

Lublin, Poland, 5th April, 2023

Dear Valuable Customers,

We would like to inform that PZ Cormay S.A. due to global supply chain disturbances, was affected by the lack of raw material for the production of: **5-105**, **CORMAY ETHANOL CALIBRATORS** and **5-106**, **CORMAY ETHANOL CALIBRATOR 100**, therefore the availability of the above-mentioned kits is suspended until further notice. In order to enable further determinations of ethyl alcohol concentration and calibration, we recommend alternative solution.

For calibration, we recommend using products from ACQ Science GmbH:

- ✓ cat. no.: AQ10-015, name: EtOH Cal AQ 1.0 g/L, composition: 10 x 1.5 ml
- ✓ cat. no.: AQ30-015, name: EtOH Cal AQ 3.0 g/L, composition: 10 x 1.5 ml

Calibration rules on automatic analyzers and manual determinations do not change:

- ✓ For calibration on automatic analyzers, it is recommended to use two levels of calibrator (1.0 g/L and 3.0 g/L) and deionized water or 0.9% NaCl solution as calibrator 0; more details can be found in the dedicated instructions for use.
- ✓ When calibrating manual assays, it is recommended to use one lower calibrator level (1.0 g/L).

Additional information:

- ✓ Both calibrator levels must be ordered separately.
- ✓ The expiration date of the bundles available for sale is: May 2029.
- ✓ ACQ Science GmbH gives values for ethanol in 'g/L' units. If you use units in 'mg/dl', harmonize both units and enter the correct values into the analyzers:
 - $1.0 \text{ g/L} \rightarrow 100 \text{ mg/dL}$
 - $3.0 \text{ g/L} \rightarrow 300 \text{ mg/dL}$
- ✓ Storage and stability of the EtOH Calibrator:
 - a) Unopened calibrators stored at 2-8°C are stable until the date stated on the package.
 - b) Stability after opening:

It is recommended to use the contents of the ampoule / vial immediately after opening due to changes in concentration caused by alcohol evaporation. An opened ampoule/vial can only be used once! Do not freeze calibrators!

PZ Cormay S.A.

Poland, 05-092 Łomianki 22 Wiosenna Street NIP: 1181872269 REGON: 140777556 Corespondence address:

PZ Cormay S.A. Poland, 02-785 Warsaw, 303 Pulawska Street office@cormay.com tel. +48 (22) 751 79 10



- ✓ Instructions for use (IFU) for ethanol parameter have been updated about new calibrator recommendation.
- ✓ Registration topic: Calibrators can be bought directly from Cormay and redistributed on EU territory. Registration may be required for other markets. For registration questions please, contact with Cormay Regulatory Affairs Team.

We apologize for any inconvenience.

For any further information, please contact our Sales Representatives.

Yours sincerely,

Clinical Chemistry Product Manager

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REGON: 140777556

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