

Urgent Field Safety Notice

Notice Ref No:	FSN SB RPD 2013_05
Document Date:	
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	Elecsys β-CrossLaps
SYSTEM AFFECTED:	All Elecsys and cobas e systems
MATERIAL NUMBERS:	Mat. no. 11972308-122 Mat. no. 11972308-160
LOT NO (IF APPLICABLE):	n/a
SUMMARY OF ISSUE:	Revised Package Insert claims for sample stability (serum and heparinized plasma) and biotin interference
ACTION REQUIRED:	Customers must be informed of the revised claims before the new Package Insert becomes available
CONTACTS:	Technical Services: Country:

Dear valued customer,

We would like to inform you that the Package Insert of Elecsys β -CrossLaps will be updated to reflect the results of recent testing for sample stability and biotin interference, as follows:

- The sample stability claim for serum kept at 20-25°C will be revised from 8 hours to 6 hours.
- The sample stability claim for heparinized plasma kept at 20-25°C will be revised from 24 hours to 4 hours.
- The sample stability claim for heparinized plasma kept at 4-8°C will be revised from 24 hours to 8 hours.
- The biotin interference claim “The assay should be unaffected by biotin up to 368 nmol/L or 90 ng/mL” will be revised to “The assay should be unaffected by biotin up to 123 nmol/L or 30 ng/mL”.

Please note that the claims for EDTA plasma samples, which is the recommended sample material, remain unchanged.

Also note that these changes were not triggered by customer complaints but by recent internal testing.

Impact on results:

If serum or heparinized samples are stored based on the time periods currently stated in the Package Insert, the Elecsys β -CrossLaps result may be reduced.

If patient samples contain increased biotin value (up to 90 ng/mL biotin) the Elecsys β -CrossLaps result may be reduced depending on sample concentration.

Action required:

With this letter we ask you to apply the correct storage conditions reported above and to inform all relevant parties about the correct biotin interference claim before the changes are implemented in the Package Insert of the new lot of Elecsys β -CrossLaps, which will be in stock on August 6, 2013.

We apologize for any inconvenience this may cause and hope for your understanding and your support.

Kind regards,

Roche Diagnostics

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency
(Closing paragraph)
Signature