URGENT: MEDICAL DEVICE RECALL

Product: **MicroVue Bb Plus EIA**
Reorder Number: **A027**
Lot number: **018186**

10/16/2014

Attention: Quidel MicroVue Bb Plus EIA Customer

Quidel is conducting a recall on the above referenced product. Quidel has determined that some human plasma and human serum samples are quantitating incorrectly, with approximately 50% higher concentration values than previously reported and historically documented. Any patient samples tested with the above-mentioned product and lot will need to be retested.

YOU NEED TO TAKE THE FOLLOWING ACTIONS:

1. Immediately review your inventory and determine if you have any of the affected product. If so, please remove it from inventory and destroy it immediately by discarding it into your normal biomedical waste stream.

2. Complete the enclosed Certificate of Destruction. Upon receipt of the Certificate of Destruction, Quidel will then schedule your shipment of replacement product. At this time, we do not have an estimated date as to when the replacement product will be available.

3. In addition, if you have further distributed the product(s) subject to this notice, please identify the customers and provide them with this Urgent Medical Device Recall. Please monitor and reconcile the quarantine of product with the customers as this information may need to be provided to the authorities.

This recall only affects product and lot listed above.

Representatives are available to assist you in this process and answer any questions you may have about this recall, the product return procedure, and how to obtain replacement product. Please contact Technical Support at technicalsupport@quidel.com or by calling 800.874.1517, Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

Please accept our apology for any inconvenience this recall may cause. We are committed to providing our customers with the highest quality products and appreciate your continued support.

Sincerely,

Senior Director, Clinical and Regulatory Affairs

MEDICAL DEVICE RECALL

Certificate of Destruction

Customer instructions: Please confirm that the product shown below has been **DESTROYED**, sign and date below, then return to Quidel Technical support by FAX at 740.592.9820 or by email at technicalsupport@quidel.com.

Product Information/Description:
Reference Number: **A027**

Product Description: MicroVue Bb Plus EIA
Lot Numbers: 018186
Expiration Date: 2015DEC31

Confirmation: Receipt of product destruction

Customer Information:
Contact Person (Name, Title, Department):

Company Name:

City, State, Zip Code:

Country:

Telephone Number:

FAX Number:

E-mail:

Number of kits received: _____ Number of kits (full or partial) destroyed: _____

Customer Signature:
To acknowledge that the product shown above **has been destroyed** .

_____	_____	_____
Signature	Title	Date

Comments: