Abbott GmbH & Co. KG
Max-Planck-Ring 2
65205 Wiesbaden
Germany

Urgent Field Safety Notice
Product Correction

Immediate Action Required

Date Issued July 24, 2018

Product

Product Description	List Number (LN)	Lot Number	UDI
ARCHITECT EBV VCA IgM Reagent Kit	3P66-25	85278LI00	N/A
	3P66-35	85279LI00	N/A

Explanation

This letter is to inform you of a Product Correction for ARCHITECT EBV VCA IgM Reagent lots 85278LI00 and 85279LI00 and provide instructions on the actions your laboratory must take.

Abbott has identified the two ARCHITECT EBV VCA IgM Reagent lots listed above may show reduced RLU (Relative Light Units) signal when used in combination with certain lots of ARCHITECT EBV VCA IgM Calibrator (LN 3P66-01). This reduced RLU signal may cause up to a 20% decrease in cutoff RLU values in assay calibration resulting in:

- Upward shift in Quality Control S/CO values
- False grayzone patient results in the range of 0.50-0.60 S/CO
- False reactive patient results in the range 1.00-1.20 S/CO

The effect of decreased cutoff RLU values is observed when using ARCHITECT EBV VCA IgM reagent lots 85278LI00 and 85279LI00 in combination with ARCHITECT EBV VCA IgM calibrator, LN 3P66-01, lot(s) 71146LI00, 73014LI00, 79576LI00, and 83327LI00.

The effect is not observed when using ARCHITECT EBV VCA IgM reagent lots 85278LI00 and 85279LI00 in combination with ARCHITECT EBV VCA IgM calibrator lots 60055LI00, 69054LI00 and 88224LI00.

The effect is not observed when using other currently available reagent lots with any available calibrator lots.

The root cause for this issue is under investigation for an appropriate corrective action.

Patient Impact

The shift in S/CO values may potentially lead to false grayzone or false reactive patient results when using the described reagent and calibrator lot combinations.

Necessary Actions

Do not use the combination of reagent lot 85278LI00 and/or 85279LI00 with calibrator lot(s) 71146LI00, 73014LI00, 79576LI00 or 83327LI00.	
If….	**Then…**
you have calibrated using the combination of reagent lots 85278LI00 and/or 85279LI00 with calibrator lot(s) 71146LI00, 73014LI00, 79576LI00 or 83327LI00.	re-calibrate with calibrator lot 88224LI00 or higher according to your laboratory procedures.
you have calibrated using the combination of reagent lots 85278LI00 and/or 85279LI00 with calibrator lot (s) 60055LI00, 69054LI00 and 88224LI00.	no action is necessary
you have calibrated using currently available reagent lots **NOT** referenced in this product correction.	no action is necessary

- Please review this letter with your Medical Director or Laboratory Management and follow your laboratory protocol regarding the need for reviewing previously reported patient results.
- If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.
- Complete and return the Customer Reply Form
- Please retain this letter for your laboratory records.

Contact Information

We sincerely regret any inconvenience this issue may cause. If you or any of the health care providers you serve have any questions regarding this information, please contact your local area Customer Service.