



Urgent Field Safety Notice Product Recall

Immediate Action Required

Date Issued

24 February 2015

Product

ARCHITECT Anti-HBc II Reagent Kit

List Number	Lot Number	Expiration Date	UDI Number
8L44-25	42072LI00	28-May-2015	Not Applicable
8L44-25	42072LI01	28-May-2015	Not Applicable
8L44-25	42253LI00	30-Jun-2015	Not Applicable
8L44-25	42253LI01	30-Jun-2015	Not Applicable
8L44-30	42255LI00	30-Jun-2015	Not Applicable
8L44-30	42255LI01	30-Jun-2015	Not Applicable
8L44-35	42256LI00	30-Jun-2015	Not Applicable

Explanation

The ARCHITECT Anti-HBc II assay shows lower calibrator, control and sample RLU values, potentially leading to reduced specificity and increased false reactive results.

Patient Impact

- Internal testing showed specificity dropped to 99.2% which is below the package insert claim of 99.5% on a blood donor population.
- There is the potential for false reactive patient results.
- Assay sensitivity is not impacted.

Necessary Actions

- Discontinue use of the lots listed above and destroy any remaining inventory of these lots according to your laboratory procedures.
- In the event you are currently using or have inventory of one of the lots listed above, immediately contact Customer Support for replacement material.
- Abbott recommends discussing the content of this letter with your laboratory management and communicating this information to the health care providers you serve to determine if any further testing is 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. An investigation is underway to determine the cause of this issue. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.