

Urgent Field Safety Notice

Protease Digestive Enzyme
FSCA-identifier 2017-07-25
Type of action: Advice given by Manufacturer

Date: 29 July 2017

Details on affected devices:

Protease Digestive Enzyme
Catalogue Number 937B-02
Lots 1516913A, 1603508A, 1620203A

Description of the problem:

These lots of protease reagent have exhibited decreased performance. This decreased performance is characterized by lighter staining intensity than previous lots. Users may see lighter, but acceptable staining results. To date, this effect has only been observed in Cell Marque's quality control laboratory; this safety notice is a precautionary measure to keep our customers informed and to give them the option of replacing the lots, at Cell Marque's expense, if they are not satisfied with product performance.

Clinical Risk Assessment:

The product poses negligible risk to patient, user or environment; each laboratory is required to establish and validate their own protocols for use. If protease reagent is not working properly, test controls will not perform appropriately indicating invalid test results.

Advise on action to be taken by the user:

No actions are required if users are satisfied with staining results. Users should contact their distributor for replacement or refund if they are not satisfied with product performance

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

Robert De Vos
Head of Quality
Cell Marque Tissue and Cellular Diagnostics
MilliporeSigma, Life Science
6600 Sierra College Blvd



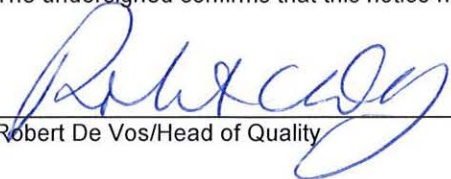
The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

Cell Marque™ Tissue and Cellular Diagnostics

MilliporeSigma, Life Science
6600 Sierra College Blvd. · Rocklin CA 95677·United States
Tel. 916 746 8900
Fax 916 746 8989
milliporesigma.com

Rocklin, CA 95677 United States
Telephone: 916.746.8932
Fax: 916.746.8989
bdevos@cellmarque.com

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency:


Robert De Vos/Head of Quality

01 August 2017

