



Urgent Field Safety Notice

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PRODUCT AFFECTED: Ammonia/Ethanol/CO2 Calibrator
Ammonia/Ethanol/CO2 Control N
Ammonia/Ethanol/CO2 Control A

SYSTEM AFFECTED: Roche / Hitachi / cobas c / COBAS INTEGRA®
analyzers

MATERIAL NUMBERS: 20751995 190 Calibrator
20753009 190 Control A
20752401 190 Control N

LOT NO (IF APPLICABLE): 179070 01 and 179070 02 Calibrator
179021 01 and 179021 02 Control A
178993 01 and 178993 02 Control N

SUMMARY OF ISSUE: Reduced concentration of Bicarbonate

ACTION REQUIRED: Do not use Calibrator Lot No. 179070 01 and
179070 02 in combination with Controls N and A of
lot numbers shown above.

CONTACTS: Technical Services:
Country:

Reason for bulletin:

False values for Bicarbonate when using affected lots of calibrator in combination with the Controls A and N of lots shown above.

Dear Customer,

We would like to inform you that the Ammonia/Ethanol/Bicarbonate Calibrator (lot numbers 179070-01 and 179070-02) must not be used any longer for the calibration of Bicarbonate reagents on Roche / Hitachi, cobas c and COBAS INTEGRA® systems in combination with the Control N of lot 178993-01 and -02 and Control A lot 179021-01 and -02.

Internal investigations following a customer complaint showed an in-homogeneity of the concerned lots. In 8 out of 180 investigated retention calibrator and control vials the Bicarbonate concentration was lowered by more than 10 % (worst case 26 %). The reason for the inhomogeneity is leaking of some bottles due to physical stress during transportation and/or handling.

New lots of calibrator (181590-01), Controls A (180419-01) and N (180429-01) have been tested and found to be unaffected. Safe determination of Bicarbonate is possible by combination of proper Calibrator/potentially leaking Controls or potentially leaking Calibrator/proper Controls.

If in these combinations there is a leaking bottle, the result would be flagged as invalid and would lead to repeated calibration.

The following combinations may be used:

Yellow: Could possibly exhibit signs of leakage and could possibly be affected.

Green: No signs of leakage. Not affected.

Calibrator Lot No.	Control N Lot No.	Control A Lot . No.	Calibration
179070-01 and -02	██████████	██████████	Valid if result is not flagged.
██████████	178993-01 and -02	179021-01 and -02	Valid if result is not flagged
██████████	██████████	██████████	Valid

The following combination must not be used:

Calibrator Lot No.	Control N Lot No.	Control A Lot . No.	Calibration
179070-01 and -02	178993-01 and -02	179021-01 and -02	Do not use this combination.

The root-cause investigation is still ongoing.

We confirm that the Ethanol and Ammonia recovery of the concerned calibrator and control lots is not affected. All lots of Control and Calibrator A and N may be used for Ethanol and Ammonia without any restriction.

Action required:

1. Only use Calibrators in combination with the Control lots shown in the table above for the determination of Bicarbonate on Roche / Hitachi / cobas c / COBAS INTEGRA® analyzers any more.
2. Contact your local Roche representative for the availability of replacement products.

We apologize for any inconvenience this problem may cause you.

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

Kind regards,

Signature