

ADVISORY NOTE

Date of issue	05.09.2023
<b>Note number</b>	<b>ND_2309_01</b>
Product name and catalogue numer	<b>CORMAY HbA1c DIRECT CALIBRATORS Nr kat. 4-308</b>
Lot number	<b>207-41 210-42 304-43</b>
Expiry date	<b>2025-03</b>

Issue description

**APPLIES ONLY TO USERS OF ACCENT-300, BS-400, BS-480, BS-800, BS-800M, ACCENT S120, ACCENT MC240 and ACCENT M320 ANALYZERS!!!**

Results obtained during routine reagent quality control exceeded the internal acceptance criteria. To solve the problem the value for **LEVEL 2** of the **CORMAY HbA1c DIRECT CALIBRATORS** (Cat. No. **4-308**) was redetermined. New calibrator value is:

CALIBRATOR	LOT NUMBER	VALUE
CORMAY HbA1c DIRECT CALIBRATORS	207-41	8,2 %
	210-42	
	304-43	

The updated values sheets are attached to the Advisory Note (Attachment 1-3).

Necessary actions

- Read carefully advisory note and corrected value sheet (Attachment 1-3) and **use the calibrator values appropriate for your analyzer.**
- Perform **calibration and quality control** prior to ordering patient samples.
- Complete and return the Verification Form.

The note is only for reference. **Do not discard the product!**

**Please provide this information to all Users of the above product and keep the Advisory Note as a quality system documentation.**

**Please complete and return the attached Verification Form to confirm receipt of the Advisory Note.**

**We apologize for any inconvenience caused by the above situation.**

Sincerely,

Quality Assurance Coordinator