

Urgent Field Safety Notice

Notice Ref No:	FSN SB RPD 2013_11
Document Date:	06 September 2013
Type of Action	Field Corrective Action

PRODUCT AFFECTED:	cobas HbA1c Test
SYSTEM AFFECTED:	cobas b101 system
MATERIAL NUMBERS:	Mat. no. 06378676190
LOT NO (IF APPLICABLE):	303022-01, 304021-01, 304022-01, 304023-01, 304024-01, 304025-01, 305021-01, 306022-01, 306023-01, 307021-01
SUMMARY OF ISSUE:	Comparing to lab methods, these 10 disc lots show imprecision for HbA1c patient results.
ACTION REQUIRED:	Current customers must stop using the affected disc lots and discard them locally.
CONTACTS:	Technical Services: Country:

Reason for notice:

Recent complaints are reporting an imprecision of HbA1c patient results of the above listed lots when comparing to laboratory methods. Customers experienced a bias of up to - 43 %.

Detailed investigations of the above listed lots were conducted by Panasonic Healthcare, the provider of the HbA1c discs. The storage stability data shows a deviation in the range of -10% up to -30% from the target value with an error rate of up to 40%. No deviation was found with previous lots.

The detailed analysis showed that the problem is caused by the serum-based CGG material. PHC stated that low solubility proteins such as prothrombin in serum-based CGG-material might have caused the imprecise results by following reasons:

1. Higher agglutination concentration causes impurity.

2. The impurity accelerates the stability issue which occurs 1~3 months later after manufacturing.

Dear valued customer,

We regret to inform you about the fact that 10 disc lots show imprecision for HbA1c patient results as follows:

Product Name	Material No. (GMMI)	Lot
HbA1c Test	06378676190	303022-01 304021-01 304022-01 304023-01 304024-01 304025-01 305021-01 306022-01 306023-01 307021-01

As a precaution, distribution of 06378676190 (HbA1c test for cobas b 101) was stopped on 27. Aug 2013. Production of HbA1c test will return to the material with its original specification. The original quality will be available during November 2013. You will be proactively informed once the original quality of the HbA1c is available again.

Please note that the other tests currently running on cobas b 101 (cobas Lipid Panel) are NOT affected by the issue.

Actions required:

With this letter we ask you to stop using the affected disc lots and discard them locally.

We sincerely apologize for any inconvenience caused by this issue.

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