



Product Recall

Immediate Action Required

Date Issued

July 11, 2011

Product

Product Name	List Number	Lot Number
ARCHITECT C-Peptide Reagent	03L53-25	03610K000
ARCHITECT C-Peptide Reagent	03L53-25	00110L000
ARCHITECT C-Peptide Reagent	03L53-25	01711A000
ARCHITECT C-Peptide Reagent	03L53-25	01411B000
ARCHITECT C-Peptide Reagent	03L53-25	00611E000

Explanation

- The purpose of this communication is to inform you of a situation with ARCHITECT C-Peptide and provide instructions on what actions your laboratory can take if you are currently using and/or have inventory of the reagent lots above.
- Abbott has confirmed that the C-Peptide lots listed above have the potential to generate falsely elevated results with certain patient samples and with non-Abbott Controls.
- Abbott Controls do not show the upward shift.
- The positive bias is linked to a new antibody lot used in the manufacture of the reagent lots listed above. All current inventory at Abbott is impacted.
- We are working diligently to investigate root cause of this issue and will provide the information on future reagent lots as soon as it becomes available.

Patient Impact

Only certain patient samples will show a shift in results. The effect on results varies from sample to sample. In order to estimate the frequency of occurrence and the magnitude of the shift, we reviewed worldwide patient results comparing the lots above with previously manufactured lots. From this analysis, 1.6% of results were impacted at the medical decision point for the diagnosis of insulinoma (0.6 ng/ml).

Necessary Actions

- Determine if you are currently using and/or have inventory of the lots listed above.
- Discontinue use and destroy any remaining inventory of these lots according to your laboratory procedures.
- If you have forwarded any kits of the lots above to other laboratories, please inform them of this Product Recall and provide a copy of this letter to them.
- To continue C-Peptide testing at your laboratory, Abbott recommends that you identify an alternate method for testing patient samples.

Contact Information

We sincerely apologize for any inconvenience this may cause. Abbott is committed to providing you with the highest quality diagnostic products and support services to meet the needs of your laboratory and the providers and patients you serve.

If you or any of the health care providers you serve have any questions regarding this information, U.S. customers should call Customer Service at 1-877-4ABBOTT. Customers outside the U.S., please contact your local Customer Service representative.