



Field Safety Notice / Recall

30 July 2019

Notification Number: NC-63932618

The purpose of this Field Safety Notice/Recall is to inform you of an issue impacting product(s) purchased by your company. A copy of this letter should be forwarded immediately to the personnel in your organization that utilize this product.

Affected Product(s)

Item No.	Item Description	Lot / Batch
274R-14	<i>Kappa (EP171) Rabbit Monoclonal Antibody</i>	0000057588
274R-14	<i>Kappa (EP171) Rabbit Monoclonal Antibody</i>	0000064775
274R-17	<i>Kappa (EP171) Rabbit Monoclonal Antibody</i>	0000057617
274R-18	<i>Kappa (EP171) Rabbit Monoclonal Antibody</i>	0000057618

Description of the Issue

Product labelled Kappa (EP171) Rabbit Monoclonal Antibody contains Lambda (EP172) Rabbit Monoclonal Antibody.

Reason for the Notification

The labelling of the affected products does not accurately represent the content.

Corrective Action

Cell Marque placed an immediate block on all affected product, including raw materials and in-process components, and placed in quarantine. This product recall was initiated for impacted IVD material.

A full investigation and root cause analysis has been initiated and is ongoing. Corrective actions include revisions to key processes associated with the receipt, inspection, testing and release of antibody reagents.

Required/Recommended Action

Please immediately examine your inventory to determine if you have any remaining impacted product and forward a copy of this letter to the personnel in your organization that utilize this product and/or need to be made aware of this issue. Please complete the attached confirmation of receipt form and return to local contact indicated below.

In addition, if you may have further distributed this product, please identify your customers and notify them at once of this issue. Your notification to customers should include a copy of this notification and attachments.

The use of the affected materials should cease immediately.

Merck KGaA, Darmstadt, Germany
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany
Phone +49 6151 72-0

Sigma-Aldrich Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
3050 Spruce Street
St. Louis, MO 63103, USA
Phone +1 (800) 521-8956 +1 (314) 771-5765

EMD Millipore Corporation
A subsidiary of Merck KGaA, Darmstadt, Germany
400 Summit Drive
Burlington, MA 01803, USA
Phone +1 (781) 533-6000



Material should either be destroyed and/or discarded or returned to Cell Marque. If you wish to return the materials, please contact Cell Marque Customer Service by phone at +1 916-746-8900 or by email at service@cellmarque.com for US and international@cellmarque.com for all other regions.

Please complete and return the attachments to this notification.

Additional Information

Notified body and competent authorities in the countries where the product has been distributed will be notified of this Field Corrective Action.

Attachments

Attachment #1 – Confirmation of receipt of notification

Attachment #2 – Product Reconciliation

Customer notifications are created by an electronic tool that allows evaluation and approval through our documented systems by representatives from Product Management and Quality. Therefore, this document is valid without signature.

If you would like more information about this customer notification, please contact your local representative or use the link www.emdmillipore.com/offices for our website to obtain the phone number and/or email address of your local office.

We apologize for any inconvenience that this issue may cause you. Thank you for your loyal business.

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Attachment 1

CONFIRMATION OF RECEIPT OF NOTIFICATION

Kappa (EP171) Rabbit Monoclonal Antibody and NC-63932618

Company Name: _____

I/We confirm receipt of the above-mentioned notification.

Name (Block capitals): _____

Position: _____

Email address (for follow-up contact): _____

Signature: _____

Date: _____

Return completed form to Farhad Dashty farhad.dashty@milliporesigma.com and service@cellmarque.com for US and international@cellmarque.com for all other regions.

For Return of Product: Please contact Cell Marque Customer Service by phone at +1 916-746-8900 or by email at service@cellmarque.com for US and international@cellmarque.com for all other regions. Returns must indicate the Return Authorization number. This will be provided by Cell Marque Customer Service once contact has been made.

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Attachment 2

Product Reconciliation

Product	Item Number	Lot Number	Quantity of Vials Received	Quantity of Vials Used	Quantity of Vials to Return/ Destroy
Kappa (EP171) Rabbit Monoclonal Antibody					

Name (Block capitals): _____

Position: _____

Signature: _____

Date: _____

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