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# GUIDANCE DOCUMENT

## Labelling of *In Vitro* Diagnostic Devices

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**Health Products and Food Branch**

Canada 

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## FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant Sections of other applicable guidance documents.

<b>Document Change Log</b>			
<b>File name</b>	Guidance for the Labelling of In Vitro Diagnostic Devices	<b>Replaces</b>	Draft Guidance for the Labelling of In Vitro Diagnostic Devices
<b>Date</b>	2016/04/22	<b>Date</b>	1998/06/16

<b>Change</b>	<b>Location (Section, paragraph)</b>	<b>Nature of and/or Reason for Change</b>
1	Whole Document	Rewritten to add clarity; conform to Good Guidance Practices; and update examples
2	Glossary	Definitions added to provide clarity, edited to match Food and Drugs Act, Medical Devices Regulations, and ISO18133-1:2009
3	Guidance for Implementation	Updated and clarified text; bolded glossary terms
4	Labelling as required by Section 21(2)	Added information on e-labelling and labelling smaller containers
6	Special considerations for blood glucose monitoring systems	Added information on requirements for labelling these devices
7	Labelling information for IVDDs as required by Section 23	Added section to update information provide clarity
8	Bibliography	Added references

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## **1 INTRODUCTION**

### **1.1 Policy Objectives**

This guidance document is intended to assist manufacturers in the labelling of *in vitro* diagnostic devices (IVDDs). The labelling requirements for these devices are set out in Sections 21, 22, and 23 of the Medical Devices Regulations (Regulations).

### **1.2 Policy Statements**

Medical devices offered or imported for sale or use in Canada must meet the labelling requirements listed in Sections 21 - 23 of the Regulations. This guidance is to be used in the preparation of labelling material for IVDDs.

### **1.3 Scope and Application**

This guidance document applies only to the labelling of products deemed to be IVDDs under the Regulations. This may apply to IVDDs intended for research use if they are also labelled or otherwise represented by manufacturers for a specific diagnostic, investigational or therapeutic application. The guidance document “Guidance for the Classification Rules for *In Vitro* Diagnostic Devices GD007/RevDR-MDB” ([http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl\\_etiq\\_dv10-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/guide-ld/labl_etiq_dv10-eng.php)) provides additional information on these topics.

Additional information regarding the labelling requirements for other medical devices can be found in the guidance document “Guidance for the Labelling of Medical Devices, not including *in vitro* diagnostic devices - Appendices for the Labelling of Soft Contact Lenses, Decorative Contact Lenses, and Menstrual Tampons”.

Although this guidance document does not specifically address the labelling for IVDDs intended for near-patient use (with the exception of blood glucose monitoring systems) the information for these products, required by Sections 21 to 23 of the Regulations, should be expressed and presented with the intended user of the device in mind. Directions for use should be clearly written in a step-by-step format and include illustrations and drawings where appropriate. The user should have a clear understanding of the action to be taken in the case of a particular result and on the possibility of a false positive or false negative result. The Medical Devices Bureau reserves the right to ask for more labelling information than is indicated in this guideline if it is felt that such labelling will impact on the safe and effective use of this device.

## 1.4 Definitions

The following definitions were created to guide and explain technical terms specific to this guidance document:

**Adverse Effect:** an undesirable effect, usually seen in clinical studies, and has associated frequency data. (*Effet nocif*)

**Cautions and Precautions:** pieces of information which alert the user to exercise special care necessary for the safe and effective use of the device. (*Avertissements et précautions*)

**Contraindications:** describe situations where the device should not be used because the risk of use clearly outweighs any foreseeable benefits. (*Contre-indications*)

**Control number:** a unique combination of letters or symbols that is assigned to a medical device by the **manufacturer** and from which a complete history of the manufacture, control, packaging and distribution of a unit, lot or batch of the device can be determined. This includes **lot number**. (*Numéro de contrôle*) (*Medical Devices Regulations*)

**Directions for Use:** full information as to the procedures recommended for achieving the optimum performance of the device and includes **cautions, warnings, contraindications** and possible **adverse effects**. (*mode d'emploi*) (*Medical Devices Regulations*)

**Indications for Use:** a general description of the disease(s) or condition(s) the device will diagnose, treat, prevent or mitigate, including where applicable a description of the patient population for which the device is intended. The indications include all the labelled uses of the device, for example the condition(s) or disease(s) to be prevented, mitigated, treated or diagnosed, part of the body or type of tissue applied to or interacted with, frequency of use, physiological purpose and patient population. The indications for use are generally labelled as such, but may also be inferred from other parts of the labelling, including the **Directions for Use, Precautions, Warnings** and bibliography sections. (*Indications d'emploi*).

**Intended use:** objective intent of an *in vitro* diagnostic device (IVD) **manufacturer** regarding the use of a product, process or service as reflected in the specifications, instructions and information supplied by the IVD **manufacturer**. (*ISO 18113-1:2009*)

**Identifier:** means 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 it from similar devices. (*Identificateur*) (*Medical Devices Regulations*)

**In vitro Diagnostic Device (IVDD):** a medical device or a product subject to Section 3.1 of the Medical Devices Regulations that is intended to be used *in vitro* for the examination of

specimens derived from the human body. (*Instrument diagnostique in vitro ou IDIV*) (*Medical Devices Regulations*)

**Immediate Container:** packaging that protects the contents from contamination and other effect of the external environment. (*Contenant immédiat*) (*ISO 18113-1:2009*)

**Name of The Device:** in respect of a medical device, includes any information necessary for the user to identify the device and to distinguish it from similar devices. (*Nom de l'instrument*) (*Medical Devices Regulations*)

**Near patient *in vitro* diagnostic Device (near patient IVDD):** means an *in vitro* diagnostic device 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 the bedside. (*Instrument diagnostique clinique in vitro*) (*Medical Devices Regulations*)

**Label:** any legend, word or mark attached to, included in, belonging to or accompanying any food, drug, cosmetic, device or package. (*Étiquette*) (*Food and Drugs Act*)

**Manufacturer:** a person who sells a medical device under their 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. (*Fabricant*) (*Medical Devices Regulations*)

**Outer Container:** sales packaging material used in the packaging of the immediate container or containers of an IVDD which can consist of a single component, a kit or an assembly of different or identical components. (*Contenant extérieur*) (*ISO 18113-1:2009*)

**Package:** includes anything in which any food, drug, cosmetic or device is wholly or partly contained, placed or packed. (*Emballage*) (*Food and Drugs Act*)

**Sell:** includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration. (*Vente*) (*Food and Drugs Act*)

**Test Kit:** an IVDD that consists of reagents or articles or any combination of these, and that is intended to be used to conduct a specific test. (*Trousse d'essai*) (*Medical Devices Regulations*)

**Warning:** describes serious adverse reactions and potential safety hazards that can occur in the proper use, or misuse, of a device, along with the consequent limitations in use and mitigating steps to take if they occur. (*Mise en garde*)

## 2 GUIDANCE FOR IMPLEMENTATION

### 2.1 Label

All IVDDs must have a **label** which provides the information specified in sections 21(1)(a) to (j) of the Regulations. The definition of **label** as defined in the *Food and Drugs Act* allows flexibility in that the information need not be affixed to the device but may be provided with the device; for IVDDs this includes, but is not limited to the **outer container label**, the **immediate container** (reagent/component) **label**, the **package** insert, brochures, leaflets, user manuals and operator manuals.

### 2.2 Requirements for a Package Insert

**Package** inserts are essential for most IVDDs. The requirements for a **package** insert indicated in this section of the guidance document apply to the majority of devices for all classes of IVDDs. 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.

The information required for a **package** insert may be presented in a different format than the examples in 2.2.1 to 3.1.11 of this guidance document.

#### 2.2.1 Section 21(1)(a) - The name of the *in vitro* diagnostic device (IVDD)

Each device including a system, medical device group, medical device family, or medical device group family must have a name. The device license is issued for (a) the device name on the **label** which may describe one device, (b) an administrative grouping of devices sold for convenience under a single name or (c) a grouping of devices that carry the same generic name specifying the **intended use** of the devices. The name of the IVDD on the **package** insert should enable the user to identify the device and distinguish it from other similar devices.

#### 2.2.2 Section 21(1)(b) - The name and address of the manufacturer

The name and address of the **manufacturer** is required on the **package** insert. The name and address of the importer or distributor may also appear on the **package** insert. If more than one name appears on the **package** insert, the relationship of each name to the device must be made clear, such as in the case of private labelling agreements between the **manufacturer** and the distributor or importer. The device licence is issued to the **manufacturer** named on the **package** insert.

The name and address should be in sufficient detail to serve as a postal address.

### 2.2.3 Section 21(1)(c) - Identifier

The **identifier** is a unique number assigned to the device by the **manufacturer**, which along with the name of the device will permit a device to be distinguished from all other devices. It may be a catalogue number, model number, or a barcode and will permit, in combination with the name, a certain level of control and traceability in the market place.

### 2.2.4 Section 21(1)(h) - The intended use of the device

The **package** insert should clearly indicate the **intended use(s)** and **indications** of the IVDD. The following information should be included:

- Nature of the **intended use** (for example [e.g.], screening, monitoring, diagnostic, etc.).
- Class IV IVDDs not intended for donor screening must indicate “**Not for donor screening**” on the device container **label** and **package** insert.
- Technology of the IVDD (e.g., ELISA, chromatographic).
- Type of test: qualitative or quantitative.
- The specific disorder, condition, or risk factor of interest for which the test is intended, (that is [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, point of care sites, or home use.

Note: The limitations section of the **package** insert should include any specific training required for test performance or 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 **contraindications** for use, for example “Use of this device is contraindicated in recent influenza vaccine recipients...”, when considerable cross-reactivity can be expected in recent influenza vaccine recipients.
- If the IVDD is for use only on a single patient, this should be indicated.

An example of an **intended use** statement is the following:

[Assay Name] version 1.0 is a qualitative in vitro test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) RNA in human plasma in conjunction with licensed tests for detecting anti bodies to HIV-1. This product is intended for use as a donor screening test to detect HIV-1 RNA in plasma specimens from individual human donors, including donors of whole blood and blood components, source plasma and other living donors. It is also intended for

use to screen organ donors when specimens are obtained while the donor's heart is still beating and to detect HIV-1 RNA in blood specimens from cadaveric (non-heart-beating) organ and tissue donors.

This test is not intended for use on samples of cord blood or as an aid in diagnosis. Plasma from all donors may be screened as individual specimens. Plasma may be tested in pools comprised of equal aliquots of not more than 16 individual donations for donations of whole blood and blood components, hematopoietic stem/progenitor cells (HPCs) sourced from bone marrow, peripheral blood or cord blood, and donor lymphocytes for infusion (DLI). For donations of Source Plasma, plasma may be tested in pools comprised of equal aliquots of not more than 96 individual donations.

### 2.2.5 Section 21(1)(h) - Summary and explanation

The **package** insert should 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 the **intended use**. It must also describe the technique(s) and reactions (biological, chemical, microbiological, immunochemical, etc.) used, citing literature references where appropriate.

The summary should include, where appropriate, descriptions of the types of antibodies and antigens used in the test (e.g., synthetic peptide, monoclonal, recombinant, etc.), and purification methods.

### 2.2.6 Section 21(1)(i) - Directions for use (or Instructions for Use)

Refer to the definitions section of this guidance for **directions for use**. This is the information supplied to the lay person and/or the health care professional enabling them to use the device without causing unnecessary harm to themselves or another person and to achieve the desired result. The **directions for use** should be written at a level commensurate with the training of the expected user(s). **Directions for use** must be provided in the **package** insert unless they are not required for the device to be used safely and effectively. Most IVDDs will require **directions for use**.

The required information may be presented in the **package** insert in a format different from that indicated in Sections 2.2.4.1 - 2.2.4.9 of this guidance document.

For example, **warnings and precautions** may be indicated under a separate heading than the **directions for use**. Components of a **test kit** or system may be indicated in a table format along with instructions for preparation and use, storage conditions, stability information, **warnings and precautions**, etc.

### 2.2.6.1 Components (for example, reagents, test strips, supplies, etc.)

The **directions for use** should include a description of all the parts or components supplied in the **package** of the IVDD. This helps ensure that the user is aware of all the components of the device prior to use.

The description of a component should include the following:

- The name of the component;
- The contents in terms of quantity (e.g. number of vials, if applicable), mass and/or volume or concentration.
- For reagents, indicate the following:
  - Quantity, proportion, concentration or activity of each reactive ingredient. For biologics, indicate the source and measure of activity;
  - 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;
  - Specify the maximum number of tests that can be performed with stated contents;
  - Complete directions for preparation (reconstitution, mixing, or dilution);
  - Storage instructions for both opened and unopened reagents;
  - Information regarding possible deterioration of the reagent, i.e. indicators of reagent, calibrator or quality control material deterioration, where applicable; and,
  - Appropriate **warnings and precautions**.

The **directions for use** should also indicate any essential components and/or special equipment or instruments not provided with the IVDD. The description of these components should include details such as size, number, type, and quality.

Examples of essential components that may not be provided with an IVDD:

- incubators
- precision pipettes
- appropriate reaction vessels
- buffers
- controls

For instruments such as microplate readers, indicate required specifications such as wavelength, band width, absorbance, precision, and filters.

The **directions for use** should also indicate any dedicated instruments, equipment, or software. Include the following:

- Name of the instrument.
- Model number(s)/version number(s).
- Brief description of use or function, performance characteristics/specifications, **warnings and precautions**, limitations, etc.
- Refer to the instrument manual, where appropriate, for a more detailed description of instrument procedures.

#### ***2.2.6.2 Warnings and Precautionary Statements***

The **directions of use** should indicate appropriate **warnings** and precautionary statements for the safe and effective use of the IVDD. **Warnings** alert the user to potential serious adverse reactions, performance issues, and safety hazards that can occur with the proper use, or misuse, of an IVDD. **Precautions** alert the user to the special care or procedures necessary 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.

For all classes of IVDDs, indicate the statement:

**For *in vitro* diagnostic use.**

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 may transmit infectious agents and should be handled with extreme caution. No known test method can offer complete assurance that products derived from human sources will not transmit infectious agents.**

For IVDDs containing potentially infectious agents, indicate whether any reagents have been inactivated and provide a description of how they were inactivated, what tests were performed, and results obtained for HCV, HBV, HTLV and HIV.

Section 21(1)(f) the Regulations requires the word “Sterile”, if the **manufacturer** intends the device or components to be sold in a sterile condition.

Examples of appropriate **warnings and precautions** include:

- Do not pipette by mouth.
- Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
- Wear protective clothing and disposable gloves while handling the kit reagents.
- Wash hands thoroughly after performing the test.
- Use in ventilated area.
- Avoid contact with eyes; use safety glasses; in case of contact, flush with water immediately and contact a doctor.
- Avoid contact with skin; use gloves; in case of contact with skin, flush immediately and thoroughly with water.
- Handle DMSO containing reagents with care, since DMSO is readily absorbed through the skin.
- For acids, include appropriate warnings for spills such as “wipe up spills immediately and flush with water” and “should the reagent contact eyes or skin, flush with copious amounts of water and consult a physician”.
- For biological spills, indicate appropriate disinfectants and disinfection procedure.
- Dispose of all specimens and components of the kit as potentially infectious agents.
- Do not use the kit or any kit component past the indicated expiry date.
- Do not use any other reagents from different lots in this test, unless the reagent is designated to be used with other lots of the same kit.
- Do not use any reagent in other test kits, unless the reagent is designated to be used with other kits.
- Avoid microbial contamination of reagents.
- Bring all reagents or components to room temperature before use.
- For manual pipetting of samples and controls, use individual pipette tips to eliminate carryover.

### ***2.2.6.3 Specimen collection and handling***

For IVDDs which are used to collect and handle specimens, the **directions for use** should indicate the following:

- A description of the specimen.
- The criteria for acceptance or rejection of samples.
- Information on patient preparation, **precautions** and procedure for specimen collection (e.g., removal of particulate matter by centrifugation, etc.).
- The additives and preservatives to be added to the specimen, to preserve the integrity of the specimen.
- Appropriate storage and handling requirements and any known interferences.

#### 2.2.6.4 Test Procedure

For a test method the **directions for use** should provide complete information relevant to the safe and effective use of the IVDD. The following information should be included:

- a description of the required amounts of reagents, samples, and controls; incubation schedules, temperature, wavelengths used for measurement, and other relevant parameters and environmental conditions under which the device is to be used;
- information on sample collection and handling;
- expected performance/ turnaround time;
- calibration where applicable;
- the acceptable time period for reading of final test results, where appropriate.
- the quality control procedures and materials are required where applicable:
  - these instructions should indicate whether positive and negative controls are required and what are considered to be satisfactory limits of performance; and,
- for individual reagents:
  - the complete instructions for preparing - dilutions or mixing of individual reagents, unless provided in an alternate section of the **package** insert; and,
  - the test volumes and **directions for use**, unless provided in an alternate section of the **package** insert.

#### 2.2.6.5 Results

The **directions for use** should indicate the step-by-step procedure for calculating the value of the test sample, including appropriate formulae, definition of each component of the formula and a sample calculation.

#### 2.2.6.6 Interpretation of results

The **directions for use** must indicate the criteria for acceptance or rejection and whether further testing is required if a particular result is obtained. For example, indicating the requirements for duplicate tests if an initial test is reactive.

The **directions for use** should also indicate the significance of the test results obtained. A test intended to provide either positive or negative results should include information as to what degree a negative test does, or does not, exclude the possibility of exposure to, or infection with, the organism. A positive or negative result must be clearly defined with cut off levels where appropriate.

If the test requires the interpretation of “visual” results, e.g. colorimetric reactions, a clear description of the criteria must be provided and a high quality photographic representation or reproduction of results should be included.

#### ***2.2.6.7 Limitations***

The **directions for use** must indicate test limitations and all known **contraindications**, if not stated in a previous section of the **package** insert, with references if appropriate. This section may include:

- the 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,
- any known interfering substances and factors that should be considered when interpreting test results.

#### ***2.2.6.8 Expected values***

The **directions for use** must 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 populations which were used for the testing. Literature references should be included where appropriate.

#### ***2.2.6.9 Disposal***

The **directions for use** must indicate the 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**” section of the **package** insert.

#### ***2.2.6.10 Cleaning and Disinfection***

When applicable, the **directions for use** must include cleaning and disinfection steps in sufficient detail to ensure the user understands why the steps are needed and how to perform the procedure effectively. The instructions must include the recommended frequency of cleaning and/or disinfection, the specific recommended cleaning agent and disinfectant, parts of device to be cleaned or disinfected and exposure time.

### 2.2.7 Section 21(1)(h) - Performance characteristics

The performance characteristics section must include a summary of data from analytical and clinical evidence upon which the performance of the test is based. Performance characteristics such as diagnostic sensitivity, diagnostic specificity, predictive values, accuracy, reproducibility, repeatability, stability, limits of detection and measurement range, earliest clinical detection in comparison with tests of reference, etc. are required. Performance characteristics should indicate 95% confidence intervals where appropriate.

### 2.2.8 Section 21(1)(j) - Storage instructions

The **package** insert must indicate the storage conditions necessary to ensure the stability of the product in the unopened state for both device and individual reagents. Recommended environmental conditions as they relate to temperature intervals, light, or humidity should be stated. The user must be provided with this information in order to decide if such storage conditions are accessible or within their means.

Examples of appropriate statements are:

- 2° C to 8° C
- 2-8° C
- -20° C or below
- $\leq$  -20° C
- protect from freezing
- do not freeze
- store in the dark
- store desiccated

The **package** insert should also indicate storage conditions as outlined above for opened, on-board or reconstituted/mixed reagents.

### 2.2.9 Date of issue and version number

The date of issue of **directions for use** or of any revision should be indicated. A version number should be provided.

### 2.2.10 Bibliography

The bibliography should include pertinent up-to date references for information cited in the text and any other references related to the subject matter.

## 2.3 Outer Container Label Requirements

The **manufacturer** should refer to Section 2.2 - Requirement for a Package Insert of this guideline for a complete description of the abbreviated requirements indicated below.

### 2.3.1 Section 21(1)(a) - Name of the IVDD

The name of the IVDD must be included on the **outer container**.

### 2.3.2 Section 21(1)(b) - Name and address of the manufacturer

The name and address of the **manufacturer** must be included on the **outer container**.

### 2.3.3 Section 21(1)(c) - Identifier

The **identifier** or catalogue number of the IVDD must be included on the **outer container**.

### 2.3.4 Section 21(1)(d) - Lot or Batch Number

The **lot number** is required for 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 **lot number** should permit tracing the identity of the individual units.

### 2.3.5 Section 21(1)(e) - Contents

If the contents are not readily apparent, the **outer container** should include a list of the container's contents including quantities, volumes, and number of tests. 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. The information will also allow the user to select a size suitable for their purposes. Units should be expressed in metric or SI Units (International System of Units).

### 2.3.6 Section 21(1)(g) - Expiration date

The expiration date is based upon the component of the IVDD having the shortest projected useful life. The expiration date must be based on the results of studies which demonstrate that the device will perform as intended and will meet its specifications until that date. The date should be expressed in the internationally accepted format (ISO 8601

Data Elements and Interchange Formats-Information Exchange-Representation of Dates and Times): year (in four digits), month (in two digits), and day (in two digits). The separator for the three portions of the date should be a hyphen (-).

Expiration dates are required for the unopened IVDD or its components (e.g., reagents, calibrators, and quality control materials) and for the opened IVDD or its components if different from the unopened IVDD.

### 2.3.7 Section 21(1)(h) - Intended use

An abbreviated **intended use** statement is appropriate, for example:

**A qualitative test for the detection of antibodies to Human Immunodeficiency Virus Types I and II (HIV-1/HIV-2) in human serum or plasma. Not for donor screening.**

**Note:** Class IV IVDDs not intended for donor screening must indicate “**Not for donor screening**” on the immediate container label and package insert.

### 2.3.8 Section 21(1)(i) - Warnings and precautions

**Warnings** or **precautions** for users appropriate to the IVDD, including the statement “**For In Vitro Diagnostic Use**” for all IVDDs, and “**Sterile**”, if the **manufacturer** intends the kit to be sold in a sterile condition.

For IVDDs containing potentially infectious agents, whether inactivated or not, indicate a statement to the effect:

**Handle all the reagents as though capable of transmitting infection.**

### 2.3.9 Section 21(1)(j) - Storage and handling instructions

The **outer container** must include storage and handling instructions, including any special storage conditions applicable to the IVDD.

### 2.3.10 Specific operating instructions

The specific operating instructions should be included on the **outer container** where applicable.

## 2.4 Immediate Container Label Requirements

If the **immediate container** is the **outer container** (i.e. the **immediate container** is the packaging used at the point-of-sale) refer to Section 2.3 - Outer Container Label Requirements. The **manufacturer** should refer to Section 2.2 - Requirements for Package Insert for a complete description of the abbreviated requirements indicated below.

### 2.4.1 Section 21(1)(a) - Name of the IVDD and component(s)

For components to be used within a single kit indicate the name of the component and the name of the IVDD. For a multipurpose component which can be used with a number of kits, the name of the component should be sufficient.

### 2.4.2 Section 21(1)(b) - Name and address of the manufacturer

The name and address of the **manufacturer** is required on the **immediate container label**.

### 2.4.3 Section 21(1)(c) - Identifier

The **identifier** or catalogue number of the device and components, where applicable.

### 2.4.4 Section 21(1)(d) - Lot or batch number

The lot number is required in order to determine the complete manufacturing history of the product. It is standard convention for most IVDD reagents and **test kits** to indicate a lot number.

### 2.4.5 Section 21(1)(g) - Expiration date

Expiration date is based on the stability of the individual component in both its unopened and opened state.

### 2.4.6 Section 21(1)(i) - Contents

Quantity, proportion or concentration of each reactive ingredient; and for a reagent derived from a biological material, the source and a measure of its activity.

If more than a single determination may be performed using the product, any statement of the number of tests should be consistent with instructions for use and amount of material provided.

### 2.4.7 Section 21(1)(i) - Warnings and precautions

Indicate **warnings and precautions** appropriate to the component, including the statement “**For In Vitro Diagnostic Use**” for all reagents, and “**Sterile**”, if the **manufacturer** intends the reagent to be sold in a sterile condition.

For reagents containing potentially infectious agents, whether inactivated or not, indicate a statement to the effect:

**Handle the reagent as though capable of transmitting infection.**

### 2.4.8 Section 21(1)(j) - Storage and handling instructions

The storage and handling instructions should be adequate enough to ensure the stability of the product. Where applicable, include information such as conditions of temperature, light, humidity, and other pertinent factors.

For products requiring further manipulation, such as reconstitution and/or mixing before use and with storage in the original bottle, appropriate storage instructions should be provided for the reconstituted or mixed product.

## 3 LABELLING INFORMATION FOR IVDDs AS REQUIRED BY SECTION 21(2)

The information must be presented in a legible, prominent, and permanent (at a minimum the lifetime of the device) manner. The **label** information must be presented in a format most likely to be understood by the intended user.

### 3.1 Section 21(2) as it pertains to the electronic labelling (e-labelling)

As it pertains to the electronic labelling (e-labelling) of certain medical devices not sold to the general public Health Canada considers e-labelling to refer to the information required by section 21(1) of the Regulations that would ordinarily be found in the **directions for use**. The **directions for use** may include an operator’s manual or user’s manual.

For devices that are not sold to the general public, this information may be provided as downloadable from the internet and/ or on electronic data storage devices (e.g., compact disc, digital video disc, or USB flash drive). The electronic **label** or internet web address must accompany the device at the time of sale and/or delivery and be displayed in a manner that alerts the user to its purpose. The information provided electronically should be easily navigable. **Manufacturers** should ensure that the electronic **label** is identical in content to the paper format (where applicable).

### 3.2 Use of symbols on small containers

Health Canada recognizes the use of symbols can facilitate the inclusion of all relevant information on labels that due to their size cannot accommodate the full text. The use of internationally recognized symbols is acceptable as long as a glossary of terms associated with the symbols is provided with the accompanying labelling (e.g. **package insert** or **directions for use**) to explain the meaning of these symbols.

## 4 LABELLING FOR IVDDs CONTAINING EXPLOSIVE OR CORROSIVE MATERIALS OR COMPONENTS

In addition to the requirements referred to in Section 21 of the Regulations, an IVDD containing explosive or corrosive 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; and,
- the **precautions** that should be taken during handling, storage or disposal of the device in order to avoid an explosion or hazard to the operator or patient.

## 5 SPECIAL CONSIDERATIONS FOR BLOOD GLUCOSE MONITORING SYSTEMS

A blood glucose monitoring system may consist of a blood glucose meter, lancing device, controls and test strips. Additional information on the requirements for these products may be found in the Health Canada document *Notice: New Requirements for Medical Device Licence Applications for Lancing Devices and Blood Glucose Monitoring Systems*. The following requirements for the labelling of these products ensure the safety of the end user.

The following information must be included in the **intended use section** of the **package insert**:

- If applicable, alternate sites that may be used
- If the meter is to be used for multiple users or a single user
- Not for the diagnosis of diabetes.
- If it is intended for testing neonate samples or not.
- If the meter is to be used for self-testing and for professional use on a single patient the **intended use** must indicate this.

The **package insert** must include specific cleaning and disinfection instructions for the meter and where applicable for the lancing device.

If the blood glucose meter system is for multiple patients use, the labelling must state to clean and disinfect the meter between patients, to change gloves between patients and to only use auto-disabling single use lancing devices.

The following **warnings and cautions** should be included on the **label**:

- Lancing devices to be used multiple times must have a clear **warning** that they are for single patient use and are not to be shared.
- If meter may be used by multiple users and a single user, separate catalogue numbers, distinct device names, and labelling materials must be provided for each of the meter systems

Finally, the Quick Reference Guide, if provided, must refer to the user manual for complete instructions.

## 6 LABELLING INFORMATION FOR IVDDS AS REQUIRED BY SECTION 23

Section 23 of the Regulations reflects the need to accommodate the two official languages set out in the *Official Languages Act* and ensures that devices sold in Canada are 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 in addition to which other languages are permitted. Section 23(2) recognizes that it may not be economically reasonable or necessary to supply the **directions for use** in both official languages at the time and point of sale for every device. It should be noted that the **directions for use** must be readily available in the other official language at the request of the purchaser.

Devices sold to the general public at a self-service display are a special case. Self-service implies the absence of a “learned intermediary” such as a health care professional, to assist the user in the safe and effective use of the device. Self-service also implies sale in a variety of ways, for example, by catalogue mail order and via the Internet. In such cases, the **directions for use** must be supplied in both official languages at the time of purchase.

## 7 BIBLIOGRAPHY

Food and Drugs Act. R.S. c. F-27, S.1.

Medical Devices Regulations, Chapter 871

21 CFR Food and Drugs Parts 800 to 1299.

Guidance for the Labelling of Medical Devices: Sections 21 to 23 of the Medical Devices Regulations.

21 CFR Food and Drugs Part 660.

ISO 18113-1 First edition 2009-12-15 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements.

ISO 18113-2 First edition 2009-12-15 *In vitro* diagnostic medical devices-Information supplied by the manufacturer (labelling) - Part 2: *In vitro* diagnostic reagents for professional use.

Health Canada Notice: New Requirements for Medical Device Licence Applications for Lancing Devices and Blood Glucose Monitoring Systems ([http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md\\_notice\\_gluco\\_im\\_avis\\_glyco-eng.php](http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_notice_gluco_im_avis_glyco-eng.php))