, Appendix B.8.8 o)]*	Indicate test limitations and all known contraindications, if not stated in a previous Sec. of the package insert, with references if appropriate. This Sec. may include — qualifications of personnel performing the test and/or — interpreting test results; — an indication that results should only be used in conjunction with other clinical and laboratory data; — various patient and clinical factors that may affect marker levels; and — factors that should be considered when interpreting test results. *[4, §3.2.5.7]*	The measurement procedure must include, as appropriate, the limitations of the method *[8, Annex I.B.8.7 (h)]*	Not required except for specimen.	Include a statement of limitations of the procedure. *[31, Sec. 809.10(b)(10)]* If further testing, either more specific or more sensitive, is indicated in all cases where certain results are obtained, the need for the additional test shall be stated. *[31, Sec. 809.10(b)(10)]*	The labelling should bear any warnings, precautions, limitations or contraindications. *[16, §5.2]* The labelling should bear information where applicable regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment). *[16, §5.2]*
169	Diagnostic information	Where appropriate, information on the diagnostic sensitivity and specificity shall be given taking account of the intended use of the results in the diagnostic procedure *[10, §5.12.2]*		The Performance characteristics Sec. must include a summary of data from clinical trials upon which the performance of the test is based. Performance characteristics such as sensitivity, specificity, predictive values, … earliest clinical detection in comparison with tests of reference, etc., are required.		Not required	All package inserts for laboratory tests should clearly explain how performance has been deduced or determined. In situations where a candidate device is being compared to a “true” diagnostic state, the case definition against which new test results are being compared should be clearly stated and	*For* in vitro *diagnostic medical devices,* the labelling may include diagnostic performance characteristics, such as sensitivity and specificity. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
				Indicate 95 % confidence intervals where appropriate. *[4, §3.2.6]*			both strengths and limitations likely to result from the selection of this definition should be discussed. *[41]*	
170	Reagent preparation	All required aspects of reagent preparation including reconstitution, incubation and dilution shall be described. *[10, §5.12.3]*	A detailed description of the procedure to be followed should include the details of any further procedure or handling needed before the IVD can be used (for example, reconstitution, incubation, dilution, instrument checks, etc), *[1, Appendix B.8.8 o)]*	The description of a component should include the complete directions for preparation (reconstitution, mixing or dilution). *[4, §3.2.5.1(a)]* Include Complete instructions for preparing use-dilutions or mixing of individual reagents, unless provided in an alternate section of the package insert. *[4, §3.2.5.4 (b)]*	The measurement procedure must include, as appropriate, the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, instrument checks, etc.), *[8, Annex I.B.8.7 (h)]*	Indicate the methods of preparing reagents (including those that need to be supplied and prepared in advance by the user) and their storage conditions and expiration dates after preparation. When a lyophilize reagent is provided with a diluent, indicate the method of reconstituting it with the diluent and its storage conditions and expiration date after reconstitution. When any instrument needs to be specifically readied beforehand by the user, it should be indicated.	Reagent labelling shall include: Adequate instructions for reconstitution, mixing, dilution, etc. *[31, Sec. 809.10(b)(5)(iii)]* A statement of any purification or treatment required for use. *[31, Sec. 809.10(b)(5)(v)]* Physical, biological, or chemical indications of instability or deterioration. *[31, Sec. 809.10(b)(5)(vi)]*	The labelling should bear details of any further treatment or handling needed before the device can be used (e.g. preparation of reagents and/or control materials, etc.). *[16, §5.2]*
171	Calculation of results	The mathematical approach and if appropriate the name and version number of the computer programme upon which calculation of the analytical results is made shall be given. *[10, §5.13]*	Instructions for use must contain the mathematical approach upon which the calculation of the analytical result is made; *[1, Appendix B.8.8 o)]*	Indicate the step-by-step procedure for calculating the value of the test sample, including appropriate formulae and a sample calculation. *[4, §3.2.5.5]*	Instructions for use must contain the mathematical approach upon which the calculation of the analytical result is made; *[8, Annex I.B.8.7 (i)]*	Not required but generally provided.	Explain the procedure for calculating the value of the unknown. Give an explanation for each component of the formula used for the calculation of the unknown. Include a sample calculation, step-by-step, explaining the answer. The values shall be expressed to the appropriate number of significant figures.	*For* in vitro *diagnostic medical devices,* the labelling should bear the assay procedure including calculations and interpretation of results. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
							If the test provides other than quantitative results, provide an adequate description of expected results. *[31, Sec. 809.10(b)(9)]*	
172	Reporting units	When possible, results shall be expressed in units according to ISO 1000. *[10, §5.13]*			When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 *[8, Annex I B.4.2.]*			
173	Interpretation of results	NA		Indicate the criteria for acceptance or rejection and whether further testing is required if a particular result is obtained. For example, requirements for duplicate tests if the initial test is reactive. *[4, §3.2.5.6]* Indicate the significance of the test results obtained, including information as to what degree a negative test does or does not exclude the possibility of exposure to, or infection with, the organism, etc. *[4, §3.2.5.6]* See also NOTE 8.			If the test provides other than quantitative results, provide an adequate description of expected results. *[31, Sec. 809.10(b)(9)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the assay procedure including calculations and interpretation of results. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
174	Change notification	It shall be ensured that the user is informed of any substantial changes in the procedure and/or analytical performance of the IVD reagent *[10, §5.14]*	*Required by other regulations.*	*Required by other regulations.*		If any major change is made on the product, give necessary information such as the content of the change in the package insert. An attached sheet may be used to inform the user of the minor change. The information about the change should be available for a reasonable period of time to make it widely known (at least six months). If the package insert needs to be revised in association with the change, it should be revised.	*Required by other regulations.*	
175	Corrective actions	It shall be ensured that the user is informed of … measures to be taken in this event [of any substantial changes in the procedure and/or analytical performance of the IVD reagent] *[10, §5.14]*	Instructions for use must contain measures to be taken in the event of changes in the analytical performance of the IVD; *[1, Appendix B.8.8 o)]*		Instructions for use must contain the measures to be taken in the event of changes in the analytical performance of the device; *[8, Annex I.B.8.7 (j)]*			

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
176	Quality control	Suitable procedures for internal quality control shall be given including a means for the user to establish criteria for assessing the validity of the measurement procedure. *[10, §5.15]*	Instructions for use must contain information appropriate to users on: internal quality control including specific validation procedures, *[1, Appendix B.8.8 s)]*	Quality control procedures and materials required. Indicate whether positive and negative controls are required and what are considered to be satisfactory limits of performance. *[4, §3.2.5.4 (a)]*	Instructions for use must contain information appropriate to users on internal quality control, including specific validation procedures, *[8, Annex I.B.8.7 (k)]*	*The laboratory is responsible for establishing internal quality control procedures.*	Labelling shall include: details of kinds of quality control procedures and materials required. State what are considered satisfactory limits of performance. If there is need for both positive and negative controls, this should be stated. *[31, Sec. 809.10(b)(8)(vi)]* See also NOTE 9.	
177	Metrological traceability	Information shall be given on the metrological traceability of the values assigned to calibrators and control materials, referring to available reference materials of higher order (e.g. WHO, or International or European reference materials), or literature or other available documents or source of reference material. *[10, §5.16]*	Instructions for use must contain information appropriate to users on: the traceability of the calibration of the IVD; *[1, Appendix B.8.8 t)]*		Instructions for use must contain information appropriate to users on the traceability of the calibration of the device; *[8, Annex I.B.8.7 (k)]*		FDA currently requires information on calibration procedures performed … Whenever possible we encourage traceability of device performance to a reference method or material. *[42]*	
178	Reference intervals	If known, the reference intervals and, where significant, a description of the reference population or a pertinent literature reference shall be given. *[10, §5.17]*	Instructions for use must contain information appropriate to users on: the reference intervals for the quantities being determined, including a description of the appropriate reference population; *[1, Appendix B.8.8 u)]*	Indicate the range of expected values based on studies of test results from various populations. Indicate how the range was established and clearly identify the population(s) which were used for the testing. Include literature references where appropriate. *[4, §3.2.5.8]*	Instructions for use must contain the reference intervals for the quantities being determined, including a description of the appropriate reference population; *[8, Annex I.B.8.7 (l)]*	Requires manufacturer to provide information, and can be a manufacturer's study (unpublished).	State the range(s) of expected values as obtained with the product from studies of various populations. Indicate how the range(s) was established and identify the population(s) on which it was established. *[31, Sec. 809.10(b)(11)]*	*For* in vitro *diagnostic medical devices,* the labelling may include: Reference intervals. *[16, §5.2]*

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179	Reference intervals - units	When possible, reference intervals shall be expressed in units according to ISO 1000. *[10, §5.17]*			When values are expressed numerically, they must be given in legal units conforming to the provisions of Council Directive 80/181/EEC of 20 December 1979 on the approximation of the laws of the Member States relating to units of measurement *[8, Annex I.B.4.2.]*			
180	Literature references	Literature references shall be given if applicable, e.g. for reference intervals. *[10, §5.18]*		The Bibliography should include pertinent up-to-date references for information cited in the text and any other references related to the subject matter. *[4, §3.2.10]*			Bibliography: Include pertinent references keyed to the text. *[31, Sec. 809.10(b)(13)]*	
181	Version control	The date of issue or latest revision of the instructions for use shall be given. *[10, §5.19]*	Instructions for use must contain the date of issue or latest revision. *[1, Appendix B.8.8 y)]*	The date of issue of DIRECTIONS FOR USE or of any revision should be indicated. *[4, §3.2.9]*	Instructions for use must contain the date of issue or latest revision of the instructions for use. *[8, Annex I.B.8.7 (u)]*	Date of the package insert prepared or revised. When the package insert is first prepared, the date of preparation should be indicated at the beginning of the package insert, e.g. in the upper right (left) corner. In indicating the date the package insert was revised, follow the following rules: (details are omitted)	Labelling shall include: Date of issuance of the last revision of the labelling identified as such. *[31, Sec. 809.10(b)(15)]*	

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182	**Instructions for Use (Instruments) (EN 591)**							
183	Form and presentation - comprehension	The wording shall be readily understandable. *[11, §4]*		The required labelling information shall be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user. *[5, Part 1, Sec. 21. (2)]* The required Labelling information must be conspicuous and clear enough to read as well as intended to last for the life of the device. The label information must be presented in a format most likely to be understood by the expected user. Test marketing of the device labelling may be required in some cases. *[4, §4]*		The DOCI and DOCM shall comply with the format requirements specified separately (details omitted).	See general requirements.	Instructions for use should be written in terms readily understood by the intended user. *[16, §5.1]*
184	Form and presentation - overview	The following shall be given, where appropriate: overview of operating elements; *[11, §4(a)]*						
185	Form and presentation – flow/block diagrams	The following shall be given, where appropriate: flow and block diagrams of instrument construction; *[11, 4(b)]*				The DOCM shall contain the shape and structure, or drawing of the instrument using block diagram, and/or configuration.		For *in vitro* diagnostic medical devices, the use of drawings and diagrams is highly recommended. *[16, §5.2]*
186	Form and presentation - format	The following shall be given, where appropriate: integration and arrangement of text/illustrations; *[11, §4(c)]*						See above

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187	Form and presentation – graphic warnings	The following shall be given, where appropriate: graphic emphasis of warnings; *[11, §4(d)]*		The use of international symbols and signal words such as “warning” and “caution” are effective in alerting the user to a hazard. *[4, §3.2.5.2]*		Figures, graphics or illustrations referred to the text. Supplemental videotape or other media materials are recommended.		
188	Form and presentation examples	The following shall be given, where appropriate: examples; *[11, §4(e)]*		An example of an intended use statement is given. *[4, §3.2.3]*		Major accessories and attachments with example of use, if necessary.		
189	Form and presentation - procedure diagram	The following shall be given, where appropriate: diagrams of procedural steps; *[11, §4(f)]*						
190	Form and presentation – literature references	The following shall be given, where appropriate: relevant scientific literature. *[11, §4(g)]*		The Bibliography should include pertinent up-to-date references for information cited in the text and any other references related to the subject matter. *[4, §3.2.10]*		Scientific literature and/or references may be obtained from the manufacturer. Responsible person’s or section’s name, address, telephone number should be provided.	Include pertinent references keyed to the text. *[31, Sec. 809.10(b)(13)]*	
191	Required information	Instructions for use for IVD instruments shall contain the information given in EN 591, §5.2 to 5.23. *[11, §5.1]*	Where appropriate, the instructions for use must contain [specified] particulars: *[1, Appendix B.8.8]*	DIRECTIONS FOR USE are requested unless directions are not required for the device to be used safely and effectively. Most IVDDs will require DIRECTIONS FOR USE. *[4, §3.2.5]*	Where appropriate, the instructions for use must contain the following particulars [specified below]: *[8, Annex I.B.8.7.]*	The DOCI and the DOCM shall contain the information in the order as specified separately (details omitted)	Labelling accompanying each product, e.g. a package insert, shall state in one place the following information in the format and order specified below, except where such information is not applicable, or as specified in a standard for a particular product class *[31, Sec. 809.10(b)]* The labelling for a multiple-purpose instrument used for	

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							diagnostic purposes, and not committed to specific diagnostic procedures or systems, may bear only the information indicated in paragraphs (b) (1), (2), (6), (14), and (15) of this Sec. *[31, Sec. 809.10(b)]*	
192	Media and means of delivery	This information may be supplied in different ways, e.g. as user manual, part of the built-in software of the instrument, audio or video recording or other electronic means. *[11, §5.1]*	The format, content and location of the information must be appropriate for the IVD and its intended use. *[1, Appendix B.8.3]*		Instructions for use must accompany or be included in the packaging of one or more devices. In duly justified and exceptional cases, no such instructions for use are needed for a device if it can be used properly and safely without them. *[8, Annex I.B.8.1.]*	The instruction for use shall be provided as printed documents.		Labelling may be provided to the user in various media and by several means such as printed documents, through a display screen incorporated into the device, downloaded from the manufacturer's Web Site using the Internet, magnetic or optical media. Whatever the media or the means, information should be targeted to the anticipated user population. *[16, §5.1]*
193	Table of contents/ index.	Instructions for use shall include a table of contents and an index. *[11, §5.1]*				The DOCM shall include a Table of Contents and Index.		

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194	Language	Languages shall be used in accordance with the requirements of the country(ies) in which the IVD instrument is distributed. *[11, §5.1]*	The information must be provided in English, and may also be provided in any other language. *[1, Appendix B.8.2 a) b).]*	Subject to subsection (3), the information required by subsection 21(1) shall, as a minimum, be in either English or French. Subject to subsection (3), where the directions for use are supplied in only one official language at the time of sale, directions for use in the other official language shall be made available by the manufacturer as soon as possible at the request of the purchaser. *[5, Part 1, Sec. 23. (1) (2) (3)]*	Member States may require the information to be supplied pursuant to Annex I, part B, Sec. 8 to be in their official language(s) when a device reaches the final user. Provided that safe and correct use of the device is ensured, Member States may authorize the information referred to in the first subparagraph to be in one or more other official Community language(s). In the application of this provision, Member States shall take into account the principle of proportionality and, in particular: a) whether the information can be supplied by harmonized symbols or recognized codes or other measures; b) the type of user anticipated for the device. *[8, Article 4.4]*	Shall be in Japanese.	All required words, statements, and other information shall appear in English, or Spanish in Puerto Rico, or the predominant language of the Territory. *[29, Sect. 801.15 (c)(1)]* If the labelling contains any representation in a foreign language, all required words, statements, and other information on the label or labelling shall appear on the labelling in the foreign language. *[29, Sect. 801.15 (3)]*	Taking into consideration the type of user anticipated for the device, national language requirements should be kept to a minimum. *[16, §5.1]*
195	Graphical symbols	Any graphical symbols used on the IVD instrument shall be explained in the instructions for use, if no European or International Standards exist to which the symbols used conform.	Required information may take the form of symbols as appropriate: *[1, Appendix B.8.5]*	The use of international symbols and signal words such as “warning” and “caution” are effective in alerting the user to a hazard. *[4, §3.2.5.2]*	Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colour used	Letter(s) appeared on graphical symbols shall be in Japanese.	FDA has recognized 25 symbols for IVD devices for professional use from ISO 15223 and EN 980. Although some provisions of *21* CFR 809.10 and 21 CFR 610 and 660 specify particular labelling language, as a matter	The use of internationally recognized (i.e. standardized) symbols should be encouraged provided that device safety is not compromised by a lack of understanding on the part of the patient or user. Where the meaning of the

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		NOTE Any graphical symbols used on the IVD instrument should be explained and/or the relevant European or International Standards should be given. *[11, §5.2]*			must be described in the documentation supplied with the device. *[8, Annex I.B.8.2.]*		of enforcement discretion, FDA does not intend to object to the use of [specified] symbols without accompanying text. *[39]* A product is misbranded "if it does not bear such symbols from the uniform system for identification of devices prescribed under Sec. 510(e) as the Secretary by regulation requires". *[37, Sec. 502(o)]*	symbol is not obvious to the device user, e.g. for a lay-user or for a newly introduced symbol, an explanation should be provided with the device. *[16, §5.1]*
196	Manufacturer	The name and address of the manufacturer shall be given. NOTE The manufacturer is the entity which has taken the legal responsibility for the IVD instrument. *[11, §5.3]*	Instructions for use must contain the manufacturer's name, or trade name and address; *[1, Appendix B.8.8 a)]*	The label must indicate the name and address of the manufacturer; *[5, Part 1, Sec. 21. (1) (b)]* The name and mailing address of the manufacturer is required. *[4, §3.2.2]*	The label must bear the name or trade name and address of the manufacturer. *[8, Annex I.B.8.4(a) required by Annex I B.8.7.(a)]*	Name and address and telephone number of the manufacturer or imported/distributor shall be given on the DOCI and the DOCM.	809.10(b) (14) Name and place of business of manufacturer, packer, or distributor. NOTE "Manufacturer" symbol may be used in place of the statement "Manufactured by_____" *[39]*	The labelling should bear the name or trade name and address of the manufacturer and, if appropriate, a phone number and/or fax number and/or website address to obtain technical assistance. *[16, §5.2]*
197	Authorized representative /importer/ distributor	The name and address of the authorized representative shall also be given when this is a legal requirement. *[11, §5.3]*	All IVDs must be accompanied by information, where applicable, allowing the sponsor of the device to be identified. *[1, Appendix B.8.1 d)]*		For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorized representative of the manufacturer; *[8, Annex I.B.8.4(a).]*	Contact person or Sec. shall be given with address and telephone number on the DOCI. In case of the imported IVD instruments, exporter and the name of country shall also be given.	Labelling shall include: Name and place of business of manufacturer, packer, or distributor. *[31, Sec. 809.10(b)(14)]* The "Authorized representative" symbol as long as the use of this symbol does not violate other U.S. labelling requirements. For example, if the symbol interferes with	The labelling should bear for imported devices, the label, or the outer packaging, or instructions for use, may be required to contain in addition, the name and address of either the importer established within the importing country/region or of an authorized representative of the manufacturer established within the importing

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							the communication of information required by U.S. law, the device could be misbranded under Sec. 502(c) of the Act. *[39]*	country/region. *[16, §5.2]*
198	Device name/ identifier	The name of the IVD instrument and/or separate instrument modules, including, where applicable, software shall be given. *[11, §5.4]*	All IVDs must be accompanied by information identifying the IVD; *[1, Appendix B.8.1 a)]*	The label must indicate the name of the device; *[5, Part 1, Sec. 21. (1) (a)]* The label must indicate the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family; *[5, Part 1, Sec. 21. (1) (c)]* Include Model number(s)/version number(s) of any dedicated instruments/equipment/ software. *[4, §3.2.5.1(c)]*	The label must bear the details strictly necessary for the user to uniquely identify the device and the contents of the packaging; *[8, Annex I.B.8.4(b) [required by Annex I B.8.7.(a)]* The label must bear the serial number; *[8, Annex 1.B.8.4 (d)]* Wherever reasonable and practicable, the devices and separate components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components. *[8, Annex I.B.8.6.]*	Legal category and generic name, and the approved or admitted sales name shall be given.	The labelling must indicate: The proprietary name and established name, i.e. common or usual name, if any. *[31, Sec. 809.10(b)(1)]* For an instrument, the lot or control number shall permit tracing the identity of all functional subassemblies. *[31, Sec. 809.10(a)(9)(ii)]*	The labelling should bear sufficient details for the user to identify the device or, where relevant, the contents of any packaging. *[16, §5.2]*
199	Mark of conformity	NA			The CE marking of conformity must appear in a visible, legible and indelible form on the device, where practicable and appropriate, and on the instructions for use. The CE marking of conformity must also appear on the sales packaging. The CE marking shall be accompanied by the identification number of the notified body. *[8, Article 16.2]*			

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200	Storage and handling	Instructions relevant to any particular storage and/or handling conditions shall be given. NOTE Storage and handling of reagents are covered in EN 375. *[11, §5.5]*	Instructions for use must contain the storage conditions, *[1, Appendix B.8.8 d)]*		The label must bear any particular storage and/or handling conditions; *[8, Annex I.B.8.4 (h)]* NOTE Storage and handling of reagents is covered in EN 375.	Instructions of storage conditions shall be given on the DOCI. The DOCM may cover the details of those instructions, if necessary.		The labelling should bear any special storage and /or handling conditions at the appropriate packaging level. *[16, §5.2]*
201	Warnings and precautions	Any warnings and precautions shall be given relevant to: a) any special, unusual risks related to installation, operation, maintenance, transportation, storage or disposal of the IVD instrument; *[11, §5.6]* NOTE Examples of such risks are those related to handling and disposal of infectious or potentially infectious materials. *[11, §5.6]*	Instructions for use must contain any undesirable side effects caused by the use of the device; *[1, Appendix B.8.8 b)]*	Include warnings and precautions for any dedicated instruments/ equipment/software. *[4, §3.2.5.1(c)]* Indicate appropriate warnings and precautionary statements for the safe and effective use of the IVDD. The use of international symbols and signal words such as “warning” and “caution” are effective in alerting the user to a hazard. *[4, §3.2.5.2]* an IVDD containing explosive material or components is required to have the following information on the LABEL: — identity of the material or the components. — nature of the potential hazard. — precautions that should be taken during handling, storage or disposal of the device in order to avoid an explosion. *[4, §7]*	The manufacturer must … inform users of the residual risks due to any shortcomings of the protection measures adopted. *[8, Annex 1.A.2]* Where there is insufficient space to put all the information on the device itself or on its label, the relevant danger symbols shall be put on the label and the other information required by those Directives shall be given in the instructions for use. *[8, Annex I.B.8.3.]* In the case of devices containing or a preparation which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant danger symbols and labelling requirements of Directive 67/548/EEC (2) and Directive 88/379/EEC (3) shall apply. *[8, Annex I.B.8.3.]* where the device includes substances of human or animal origin, attention	Cautions for use specified in the approval or standard shall be given in the DOCI, if any. General warning on use as specified separately (detail omitted) shall be given on both the DOCI and the DOCM. The DOCM shall give intended use and prohibition on application and conditions required to use the IVD instruments safely. Those shall be classified into 3 categories, hazardous, warning, and caution, and stated as specified. Taboo and/or prohibition appeared on the application form for approval or that for admission shall be stated on the DOCI with 8-point letters or above. Any warnings and precautions in the approved or admission form shall be stated on the	Instrument labelling shall include: Operational precautions and limitations. *[31, Sec. 809.10(b)(6)(vii)]* Hazards. *[31, Sec. 809.10(b)(6)(viii)]*	The labelling should bear any warnings, precautions, limitations or contraindications. *[16, §5.2]*

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					must be drawn to their potential infectious nature; *[8, Annex I.B.8.7 (s)]*	DOCI in red with red-bordered obituary relevant to: a) a fatal or irreversible serious events, b) malfunctions related to a) and that need special attention. Warnings and precautions for infection related to using IVD instruments shall be documented.		
202	Handling/ disposal	…or disposal of the IVD instrument: NOTE Examples of such risks are those related to handling and disposal of infectious or potentially infectious materials. *[11, §5.6]*	Instructions for use must contain precautions to be taken against any special, unusual risks related to the use of disposal of the IVD including special protective measures where the IVD includes substances of human or animal origin; *[1, Appendix B.8.8 w)]*	Disposal: Indicate appropriate decontamination and disposal procedures of used or expired kits and/or reagents. Disposal of all specimens and kit components must comply with all applicable waste disposal requirements. NOTE decontamination and disposal information may also be provided in the "warning and precautions" Sec. of the package insert. *[4, §3.2.5.9]*	Instructions for use must contain the precautions to be taken against any special, unusual risks related to the use or disposal of the device, including special protective measures. *[8, Annex I.B.8.7 (s)]*	Any use or objectives out of intended use, designing, or those not covered by manufacturer's responsibilities shall be stated on the DOCI. This information shall be given in black with red-bordered obituary relevant to: a) any taboo for the proper use of IVD instruments as intended or avoidance of any serious hazard upon application, b) serious malfunctions caused by not maintaining the IVD instrument or replaced parts as directed by manufacturer, c) expected misuse, if any, d) any prohibited	Local laws/federal law applies.	The labelling should bear where applicable precautions to be taken against any special, unusual risks related to the disposal of the device. *[16, §5.2]*

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						realignment, readjustment or repairs which may impact safety of the IVD.		
203	Warnings and precautions - interferences	Any warnings and precautions shall be given relevant to: b) known interferences; *[11, §5.6]*	A detailed description of the procedure to be followed should include information needed for the control of known relevant interferences, *[1, Appendix B.8.8 o)]*	Indicate any known interferences. *[4, §3.2.5.3]*	Instructions for use must contain the precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; *[8, Annex I.B.8.7 (r)]* The specific analytical performance characteristics must include the information needed for the control of known relevant interferences, *[8, Annex I.B.8.7 (h)]*	Known interference shall be documented on DOCI.	Labelling shall include: Known interfering substances. *[31, Sec. 809.10(b)(7)(iii)*] State known extrinsic factors or interfering substances affecting results. *[31, Sec. 809.10(b)(10)]*	The labelling should bear information where applicable regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment). *For* in vitro *diagnostic medical devices,* the labelling should bear information on interfering substances that may affect the performance of the assay. *[16, §5.2]*
204	Uses not recommended	Any warnings and precautions shall be given relevant to: c) use not recommended by the manufacturer. *[11, §5.6]*	A detailed description of the procedure to be followed should include any contra-indications, warnings, restrictions, or precautions that may apply in relation to the use of the IVD; *[1, Appendix B.8.8 o)]*	The package insert should indicate specific contraindications for use, *[4, §3.2.3]*		Precautions for off-label uses shall be documented on DOCM.		

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205	Intended purpose	The intended purpose of the IVD instrument shall be clearly stated. *[11, §5.7]*	Instructions for use must contain the intended purpose of the IVD; *[1, Appendix B.8.8 b)]*	Unless self-evident to the intended user, the label must indicate the medical conditions, purposes and uses for which the device is manufactured, sold or represented, *[5, Part 1, Sec. 21. (1) (h)]* The package insert should clearly indicate intended use(s) and indications for use of the IVDD. *[4, §3.2.3]*	If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state the intended purpose in the instructions for use and, if appropriate, on the label. *[8, Annex I.B.8.5.]*	The approved intended purpose shall be stated on DOCI. For those IVD instruments not required approval, summary of statements appeared on the document titled "generic name and its legal category" shall be stated. Limitations of application or conditions specified on the approval shall be stated on the DOCI, if any. *[25]*	The labelling must indicate: The intended use or uses of the product and the type of procedure, e.g. qualitative or quantitative. *[31, Sec. 809.10(b)(2)]*	*For in* vitro *diagnostic medical devices,* the labelling should include the intended use (e.g. monitoring, screening or diagnostic) including an indication that it is for *in vitro* diagnostic use. The labelling should bear the intended purpose, user and patient population of the device where these are not obvious. *[16, §5.2]*
206	Installation instructions	Instructions for setting up the IVD instrument shall be given when the installation can be carried out by the user. NOTE These instructions are not necessary when the installation is carried out exclusively by personnel from the manufacturer or a service organization. *[11, §5.8.1]*				Any conditions and facilities required for the proper and safety use of IVD instrument shall be given on the DCOM. Configuration of package shall be given on the DOCI. Instructions for installation and setting up the IVD instrument shall be given on both DOCI and DOCM. *[25]*	[Provide the following information for] instruments: Installation procedures and special requirements *[31, Sec. 809.10(b)(6)]*	
207	Pre-installation preparation	Information shall be provided on the following: a) unpacking; b) checking delivery for completeness; c) checking for damage during transport. *[11, §5.8.2]*	Instructions for use must contain necessary instructions in the event of damage to the protective packaging; *[1, Appendix B.8.8 k)]*					

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208	Installation requirements	Information shall be provided on the following: a) installation site requirements; b) technical prerequisites, e.g. load bearing capacity. *[11, §5.8.3]*		Include relevant environmental conditions under which the device is to be used. *[4, §3.2.5.4 (a)]*		The following information shall be provided on DOCM: a) Limitations on physical environment required for safe and correct use of the IVD instruments, e.g. humidity, temperature, rating voltage, frequency and current, and acceptable fluctuations range of power supply. b) typical dimensions, mass, power consumption, leakage current, performances.	Instrument labelling shall include: Installation procedures and special requirements. *[31, Sec. 809.10(b)(6)(ii)]*	Precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, proximity to other devices, etc *[16, §5.2]*
209	Installation setup	Information shall be provided on the following: a) setting up; *[11, §5.8.4]*	Instructions for use must contain details of any further treatment or handling needed before the IVD can be used, e.g. sterilization, final assembly, etc; *[1, Appendix B.8.8 i)]*		Instructions for use must contain details of any further treatment or handling needed before the device can be used (for example, sterilization, final assembly, etc.); *[8, Annex I.B.8.7 (o)]*		Instrument labelling shall include: Installation procedures and special requirements. *[31, Sec. 809.10(b)(6)(ii)]*	
210	Installation – introduction and description	Information shall be provided on the following: b) introduction, brief description; *[11, §5.8.4]*		Include a brief description of use or function of any dedicated instruments/ equipment/software. *[4, §3.2.5.1(c)]*			Instrument labelling shall describe: Use or function. *[31, Sec. 809.10(b)(6)(i)]*	
211	Installation verification	c) checks for proper installation. *[11, §5.8.4]*	Instructions for use must contain all the information needed to verify whether the IVD is properly installed and can operate correctly and safely, *[1, Appendix B.8.8 g)]*		Instructions for use must contain all the information needed to verify whether the device is properly installed and can operate correctly and safely, *[8, Annex I.B.8.7 (n)]*			The labelling should bear the information needed to verify whether the device is properly installed and can operate correctly and safely, *[16, §5.2]*

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212	Instrument operation - theory	Basic theory of the instrument operation shall be given. *[11, §5.9]*	A detailed description of the procedure to be followed should include the principle of the method, *[1, Appendix B.8.8 o)]*	Indicate a brief summary and explanation of the test and how it works, including the clinical benefits and limitations of the test with respect to intended use. *[4, §3.2.4]*	The measurement procedure must include, as appropriate, the principle of the method, *[8, Annex I.B.8.7 (h)]*	Principle of operation shall be given on DOCM and brief one on DOCI with reference to DOCM. Information shall be given on DOCM on the following: but not limited to a) unctions and example of use, b) accessories and installation procedures, and c) configuration of the IVD instruments with pictures, figures, and/or block diagram.	Instrument labelling shall include: Principles of operation. *[31, Sec. 809.10(b)(6)(iii)]*	
213	User training	If any particular training of the user is required this shall be indicated. *[11, §5.9]*	A detailed description of the procedure to be followed should include … whether any particular training is required; *[1, Appendix B.8.8 o)]*	The Limitations Sec. of the package insert should include any specific training required for test performance or use. *[4, §3.2.3 (Note)]*	The measurement procedure must include, as appropriate, an indication whether any particular training is required; *[8, Annex I.B.8.7 (h)]*	User training program for safety shall be introduced on DOCM.		
214	Instrument functions	Information shall be provided on the following: a) description, purpose; b) principles of working; c) operation; d) specifications; e) automatic checks on the system; f) specific performance checks. *[11, §5.10]*		For any dedicated instruments/equipment/ software: Include a brief description of use or function *[4, §3.2.5.1(c)]* The label must include the performance specifications of the device if those specifications are necessary for proper use; *[5, Part 1, Sec. 21. (1) (h)]* Include performance characteristics/ specifications. *[4, §3.2.5.1(c)]*		Brief information of the IVD instrument, and name and structure of units and accessory shall be given on DOCM.	Labelling accompanying each product, e.g. a package insert, shall state, except where such information is not applicable, or as specified in a standard for a particular product class: Instruments: Use or function *[31, Sec. 809.10(b)(6)(i)]* Performance characteristics and specifications. *[31, Sec. 809.10(b)(6)(iv)]*	

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215	Instrument performance and limitations of use	Information shall be provided on the following: — general statements [of limitations]; *[11, §5.11]*		Include limitations, etc. of any dedicated instruments/ equipment/software. *[4, §3.2.5.1(c)]*	If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label and/or in the instructions for use. *[8, Annex I.B.3.1]*	Information shall be provided on the following: a) general statement b) any limitation or prohibition for the operator, if any, on the DOCM.	Instrument labelling shall include: Operational precautions and limitations. *[31, Sec. 809.10(b)(6)(vii)]*	
216	Performance characteristics	Information shall be provided on the following: — performance characteristics of the IVD instrument, e.g. precision, throughput. *[11, §5.11]*	A detailed description of the procedure to be followed should include the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, *[1, Appendix B.8.8 o)]*	The label must include the performance specifications of the device if those specifications are necessary for proper use; *[5, Part 1, Sec. 21. (1) (h)]* The Performance characteristics Sec. must include a summary of data from clinical trials upon which the performance of the test is based. See also NOTES 10-12.	The measurement procedure must include, as appropriate, the specific analytical performance characteristics (e.g. sensitivity, specificity, accuracy, repeatability, reproducibility, limits of detection and measurement range, *[8, Annex I.B.8.7 (h)]*	The performance of the IVD instrument shall be provided with repeatability, specificity and sensitivity of major applicable tests or physical performance characteristic on the DOCI.	Instrument labelling shall include: Performance characteristics and specifications. *[31, Sec. 809.10(b)(6)(iv)]*	The labelling should bear the performance intended by the manufacturer and any undesirable side effects. *[16, §5.2]* *See also Reagents Instructions for Use – Analytical Performance Characteristics*
217	Required materials and/or equipment	Information shall be provided on the following: — any special materials and/or equipment required in order to use the IVD instrument properly; *[11, §5.12]*	Instructions for use must contain an indication of any special equipment required including information necessary for the identification of that special equipment for proper use of the IVD; *[1, Appendix B.8.8 e)]* if the IVD must be used in combination with, installed with, or connected to other IVDs or equipment in order to operate as required, the instructions for use must contain	Indicate any essential components and/or special equipment or instruments not provided. Include details such as sizes, numbers, types, quality, etc. Examples are: incubators, precision pipettes, calibrated thermometers, appropriate disinfectants and disinfection procedures, appropriate reaction vessels (specify glass, polystyrene, polypropylene), etc.	Instructions for use must contain an indication of any special equipment required including information necessary for the identification of that special equipment for proper use; *[8, Annex I.B.8.7 (e)]* if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its	Information shall be provided on DOCM, if any. This information should include power-on orders or connecting orders of units or equipments, if necessary.	Labelling shall include: A list of all materials provided, e.g. reagents, instruments and equipment, with instructions for their use. *[31, Sec. 809.10(b)(8)(i)]* A list of all materials required but not provided. Include such details as sizes, numbers, types, and	The labelling should bear details of the replacement of consumable components, *[16, §5.2]*

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			sufficient details of its characteristics to identify the correct IVD or equipment to use in order to obtain a safe and proper combination; *[1, Appendix B.8.8 f)]*	For instruments such as microplate readers, indicate required specifications such as wavelength, band width, absorbance, precision, filters, etc. *[4, §3.2.5.1(b)]*	intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination; *[8, Annex I.B.8.7 (m)]*		quality. *[31, Sec. 809.10(b)(8)(ii)]*	
218	Reagent preparation	Information shall be provided on the following: — reagent(s); *[11, §5.12]*		Include a Description of the required amounts of reagents, samples, and controls; incubation schedules, temperature, wavelengths used for measurement, *[4, §3.2.5.4]*	The measurement procedure must include, as appropriate, the details of any further procedure or handling needed before the device can be used (for example, reconstitution, incubation, dilution, ... etc.), *[8, Annex I.B.8.7 (h)]*	Information shall be provided on proper preparation and setting of reagent(s).	Labelling shall include: A description of the amounts of reagents necessary, times required for specific steps, proper temperatures, wavelengths, etc. *[31, Sec. 809.10(b)(8)(iii)]* Adequate instructions for reconstitution, mixing, dilution, etc. *[31, Sec. 809.10(b)(5)(iii)]*	*For* in vitro *diagnostic medical devices,* the labelling should include: Reagent description and any limitation (e.g. use with a dedicated instrument only). *[16, §5.2]* The labelling should bear details of any further treatment or handling needed before the device can be used (e.g. preparation of reagents and/or control materials, etc.). *[16, §5.2]*
219	Specimen	Information shall be provided on the following: — type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions; *[11, §5.12]*	Instructions for use must contain the type of specimen (sample) to be used with the IVD, including any special conditions of collection, pre-treatment and, if necessary, storage conditions; *[1, Appendix B.8.8 m)]*	The package insert should indicate the type of specimen(s) required (e.g. serum, plasma, etc.). *[4, §3.2.3]* Indicate the following: Description of the specimen. Criteria for acceptance or rejection of samples. Patient preparation, precautions and procedure for specimen collection (e.g. removal of particulate matter by centrifugation, etc.).	Instructions for use must contain the type of specimen to be used, any special conditions of collection, pre-treatment and, if necessary, storage conditions and instructions for the preparation of the patient; *[8, Annex I.B.8.7 (f)]*	Information shall be provided on DOCM for type of specimen and general pretreatment procedures with expected improper pretreatment.	Labelling shall include: Specimen collection and preparation for analysis, including a description of: Special precautions regarding specimen collection including special preparation of the patient as it bears on the validity of the test. *[31, Sec. 809.10(b)(7)(i)]* Additives, preservatives, etc., necessary to maintain the integrity of the specimen. *[31, Sec. 809.10(b)(7)(ii)]*	The labelling should bear additional directions/instructions for the proper use of *in vitro* diagnostic medical devices which may include: Specimen type, collection, handling and preparation. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
				Additives and preservatives to be added to the specimen, to preserve the integrity of the specimen. Storage and handling requirements. *[4, §3.2.5.3]*			Recommended storage, handling or shipping instructions for the protection and maintenance of stability of the specimen. *[31, Sec. 809.10(b)(7)(iv)]*	
220	Instrument operation checks	Information shall be provided on the following: — instrument checks for correct and safe operation; *[11, §5.12]*			The measurement procedure must include, as appropriate, the details of any further procedure or handling needed before the device can be used (for example, … instrument checks, etc.), *[8, Annex I.B.8.7 (h)]*	The DOCM shall state following items for correct and safe operation; a) preparation procedures, check items and checking procedures for pre-analytical stages, b) maintenance of reagents and c) specimen including general pretreatment procedures with expected improper pretreatment.		The labelling should bear details of any further treatment or handling needed before the device can be used (e.g. sterilization, final assembly, calibration, preparation of reagents and/or control materials, etc.). *[16, §5.2]*
221	Instrument adjustment/ calibration	Information shall be provided on the following: — adjustment. *[11, §5.12]*	Instructions for use must contain details of the nature and frequency of the calibration needed to ensure that the IVD operates properly and safely; *[1, Appendix B.8.8 g)]*	Include calibration information: controls, reference samples, blanks, preparation of standard curve *[4, §3.2.5.4 (a)]*	Instructions for use must contain details of the calibration needed to ensure that the device operates properly and safely; *[8, Annex I.B.8.7 (n)]* The measurement procedure must include, as appropriate, information about the use of available reference measurement procedures and materials by the user, *[8, Annex I.B.8.7 (h)]*	A detailed description of the procedure to be followed which can be clearly understood by the user of the IVD instrument including calibration and/or adjustment shall be provided on the DOCM. If any particular training of the user is required, this shall be indicated.	Instrument labelling shall include: Calibration procedures including materials and/or equipment to be used. *[31, Sec. 809.10(b)(6)(vi)]*	The labelling should bear details of any further treatment or handling needed before the device can be used (e.g. calibration, etc.). *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
222	Detailed procedure	A detailed description of the procedure to be followed which can be clearly understood by the user of the IVD instrument shall be provided. *[11, §5.13]*	A detailed description of the procedure to be followed should include any special operating instructions for the use of the device, including whether any particular training is required; *[1, Appendix B.8.8 o)]*	The directions for use, unless directions are not required for the device to be used safely and effectively. *[5, Part 1, Sec. 21(1)(i)]* For the test procedure: instructions for use must provide complete information relevant to the safe and effective use of the IVDD… *[4, §3.2.5.4 (a)]* Include Sample selection and handling. *[4, §3.2.5.4 (a)]*	Instructions for use must contain a detailed description of the procedure to be followed in using the device; *[8, Annex I.B.8.7 (g)]*	A detailed description of the procedure to be followed which can be clearly understood by the user of the IVD instrument including calibration and/or adjustment shall be provided on the DOCM. If any particular training of the user is required, this shall be indicated.	Labelling shall include: Procedure: A step-by-step outline of recommended procedures from reception of the specimen to obtaining results. List any points that may be useful in improving precision and accuracy. *[31, Sec. 809.10 (b)(8)]* A statement describing the stability of the final reaction material to be measured and the time within which it shall be measured to assure accurate results. *[31, Sec. 809.10(b)(8)(iv)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the assay procedure including calculations and interpretation of results. *[16, §5.1]*
223	Principle of the method	This shall include the principle of the method … *[11, §5.13]*	A detailed description of the procedure to be followed should include the principle of the method, *[1, Appendix B.8.8 o)]*	Indicate a brief summary and explanation of the test and how it works, … *[4, §3.2.4]*	The measurement procedure must include, as appropriate, the principle of the method, *[8, Annex I.B.8.7 (h)]*	Principle of the method and mechanism shall briefly be documented on DOCI and details on DOCM if necessary.	The labelling must indicate: The chemical, physical, physiological, or biological principles of the procedure. Explain concisely, with chemical reactions and techniques involved, if applicable. *[31, Sec. 809.10(b)(4)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the scientific test principle. *[16, §5.2]*
224	Operating procedure	… as well as all phases of the operation from start-up to reading of result(s). *[11, §5.13]*	Instructions for use must contain a detailed description of the procedure to be followed in using the IVD; *[1, Appendix B.8.8 o)]*	For the test method: Instructions for use must provide complete information relevant to the safe and effective use of the IVDD. *[4, §3.2.5.4 (a)]*	Instructions for use must contain the measurement procedure to be followed with the device including as appropriate: *[8, Annex I.B.8.7 (h)]*	Installation, assembling and operation procedures shall be provided on DOCI.	Instrument labelling shall include: Operating instructions. *[31, Sec. 809.10(b)(6)(v)]*	

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225	Limitations of the method	NA	A detailed description of the procedure to be followed should include limitations of the method *[1, Appendix B.8.8 o)]*	Indicate test limitations and all known contraindications, if not stated in a previous Sec. of the package insert, with references if appropriate. *[4, §3.2.5.7]*	The measurement procedure must include, as appropriate, the limitations of the method *[8, Annex I.B.8.7 (h)]*	Limitations of the use including off-label use shall be stated on DOCI..	Include a statement of limitations of the procedure. *[31, Sec. 809.10(b)(10)]*	
226	Calculation of results	A description of the mathematical approach used for calculation of the analytical result shall be given. *[11, §5.14]*	Instructions for use must contain the mathematical approach upon which the calculation of the analytical result is made; *[1, Appendix B.8.8 o)]*	Indicate the step-by-step procedure for calculating the value of the test sample, including appropriate formulae and a sample calculation. *[4, §3.2.5.5]*	Instructions for use must contain the mathematical approach upon which the calculation of the analytical result is made; *[8, Annex I.B.8.7 (i)]*	Calculation of results may be a part of "Principle of the method", if appropriate.	Explain the procedure for calculating the value of the unknown. Give an explanation for each component of the formula used for the calculation of the unknown. Include a sample calculation, step-by-step, explaining the answer. The values shall be expressed to the appropriate number of significant figures. *[31, Sec. 809.10(b)(9)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the assay procedure including calculations and interpretation of results. *[16, §5.2]*
227	Interpretation of results	This shall be easily understandable for users of the IVD instrument and shall help them to interpret the analytical results. *[11, §5.14]*		Indicate the significance of the test results obtained, including information as to what degree a negative test does or does not exclude the possibility of exposure to, or infection with, the organism, etc. A positive or negative result must be clearly defined with cut-off levels where appropriate. *[4, §3.2.5.6]* See also NOTE 13.			If the test provides other than quantitative results, provide an adequate description of expected results. *[31, Sec. 809.10(b)(9)]*	*For* in vitro *diagnostic medical devices,* the labelling should bear the assay procedure including calculations and interpretation of results. *[16, §5.2]*

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228	Units	When possible, results shall be expressed in units according to ISO 1000. *[11, §5.14]*			When values are expressed numerically, they must be given in legal units conforming to the provisions of council Directive… *[8, Annex I.B.4.2.]*			
229	Special functions	Information shall be provided on special functions where applicable. EXAMPLES: Special function and performance checks; specimen identification; data output, notation, storage, security and transfer; special settings other than the normal mode of operation; interface protocol. *[11, §5.15]*						
230	Stand-by/ shut-down	Information shall be provided on the following: a) placing on stand-by; b) switching off; c) taking out of operation. *[11, §5.16]*				Shut-down procedure shall be stated on the DOCM. Checklist for the shut-down should be provided.		
231	Emergency specimens	Operating procedure for emergency specimens shall be provided where applicable. *[11, §5.17]*						

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
232	Instrument function checks	Information shall be provided on the following: — checking the function of the IVD instrument; *[11, §5.18]*			Instructions for use must contain information appropriate to users on internal quality control, *[8, Annex I.B.8.7 (k)]*	Instrument function checks may be stated on the item of "maintenance checks" briefly on DOCI. Supplemental information will be provided on DOCM, if necessary.	Any internal, electronic, reagent, or process control which is an integral component of the device must be clearly described and the nature of the information provided by its use explained. *[42]*	
233	Verification of results	Information shall be provided on the following: — verification of results; *[11, §5.18]*	Indicate the criteria for acceptance or rejection and whether further testing is required if a particular result is obtained. For example, requirements for duplicate tests if the initial test is reactive. *[4, §3.2.5.6]* Instructions for use must include specific validation procedures, *[1, Appendix B.8.8 s)]*		Information appropriate to users on internal quality control should include specific validation procedures, *[8, Annex I.B.8.7 (k)]*			
234	Quality control	Information shall be provided on the following: — internal quality control of the entire *in vitro* diagnostic system. *[11, §5.18]*	Instructions for use must contain information appropriate to users on: internal quality control, *[1, Appendix B.8.8 s)]*	Include Quality control procedures and materials required. Indicate whether positive and negative controls are required and what are considered to be satisfactory limits of performance. *[4, §3.2.5.4 (a)]*	Instructions for use must contain information appropriate to users on: internal quality control, *[8, Annex I.B.8.7 (k)]*	The laboratory is responsible for establishing internal quality control procedures.	Labelling shall include: Details of kinds of quality control procedures and materials required. If there is need for both positive and negative controls, this should be stated. State what are considered satisfactory limits of performance. *[31, Sec. 809.10(b)(8)(vi)]* FDA currently requires that the package inserts of all devices contain information on the quality control materials appropriate	

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
							for a test system. Recommended QC specific rules including run frequencies to be followed for assessing quality are left to the discretion of the individual laboratory. *[42]*	
235	Waste disposal	Where appropriate, information shall be provided on the safe disposal of waste materials (e.g. consumables, used reagents or reagent products including those mixed with specimens, instruments or components thereof). *[11, §5.19]*	Instructions for use must contain information about safe waste disposal; *[1, Appendix B.8.8 h)]*	Indicate appropriate decontamination and disposal procedures of used or expired kits and/or reagents. Disposal of all specimens and kit components must comply with all applicable waste disposal requirements. NOTE Decontamination and disposal information may also be provided in the "Warnings and precautions" Sec. of the package insert. *[4, §3.2.5.9]*	Instructions for use must contain information about safe waste disposal; *[8, Annex I.B.8.7 (n)]*			The labelling should bear where applicable precautions to be taken against any special, unusual risks related to the disposal of the device. *[16, §5.2]*
236	Single-use devices	NA				For single-use instruments, "NO REUSE" shall be stated on the DOCI.		The labelling should bear an indication, where applicable, that the device has been specified by the manufacturer for single use only. *[16, §5.2]*
237	Maintenance	Information shall be provided on: — preventive maintenance (nature and frequency); *[11, §5.20]*	Instructions for use must contain details of the nature and frequency of the maintenance needed to ensure that the IVD operates properly and safely; *[1, Appendix B.8.8 g)]*		Instructions for use must contain details of the nature and frequency of the maintenance. *[8, Annex I.B.8.7 (n)]*	Information for periodical check points and maintenances by the user, including check list and checking procedures with precautions, frequencies, and necessary tools, but not limited to items maintained by	Instrument labelling shall include: Service and maintenance information. *[31, Sec. 809.10(b)(6)(ix)]*	The labelling should bear details of the nature, and frequency of preventative and regular maintenance, *[16, §5.2]*

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						professionals shall be stated clearly distinguished from those carried out by users.		
238	Cleaning instructions	Information shall be provided on: — cleaning instructions; *[11, §5.20]*			If the device is reusable, the instructions for use must contain information on the appropriate processes to allow reuse, including cleaning, … and any restriction on the number of reuses; *[8, Annex I.B.8.7 (q)]*	Information shall be provided on DOCM.		The labelling should bear where applicable information on the appropriate processes to allow reuse, including cleaning, … and any restriction on the number of reuses.
239	Sterilization, decontamination or disinfection	Information shall be provided on: — sterilization, decontamination or disinfection; *[11, §5.20]*	If the IVD is reusable, the instructions for use must contain information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and re-sterilization or decontamination, and any restriction on the number of reuses *[1, Appendix B.8.8 l)]*		If the device is reusable, the instructions for use must contain information on the appropriate processes to allow reuse, including disinfection, and, destabilization or decontamination, and any restriction on the number of reuses; *[8, Annex I.B.8.7 (q)]* Instructions for use must contain the details of appropriate methods of destabilization or decontamination; *[8, Annex I.B.8.7 (p)]*	Information on cleaning or decontamination procedures, including prohibited procedure, shall be given on DOCM.		The labelling should bear where applicable information on the appropriate processes to allow reuse, including disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where a device is supplied with the intention that it is sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with the *Essential Principles of Safety and Performance of Medical Devices.* *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
240	Components list, including relevant working materials, tools	Information shall be provided on: — components list, including relevant working materials, tools; *[11, §5.20]*						
241	Consumables	Information shall be provided on: — consumables; *[11, §5.20]*				— replacing frequency of consumables and parts and their procedures.		
242	Servicing	Information shall be provided on: — servicing; *[11, §5.20]*					Instrument labelling shall include: Service and maintenance information. *[31, Sec. 809.10(b)(6)(ix)]*	
243	Spare parts	Information shall be provided on: — list of recommended spare parts. *[11, §5.20]*						
244	Trouble-shooting error messages	Information shall be provided on: a) messages, error signals; b) establishing cause(s) of error(s); c) correction and elimination of error by the user; *[11, §5.21]*				Information shall be provided on the DOCM of the a) checkpoints and procedures for safety use after fixing a problem, b) procedures to determine causes of malfunction and c) information for repairs.		

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245	Service calls	Information shall be provided on: — errors necessitating service calls; *[11, §5.21]*				Information on after-service and service call shall be provided on DOCM.		
246	Trouble-shooting performance change	Information shall be provided on: — measures to be taken in the event of a change of the analytical performance of the IVD instrument. *[11, §5.21]*	Instructions for use must contain measures to be taken in the event of changes in the analytical performance of the IVD; *[1, Appendix B.8.8 o)]*		Instructions for use must contain the measures to be taken in the event of changes in the analytical performance of the device; *[8, Annex I.B.8.7 (j)]*			The labelling should bear precautions to be taken in the event of changes in the performance, or malfunction, of the device including a contact telephone number, if appropriate. *[16, §5.2]*
247	Environmental specifications	Information shall be supplied on: — if appropriate, limitations on physical environment required for function according to manufacturer's specifications, e.g. humidity, temperature, vibration, magnetic fields, external electrical influences, electrostatic discharge, pressure, acceleration, thermal ignition sources; *[11, §5.22]*	Instructions for use must contain precautions to be taken as regards to exposure environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; *[1, Appendix B.8.8 v)]*			Information shall be provided on; a) physical environments, e.g. temperature, allowable temperature fluctuation, humidity, power supplies, grounding. b) other conditions necessary for performance guarantee, if any.		The labelling should bear, where applicable, precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, temperature, humidity, acceleration, thermal ignition sources, proximity to other devices, etc. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
248	Technical specifications	Information shall be supplied on: a) dimensions, mass; b) basic settings made by the manufacturer c) physical data, e.g. voltage, water pressure; *[11, §5.22]*				Technical specifications shall be listed and provided on DOCM.		
249	Utility requirements	Information shall be supplied on: — consumption values in units according to ISO 1000, e, g. electrical power, water; *[11, §5.22]*				Information shall be provided on necessary utilities, e.g. electrical power, water.		
250	Electro-magnetic compatibility	Information shall be supplied on: — if appropriate, electromagnetic emission and immunity. *[11, §5.22]*	Instructions for use must contain precautions to be taken as regards to exposure environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.; *[1, Appendix B.8.8 v)]*		Instructions for use must contain the precautions to be taken as regards exposure, in reasonably foreseeable environmental conditions, to magnetic fields, external electrical influences, electrostatic discharge, … etc.; *[8, Annex I.B.8.7 (r)]*	EMC standards and criteria applied on the EMC validation shall be stated, if appropriate.		The labelling should bear where applicable information regarding the risks of reciprocal interference posed by the reasonably foreseeable presence of the device during specific investigations, evaluations, treatment or use (e.g. electromagnetic interference from other equipment). *[16, §5.2]*
251	Date of manufacture							The labelling for devices other than those [that bear an expiry date], and as appropriate to the type of device, should bear an indication of the date of manufacture. This indication may be included in the batch code or serial number. *[16, §5.2]*

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252	Revision control	The date of issue or latest revision of the instructions for use shall be given. *[11, §5.23]*	Instructions for use must contain the date of issue or latest revision. *[1, Appendix B.8.8 y)]*	The date of issue of DIRECTIONS FOR USE or of any revision should be indicated. *[4, §3.2.9]*	Instructions for use must contain the date of issue or latest revision of the instructions for use. *[8, Annex I.B.8.7 (u)]*	The identifier and the date of issue shall be stated on the DOCM. The date of issue or latest and previous revision, if any, of the DOCI shall be given. The revised portion of each revision shall be marked by asterisk as example for respective changes.	Labelling shall include: Date of issuance of the last revision of the labelling identified as such. *[31, Sec. 809.10(b)(15)]*	
253	Required supplementary information	If appropriate, instructions for use for IVD instruments shall provide the supplementary information given in EN 591, §6.2 to 6.8. *[11, §6.1]*						
254	Abbreviated operating instructions	Brief operating instructions shall be provided. NOTE This can be provided in the form of a card to be attached to the instrument. *[11, §6.2]*						
255	List of uses and applications	Information on uses and applications shall be provided. *[11, §6.3]*				List of uses and applications. Both the DOCI and DOCM shall give the information and caution about usage of the IVD instrument in combination with others to keep the safety and the performance.		

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256	Warranty limitations	A statement of specific warranty limitations shall be provided. NOTE An example is the action by users which may invalidate the manufacturer's warranty. *[11, §6.4]*				Warning shall be stated on the DOCM that the user shall have sole responsibilities of any events caused if any stated taboo or prohibition is committed.		
257	Ordering information	Information shall be provided on the following: a) list of spare parts and consumables; b) relevant addresses, e.g. source of appropriate IVD reagents. *[11, §6.5]*						
258	Extension, expansion, connectivity	Information shall be provided on the following: a) interface description; b) modules; c) software; d) nature and function of connectors. *[11, §6.6]*						If the device is to be installed with or connected to other medical devices or equipment, or with dedicated software, in order to operate as required for its intended use, the labelling should bear sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination. *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
259	Assistance	Information shall be provided on the following: a) training; b) service request protocol; c) list of offices and sources of service (mailing addresses, telephone numbers, telephone trouble-shooting, etc.); d) logbook; e) user updatable software. *[11, §6.7]*				Following information shall be documented on the DOCM. a) recommended educational program for user or relevant program provided by manufacturer for safety and efficient operation and for efficient maintenance procedure of the IVD instruments done by the user. b) service request and protocol, including available service program and cost system, c) list of offices and sources of service including service organization, mailing addresses, telephone numbers, etc. d) available period of time for service parts, and e) instrument disposal procedures. Name of responsible person or section shall be provided with address and telephone number.		

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260	Supplementary theoretical information	Supplementary theoretical information shall be given. *[11, §6.8]*						
261	**Exemptions**							
262	Investigational use devices			No person shall import or sell a medical device for investigational testing unless the device has a label that sets out a) the name of the manufacturer; b) the name of the device; c) the statements “Investigational Device” and “Instrument de recherche”, or any other statement, in English and French, that conveys that meaning; d) the statements “To Be Used by Qualified Investigators Only” and “Réservé uniquement à l'usage de chercheurs compétents”, or any other statement, in English and French, that conveys that meaning; and e) in the case of an IVDD, the statements “The performance specifications of this device have not been established” and “Les spécifications de rendement de l'instrument n'ont pas été établies,” or any other statement, in	In case of devices for performance evaluation, the label must bear the words 'for performance evaluation only; *[8, Annex 1.B.8.4 (f)]*	Indicate that the reagent is for a clinical trial. NOTE Clinical trials are to assess the safety and clinical efficacy or effectiveness in clinical environments. Clinical trial shall be approved and during the trial, any advertisement, exhibition, or transfer to others of the objects is strongly prohibited. Name and address of the sponsor — (where the sponsor does not have an address in Japan, the name and country of address of the sponsor and the name and address of the domestic clinical trial caretaker — Chemical name or identifying symbols Parameters for determining storage and expiry, etc. where necessary Name under which	For a product being shipped or delivered for product testing prior to full commercial marketing (for example, for use on specimens derived from humans to compare the usefulness of the product with other products or procedures which are in current use or recognized as useful), all labelling bears the statement, prominently placed: “For Investigational Use Only. The performance characteristics of this product have not been established.” *[31, Sec. 809.10(c)(2)(ii)]* FDA is proposing that the “For IVD Performance Evaluation only” symbol may be used in place of the statement, “For Investigational Use Only … etc.” *[39]* For a product in the laboratory research phase of development, and not represented as an	The labelling should bear an indication, where applicable, that the device is intended for premarket clinical investigation or, for *in vitro* diagnostic medical devices, performance evaluation only. *[16, §5.2]* Where applicable: An indication that the device is intended for clinical and /or performance investigations prior to placing it on the market

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				English and French, that conveys that meaning. *[5, Part 3, Sec. 86]*		the product is expected to be marketed. No expected indications, or performance (This does not mean that performance characteristics have not been established, but that the clinical trial be conducted without preconception before the trial is completed.) No expected administration and dosage	effective *in vitro* diagnostic product, all labelling bears the statement, prominently placed: "For Research Use Only. Not for use in diagnostic procedures." *[31, Sec. 809.10(c)(2)(i)]* IVDs subject to other labelling requirements regarding their investigational or research status must continue to bear the required textual statements and should not bear this symbol. *[39]*	
263	Presentation/ demonstration devices	NA						The labelling should bear an indication, where applicable, that the device is intended only for presentation or demonstration purposes. *[16, §5.2]*
264	Custom-made devices	NA						The labelling should bear an indication, where applicable, that that the device is for use by a single individual and has been manufactured according to a written prescription or pattern (i.e. it is custom-made). *[16, §5.2]*

#	Subject	CEN Standard	Australia	Canada	European Union	Japan 2003[a]	United States	GHTF
265	Analyte-specific reagents	NA					The labelling for analyte-specific reagents (e.g. monoclonal antibodies, deoxyribonucleic acid (DNA) probes, viral antigens, ligands) shall bear [specified] information: *[31, Sec. 809.10(e) (1)]*	
266	General-purpose reagents	NA			Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination; *[8, Article 1.2(b)]*	Separate Section in pharmaceutical law	The labelling of general-purpose laboratory reagents (e.g. hydrochloric acid) and equipment (e.g. test tubes and pipettes) whose uses are generally known by persons trained in their use need not bear the directions for use required by Sec. 809.10(a) and (b), if their labelling meets the requirements of this paragraph. *[31, Sec. 809.10*(d)*]*	
267	General purpose laboratory equipment	NA			Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro* diagnostic examination; *[8, Article 1.2(b)]*		The labelling of general-purpose laboratory … equipment (e.g. test tubes and pipettes) whose uses are generally known by persons trained in their use need not bear the directions for use required by Sec. 809.10(a) and (b), if their labelling meets the requirements of this paragraph. *[31, Sec. 809.10(d)]*	

NOTE 1 The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name which may be preceded or followed by the name of the particular division of the corporation. Abbreviations for “Company,” “Incorporated,” etc., may be used and “The” may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used. [29, Sect. 801.1 (b)]

Where a device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase that reveals the connection such person has with such device; such as, “Manufactured for ----------”, “Distributed by ----------”, or any other wording that expresses the facts. [29, Sect. 801.1 (c)]

NOTE 2 The term “accompanying” is interpreted liberally to mean more than physical association with the product. It extends to posters, tags, pamphlets, circulars, booklets, brochures, instruction books, direction sheets, fillers, etc. “Accompanying” also includes labelling that is brought together with the device after shipment or delivery for shipment in interstate commerce. [36, Sec. 201(m)]

NOTE 3 Information required by the FDCA to appear on the label or labelling will be deemed to lack the requisite prominence if: 1) the information does not appear on the part of the label presented or displayed under customary conditions of purchase; 2) the label does not extend over the area of the container or package available so as to provide sufficient label space for the prominent placing of such information; 3) the label does not provide enough space for such information because of the use of label space for information not required by or under the authority of the FDCA; or 4) the information is presented in type that is too small, fades into the background, is obscured, or crowded with other graphic matter. [37]

NOTE 4 The following information should be included: Nature of the intended use (e.g. screening, monitoring, diagnostic); Type of test: qualitative or quantitative; The specific disorder, condition, or risk factor of interest for which the test is intended, i.e. the analyte to be measured; Description of the patient population the IVDD is to be used in; Indicate if the device is for use in clinical laboratories, alternative care sites, or home use; Type of specimen(s) required (e.g. serum, plasma, etc.); Indicate if the IVDD must be used in combination with or installed with or connected to other medical devices or equipment; Specific contra-indications for use. [4, §3.2.3]

NOTE 5 For IVDDs containing potentially infectious agents, indicate whether any antigens and/or control sera have been inactivated and provide a complete description of what tests have been performed on positive and negative controls, and results obtained, for HCV, HBV, HTLV and HIV. If the testing revealed the presence of an infectious agent, a hazard statement should be included to the effect: “HAZARD: The device may transmit [infectious agent] and should be handled with extreme caution. No known test method can offer complete assurance that products derived from human blood will not transmit infectious agents.” [4, §3.2.5.2]

NOTE 6 Indicate the storage conditions necessary to ensure the stability of the product in the unopened state for both device and individual reagents. Recommended storage temperature intervals and other conditions for storage such as light, humidity, etc. should be stated. [4, §3.2.7]

NOTE 7 Indicate any essential components and/or special equipment or instruments not provided. Include details such as sizes, numbers, types, quality, etc. Examples are: incubators, precision pipettes, calibrated thermometers, appropriate disinfectants and disinfection procedures, appropriate reaction vessels (specify glass, polystyrene, polypropylene), etc. For instruments such as microplate readers, indicate required specifications such as wavelength, band width, absorbance, precision, filters, etc. [4, §3.2.5.1(b)]

NOTE 8 Indicate the significance of the test results obtained, including information as to what degree a negative test does or does not exclude the possibility of exposure to, or infection with, the organism, etc. A positive or negative result must be clearly defined with cut-off levels where appropriate. If the test is designed to provide qualitative results, provide an explanation of expected results. If the test requires the interpretation of “visual” results, e.g. colorimetric reactions, include a high quality photograph or reproduction of results. [4, §3.2.5.6]

NOTE 9 FDA currently requires that the package inserts of all devices contain information on the quality control materials appropriate for a test system. In addition any internal, electronic, reagent, or process control which is an integral component of the device must be clearly described and the nature of the information provided by its use explained. QC specific rules including run frequencies to be followed for assessing quality are left to the discretion of the individual laboratory. [42]

NOTE 10 Performance characteristics such as sensitivity, specificity, predictive values, reproducibility, repeatability, stability, limits of detection and measurement range, earliest clinical detection in comparison with tests of reference, etc., are required. Indicate 95 % confidence intervals where appropriate. [4, §3.2.6]

NOTE 11 Include performance characteristics/specifications of any dedicated instruments/ equipment/software. [4, §3.2.5.1(c)]

NOTE 12 Include Performance/ turnaround time. Indicate the maximum and minimum levels of detection, etc. [4, §3.2.5.4 (a)]

NOTE 13 If the test is designed to provide qualitative results, provide an explanation of expected results. If the test requires the interpretation of “visual” results, e.g. colorimetric reactions, include a high-quality photograph or reproduction of results. [4, §3.2.5.6]

NOTE 14 The following information for repairs is required in the DOCM:

1) manufacturer's responsible repairs and users;
2) high risk re-adjustments and/or repairs for safety and relevant prohibition;
3) manufacturer's educational program which allows users to repair specified portion, if any; and
4) user's responsibilities upon repairs conducted by using tools other than specified or provided.

[a] Translation and interpretation was provided by the Japanese Delegation to ISO/TC212. They have not been authorized by the Japanese government and are intended only for use in this summary.

[b] The number in brackets indicates specific reference in the bibliography (e.g. [*10*] references Bibliography reference #10 which is the EN 375:2001 standard).

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