

**Urgent Field Safety Notice
N. 01/2015**

Product Name	List Number (LN)	Lot Number	Expiration Date
Ammonia Ultra	6K89-30	50083Y600	31 Jul 2016

September 22, 2015

Dear Valued Customer,

This letter contains important information regarding the MULTIGENT Ammonia Ultra Reagent, LN 6K89-30, lot 50083Y600, expiration date 31 Jul 2016. Please review the information carefully and follow the necessary actions.

Description of the Problem:

Due to a manufacturing issue with MULTIGENT Ammonia Ultra Reagent, list number 6K89-30, lot 50083Y600 is being removed from use. This lot is producing results below the linear range of the assay for samples that have been collected in sodium or lithium heparin tubes. Quality Control results are not affected.

Complaints relating to out of range patient results have been confirmed through internal testing as no measurable Ammonia values were obtained for samples tested per package insert instructions.

A review of complaint data for the impacted lot of Ammonia also indicates there is potential for lower than expected results to be generated, however, this has not been confirmed during internal testing.

Based on testing of all in-date lots no other reagent lots or sample tube types are known to be impacted.

Corrective and preventive actions have been already put in place to avoid any future issue.

Patient Impact

A delay in obtaining patient results for samples collected in sodium or lithium heparin tubes may occur. This issue may also potentially cause lower than expected results to be generated, however, this has not been confirmed through internal testing to date.

Actions to be Taken

1. Immediately discontinue use of lot 50083Y600 and destroy any remaining inventory.
2. Order a replacement Ammonia Ultra reagent lot.
3. Follow your individual laboratory protocol regarding reviewing previously reported patient results.
4. Please retain this communication for future reference. If you have forwarded any MULTIGENT Ammonia Ultra reagent lot 50083Y600 to another laboratory, please provide a copy of this letter to them.

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 your local area Customer Service.

Best regards
Sentinel CH. SpA

Paola Canfora
QSM