QUALITY ASSURANCE
545 South Ewing Avenue, Saint Louis, MO 63103 USA
Tel: (800) 521-8956 (314) 771-5765 Fax: (800) 325-5052 (314) 286-7829
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V-05/07

Report Form
Field Safety Corrective Action

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 5)

1. Administrative information **Destination**
Name of national competent authority (NCA) Ministry of Health
Address of national competent authority Ministry of Labour, Health and Social Affairs Department of Innovation Directorate General of Medicine and Medical Devices Head of Unit 4 Via Giorgio Ribotta 5 00144 Roma Italy
Date of this report October 9, 2009
Reference number assigned by the manufacturer 2009-01
Incidence reference number and name of the co-ordinating national competent authority (if applicable) Vk_20090818_01: Swissmedic. Revised: Vk_20090930_01, Swissmedic
Identify to what other national competent authorities this report was also sent Competent authorities in the following countries: AT, BE, CH, CY, CZ, DE, DK, ES, FI, FR, GB, HU, IE, IS, IT, LI, LU, LV, MT, NL, NO, PL, PT, SE, SI, UK,

2 Information on submitter of the report
Status of submitter X Manufacturer ☐ Authorised representative within EEA ☐ Others (identify the role):

3 Manufacturer information	
Manufacturer name Sigma-Aldrich	
Manufacturer's contact person Marilyn L. Baltz	
Address 545 South Ewing Avenue	
Postal code 63103	City St. Louis/MO
Phone 314-286-6672	Fax 314-286-7829
E-mail mbaltz@sial.com	Country USA

4 Authorised representative information
Name of the authorised representative AR-MED, a Division of Quintiles, Ltd.
The authorised representative's contact person

Phil Johnson	
Address Ringside, 79 High Street	
Postal code RG 12 1DZ	City Bracknell/Berkshire
Phone +44(0) 1344 601278	Fax +44(0) 1344 601001
E-mail Phil.Johnson@quintiles.com	Country UK

5 National contact point information	
National contact point name Sigma-Aldrich	
Name of the contact person Marco Savazzi	
Address Via Gallarate, 154	
Postal code 20151	City Milano
Phone 39 02 33417 310	Fax 39 02 38010 737
E-mail itclient@sial.com	Country Italy

6 Medical device information

Class

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

Nomenclature system (preferable GMDN)
EDMA System

Nomenclature code
EDMA code: 13.90.90.90.00

Nomenclature text
Other Haematology

Commercial name/brand name/make
Histopaque-1077

Model number
1077-1

Serial number(s) and/or lot/batch number(s)
038K6170

Software version number (if applicable)
na

Manufacturing date/expiry date (if applicable)
Expiry date 2011-04

Accessories/associated device (if applicable)
na

Notified body (NB) ID- number
na

7 Description of FSCA

Background information and reason for the FSCA
Sigma-Aldrich has been made aware of bacterial contamination (Pseudomonas mendocina) in the

affected device. The device is a cell separation media and in the reported instance was used to isolate stem cells from bone marrow specimens. The isolated cells were placed into cell culture for further diagnostic testing. Contamination was evident after 14 days of culture. The laboratory confirmed the source of the contamination was the device.

Samples had to be redrawn from eight patients and the stem cells again isolated and cultured. The potential hazard to the patient was the collection of a repeat bone marrow specimen. Additionally, there would have been a delay in the report of the subsequent diagnostic test result as the cells had to be isolated and cultured. There is no direct contact of the device with the patient.

Description and justification of the action (corrective/preventive)

1. Global Sigma-Aldrich inventory of the affected lot number of the device was blocked from further distribution.
2. The complaint of bacterial contamination was confirmed in 6 out of 8 bottles when testing was performed in St. Louis (colony count and identification not performed).
3. 200 bottles of the device are currently being tested by an external contract -testing laboratory for colony count and identification of organism(s).
4. Root cause analysis of the incident is ongoing. A change analysis of manufactured lots will be performed: two lots manufactured prior to the affected lot, the lot of the affected device and two lots of devices manufactured after the affected lot. An Ishikawa Diagram will be used to explore and display opinion about sources of variation in the process (Fishbone Diagram).
5. Global Sigma-Aldrich inventory of the affected lot number will be disposed of. Recipients of the product will be instructed to dispose of the product as Sigma-Aldrich confirmed the presence of bacterial contamination.

Advice on actions to be taken by the distributor and the user

1.Dispose of device following Sigma-Aldrich Material Safety Data Sheet instructions provided with the device (available in local language on-line at www.sigmaaldrich.com)

Section 13 Disposal Considerations

APPROPRIATE METHOD OF DISPOSAL OF SUBSTANCE OR PREPARATION

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

2. Recipient will provide to manufacturer the name and address of their institution with the number of devices on hand the date the FSN was received and the number of devices disposed with the date of disposal.

Field Safety Notice (FSN) in English

X FSN in national language. The FSN will be in national language when sent to all competent authorities and also to recipients of the product.

☐ Others (please specify):

Time schedule for the implementation of the different actions

1. Global Sigma-Aldrich inventory of affected lot number blocked from further distribution: August 21, 2009
2. Confirmation of bacterial contamination in 6/8 bottles by St. Louis. September 8, 2008
3. 200 bottles of the device are being tested by an external contract-testing laboratory for colony count and identification of the organism(s). October 2, 2009.
4. Root cause analysis completion. September 21, 2009.
5. Corrective/preventive action. To be determined pending root cause analysis.
6. Destruction of global inventory in Sigma-Aldrich's custody: September 18, 2009.

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

Within EEA and Switzerland:

X AT	XBE	BG	X CH	X CY	X CZ	XDE	X DK	☐ EE	X ES
X FI	X FR	X GB	XGR	X HU	X IE	X IS	X IT	XLI	LT

XLU	X LV	XMT	X NL	X NO	XPL	X PT	☐ RO	XSE	XSI
☐SK									

Candidate Countries:

☐ HR ☐ TR

☐ All EEA, Candidate Countries and Switzerland

Others:

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

CA, USA, India, China, Korea, Mexico, Australia, Japan, Colombia, Hong Kong, Peru, Taiwan

8 Comments

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

.....
Signature

Marilyn L. Baltz	St. Louis, MO USA	October 9, 2009
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.

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Avviso urgente di sicurezza sul campo

Prodotto: **Sigma-Aldrich Histopaque® 1077-1**
Identificatore FSCA: **FSCA 2009-01**
Tipo di azione: **Distruzione del dispositivo**

Data: October 1, 2009

All'attenzione di:
Tutti i responsabili di laboratorio

Dettagli sui dispositivi interessati:
Nome del prodotto: Histopaque 1077-1
Numero del prodotto: 1077-1
N. di lotto: 038K6170

Descrizione del problema:
Sigma-Aldrich è stata informata di una contaminazione batterica (*Pseudomonas mendocina*) nel dispositivo interessato. Il dispositivo è un mezzo di separazione delle cellule e nel caso riferito è stato utilizzato per isolare cellule staminali da campioni di midollo osseo. Le cellule isolate sono state collocate in una coltura cellulare per ulteriori test diagnostici. La contaminazione era evidente dopo 14 giorni di coltura. Il laboratorio ha confermato che la fonte della contaminazione era il dispositivo.

È stato necessario prelevare nuovamente i campioni da otto pazienti e isolare e coltivare nuovamente le cellule staminali. Il rischio potenziale per il paziente era la raccolta di un campione ripetuto di midollo osseo. Inoltre, vi sarebbe stato un ritardo nel referto diagnostico successivo in quanto è stato necessario isolare e coltivare le cellule. Non esiste alcun contatto diretto del dispositivo col paziente.

Azione da intraprendere da parte dell'utente:

- Smaltire il dispositivo seguendo le istruzioni del foglio dati relativo alla sicurezza dei materiali Sigma-Aldrich fornito assieme al dispositivo (disponibile online in lingua locale all'indirizzo www.sigmaaldrich.com)
  Sezione 13 Considerazioni sullo smaltimento
  METODO APPROPRIATO DI SMALTIMENTO DELLA SOSTANZA O DEL PREPARATO
  Per lo smaltimento di questo materiale, contattare un servizio professionale autorizzato allo smaltimento dei rifiuti. Dissolvere o mescolare il materiale con un solvente combustibile e bruciarlo in un inceneritore chimico dotato di un post-bruciatore e di un depuratore. Rispettare tutte le normative nazionali, regionali e locali.

- Completare le informazioni seguenti e inviare per fax o posta elettronica l'avviso completato di sicurezza sul campo al contatto Sigma-Aldrich riportato.

Nome di contatto del destinatario:

_____

Nome e indirizzo dell'istituzione:

_____

Numero di dispositivi disponibili alla data di ricezione dell'avviso di sicurezza sul campo (FSN):

_____

Numero di dispositivi smaltiti e data di smaltimento:

_____

Marilyn L. Baltz

Marilyn L. Baltz, Ph.D.
Responsabile QA
Sigma-Aldrich, St. Louis (USA)

CONTATTO:

Marco Savazzi
Via Gallarate, 154
Milano, 20151 Italy
Phone: 39 02 33417 310
Fax: 39 02 38010 737
Email: itclient@sail.com