



Product Recall

Immediate Action Required

To Chairman Medical Board and Head of Departments

Date Issued June 05, 2017

Product

Product Name	List Number	Lot Number	Expiration Date	UDI Number
MULTIGENT Creatinine (Enzymatic)	8L24-31	60335Y600	28-FEB-2018	(01)00380740017682(17)180228 (10)60335Y600(240)8L2431
		60382Y600		(01)00380740017682(17)180228 (10)60382Y600(240)8L2431
	8L24-41	60334Y600		(01)00380740017699(17)180228 (10)60334Y600(240)8L2441

Explanation

Abbott received the attached letter from Sentinel, the manufacturer of the MULTIGENT Creatinine (Enzymatic) reagent. Sentinel have confirmed a performance issue with the three lots listed above which may result in Quality Control values shifting out of acceptable ranges or erratic patient results. The issue is not resolved through recalibration and a Product Recall is required.

Patient Impact

Please refer to the attached letter from Sentinel.

Necessary Actions

- Please review the attached Sentinel letter carefully and follow the instructions.
- Complete and return the Customer Reply Form.
- Contact Abbott Customer Service for assistance if needed.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Recall and provide to them a copy of this letter.
- Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this issue may cause your laboratory. If you or any of the health care providers you serve have any questions regarding this information, U.S Customers, please contact Customer Service at 1-877-4ABBOTT (available 24 hours a day, 7 days a week). Customers outside the U.S., please contact your local area Customer Service.