

Urgent Field Safety Notice
N.01/2017

Product Name	REF	Lot Number	Expiration Date
Creatinine (Enzymatic)	8L24-31	60335Y600	2018-02-28
		60382Y600	2018-02-28
	8L24-41	60334Y600	2018-02-28

May 22, 2017

Dear Valued Customer,

This letter contains important information regarding the MULTIGENT Creatinine (Enzymatic) assay, REF 8L24-31 and 8L24-41, lots 60335Y600, 60382Y600 and lot 60334Y600 respectively, all having expiration date February 28, 2018. Please review the information carefully and follow the necessary actions.

Description of the Problem

Sentinel has detected a performance issue with the reagent 1 component of the three impacted lots listed above. This issue may result in Quality Control values shifting out of acceptable range, which is not resolved by recalibration. Only replacement of the impacted lots with a new lot resolves the issue. In addition, some customers have reported erratic patient results.

The investigation has determined that this issue is isolated to the 3 impacted lots listed above. The corrective and preventive actions already in place will avoid any future recurrence.

Patient Impact

Sentinel has determined that although the probability of occurrence is remote, a potential delay may exist in the generation of patients' results due to Quality Control values falling outside of expected ranges. Internal investigations made on Quality Controls showed a variability from -26% to +4% for serum samples and from -20% to +4% for urine samples. This variability may affect your patients' results, depending on the acceptance criteria for Quality Controls established in your laboratory. Therefore, the following actions must be taken.

Actions to be Taken

1. Discontinue the use of the impacted lots immediately and destroy any remaining inventory of impacted lots according to your laboratory procedures.
2. If you have an alternate reagent lot available in inventory, switch to this alternate lot, or use a new lot provided.
3. Please review the content of this communication with your Medical Director and retain this letter for any future reference.

Contacts

We sincerely regret any inconvenience this may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, U.S. Customers should contact Customer Service at 1-877-4 ABBOTT. Customers outside the U.S. should contact their local Customer Service.

Best regards

To be sent to fax no. + 39 02 34551464 or to the following mail address:
customerservice@sentinel.it.

ANNEX 1

Field Safety Notice Receipt

Field Safety Notice N.01/2017 Date: 22/05/2017	Product: Creatinine (Enzymatic) REF: 8L24-31 Lots: 60335Y600 / 60382Y600 REF: 8L24-41 Lots: 60334Y600
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- The undersigned declares to have read and understood the above mentioned Field Safety Notice.
- The undersigned declares that the following product has been destroyed and disposed in accordance to local regulations regarding chemical waste management.

CODE	LOT	RECEIVED QUANTITY	DESTROYED QUANTITY
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Name
Title
Company
Complete address
Telephone n.
Fax n.
e-mail address

Notes/Comments :

Date, signature and company stamp