

14 August 2008

Batch Recall TruCal Homocysteine FS and Trulab Homocysteine FS

1 3400 TruCal Homocysteine FS

Lots: **10568, 10569, 10570**, exp. 2009-08

5 9770 TruLab Homocysteine FS Level I

Lots: **9932**, exp. 2008-09, **10239**, exp. 2009-07, **10571**, exp. 2009-07

5 9780 TruLab Homocysteine FS Level II

Lots: **9933**, exp. 2008-09, **10240**, exp. 2009-07

Dear Sir or Madam,

Due to customer complaints we recently rechecked our calibrators and controls TruCal Homocysteine FS and TruLab Homocysteine FS and found a decreased recovery of target values in controls and inhomogeneous results in single vials of the calibrator.

Both deviations are obviously caused by microbial contamination. Depending on the progression of contamination and thus degree of damage in single vials homogeneity of results is no longer ensured.

As an immediate measure we adjusted the preservation and optimized the production process of the concerned products to prevent reoccurrence of contamination.

In this way improved products will be available from week 33 on.

Please make sure that you and your customers will not use the affected lots anymore. Put all remaining material in your stock on hold, call back residual kits from your customers and report to us how many packs need to be replaced. We will then advise you to either destroy the material or send it back to us.

For regulatory reasons we need your confirmation that you received and communicated this information to your customers.

Therefore we kindly ask you to sign and send back the attached form via fax to :

0049 6432 9146 32


Of course you can also attach the signed document as PDF file and return it to us. We expect your answer until **August 22, 2008**.


We apologize for all inconvenience caused by this and hope for your understanding and continuous support.

Sincerely yours

(Name Export – Verantwortliche(r))

on behalf of


(President)


(President)

To :

DiaSys Diagnostic Systems GmbH
Alte Strasse 9

65558 Holzheim

CONFIRMATION

We have received the information concerning defective batches as follows :

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Lots: **9933**, exp. 2008-09, **10240**, exp. 2009-07

and have advised our customers accordingly.

.....
Company

Date

Signature