

## Urgent Field Safety Notice

<b>Notice Ref No:</b>	<i>&lt;reference number&gt; FSN RPD 07/2009</i>
<b>Document Date:</b>	<b>27 April 2009</b>
<b>Type of Action</b>	<b>Field Corrective Action</b>

<b>PRODUCT AFFECTED:</b>	<b>Folate III Elecsys, cobas e</b>
<b>SYSTEM AFFECTED:</b>	<b>Elecsys® / cobas® e MODULAR ANALYTICS &lt;E&gt;</b>
<b>MATERIAL NUMBERS:</b>	<b>04476433190</b>
<b>LOT NO (IF APPLICABLE):</b>	<b>150682 / 151272</b>
<b>SUMMARY OF ISSUE:</b>	<b>Discrepancies in recovery between serum and heparin plasma samples.</b>
<b>ACTION REQUIRED:</b>	<b>Please stop using heparin plasma samples</b>
<b>CONTACTS:</b>	<b>Technical Services: Country:</b>

**Reason for notice:**

Elecsys Folate III (lot 150682 and 151272) should not be used with heparin plasma samples anymore.

The evaluation by a customer as well as internal investigations showed that the two concerned lots show a borderline performance in serum/heparin plasma comparisons.

The discrepancy is caused by the slow degradation of a polypeptide added to the folate test.

There is no risk using the affected reagent kit lots for measurement of folate in serum samples.

Using Heparin-Plasma under worst case conditions the elevated recovery may

result in incorrect clinical classification of a folate deficient patient, however the medical risk is considered to be remote.

**Action required:**

Do not to use anymore heparin plasma samples with the two affected lots, since the future performance of the two lots cannot be predicted.

We apologize for any inconvenience this problem may cause you.

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