SIEMENS

Urgent Field Safety Notice

10990963

July 2014

VERSANT HCV 2.0 Genotype Assay (LiPA)

Defective LiPA Substrate Vial Allows Reagent Leakage if the Vial is not Upright

Our records indicate that your facility has received the following product:

Table 1. Affected Product(s)

Assay	Test Code	Catalog Number	Siemens Material Number (SMN)	Lot Number
VERSANT HCV 2.0 Genotype Assay (LiPA)	N/A	06719382	10325052	238273 and 240475

Reason for Correction

Siemens Healthcare Diagnostics has become aware of a problem with the Substrate component. The vial containing the substrate is defective and the cap does not fit securely, allowing substrate reagent to leak out of the vial if it is not stored upright at all times. The leakage could present itself as an empty or underfilled substrate reagent. No evidence shows that this problem will impact the quality of any test results produced from this reagent. This issue has been investigated and confirmed by the manufacturer.

Risk to Health

A review of the MSDS indicates that mild irritation of the skin and irritation or injury to the eyes may occur. With minimal volume contained in this vial and with the use of personal protection in the laboratory the risk to health is negligible. A look back is not required as there is no impact on patient testing and there are no reports of operator injury.

Actions to be Taken by the Customer

- Please review this letter with your Medical Director.
- Review your inventory of these products to determine your laboratory's replacement needs and to provide information to Siemens for reporting to the authorities.
- Discontinue use of and discard the kit lots listed in Table 1.
- Complete and return the Field Correction Effectiveness Check/Product Replacement Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse events associated with the products listed in Table 1, immediately contact your local Siemens Customer Care Center or your local Siemens technical support representative.

DCR #: B40420, Eff. Date: 23 Jun 2014
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Please retain this letter with your laboratory records, and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation has caused. If you have any questions, please contact your Siemens Customer Care Center or your local Siemens technical support representative.

Siemens Healthcare Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591
www.siemens.com/diagnostics

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FIELD CORRECTION EFFECTIVENESS CHECK

Defective LiPA Substrate Vial Allows Reagent Leakage if the Vial is not Upright

This response form is to confirm receipt of the enclosed Siemens Healthcare Diagnostics Urgent Field Safety Notice 10990963 dated June 2014 regarding Defective LiPA Substrate Vial Allows Reagent Leakage if the Vial is not Upright. Please read each question and indicate the appropriate answer. Please return this completed form to Siemens Healthcare Diagnostics at the contact details 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 ☐
2. Do you now have any of the noted product on hand? Please check inventories before answering.	Yes ☐	No ☐
If the answer to the question above is yes, please complete the table below to indicate the quantity of affected product in your laboratory and replacement product required.	Date:	

Product Description Product SMN #/Lot #	**Quantity of Affected Product in inventory that has been discarded**	**Replacement Quantity Required**
VERSANT HCV 2.0 Genotype Assay (LiPA), 10325052, 238273 and 240475		

Name of person completing questionnaire:	
Title:	
Institution:	
Street:	
City:	Post Code:
Email:	Phone:
Strip Processor Serial Number:	

PLEASE FAX or EMAIL THIS COMPLETED FORM within 30 days of receipt to
FAX 0845 605 6800
EMAIL robert.davies@siemens.com

It is important that your organisation takes the actions detailed in the FSN and replies immediately using the FIELD CORRECTION EFFECTIVENESS CHECK attached to the FSN. Your organisations reply is evidence which Siemens Healthcare, and subsequently the MHRA, needs to monitor the progress of the FSN. Without your reply Siemens Healthcare Diagnostics cannot properly verify the completeness of the FSN and the MHRA may need to issue a Medical Device Alert.

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