

## Urgent Field Safety Notice

Notice Ref No:	FSN RPD No. 12/2008
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<b>PRODUCT AFFECTED:</b>	<b>Total Bilirubin Granulat (BIL-T) Total Bilirubin liquid (TBILI)</b>
<b>SYSTEM AFFECTED:</b>	All Clinical Chemistry Systems
<b>MATERIAL NUMBERS:</b>	12144336 216, 04796748 190, 04796756 190, 12144492 216, 12144506 216, 11552414 216, 11489194 216, 11489429 216, 03261638 190, 03146022 122, 04774256 190, 20737488 322, 11822713 190, 11822721 190, 11822730 190, 11877941 190, 11877950 190, 11877968 190, 11877976 190
<b>LOT NO (IF APPLICABLE):</b>	All lots in market
<b>SUMMARY OF ISSUE:</b>	Re-standardization of calibrators and controls for Total Bilirubin
<b>ACTION REQUIRED:</b>	Customer information
<b>CONTACTS:</b>	<b>Technical Services:</b> <b>Country:</b>

Dear customer,

We would like to inform you about the re-standardization and package insert update of Total Bilirubin Granulat (BIL-T) and Total Bilirubin liquid (TBILI) assays.

Roche assays are standardized against reference to the Doumas method as determined by the European IFCC reference laboratory in Germany. Due to observed differences to the US reference laboratory a correction of the Doumas method at the German reference laboratory became necessary and was established recently.

After completion of the standardization trial, the method specific deviation for the liquid reagent and the adjustment of the Doumas reference standardisation resulted in a cumulative decrease in the master-lot set-point in the range of 10-17% (see table below).

Assay		System	Set-point adjustment in C.f.a.s. master lot
Bilirubin granulate BIL-T	12144336 216 04796748 190 04796756 190 12144492 216 12144506 216 11552414 216 11489194 216 11489429 216	Roche/Hitachi and Modular	-10%
Bilirubin liquid TBILI	11822713 216 11822721 216 11822730 216 11877941 216 11877950 216 11877968 216 11877976 216	Roche/Hitachi and Modular	-17%
Bilirubin liquid BILTS	03261638 190	COBAS INTEGRA®	-13%
Bilirubin liquid DPD BILT2	03146022 122	COBAS INTEGRA®	-12%
Bilirubin Total BIL-T	20737488 322	COBAS INTEGRA®	-13%
Bilirubin liquid BILTS	03261638 190	<b>cobas c 501</b> <b>cobas c 311</b>	-14%
Bilirubin liquid DPD BILT2	03146022 122	<b>cobas c 501</b> <b>cobas c 311</b>	-11%
Bilirubin liquid BILTS	04774256 190	<b>cobas c 111</b>	-13%

In neonates the Bilirubin concentration is the only criterion used, to determine the risk of chronic Bilirubin encephalopathy (kernikterus). Therapeutic measures can be phototherapy or a blood exchange as a more aggressive treatment.

The underestimation of the Bilirubin concentration would have severe consequences for the newborn because of an untreated or too late treated kernicterus. The overestimation of Bilirubin (like in this case) may have caused the unnecessary treatment of newborns by phototherapy. However, an unnecessary blood exchange is less likely since this measure is typically considered when a fast and significant raise of the Bilirubin concentration within hours occurred or an already very high bilirubin result was measured.

For adults a medical risk is remote, as Total Bilirubin is used for differential diagnosis together with other clinical parameters in connection with clinical examination.

Please inform your laboratory staff and physicians accordingly.

Attached you will find the new assigned Bilirubin target values.

For further information please contact your local affiliate.

We apologize for any inconvenience caused by that issue.

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

Signature

Attachments