Urgent Field Safety Notice

Notice Ref No:	*<reference number>*
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PRODUCT AFFECTED:	**Elecsys® Anti-HBs** **Elecsys® HBsAg II**
SYSTEM AFFECTED:	**MODULAR *ANALYTICS* <E>** **cobas® e** 601
MATERIAL NUMBERS:	**Cat. No. 11820524-122 (Elecsys® Anti-HBs)** **Cat. No. 04687787-190 (Elecsys® HBsAg II)**
LOT NO (IF APPLICABLE):	**All Lots.**
SUMMARY OF ISSUE:	**Interference of Elecsys HBsAg II assay with the Elecsys Anti-HBs leading to weakly false positive anti-HBs results**
ACTION REQUIRED:	**The implementation of wash steps is required on MODULAR *ANALYTICS* <E> and cobas® e 601 systems if a customer runs both assays on the same instrument.**
CONTACTS:	**Technical Services:** **Country:**

Reason for bulletin:
Potential interference of the Elecsys® HBsAg II assay with the Elecsys® Anti-HBs leading to weakly false positive anti-HBs results.

Dear Customer,

Investigations following complaints about weakly positive anti-HBs samples (up to 16 IU/L) that recovered negative (< 2 IU/L) on rerun, revealed the potential of probe-mediated carry-over of Elecsys® HBsAg II reagent into the Assay cup or incubate of a subsequent determination.
The Elecsys® HBsAg II reagent contains a monoclonal antibody directed against HBsAg

that may mimic the analyte in a subsequent anti-HBs determination. A weakly false positive anti-HBs result could possibly be generated since about 10 IU/L are added to the endogenous anti-HBs concentration of the sample. To avoid this potential carry-over additional wash steps need to be implemented on Modular Analytics E and cobas e 601 systems when both assays run on the same instrument.

Action required:

A mandatory update of the special wash list is required and will be done by your Roche Field Service Representative. Until the updated wash list is implemented, we recommend to check anti-HBs sample results in question (anti-HBs results between 10 and 20 IU/L) by re-running these samples separately.
You may want to check with the attendant physician if retesting of previously reported weakly positive anti-HBs results (after installation of Elecsys HBsAg II assay) is required from a medical point of view.

We apologize for any inconvenience this problem may cause you.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

Kind regards,

Signature