
Urgent Field Safety Notice

Recall

concerning
EUROArray HPV, order no.: MN 2540-1005, lots: I240110AL, I240110BA; order no.: MN 2540-2005, lots: I240103AP, I240105AH, I240116AV, I240116BB, I240117AQ, I240118AI

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6 February 2024

From:
EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany
www.euroimmun.com

To:
Users and distributors

Identification of the medical/IVD products concerned:
EUROArray HPV, order no.: MN 2540-1005, lots: I240110AL, I240110BA; order no.: MN 2540-2005, lots: I240103AP, I240105AH, I240116AV, I240116BB, I240117AQ, I240118AI

Dear customers,

EUROIMMUN has initiated a field corrective action for the product specified above. This notification contains important information for your immediate attention.

Description of the problem and the determined cause:
A contamination was identified in the test kit component PCR Mix A HPV (green cap, ready for use) of the test kit lots mentioned above, which causes a DNA positive control signal for the negative control to be included in the analysis.
The section “Important notes on test procedure and safety“ in the instructions for use of the above-mentioned product contains the following note: “In order to identify any potential contamination, it is important to include negative controls in the sample extraction and also in the PCR.“
The respective test runs are invalid due to the signal caused by the negative control and the test results must not be used. Due to the need for repeat tests, test results may be delayed.
No health consequences for the patient are to be expected in the case of delayed findings as cervical cytology screening (smear cytology) is carried out in parallel, and a differential diagnostic clarification (colposcopy, biopsy) is required for the final diagnosis of cervical cancer.

Measures to be taken:
Please make sure that any remaining stocks of the above-mentioned lots are no longer used in your laboratory and are disposed of in accordance with local disposal regulations. To prove that you have read this safety information, please send the completed reply form to info@euroimmun.de immediately (**by 23 February 2024 at the latest**).

EUROIMMUN will replace the affected test kits free of charge. Please contact the product management for molecular genetic diagnostics (mdx-pm@euroimmun.de).

Information to be passed on:
This notice must be forwarded to all users and distributors of the above-mentioned test kit lots.

Thank you for your cooperation! We apologise for any inconvenience this may cause.

For further information, please do not hesitate to contact any of the following contact persons at EUROIMMUN.

Contact persons:

Product Management Molecular Genetic Diagnostics
E-Mail: mdx-pm@euroimmun.de

PRRC-V Immunobiochemical Tests
Dr. Christian Krüger
Tel.: +49 (0) 151 2261 7145
Fax: +49 (0) 451 2032 100
E-Mail: c.krueger@euroimmun.de

Signature / *Position PRRC-V*

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Please send back the customer reply as specified on the document!

2024-1

Field Safety Notice

Customer Reply Form

Mandatory fields are marked with *

1. Field Safety Notice (FSN) information	
FSN Reference number*	2024-1
FSN Date*	6 February 2024
Product/ Device name*	EUROArray HPV
Product Code(s)	MN 2540-1005; MN 2540-2005
Lot/Serial Number (s)	I240110AL, I240110BA; I240103AP, I240105AH, I240116AV, I240116BB, I240117AQ, I240118AI

2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Shipping address if different to above	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation				
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A		
☐	I performed all actions requested by the FSN.	Customer to complete or enter N/A		
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A		
Actions to affected devices/device-related components implemented:				
☐	I have returned affected devices/device-related components. Enter number returned and completion date.	Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		Qty:	Lot/Serial Number:	Date Returned (DD/MM/YY):
		N/A	Comments:	
☐	I have destroyed affected devices/device-related components. Enter number destroyed and completion date.	Qty:	Lot/Serial Number:	
		Qty:	Lot/Serial Number:	
		N/A	Comments:	

☐	I have updated/replaced the affected devices/device-related components/software. Enter number updated/replaced and completion date.	Qty:	Lot/Serial Number:
		Qty:	Lot/Serial Number:
		N/A	Comments:
☐	No affected devices/device-related components are available for return/destruction	Customer to complete or enter N/A	
☐	Other Action (Define):		

☐	I do not have any affected devices.	Customer to complete or enter N/A

☐	I have a query please contact me (e.g. need for replacement of the product).	Customer to enter contact details if different from above and brief description of query

Print Name*	
Signature*	
Date*	

4. Return acknowledgement to sender	
Email	info@euroimmun.de
Customer Helpline	Product recall 2024-1
Postal Address	Seekamp 31, 23560 Lübeck, Germany
Web Portal	www.euroimmun.de
Fax	+49-(0)-451-2032-100
Deadline for returning the customer reply form*	23 February 2024

Please send the completed Field Safety Notice Form immediately to:

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Fax: +49-(0)-451-2032-100
Email: info@euroimmun.de

Field Safety Notice

Distributor Reply Form

Mandatory fields are marked with *

1. Field Safety Notice (FSN) information	
FSN reference number*	2024-1
FSN date*	6 February 2024
Product / Device name*	EUROArray HPV
Product code(s)	MN 2540-1005; MN 2540-2005
Batch / Serial number (s)	I240110AL, I240110BA; I240103AP, I240105AH, I240116AV, I240116BB, I240117AQ, I240118AI

2. Distributor Details	
Company name*	
Address*	
Shipping address if different from above	
Contact name*	
Title or function	
Telephone number*	
Email*	

3. Return acknowledgement to Sender	
Email	info@euroimmun.de
Distributor helpline	Product recall 2024-1
Web portal	www.euroimmun.de
Deadline for returning the Distributor Reply Form*	23 February 2024

4. Distributors (Tick all that apply)		
☐	*I confirm the receipt, the reading and understanding of the Field Safety Notice.	Distributor to complete or enter N/A
☐	I have checked my stock and quarantined inventory	Number of affected kits not yet send to customers: In stock inventory: In quarantine:
☐	I have identified customers that received or may have received this device or software	
☐	I have attached the list of affected customers including the number of delivered affected devices per customer and the addresses of the customers	

☐	I have informed the identified customers of this FSN	Date of communication:
☐	I have received confirmation of reply from all identified customers	
☐	I have returned affected devices/device-related components *(Enter number of devices returned and completion date.)*	Add quantity, lot/serial number/date returned (for distributor stock and devices from customers)
☐	I have destroyed affected devices/device-related components *(Enter number of devices returned and completion date.)*	Add quantity, lot/serial number/date returned (for distributor stock and devices from customers)
☐	I have updated/replaced the affected devices/device-related components/software for all customers	
☐	Neither I nor any of my customers has any affected devices in inventory or affected software installed	
Print Name*		
Signature*		
Date *		

It is important that you take the actions detailed in the FSN and confirm that you have received the FSN.

Your reply is the evidence we need to monitor the progress of the corrective actions.