

09 October 2017

Field Safety Notification

Antibody Identification Cells – papain-treated

Product Code: Z472 Lot: V187499 Expiry Date 13th November 2017

Quotient is providing notification of an incident which occurred during manufacture of the above referenced lot. This notification is considered to be a Field Safety Notification and upon receipt requires action and response from your organization.

We can confirm that within the papain-treated Antibody Identification Panel, product Z472, lot V187499, the arrangement of two of the cells were manufactured as follows: Cell # 2 is of phenotype R₂R₂ and Cell # 3 is of phenotype R₁R₁. This discrepancy represents a change to the customary antigen profile, with which you are familiar. There are no issues with any other aspect of the panel.

The incident has been reviewed and we consider the product suitable for intended use, and as such have provided you with a replacement panel containing an updated antigen profile which reflects the current configuration of the kit.

All required regulatory notification to the applicable authorities have been completed and to meet compliance requirements we are requesting your help. Please;

1. Acknowledge receipt of this communication, by completing and signing the attached form.
2. Upon receipt of the replacement product, please return or destroy the current product you have in your possession

We sincerely apologize for any inconvenience caused by this issue. If you require any further information, please do not hesitate to contact us.

Respectfully,



Iain McIntosh
Quality Manager

CONFIRMATION OF RECEIPT OF FIELD SAFETY NOTICE

Antibody Identification Cells – papain-treated

Product code Z472

Lot: V187499, Expiry Date 13th November 2017

I/We acknowledge receipt of the above communication.

Please check When completed	I have read the communication
	I have discarded/returned the lot previously provided

Facility Name _____

Name (please print) _____

Position/Title _____

Signature _____

Date _____

Please complete and return this form by email in form of a scanned copy to david.Mcdonald@quotientbd.com