



March 02, 2011

URGENT PRODUCT CORRECTION

PRODUCT NAME	PART NUMBERS
COULTER® LH 500 Series Analyzer	178832, 178833, 178834
COULTER® HmX Hematology Analyzer	6605522, 6605523, 6605524
COULTER® HmX Hematology Analyzer with Autoloader	6605525, 6605526, 6605527

Attention Beckman Coulter® LH500/HmX/HmX Autoloader Hematology Customer;

This letter contains important information that needs your immediate attention.

ISSUE

We have identified a problem with Integrated Circuit Chips used in different boards throughout the analyzer. Your instrument has been identified as possibly containing these chips.

IMPACT

The failures listed below may be attributed to this problem. Not all analyzers will experience the failures.

System Cycle	Possible Failure Modes
Power Up	System lockup after Power Up (no response from user interface) "Download not successful" message at the user interface Solenoids and motor activation failure messages at the user interface
Start Up Fails	Light Scatter Offset, Diff background WBC or RBC or PLT Voltage Out of Range
Control Analysis	High frequency of Latron/Control Failure (controls out) High frequency of WBC, RBC and/or PLT Vote Out parameter codes
Blood Sample Analysis	High frequency of WBC, RBC and/or PLT Vote Out parameter codes High frequency of Differential Incomplete Computation parameter codes

ACTION

- If you are experiencing the failures at this time, contact Beckman Coulter Service at 800-526-7694 in the United States or Canada, or contact your local Beckman Coulter representative.
- You will be contacted by Beckman Coulter Service for a system inspection even though you may not be experiencing failures. Any suspect chips will be replaced.
- No retrospective review of patient results is required.

RESOLUTION

The suspect Integrated Circuit Chips have been removed from all systems in inventory and manufacturing.

Please share this information with your laboratory staff and retain this notification as part of your laboratory Quality System documentation. If you have forwarded any of the affected product(s) listed above to another laboratory, please provide a copy of the letter to them.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication and are taking appropriate action.

If you have any questions regarding this notice, please contact; Beckman Coulter Customer Service at 800-526-7694 in the United States and Canada or contact your local Beckman Coulter Representative. We apologize for the inconvenience that this has caused your laboratory. Thank you for your continued loyalty.

Sincerely,

Deborah Herrera
Director Regulatory Affairs, Cellular Analysis Business Group

PCA-16183

Beckman Coulter, Inc.
11800 S.W. 147th Avenue
Miami, FL 33196-2500

Mailing Address:
11800 S.W. 147th Avenue
P.O. Box 169015
Miami, FL 33116-9015

Customer Service: (800) 526-7694
Product Information: (800) 526-6932
(800) 327-6531 (305) 380-3800
Internet: www.beckmancoulter.com



PRODUCT CORRECTION RESPONSE FORM

COULTER® LH 500 Series Analyzer PN: 178832, 178833, 178834

COULTER® HmX Hematology Analyzer PN: 6605522, 6605523, 6605524

COULTER® HmX Hematology Analyzer with Autoloader PN: 6605525, 6605526, 6605527

Check the appropriate box below:

- I have read and understood the information within the accompanying Product Corrective Notification. All relevant personnel have been informed of its contents, the actions recommended in the Notification have been taken and records of these actions are being retained as part of our Laboratory Quality System documentation.
- I do not understand the Product Corrective Notification and require further assistance.
- We do not have this product.

Please print and complete this form and

➤ **Fax** this document to **786-639-7500 / 7501 / 7502 / 7503 / 7504**

OR

➤ **Mail** this document to: **Beckman Coulter, Inc.**

Attn: Regulatory Affairs Mail Code 31-B06
11800 S.W. 147th Avenue
P O BOX 169015
Miami, FL 33116-9015

OR

➤ **E-mail** your hospital/clinic name, site address, your name, job title to:

“Regulatory.Notifications@beckmancoulter.com”

Please include “COULTER® LH 500, COULTER® HmX and COULTER® HmX Hematology Analyzer with Autoloader Letter dated 03/02/11” in the subject field for the e-mail.

Facility Name: _____

Your Name (Print): _____

System ID Number(s) _____ Customer Number: _____

Job Title: _____ Email: _____

Phone #: _____

Signature: _____ Date: _____

Beckman Coulter is updating the customer address list for product notifications. To add contacts for product notifications, please provide the name(s) and email address(es), as well as product responsibility. If the current mailing address on your notifications is incomplete, please provide the appropriate level of detail below so we can improve our notification process.

Additional customer notification names, email addresses, and product responsibility:

Additional address information that would ensure more timely delivery in your facility:

Account Information: PCA-16183