

ADVISORY NOTE

Date of issue	19.05.2023
Note number	ND_2305_01
Product name and catalogue number	CORMAY HbA1C DIRECT CALIBRATORS Cat. No 4-308
Lot number	107-37 110-38 112-39 202-40
Expiry date	29.02.2024
Issue description	
<p>APPLIES ONLY TO USERS OF <u>ACCENT S120</u>, <u>ACCENT MC240</u> and <u>ACCENT M320</u> ANALYZERS!!!</p> <p>In the assigned values sheets for the above-mentioned lots of CORMAY HbA1C DIRECT CALIBRATORS, the analyzers ACCENT S120, ACCENT MC240 and ACCENT M320 were incorrectly assigned to group of devices with higher calibrator values.</p> <p>The updated values sheets with analyzers assigned to the proper group of devices are attached to the Advisory Note (Attachment 1-4).</p> <p>The numerical values of all calibrator levels have not changed.</p>	
Necessary actions	
<ul style="list-style-type: none">• Read carefully advisory note and corrected value sheet (Attachment 1-4) 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. <p>The note is only for reference. Do not discard the product!</p>	

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