

It is of the utmost importance that the official in charge receives this information as soon as possible

Subject: Recall R001_18

18 January 2018

Dear valued customer,

During the process of market surveillance, we have become aware that the below mentioned Capillary Blood Collection Tube (450556) partly shows not enough additive, which might cause falsification of analysis results, if the collected blood sample is used for analysis.

For safety reasons, we have decided to recall the affected product.

We kindly ask you to **isolate** your inventory of this item and lot number on site and assure the non-use of the affected lot at your customer's premises.

Item Number	Lot Number	Product description
450556	A17044CM A171144P A17093C9	MiniCollect® Complete 1 ml 9NC Coagulation sodium citrate 3.2%, light blue cap, pre-assembled with Carrier Tube 13x75

Attached for your convenience are two templates for your completion, which will confirm to us that you have notified your customers, and will also provide us with the total quantity that is isolated in your warehouse as well as any stock that is isolated in the warehouse of your customers.

Please complete the attached template and return it to my attention before 29 January 2018.

Once we have received the above requested information from you, we will provide you with further instructions.

Kindly accept our sincerest apologies for any inconvenience this matter may cause.

If you have any additional questions, please get in touch with your respective Greiner Bio-One Sales Representative or Assistant.

Best regards



Ms Heidi Essl
Registrations & Process Specialist Sales

RETURN to:

Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Tel: +43 7583 6791
Fax: +43 7583 6318
office@at.gbo.com
Attn.: Heidi Essl, Adelheid.essl@gbo.com



Confirmation

We,

Name of company:

Address of company:

herewith confirm to Greiner Bio-One GmbH, that we have acknowledged the information regarding

FSCA Number:

R001_18

We have already informed our customers which have received the concerned products of the product recall and its related risks.

Details:

Item No.	LOT No.	No. of customers informed	Delivered quantity	Usage			Total
				Quantity used (with no reported problems)	Still held by customers	Still held in own stock	
450556	A17044CM						
450556	A171144P						
450556	A17093C9						

Name (please PRINT):

Position in company:

Signature:

Date:

Company stamp to be placed here:

Attention:

This confirmation has to be returned within 10 working days after receipt.

Once Greiner Bio-One has received this confirmation regarding quantities remaining at your premises or with your customers, further instructions will be provided.

Buyer is aware of the fact that seller is obliged to trace back each individual item to the customer and/or end user according to seller's Good Manufacturing Practice (GMP).