

Genzyme Virotech GmbH

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Reg.-Ger.: Darmstadt, HRB 82749
Geschäftsführer: Peter Kessler
2008-09-17

IMPORTANT DISTRIBUTOR INFORMATION

Product Recall - Bordetella pertussis ELISA (EC115.00) IgA cut off control Affected Lot-Numbers: 116-01 and 116-02

Dear Distributor,

We need to inform you that for the lot numbers 116-01 and 116-02 of our Bordetella pertussis ELISA we observed a decrease of the cut-off control.

To not risk a failure of the diagnostic statement of the test we decided to interchange the IgA cut-off control of the kits with the affected lot numbers precautionary.

We would like to ask you to react promptly as already advised by e-mail on Friday 9th September 2008 and **discard the IgA cut-off control of the kit-lot numbers 116-01 and 116-02** of the kits you still have on stock as well as to inform your customers to do so with the kits they still have in their lab.

To create the recall as easy as possible for you, please find attached to this letter a fax-response-form Please insert the amount of IgA cut-off controls that you will need for **Bordetella Kits of lot number 116-01 and 116-02** for a) kits you still have on stock or b) kits that are still non-tested in your customers labs. Please send the fulfilled form back to us as soon as possible (latest September 26th), so we can ensure you receive the replacements as fast as possible

Due to regulatory reasons we do need the signed fax-response-form from you confirming that you have been informed about the recall even though you do not have any of the affected kits on stock or non-tested with your customers!

Please apologize the inconvenience this recall may have caused.

Please feel free to contact us by phone or e-mail in case of additional questions.

Kind Regards,

Genzyme Virotech GmbH



Export Manager

Enclosure



Rüsselsheimer Volksbank, Kto. 12 943 00 (BLZ 500 930 00)
Ust.-IdNr.: DE 111 666 803, Ust.-Nr.: 007 234 03312



FAX-RESPONSE-FORM
+49-6142-96 66 13

➔ **Please complete form and fax back as soon as possible** ➔

Recall Bordetella pertussis ELISA (EC115.00) IgA cut off control
Affected Lot-Numbers: 116-01 and 116-02

We have been informed about the possible decrease of

We hereby confirm that we have received the information about the possible decrease of the **IgA cut-off control** of the **Bordetella pertussis ELISA (EC115.00)**, **Lot numbers 116-01 and 116-02** manufactured by our supplier Genzyme Virotech GmbH. We will discard the IgA cut-off controls (lot 80804-01 and 80131-02) of this kit lots and replace them by new ones offered by our supplier as well as we will make sure that our customers discard the IgA cut-off controls (lot 80804-01 and 80131-02) of this kit lots and provide with the replacements we receive from our manufacturer.

() we will interchange the IgA cut-off control in the kits we still have on stock and discard the faulty ones. We do need a new label fro the outer kit-box.

() with every kit of Lot 116-01 and/or 116-02 ordered by a customer we will send additionally the new IgA cut-off control plus QC certificate. We do need a short statement, so our cutomer knows how to proceed interchanging the IgA cut-off controls.

Company Stamp:

Contact Person: _____

Signature and date of reply: _____

Please fill in how many **Bordetella pertussis ELISAs** of the **kit-lots 116-01 and 116-02** are still with your customers and how many kits you still have on stock, so we can send you the adequate amount of replacement IgA cut-off controls.

CUSTOMER	Bordetella pertussis ELISA Kit Lot: 116-01	Amount:
CUSTOMER	Bordetella pertussis ELISA Kit Lot: 116-02	Amount:

YOUR STOCK	Bordetella pertussis ELISA Kit Lot: 116-01	Amount:
YOUR STOCK	Bordetella pertussis ELISA Kit Lot: 116-02	Amount:

Thanks so much for your assistance!
 Your Genzyme Virotech Team



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