

ADVISORY NOTE

Date of issue	<b>06.04.2022</b>	
Note number	<b>ND_2204_04</b>	
Product name and catalogue numer	<b>Name</b>	<b>Cat. No</b>
	CORMAY GLUCOSE HEX mini	1-228
	CORMAY GLUCOSE HEX 30	1-229
	CORMAY GLUCOSE HEX 60	1-230
	CORMAY GLUCOSE HEX 120	1-231
	CORMAY GLUCOSE HEX 500	1-232
	HC-GLUCOSE HEX	4-523
	OS-GLUCOSE HEX	9-477
	ACCENT-200 GLUCOSE HEX	7-252
	ACCENT-300 GLUCOSE HEX	7-352
	A-400 GLUCOSE HEX	7-464
	A-800 GLUCOSE HEX	7-802
	PRESTIGE 24i GLUCOSE HEX	4-231
	PRESTIGE 24i GLUCOSE HEX	4-423
	BIOLIS 15i GLUCOSE HEX	4-709
	BIOLIS 50i GLUCOSE HEX	5-511
	CORMAY GLUCOSE HEX BULK	1-233_R1
	CORMAY GLUCOSE HEX BULK	1-233_R2
Lot number	<b>all lots</b>	
Expiry date	<b>n/a</b>	
Issue description		
<p>In order to ensure traceability, based on the primary standard: NIST Standard Reference Material 965b, values assigned for glucose in calibrators and control materials were re-determined:</p> <ul style="list-style-type: none"> <li>- <b>CORMAY SERUM HN</b> (Cat. No 5-172) lot HN09,</li> <li>- <b>CORMAY SERUM HP</b> (Cat. No 5-173) lot HP09,</li> <li>- <b>CORMAY MULTICALIBRATOR LEVEL 1</b> (Cat. No 5-174 / 5-176) lot XXX-03X,</li> <li>- <b>CORMAY MULTICALIBRATOR LEVEL 2</b> (Cat. No 5-175 / 5-177) lot XXX-03XX and XXX-04X,</li> <li>- <b>CORMAY URINE CONTROL LEVEL 1</b> (Nr kat. 5-161) lot XXX-50, XXX-51, XXX-52, XXX-53, XXX-54,</li> <li>- <b>CORMAY URINE CONTROL LEVEL 2</b> (Nr kat. 5-162) lot XXX-46, XXX-47, XXX-48, XXX-49, XXX-50</li> </ul> <p>The new values have been placed in Erratum NDE_2204_02 (Attachment 1).</p>		
Necessary actions		
<ul style="list-style-type: none"> <li>• read carefully Advisory Note, Erratum NDE_2204_02 (Attachment 1) and <b>use the re-determined values</b> of calibrators and controls during determinations of glucose,</li> <li>• perform <b>calibration and 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,

X *Anna Smolira*

Anna Smolira  
 Quality Assurance  
 Podpisany przez: Anna Smolira