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**To:** Whom it may concern

## **FIELD SAFETY NOTICE**

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Friday, 18 September 2020

Commercial name: Gentian Cystatin C Calibrator and Calibrator Kit  
Gentian part No.: 1051, 1012, 8012, 8051  
Beckman Coulter part No.: A52763  
Affected lot numbers: 1809404,1904404, 1905415, 1906402

### **Dear Valued Customer,**

Gentian AS has initiated a voluntary field action regarding four (4) lots of Gentian Cystatin C Calibrator and Calibrator kit which is distributed to Beckman Coulter.

The identified lots of calibrators have shown to measure incorrect high values over time compared to the assigned values when released from Gentian AS. All lots passed acceptance criteria in production control and Quality Control prior to release and distribution by Gentian AS. The measured values of the calibrators have shown to increase approximately 10% over time, and customers may detect the issue of the respective calibrator lots when switching to another lot of calibrator with the experience of lower values for a newer calibrator lot. In worst case, this is not detected, and may result in approximately 10% higher cystatin C values measured in patients. The patient impact is evaluated to be low as diagnosis and treatment is based on several factors and not cystatin C level alone.

#### What causes the issue with the calibrator?

The investigation indicate that the antigen may be a contributing cause to the observed change in characteristics over time for the calibrator. Further investigation is ongoing to verify if the same change in characteristics over time for the calibrator can be related to other raw material lots of antigen.

#### What action is Gentian asking you to take?

- Please stop any use of the affected lots listed in this Field Safety Notice.
- Share this information with other relevant personnel in your organization

#### Withdrawal information:

Evaluation of risk:

The product is designed to be used together with control samples. During Quality Control in the hospital, the issue will be discovered when the customer change from one calibrator lot to another where an unacceptable large difference between the calibrator lots is observed.

Patient risk:

The respective calibrator lots generates appr. 10% higher cystatin c results, a deviation which does not have a significant impact on the diagnosis and treatment decisions.

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.