

Urgent Field Safety Notice

Notice Ref No:	<i>FSN RPD 13/2010</i>
Document Date:	29. September 2010
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	Calcium	
SYSTEM AFFECTED:	COBAS INTEGRA®, cobas c 111, c 311, c 501, c 502, c 701, c 711	
MATERIAL NUMBERS AND LOT NO:	Mat. No.	Lot No.
	20763128 322	626019-01
	04718933 190	626022-01
	05171989 190	627326-01
	04932650 022	627908-01
SUMMARY OF ISSUE:	Imprecision and erroneous patient results for Calcium due to precipitations in R2	
ACTION REQUIRED:	Stop using the concerned lots of the product. Products still on stock shall be discarded.	
CONTACTS:	Technical Services: Country:	

Reason for notice:

Customer reports of imprecision and erroneous patient results for calcium on COBAS INTEGRA® and cobas c 501 systems using reagent lot 626019-01 have been received. The problem occurred predominantly when the remaining tests per cassette fell below 50 tests.

Internal investigations revealed the presence of precipitate in the R2 of the affected calcium reagent lot. The precipitate observed was classified as o-cresolphthalein complexone (o-CPC), a reactive component of the calcium R2.

The root cause for the precipitation is still under investigation.

As a consequence over- and underrecovery of patient samples may occur, which poses a medical risk.

The following alternative lot numbers not showing this issue are currently on stock:

GMMI number	Lot number	Analyzer
20763128 322	630204-01	cobas c 311/501/502, COBAS INTEGRA®
04718933 190	628031-01	cobas c 111
05171989 190	632289-01	cobas c 701
04932650 022	631376-01	cobas c 711

These lot numbers are closely monitored for precipitate formation.

Action required:

Customers have to stop using the affected lots of the product. Products still on stock have to be discarded.

Unexpected calcium results produced with the affected lots should be reviewed in conjunction with the patient's medical history, clinical examination, and other findings. Where appropriate patient re-testing with unaffected lots is recommended.

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