



Product Recall

Immediate Action Required

Date Issued

July 26, 2012

Product

ARCHITECT Toxo IgG
List Number: 6C19-25
Lot Numbers: 15070LI00 and 15070LI01

Explanation

ARCHITECT Toxo IgG reagent lots 15070LI00 and 15070LI01 (List Number 6C19-25) are showing reduced specificity which may cause a shift to higher IU/mL values leading to increased grayzone and/or reactive results. The assay sensitivity is not impacted and current data indicates that no other lots are affected.

Patient Impact

There is the potential for false reactive patient results at an estimated rate of 2.65%.

Necessary Actions

- Determine if you are currently using or have inventory of lots 15070LI00 and/or 15070LI01, immediately contact Customer Support for replacement material.
- Discontinue use of lots 15070LI00 and/or 15070LI01 and destroy any remaining inventory of these lots according to your laboratory procedures.
- 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
- Retain this letter for your laboratory records. If you have forwarded any kits of this lot to other laboratories, please inform them of this Product Recall and provide a copy of this letter to them.

Additional Information

We sincerely regret any inconvenience you may have experienced. Based on our preliminary investigation, we identified that the microparticle component of the assay is causing the issue. Interim control measures will include increased internal testing to prevent reoccurrence.

If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Support.