Urgent Field Safety Notice
SBN-RMD-2014-015

RMD / **cobas®** KRAS Mutation Kit
Version 1
18-DEC-2014

Discontinue use of the cobas® KRAS Mutation Kit, lot T10786

Product Name	**cobas®** KRAS Mutation Kit
GMMI / Part No	05852170190
Device Identifier	20875197004193
Production Identifier (Lot No./Serial No.)	T10786
SW Version	N/A
Type of Action	Field Safety Corrective Action (FSCA)

Dear Valued Customer,

Description of Situation

The **cobas®** KRAS Mutation Kit, T10786, is generating invalid results for the Mutant Control and/or KRAS Calibrator. Therefore, we are requesting you to discontinue use and discard any remaining inventory immediately.

There is no risk of erroneous results being generated, as the kits controls will invalidate the run. As stated in the **cobas®** KRAS Mutation Kit Instructions for Use:

> If the KRAS Mutant Control (**KRAS MC**), negative control (**NEG CT**) or KRAS Calibrator (**KRAS CAL**) for working MMX 12/13 or working MMX 61 are invalid, the entire run is invalid and must be repeated. Prepare a fresh dilution of the previously isolated specimen DNA Stock to set up a new microwell plate (AD-plate) with controls for amplification and detection.

Actions taken by Roche Diagnostics

The issue is currently under investigation. When the root cause has been confirmed, appropriate corrective actions will be planned and executed, as required.

Discontinue use of the cobas® KRAS Mutation Kit, lot T10786

Actions to be taken by the customer/user

- Discontinue use and discard any remaining inventory of **cobas®** KRAS Mutation Kit, lot T10786 immediately.
- There is no need to review previous valid test results.
- Contact your local Roche affiliate organization to obtain replacement kits.

Communication of this Field Safety Notice (if appropriate)

This notice must be passed on to all those who need to be aware within your organization or to any organization/individual where the potentially affected devices have been distributed/supplied.

Please transfer this notice to other organizations/individuals on which this action has an impact.

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

We apologize for any inconvenience this may cause and hope for your understanding and your support.