ABBOTT
Max-Planck-Ring 2
65205 Wiesbaden
Germany

# Urgent Field Safety Notice
# Product Correction
**Immediate Action Required**

**Date Issued** November 14, 2016

**Product**

| Product Name | List Number (LN) | Lot Number | Expiration Date | UDI |
|---|---|---|---|---|
| ARCHITECT Toxo IgM | 6C20-25 | 64245LI00 | 2017-04-12 | Not Applicable |
| | | 66063LI00 | 2017-05-13 | |
| | | 67003LI00 | 2017-05-12 | |
| | | 68443LI00 | 2017-07-19 | |
| | | 69252LI00 | 2017-07-19 | |
| | | 70171LI00 | 2017-08-26 | |
| | 6C20-35 | 64248LI00 | 2017-04-12 | |
| | | 66066LI00 | 2017-05-13 | |
| | | 67006LI00 | 2017-05-12 | |
| | | 68444LI00 | 2017-07-19 | |
| | | 69253LI00 | 2017-07-19 | |
| | | 70174LI00 | 2017-08-26 | |

**Explanation**

For the ARCHITECT Toxo IgM assay an increase in grayzone and/or false reactive results have been observed for samples from immunocompromised patients or newborns as well as cord blood samples for the lot numbers above. These sample types share the commonality of low total IgM titer.

Internal studies with the ARCHITECT Toxo IgM assay have shown that pregnant women samples and serum and plasma blood donor samples are NOT impacted and meet assay specificity claims.

Abbott has identified a solution to address this issue with a planned product modification expected in Q1 2017.

**Patient Impact**

- Assay sensitivity is NOT impacted.
- There is the potential for false reactive patient results that may be due to reduced specificity in low total IgM titer samples (eg. samples from immunocompromised patients or newborns or cord blood samples).
- In-house testing confirmed that pregnant women samples and serum and plasma blood donor samples meet assay specificity claims.

**Necessary Actions**

- Please review this letter with your Medical Director
- Additional testing with a secondary method is recommended to confirm reactive results (≥ 0.60 Index or ≥ 1.00 S/CO) for samples from immunocompromised patients or newborns or cord blood samples and other samples with expected low IgM concentrations.
- Please retain this letter for your laboratory records.

**Contact Information**

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, please contact your local area Customer Service.