

New IVD symbols for compliance with the IVDR

By 26 May 2022, IVD devices will transition to the new IVD Regulation EU 2017/746. This regulation will require devices intended for self-testing, devices intended for near-patient testing and certain rapid tests (not for self-testing and not for near patient testing) to state these facts on their labels.

The use of symbols on the label is an effective way of compliance and it is permitted by the IVDR. By including these symbols proposed by MedTech Europe, the intended user of your device will be clear. It will also remove the necessity to translate that indication into all EU languages.

* Note that these symbols are not yet part of an ISO standard.

The new IVD Symbols:

1) For self-testing



WHY YOU SHOULD ADD THIS SYMBOL TO YOUR PRODUCT LABEL

This symbol indicates that the device is a self-test in vitro diagnostic device. This means that a lay person can use it even without formal healthcare or medical experience. A common example of this test are pregnancy tests or an ovulation tests, that can be purchased from a pharmacy or a drugstore.

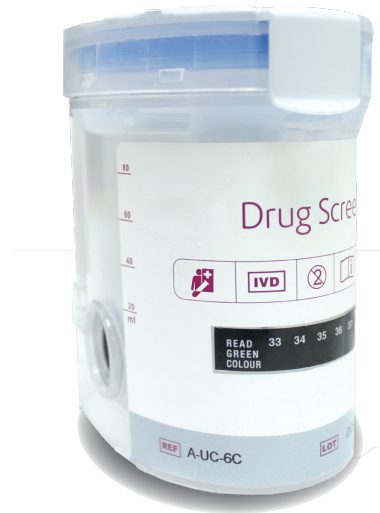
2) Not for self-testing



WHY YOU SHOULD ADD THIS SYMBOL TO YOUR PRODUCT LABEL

This symbol indicates that the device (applies to rapid tests only) is not intended for self-testing. A rapid test with this symbol should only be used by a trained medical or a lab professional in an appropriate setting. Manufacturers may choose to add this symbol next to the "for near patient testing" symbol to emphasise the intended user of the test. Examples: a test for detection of Streptococcal antigen from throat or a test for determining allergies from a blood sample.

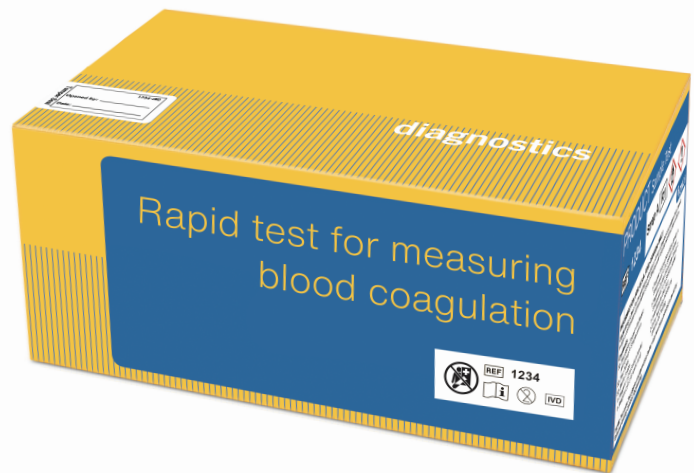
3) For near patient testing



WHY YOU SHOULD ADD THIS SYMBOL TO YOUR PRODUCT LABEL

This symbol indicates that the device is only to be used in a near patient setting by a health professional. Typically, such tests are used in ambulances, emergency units, patient homes, or workplaces etc. A 'near patient test' is not to be used by the patient themselves. For example, urine tests – rapid screening for drugs – fall into this category.

4) Not for near patient testing



WHY YOU SHOULD ADD THIS SYMBOL TO YOUR PRODUCT LABEL

This symbol indicates that the device (applies to rapid tests only) is not intended for near-patient testing. A rapid test with this symbol on its label should only be used by a trained laboratory professional in a laboratory. This symbol should be put on rapid tests that are intended for exclusive use in a laboratory environment. Examples: Handheld drug rapid test, Rapid test for measuring blood coagulation and other rapid tests for use in the laboratory only.

Should the manufacturer wish to include additional indication (for instance in forms of multiple symbols) to reinforce a particular intended user/environment they will base such decision on their risk management.