



DiaMed GmbH
Pra Rond 23
1785 Cressier FR / Switzerland
Phone: +41 (0)26 674 51 11
Fax: +41 (0)26 674 54 45

Cressier, April 13th, 2016

Urgent: Field Safety Notice / 001-16

Affected device:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-Papain	005510/005511	06311.53.1	25.04.2016
		06311.54.1	09.05.2016
		06311.55.1	23.05.2016

Dear Customer,

This letter contains important information that requires your immediate attention.

BioRad is voluntarily recalling the lots identified above. This recall is being conducted as a precautionary measure.

Description of the problem:

Further to customer complaints we have been able to confirm that the above-mentioned lots show a decrease in enzymatic activity, leading to uninterpretable results.

Impact on the patient:

A risk assessment has been carried out and revealed that difficulty in interpretation of the results involving identification, auto-control and cross-matching in the enzyme technique may be experienced; this should not affect the clinical management of the patient.

Immediate protective measure:

We kindly ask you to carry out the following actions:

1. Destroy any remaining kits of 06311.53.1, 06311.54.1 and 06311.55.1
2. Complete the Annex II, *Reply Form and certificate of destruction for Customers for this purpose.*

We are actively looking for a solution to this problem. In the interim period we recommend that you use ID-Diluent 1 (Id n°05751) instead of ID-Papain for your enzyme tests.



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To facilitate the replacement of these products, please fill out and sign the Field Safety Notice reply form and the Certificate of destruction (Annex II) and return the completed form to your distributor before **the 27th of April 2016.**

Please note that the relevant European Regulatory Agency has been advised of this FSCA.

In case of questions, in the first instance, please contact our Customer Service Laboratory:

slabor_cressier@bio-rad.com

Our representatives are briefed to help you manage this situation.

We apologize for any inconvenience that may have been caused by this action and we appreciate your prompt cooperation in this matter.

Yours sincerely,

Quality Assurance Director, Clinical
Diagnostics Group - Europe

Agnes Eude Goethals

Vice President and General Manager,
Immunohematology Division

Ann Madden



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Please fill out and sign this document until the end of the week 17.

Urgent: Field Safety Notice / 001-16
Reply Form and certificate of destruction for Customers

PRODUCT:

Product Name	Catalog No	Serial/ Lot No	Expiry Date
ID-Papain	005510/005511	06311.53.1	25.04.2016
		06311.54.1	09.05.2016
		06311.55.1	23.05.2016

CUSTOMER INFORMATION:

Hospital / Laboratory	
Address (Street, Postcode, Country)	
Phone Number	
Undersigning manager name	
Customer Account Number	

STATEMENT:

I have read and understood this Field Safety Notice, and shared the information with laboratory staff to:

- Destroy the remaining stock of ID-Papain with the lot number(s) **06311.53.1, 06311.54.1 and 06311.55.1**
- Complete the **Certificate of Destruction** below and send back this document to the distributor.

CERTIFICATE OF DESTRUCTION FOR ID-PAPAIN

LOT Number	Total Number of boxes received	Boxes Still on stock	
		Number	Date of destruction
06311.53.1			
06311.54.1			
06311.55.1			

I,.....do hereby certify that, due to the problem reported on the **ID-Papain (lot number 06311.53.1, 06311.54.1 and 06311.55.1)** and according to the instructions issued by BioRad/DiaMed GmbH, I have destroyed the above mentioned products.

Date:

Signature: