

### ADVIA® Chemistry Systems

#### ADVIA Chemistry Lactate Dehydrogenase (LDLP and LDPL) Update to Instructions For Use

Our records indicate that your facility may have received the following product:

**Table 1. Affected Product(s)**

Assay	Test Code	Reference Number	Siemens Material Number (SMN)	Lot Number
ADVIA Chemistry Lactate Dehydrogenase L-P	LDLP	07502115 (40 mL) 03029628 (70 mL)	10309501(40mL) 10341128 (70 mL)	All
ADVIA Chemistry Lactate Dehydrogenase P-L	LDPL	07502999 (40 mL) 03030863 (70 mL)	10309502(40 mL) 10341129(70 mL)	All

#### Reason for Customer Notification

Siemens Healthcare Diagnostics is providing an update to all ADVIA Chemistry Systems Lactate Dehydrogenase L-P (LDLP) and Lactate Dehydrogenase P-L (LDPL) assay Instructions For Use (IFUs). The current ADVIA Chemistry Systems Lactate Dehydrogenase IFUs intended use section contains the following statements which will be removed;

ADVIA Chemistry LDLP: They may also be used to monitor cancer therapy.

ADVIA Chemistry LDPL: They may also be used to monitor extensive cancer and cancer therapy.

The revised IFU intended use for both assays are listed below.

ADVIA Chemistry LDLP: For in vitro diagnostic use in the quantitative determination of lactate dehydrogenase activity in human serum and plasma on ADVIA Chemistry systems. Such measurements are used mainly in the diagnosis and treatment of myocardial and pulmonary infarction.

ADVIA Chemistry LDPL: For in vitro diagnostic use in the quantitative determination of lactate dehydrogenase activity in human serum and plasma on ADVIA Chemistry systems. Such measurements are used mainly in the diagnosis and treatment of myocardial and pulmonary infarction.

## **Risk to Health**

The risk to health as a result of the revisions described in this letter is negligible.

## **Actions to be Taken by the Customer**

This notification constitutes the IFU revisions described above and supersedes the current version of IFU(s). Siemens recommends that you refer to the revised intended use statement in order to use this assay as defined.

Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

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