SIEMENS

Urgent Field Safety Notice

CHC17-02.A.OUS

February 2017

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.

511 Benedict Ave.
Tarrytown, NY 10591
www.siemens.com/diagnostics

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.

ADVIA is a trademark of Siemens Healthcare Diagnostics.

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FIELD CORRECTION EFFECTIVENESS CHECK

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

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice CHC17-02.A.OUS dated February, 2017 regarding ADVIA Chemistry Lactate Dehydrogenase (LDLP and LDPL) Update to Instructions For Use. Please read the question and indicate the appropriate answer. Fax this completed form to Siemens Healthcare Diagnostics at the fax number provided at the bottom of this page.

1. I have read and understood the Urgent Field Safety Notice instructions provided in this letter. Yes ☐ No ☐

Name of person completing questionnaire:

Title:

Institution:

Date:

Signature:

Company Stamp:

Please fax this completed form to the Customer Care Center at (65) 6366-3376. If you have any questions, contact your local Siemens technical support representative.

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