




February 23, 2017

IMPORTANT PRODUCT NOTICE

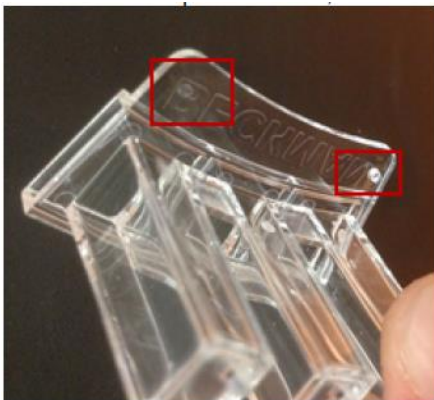
IMMAGE Immunochemistry Systems Cuvette Sectors

REF	LOT	
470706	All	N/A

Dear Beckman Coulter Customer,
CC: Chairman Medical Board*
Head of Departments*

**of affected consignees*

Beckman Coulter is sending this letter regarding the IMMAGE Immunochemistry Systems Cuvette Sectors.

ISSUE:	<p>Beckman Coulter has determined that IMMAGE Cuvette Sectors (P/N 470706) may be missing one of two positioning pins (see photo). Cuvette Sectors missing a positioning pin can become misaligned.</p> 
IMPACT:	<ul style="list-style-type: none">• If a Cuvette Sector becomes misaligned, under rare circumstances, the instrument mixer paddle may rub against the inside wall of the Cuvette and create a noise.• Beckman Coulter has no evidence of erroneous results being generated due to this issue to date.

ACTION:	<ul style="list-style-type: none"> Inspect the Cuvette Sectors on the instrument reaction wheel to determine if any are missing positioning pins. Replace any Cuvette Sectors with missing pins. Upon completion of inspection, confirm that all Cuvette Sectors are seated in the reaction carousel. [Reference: <i>IMAGE 800 Operations Manual</i>, Section 10] Inspect the spare parts inventory of Cuvette Sectors to determine if any are missing positioning pins. If you find missing positioning pins on Cuvette Sectors, fax/call for replacement. <p>For customer in the United States, if you need replacement product:</p> <ul style="list-style-type: none"> Complete and fax the attached "Replacement Order Form", or Call Client Services at (800) 526-3821 <ul style="list-style-type: none"> Discard any Cuvette Sector with missing positioning pin. A retrospective review of results is not necessary.
RESOLUTION:	Beckman Coulter is continuing to investigate the root cause of this issue.

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 them a copy of this letter.

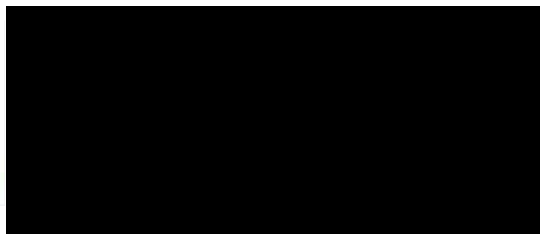
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

If you have any questions regarding this notice, please contact our Customer Support Center

- Via our website, <http://www.beckmancoulter.com/customersupport/support>
- Via phone, call 1-800-854-3633 in the United States and Canada
- Outside the United States and Canada, contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,



David Davis
Director, Regulatory Affairs

Enclosure:
Response Form
Replacement Form

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