

Urgent Field Safety Notice

Notice Ref No:	FSN RPD 10/2010
Document Date:	11 August 2010
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	Tinaquant D-Dimer Gen II
SYSTEM AFFECTED:	Roche/Hitachi 902, 912, 917, Mod P, cobas c 311, c501, c111, COBAS INTEGRA
MATERIAL NUMBERS:	04912497190; 04912551190; 05077753190
LOT NO (IF APPLICABLE):	62838001; 62837701; 62841101
SUMMARY OF ISSUE:	Instability of certain lots of Tinaquant D-Dimer Gen II
ACTION REQUIRED:	Customers shall stop using the concerned lots of the product. Products still on stock shall be discarded.
CONTACTS:	Technical Services: Country:

Reason for notice:

Internal observations with D-Dimer Gen. 2 revealed that reagent lots 62838001, 62837701 and 62841101 show an unusual signal increase when tested together with our serum based calibrators and controls, whereas native plasma samples do not show this increase.

As a consequence patient sample recover with a systematic negative bias of currently about 15%.

The issue can be detected by third party plasma based quality control material, however it will not be detected with our serum based control material.

The deviation of 15% observed in the current investigation does not pose an

immediate medical risk. However the reagent stability in future and the consequence for the performance of the lots concerned cannot be predicted.

Action required:

Customer should stop using the affected lots of the product. Products still on stock should be discarded.

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