



## Urgent Field Safety Notice Product Correction

Immediate Action Required

**Date Issued**

May 12, 2014

**Product**

**ARCHITECT EBV VCA IgM Controls**

**List Number: 3P66-10**

**Lot Number: 38938LI00**

**Expiration Date: 22-Sep-2014**

**Explanation**

The Positive Control of the ARCHITECT EBV VCA IgM Control lot 38938LI00 has reduced stability. This may result in a higher than expected number of out of range low values. The Negative Control is not impacted.

**Patient Impact**

There is no impact to patient results. If the Positive Control value is out of specification the associated test results are invalid and samples must be retested. This may lead to a delay of reporting of ARCHITECT EBV VCA IgM patient results. If the ARCHITECT EBV VCA IgM Controls are within range, assay performance is acceptable.

**Necessary  
Actions**

- Determine if you are currently using or have inventory of Control lot 38938LI00.
- If the ARCHITECT EBV VCA IgM control values are within package insert range, the associated test results are valid. If the control values are outside your internal specifications, please follow your laboratory procedures.
- If the ARCHITECT EBV VCA IgM control values are outside package insert range, discontinue use of lot 38938LI00 and destroy any remaining inventory of this lot according to your laboratory procedures.
- Immediately contact Customer Support for ordering replacement material.
- 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 Correction and provide a copy of this letter to them.

**Contact  
Information**

We sincerely regret any inconvenience you may have experienced. 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 Support.