

TELEFAX

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INNOGENETICS
BIOTECHNOLOGY FOR HEALTHCARE

Von:	Dr. Dirk Peters,
An:	Herrn Dr. Elbracht, Labor Elbracht und Müller 03445 / 770446
Datum:	15.02.02
	Seiten: 2 (inklusive dieser)

Sehr geehrter Herr Dr. Elbracht,

wie gerade telefonisch avisiert müssen wir Sie von einem möglichen Produktversagen informieren.

Sie haben am 11. 1. 2006 von uns den Phadebact CSF Test der Firma Boule/Bactus (Best. Nr. 5592-12 mit der Charge 508181 erhalten.

Der Hersteller hat uns heute informiert, dass das Phadebact CSF Pneumococcal Reagent: lot: 507830 zu falsch negativen Ergebnissen führen kann.
Setzen Sie dies Reagenz nicht mehr für die Diagnostik ein.


Das Anschreiben des Herstellers liegt zu Informationszwecken bei.

Wir bedauern die eventuell entstandenen Unannehmlichkeiten und bitte um Ihr Verständnis.

Ich werde mich morgen noch einmal an Sie wenden, um das weitere Vorgehen zu besprechen.

Mit freundlichen Grüßen

INNOGENETICS GmbH
Leiter Marketing
Dr. Dirk Peters


Bitte informieren sie mich durch Abzeichnung dieses Faxes und zurückfaxen, dass Sie diese Information erhalten haben.

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Datum, Unterschrift



Fax No:

Date: 2006-02-13

To: Marketing & QA Department

Attn.: InnoGenetics

From: Håkan Randahl

Bactus AB

Lunastigen 3

SE-141 44 Huddinge, Sweden

Tel: +46 8 608 86 32 Fax: +46 8 746 84 96

E-Mail: hakan.randahl@bactus.se

No of pages: 1 (incl. this sheet)

Message:

URGENT! RECALL OF PHADEBACT CSF KITS!

Dear Sirs,

During our check of reference stock kits we have discovered that the Phadebact CSF Pneumococcal reagent Lot: 507830 Does not fulfil our specifications (reactivity with control material) although the expiry is not until 30 sept 2006.

This reagent is included in the following Phadebact CSF (10-5592-12) lots (we have also indicated the number of kits that according to our documentation has been sent to you)

Lot (batch) 507991	_____ kits	On stock _____ kits
Lot (batch) 508118	_____ kits	On stock _____ kits
Lot (batch) 508152	_____ kits	On stock _____ kits
Lot (batch) 508161	_____ kits	On stock _____ kits
Lot (batch) 508181	<u>1</u> kits	On stock _____ kits
Lot (batch) 508236	_____ kits	On stock _____ kits

We want you to stop all deliveries of these lots with immediate effect. Please, inform customers (end users) that the Pneumococcal reagent in these lots may give a false negative result. NB! The three other components, CSF Strep B, CSF Meningococcal and CSF H.Influenzae type B reagents, are not affected. All other lots of Phadebact CSF kit are working fine.

A new lot is available for delivery, as well as single bottles with the Phadebact CSF Pneumoccal reagent. Please, give us the number of kits of these lots that still are on your stock (fax this form back to us). Kits will be replaced FOC with your next order or sooner if so agreed. Replacement of kits with end-user will be done FOC in the same way as soon as we have your request. Please, do not discard kits on your stock until we have given this issue a full investigation (we may request you to return kits)

We will keep you informed of the result of the investigation. Please, don't hesitate to contact us if there are questions.

Best regards

Håkan Randahl, Managing Director

Anette Bergman, Quality Assurance