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# IMMULITE<sup>®</sup> 2500

## Technical Bulletin

### 2012

**TO : IMMULITE<sup>®</sup> 2500 International Distributors**  
**FROM : DPC Technical Service**  
**DATE : October 22, 2004**  
**SUBJECT : Urgent - IMMULITE 2500 Homocysteine Recall**

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Due to a recently confirmed issue with the IMMULITE 2500 software, DPC is recalling all IMMULITE 2500 Homocysteine kits. There is potential for an erroneous result to be reported, due to the pipetting of an incorrect volume of pre-treated sample. The incorrect volume of pre-treated sample will be aspirated **only if the system is in Sample Pause Mode at the time of pre-treatment transfer.** At all other times, the correct volume is pipetted. Although this issue occurs infrequently, it is possible, causing DPC to take this action.

This software issue affects only IMMULITE 2500 Homocysteine, and does not impact the performance of the IMMULITE 2000 Homocysteine assay.

The problem has been identified, and the corrected software will be released imminently. Homocysteine kits will resume shipment when the updated software is available and installed on all IMMULITE 2500 systems.

**NOTE:** It is required that the updated software be installed on the IMMULITE 2500 prior to use of the Homocysteine assay onto the instrument.

Our records show that IMMULITE 2500 Homocysteine kits have been shipped to your facility. **All IMMULITE 2500 Homocysteine kits in your inventory not yet shipped to customers must be quarantined until the revised software has been installed on customer systems. Homocysteine kits in customer labs should be disposed of to preclude use of the assay until the revised software is available.**

A fax-back form confirming the quarantine and disposal of all kits is attached to this bulletin. Please fill out, sign, and return the form to DPC immediately after quarantine and/or disposal of the IMMULITE 2500 Homocysteine kits. These kits disposed of will be replaced at no charge once the issue is resolved.

DPC Technical Service has developed a software utility to review system diagnostic files and identify samples that may have been affected by this issue. Please contact DPC Technical Service for assistance in that regard.

We apologize for any inconvenience this issue may cause. If you have any questions regarding this Technical Bulletin, please contact DPC Technical Service.



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**IMMULITE® 2500**  
**Homocysteine (L5KHO) Kit Disposal**  
**Confirmation Form**

Distributor Name: \_\_\_\_\_

IMMULITE 2500 s/n (s):

_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

I verify that I have completed the following:

1. Read and understood IMMULITE 2500 Technical Bulletin #2012.
2. Properly disposed of all components of L5KHO, IMMULITE 2500 Homocysteine.
3. Acknowledge quarantine of all IMMULITE 2500 Homocysteine kits in inventory.
4. Total Number of kits disposed of at customer sites: \_\_\_\_\_

Name: \_\_\_\_\_  
(please print)

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**Please fax the completed form to DPC Technical Service at 973-927-0697.**