



April 11, 2016

IMPORTANT PRODUCT NOTICE

IRISpec CA/CB/CC and IRISpec CA/CB

REF 800-7211, 800-7702, 800-0074

Dear Iris International Customer,

Iris International is sending an important product notice for the IRISpec CA/CB/CC and IRISpec CA/CB lot numbers listed in Table 1. This letter contains important information that needs your immediate attention. Patient test results are not affected.

ISSUE:	Iris International has become aware of an issue in which premature degradation of bilirubin for specific lots may lead to bilirubin control failures for the IRISpec CA bilirubin control material. The specific lots exhibiting the issue are shown in Table 1.
IMPACT:	<ul style="list-style-type: none">• The IRISpec CA control may fail for the bilirubin analyte.• Your laboratory will be unable to process patient samples until QC passes.• Not all bottles within a specific lot may be affected.
ACTION:	If you are using any of the lots listed in Table 1: <ul style="list-style-type: none">○ Follow directions for handling and storing control material in accordance with the current product package insert to prevent premature degradation due to improper technique. (IFU part number 300-1277, 300-1223 and 300-6123)○ If the IRISpec CA control for bilirubin fails, discard the bottle and use the other bottles in the kit.○ If the problem persists, request a product replacement using the Replacement Order form included with this notice or by contacting your local Customer Service Support.
RESOLUTION:	Manufacturing process improvements have been implemented to address the control failure.

Share this information with your laboratory staff. 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.

IPN-25316

9172 Eton Avenue
Chatsworth
California 91311

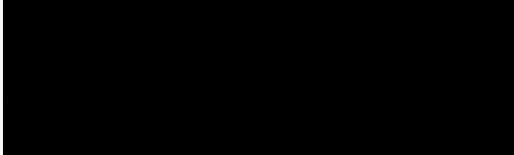
P 818.527.7000
www.beckmancoulter.com

Beckman Coulter will be managing the logistics of this notice. If you have any questions regarding this notice, please contact Beckman Coulter:

- Via our website at <http://www.beckmancoulter.com>
- Via phone at 800-854-3633 in the United States and Canada.
- Outside the United States and Canada, contact your local support representative.


We apologize for the inconvenience to your laboratory.

Sincerely,



Marwan Fathallah
Vice President, Quality Assurance and Regulatory Affairs
Enclosure: Response Form

TABLE 1

REF	LOT	
800-7211	336-15	16-Apr
	343-15	16-Apr
	004-16	16-May
	006-16	16-May
	019-16	16-May
	021-16	16-May
800-7702	313-15	16-Apr
	336-15	16-Apr
	004-16	16-May
800-0074	309-15	16-Apr

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A Division of
IRIS International, Inc.

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