

**ADVISORY NOTE**

Date of issue	19.05.2023
Note number	ND_2305_02
Product name and catalogue numer	<b>CORMAY HbA1C DIRECT CONTROLS Cat. No 4-328</b>
Lot number	107-34 110-35 112-36 202-37
Expiry date	29.04.2023
Issue description	
<p><b>APPLIES ONLY TO USERS OF <u>ACCENT S120</u>, <u>ACCENT MC240</u> and <u>ACCENT M320 ANALYZERS!!!</u></b></p> <p>In the assigned values sheets for the above-mentioned lots of CORMAY HbA1C DIRECT CONTROLS, the analyzers <b>ACCENT S120, ACCENT MC240 and ACCENT M320</b> were incorrectly assigned to group of devices with higher control 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 controls levels have not changed.</p>	
Necessary actions	
<ul style="list-style-type: none"> <li>• Read carefully advisory note and corrected value sheet (Attachment 1-4) and <b>use the control values appropriate for your analyzer.</b></li> <li>• Perform <b>quality control</b> prior to ordering patient samples.</li> <li>• Complete and return the Verification Form.</li> </ul> <p>The note is only for reference. <b>Do not discard the product!</b></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