European Diagnostic Manufacturers Association

"EDMA SYMBOLS FOR IVD REAGENTS AND COMPONENTS"

Revision, October 2009.

Introduction

In Europe, the necessity to translate the information provided on the labels in several languages creates the need for manufacturers to use symbols. The use of symbols on the labels as an alternative to written language is referenced many times in the IVD Directive (98/79/EC):

- Article. 4.4, relating to labelling language, states *: "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 harmonised symbols or recognised codes or other measures".*

- Annex I B.8, relating to labelling issue, states :

  - 8.2 *"Where appropriate, the information to be supplied should take the form of symbols. Any symbol and identification colour used must conform to the harmonised standards. In areas for which no standards exist, the symbols and colour used must be described in the documentation supplied with the device".*
  - 8.4 *"The label must bear the following particulars, which may take the form of symbols, as appropriate".*

A number of symbols that may be used for labelling in-vitro diagnostic medical devices (IVDs) have already been developed (or are described) in European Standards (e.g. EN 980) and International Standards (e.g. ISO 7000, ISO 15223-1).

These symbols are illustrated in the EDMA Guidance "IVD Symbols".

Only symbols listed in EN 980:2008 (published in the O.J.E.U. on 23rd July 2008) can be considered "harmonised" symbols at European level, so giving presumption of conformity with the relevant Essential Requirements of the three E.U. Directives on Medical Devices. This means that their meaning has not to be explained in the Instructions for Use of the device.

Action is in progress for the merging of EN 980 and ISO 15223-1 into a single symbol standard to be used internationally by the medical devices industry.

Unfortunately, because of strict conventional rules (both at CEN and ISO level), it is not always feasible to transform a specific wording into an acceptable symbol. Therefore, the essential need of IVD manufacturers in Europe to use symbols on the small size labels of the IVD reagents, cannot be met by the current development of international standards.

EDMA has therefore decided to propose to the IVD manufacturers a number of Industry "symbols" (developed by the EDMA Labelling Task Force) intended to be adopted by IVD manufacturers in the labels of IVD reagents/components placed on the European market.

Please note that the situation in the rest of the world is quite different from the European situation. Therefore this Guidance only applies to the European market.

Clearly, the meaning of such symbols will have to be explained in the Instructions for Use.

EDMA Symbols

It can be expected that these "EDMA Symbols" will be very useful for IVD labelling, particularly when widely adopted by IVD manufacturers in Europe.

They should also help to prevent the creation and use of different home-made symbols by individual manufacturers for the same concepts.

The “EDMA symbols” listed in this guidance are for what are seen as commonly used reagent/component names. This list is not exhaustive. It is intended that this list be extended with new “EDMA symbols” as and when required.

For the addition of new “EDMA symbols” in the list, IVD manufacturers are requested to contact EDMA.

Requests and proposals for new symbols will be reviewed according to the principles described below. Review and eventual modification of the "EDMA symbols" will be the responsibility of the EDMA Labelling Task Force. Updated versions of this guidance will be available on the EDMA Web site.

Although the intention is to accommodate most requests, situations may arise where some manufacturers may have some particularly unique component names, for which it will not be possible to include them in such a guideline.

Also in these particular situations, in an effort to maximize consistency in the use of symbols for the labeling of IVD products, manufacturers wishing to develop symbols themselves are kindly requested to follow some basic principles that are described below.

Basic principles for developing “EDMA Symbols”

- Take the common root for the reagent/component in different European languages (or the English name if no common root) and make an abbreviation; these should preferably be not longer than 5 letters.
- The abbreviation should be checked so as not to have a meaning in any known language.
- Put the abbreviation in a box.
- Use only capital letters, except where convention dictates otherwise (for example Antibody: Ab, Antigen: Ag)
- Use formulae for chemical substances (for example: H_2SO_4 Sulphuric Acid, H_2O Water, NaOH Sodium Hydroxide).
- Always state SI-Units, when using any units (e.g. mol/L).
- Any additional information that further qualifies a component can be added in a second or third box linked with the previous box (es). **Examples are concentration (1x, 10x, 25x, etc.) or** a substance contained in the reagent/component (e.g. TMB etc.).
- In case of radioactive reagents, the isotope used should be added in a second box, e.g.:

Ag	^{125}I

⇨ **Note:** The attached table defines the EDMA symbols for a particular wording. The table also provides some examples of the use of EDMA symbols (which is not limited to the examples provided).

I. REAGENTS / COMPONENTS

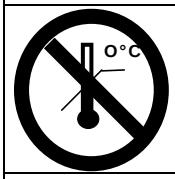
"EDMA SYMBOL"	FOR	EXAMPLES for use	FOR
REAG	Reagent	REAG A	Reagent A
		REAG B	Reagent B
DIL	Diluent	DIL SPE	Specimen Diluent (or Sample Diluent)
		DIL AS	Assay Diluent
BUF	Buffer	BUF WASH	Wash Buffer
		BUF WASH 10x	Wash Buffer Concentration: 10x
		BUF A 25x	Buffer A Concentration: 25x
SOLV	Solvent	SOLV XX	Solvent XX
		SOLV XX 5x	Solvent XX Concentration: 5x
Ag	Antigen		
Ab	Antibody (or Antiserum)	Ab IgM	Anti IgM
CONJ	Conjugate	CONJ EN	Enzyme Conjugate
SUBS	Substrate	SUBS TMB	Substrate TMB
SOLN	Solution	SOLN TMB	Solution TMB
		SOLN TMB 2x	Solution TMB Concentration: 2x

"EDMA SYMBOL"	FOR	EXAMPLES for use	FOR
		SOLN STOP	Stopping solution
		SOLN DYE	Solution Dye
		SOLN CLEAN	Cleaning Solution
SORB	Solid Phase (or Sorbent)		
CAL	Calibrator NB: The term "Calibrator" should be used in preference to "Standard"	CAL 1 CAL L CAL H	Calibrator 1 Calibrator Low Calibrator High

II. CHEMICAL SOLUTIONS

"EDMA SYMBOL"	FOR	EXAMPLES for use	FOR
H_2SO_4	Sulphuric Acid	H_2SO_4 0.5 M	Sulphuric Acid 0.5 mol/L
H_2O	Water	H_2O RO H_2O DIST H_2O SQ	RO : Reversed Osmose Water DIST: Distilled Water SQ : Ultra Pure Water

III. OTHERS

"EDMA SYMBOL"	FOR	EXAMPLES for use	FOR
CONT	**Contents (or contains)**	CONT | NaN_3	**Contains Sodium Azide**
RCNS	**Reconstitute**	RCNS | X mL	**Reconstitute with**
	**Do not freeze**	**Note:** This EDMA symbol is derived from ISO 7000: 0533 "Upper limit of temperature"	
	**Waste container**	**Note:** This EDMA symbol is derived from ISO 7000: 028 "Filling"	
	**Vacuum**	**Note:** This symbol is described in IEC 60601-218:103 for "Suction"	
	**Store in the dark**	**Note:** Not to be confused with ISO 7000:0624 for "keep away from sunlight"	
 or : MM,DD	**Shelf life, following the first opening**	**Note:** This EDMA symbol is derived from a symbol created for use in Cosmetics. The symbol was and its use is defined in EU Commission Guidance 04/ENT/COS/28 "Labelling of Product Durability: 'Period of Time After Opening'". This period is related to the shelf life, following the first opening of the primary container. This symbol shall be accompanied by a date, to indicate that the device should not be used after the end of the month or day shown. The date shall be expressed as given in ISO 8601, as two digits. The date could be months, or days and it shall be located adjacent to, **or** "inside" the symbol (see both possibilities in the example).	

"EDMA SYMBOL"	FOR	EXAMPLES for use	FOR
ORIG | Species **Note:** If other animal species are needed please make sure that you do not use the official country abbreviations according to ISO 3166 (1993) to avoid confusion between country of origin and animal species (e.g. "DK" for Denmark, "DON" for Donkey).	Origin	ORIG | SHP	Origin: sheep
		ORIG | GT	Origin: goat
		ORIG | RAB	Origin: rabbit
		ORIG | MOU	Origin: mouse
		ORIG | DON	Origin: donkey
		ORIG | GP	Origin: guinea pig
		ORIG | PIG	Origin: pig
		ORIG | HUM	Origin: human
		ORIG | HOS	Origin: horse

NOTE: CONVENTION

Please do not forget that some rules usually applied by convention can also be useful, as for example:

...	Range (e.g. 1mL...5mL)		

References:

EDMA Guidance:" IVD Symbols for reagents and instruments"

EDMA Guidance: "Labels of IVD reagents"

EDMA Guidance: "User Awareness of Symbols"

The EDMA Labelling Task Force