


Field Safety Corrective Action Notification
Gentian Cystatin C Calibrator Kit

| REF | LOT |  |
|--------|------|---|
| A52763 | 0006 | 31-Oct-2017 |
| | 0008 | 9-Nov-2017 |

Dear Beckman Coulter Customer,
copy Chairman Medical Board and Relevant Head of Departments

Gentian AS has requested Beckman Coulter to distribute the attached letter concerning the Gentian Cystatin C Calibrator Kit.

| | |
|----------------|---|
| ISSUE: | Refer to the attached letter from Gentian AS |
| IMPACT: | Refer to the attached letter from Gentian AS |
| ACTION: | To request replacement of unused product: <ul style="list-style-type: none"> • Complete the attached "Replacement Order Form" and fax to (866) 294-7850 OR • Call Client Services at (800) 526-3821 and select Option 1 |

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.

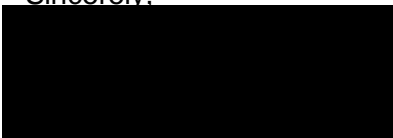
Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication

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
- Outside the United States, contact your local Beckman Coulter Representative.

We apologize for any inconvenience that this caused your laboratory.

Sincerely,



David G. Davis
Director Quality and Regulatory Affairs

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FA-17043
Beckman Coulter, Inc.
250 S. Kraemer Boulevard
Brea, CA 92821

Mailing Address:
250 S. Kraemer Boulevard
P.O. Box 8000
Brea, CA 92822-8000

Telephone: (800) 526-3821
Facsimile: (714) 961-4234
Internet: www.beckmancoulter.com

Gentian AS
Bjornasveien 5
N-1596 Moss
Norway
T: +47 99 33 99 05

URGENT FIELD SAFETY NOTICE / DEVICE RECALL

Wednesday, 12 July 2017

Commercial name: Gentian Cystatin C Calibrator Kit
Beckman Coulter part No.: A52763
Kit lot numbers: 0006 and 0008

Dear Valued Customer,

Gentian AS has initiated a voluntary field action regarding two specific lots of Gentian Cystatin C Calibrator Kit (lot 0006 and 0008). Our records indicate that at least one of the affected lot numbers have been shipped to your account.

The identified lots of calibrators resulted in a high bias when used on a DxC instrument. Potential risks associated with the increased bias is an underestimation of the Cystatin C value, which again gives an overestimation of GFR. The bias should be detected when using controls for validation of the calibration curve. In worst case, this is not detected by the controls, and the bias may be close to 20 %.

Please note, an internal investigation has verified that the AU instrument platform is not affected by this issue. The impact to the IMMAGE platform has not been assessed. However, no issues with the IMMAGE platform have been reported to date. To minimize risk, regardless which platform you have, please discard any inventory of the affected lots (0006 and 0008).

What causes this calibrator problem?

The root cause is related to the antigen used in calibrator lots 0006 and 0008. For affected instruments, the calibration curve is influenced by the instrument and application settings and may give a high bias.

What measures has Gentian taken?

Actions have been taken towards the antigen supplier, which has resulted in improved quality of antigen raw material supplied to Gentian. Gentian has now included additional verification steps to ensure antigen quality prior to use.

What action is Gentian asking you to take?

- Please immediately stop using the affected calibrator lot 0006 and 0008
- Share this notification with other relevant personnel in your organization

We regret any inconvenience this may cause you and appreciate your patience. Gentian AS is committed to providing high quality products and ensuring customer satisfaction. If you have any questions, please do not hesitate to contact your local Beckman Coulter representative.

Sincerely,

Bård Søndrehagen
Chief Executive Officer

Ole Benny Østby
Vice President QA & RA