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DX- Report Form
Field Safety Corrective Action

In accordance with the Medical Devices Vigilance System (MEDDEV 2.12/1 rev 6)

1 Administrative information

Destination Name of National Competent Authority MHRA-Medicines and Healthcare Products Regulatory Agency Address of National Competent Authority **151 Buckingham Palace Road** **London** **SW1W 9SZ** **United Kingdom**	**Stamp box for the Competent Authority (~ 60 x 40 mm)**

Date of this report
21st May 2012 (Initial Report)

Reference number assigned by the manufacturer
CHC 12-01

Incident reference number and name of the co-ordinating NCA -Competent Authority (if applicable):

Identify to what other Competent Authorities this report was **also** sent

2 Information on submitter of the report

Status of submitter

- ☐ Manufacturer
- ☒ Authorised Representative within EEA
- ☐ Others: (identify the role):

3 Manufacturer information

Manufacturer name
Siemens Healthcare Diagnostics Inc

Manufacturer's contact person
Mindy Losapio

Address
511 Benedict Avenue

Postal code 10591	City Tarrytown, NY
Phone +1 (914) 524-2312	Fax
E-mail Mindy.losapio@siemens.com	Country USA

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4 Authorised Representative information

Name of the Authorised Representative
Siemens Healthcare Diagnostics Limited

The Authorised Representative's contact person
Anthony Walsh

Address
Sir William Siemens Square

Postal code	City
GU16 8QD	Frimley, Camberley
Phone	Fax
+ 44 (0) 1908 487600	+ 44 (0) 1908 487601
E-mail	Country
Anthony.walsh@siemens.com	UK

5 National contact point information

National contact point name

Name of the contact person

Address

Postal code	City
Phone	Fax
E-mail	Country

6 Medical device information

Class

- ☐ AIMD Active implant
- ☐ MDD Class III
- ☐ MDD Class IIb
- ☐ MDD Class IIa
- ☐ MDD Class I
- ☐ IVD Annex II List A
- ☐ IVD Annex II List B
- ☐ IVD Devices for self-testing
- ☒ IVD General

Nomenclature system (preferable GMDN)
GMDN

Nomenclature code
33165 (ALPAMP)
33165 (ALPDEA)

Nomenclature text
Alkaline Phosphatase - Total

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Commercial name/ brand name / make ADVIA Chemistry Systems Alkaline Phosphatase (ALPAMP) / ADVIA Chemistry Systems Alkaline Phosphatase (ALPDEA)
Model number N/A
Serial number(s) or lot/batch number(s) ALPAMP lot # 222982 ALPDEA lot # 222987
Software version number (if applicable) N/A
Manufacturing date/ Expiry date (if applicable) ALPAMP lot 222982 2011-07-21/2012-08-30 *ALPDEA lot 222987 2011-07-22/2012-08-31*
Accessories/ associated device (if applicable) N/A
Notified Body (NB) ID-number N/A

7 Description of FSCA

Background information and reason for the FSCA, Manufacturer advises many customers observing frequent result flags (u, U, or ////) on some ALPAMP (lot 222982) and ALPDEA (lot 222987) reagent wedges, which in some cases can impede reporting of results (see below). No QC shifts or discrepant patient results observed. Note: "u" flag indicates Abnormal high reaction absorbance exceeding the Blank (u) limit. – results can be reported "U" flag indicates Abnormal high reaction absorbance exceeding the sample (u) limit. – results can be reported. //// flag indicates calculation error – no result is calculated. As the kit ages, the incidence of //// flags is increasing.
Description and justification of the action (corrective/preventive) All affected customers are being notified of the issue by an Urgent Field Safety Notice advising them to discard the affected kits. Product Hold initiated on 23rd February 2012.
Advice on actions to be taken by the distributor and the user. Urgent Field Safety Notice will be issued to affected customers through the local country organizations
Attached please find ☐ Field Safety Notice (FSN) in English ☐ FSN in national language ☐ Others (please specify) …
Time schedule for the implementation of the different actions FSCA to be issued to Siemens country RAQS organisations on 21st May 2012, to then be issued to affected customers in their local countries.

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These countries within the EEA and Switzerland are affected by this FSCA:

- within the EEA and Switzerland:

☒ AT ☒ BE ☐ BU ☒ CH ☒ CY ☒ CZ ☒ DE ☒ DK ☒ EE ☒ ES ☒ FI ☒ FR ☒ GB ☒ GR ☐ HU ☐ IE
☐ IS ☒ IT ☐ LI ☒ LT ☒ LU ☒ LV ☐ MT ☒ NL ☒ NO ☒ PL ☒ PT ☐ RO ☒ SE ☒ SI ☒ SK

- Candidate Countries ☒ CR ☒ TR

☐ ALL EEA -, Candidate Countries and Switzerland

- others:
Serbia, Vatican City

These countries outside the EEA and Switzerland are affected by this FSCA:

Algeria, Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Egypt, India, Indonesia, Israel, South Korea, Libya, Malaysia, Mexico, Morocco, New Zealand, Russian Federation, Singapore, South Africa, Thailand, Tunisia, United States of America, Vietnam

8 Comments

I affirm that the information given above is correct to the best of my knowledge.

T Mitchell

pp.

Anthony Walsh	*Frimley, Camberley*	*21st May 2012*
Name	City	Date

Submission of this report does not, in itself, represent a conclusion by the manufacturer and / or authorized representative or the National Competent Authority that the content of this report is complete or accurate, that the medical device(s) listed failed in any manner and/or that the medical device(s) caused or contributed to the alleged death or deterioration in the state of the health of any person.