

Advisory Notice for Customers - 14/07/2016

New Labelling and Instructions for Use

Changes

From August 1st 2016, all AusDiagnostics products will come with new labelling and Instructions for Use (IFUs).

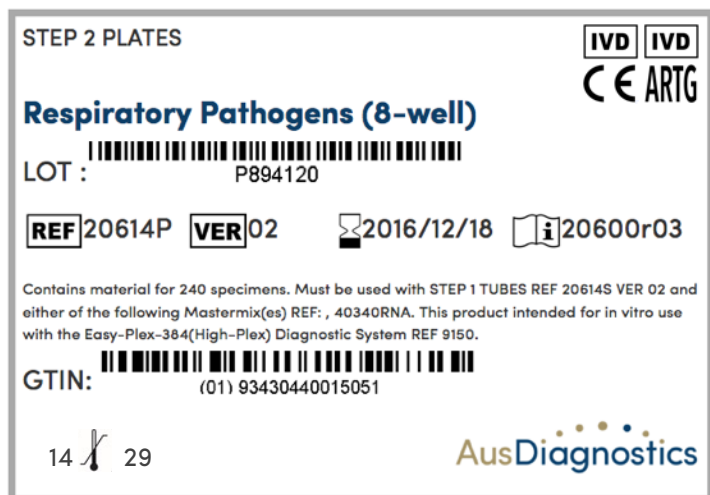
We have carried out a complete overhaul of our labelling system in order to improve labelling uniformity, compliance with the IVD Directive 98/79/EC and applicable standards, and apply a brand re-design to our products. AusDiagnostics IVD product IFUs have also been updated to comply with IVDD and some clarification has been given in terms of the risks associated with using the products.

The storage conditions and intended use of the products have not changed.

Labels

The labels on the packaging of products will now contain much more information. Below is an example of what a new Step 2 Plate outer box label will look like with some changes outlined:

- The GTIN and IVD statement (where relevant)
- CE and ARTG symbols are displayed for applicable products
- Internationally recognised symbols
- The catalogue and version numbers are more clearly identified along with the document ID of the IFU for that product.
- Expiry date and storage conditions stated
- All other products that are to be used in conjunction with the product are specified
- Our new logo















Instructions for Use (IFUs)

The format of, and the information contained within the IFUs has been updated. Core products (as displayed on our website, <http://www.ausdiagnostics.com>) now have individual IFUs for each product.

Research Use Only (RUO) products now have combined IFUs, grouped according to their product type. The formatting of the IFUs has been unified to ensure consistency and ease of use. Additional information for proper use, and references to other relevant IFUs have now been included.








Symbols

We have implemented the use of internationally recognised symbols throughout the IFUs and on the labels. They are shown below along with their meaning:

	Manufacturer		Indicates a positive control
	Authorised Representative in the European Union		Expiry Date
	Catalogue Number		Do not re-use
	Version Number		Storage Temperature
LOT	Lot/Batch Number		Please consult the identified Instructions for Use before use
GTIN	Global Trade Identification Number	IFU	Instructions for Use
	Indicates that the relevant product is intended for <i>in vitro</i> diagnostic use in Australia and been entered in the Australian Register of Therapeutic Goods (ARTG)	WARNING	Indicates a statement that alerts users about a situation that if not avoided, could result in hazards or other serious adverse consequences from the use of the device
	Indicates that the relevant product is intended for <i>in vitro</i> diagnostic use in the European Economic Area. This product complies with IVD Directive 98/79/EC	IMPORTANT	Indicates a statement that alerts the user to special care or special activities necessary for the safe and effective use of the device
	WARNING. Please read the indicated section carefully	Note	Indicates additional information

AusDiagnostic Symbols

In addition to the above symbols, we have also implemented a set of symbols for some of our products.

	Blue capped Water Tube		Dilution Plate
	Green capped Oil Tube		Bleach container
	Yellow capped Step 1 Mastermix		Tip disposal bag
	Red capped Step 2 Mastermix		

Further Information

If you would like more information on any of the above changes, please do not hesitate to contact us.

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