

ADVISORY NOTE

Date of issue	06.04.2022
Note number	ND_2204_02
Product name and catalogue number	ACCENT-300 GLUCOSE, Cat. No 7-301
Lot number	all lots
Expiry date	n/a
Issue description	
<p>Results obtained during routine reagent quality control exceeded the internal acceptance criteria. To correct the problem:</p> <ol style="list-style-type: none"> <li>The application program for the ACCENT-300 analyzer has been optimized (Attachment 1).</li> <li>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: <ul style="list-style-type: none"> <li>- CORMAY SERUM HN (Cat. No 5-172) lot HN09,</li> <li>- CORMAY SERUM HP (Cat. No 5-173) lot HP09,</li> <li>- CORMAY MULTICALIBRATOR LEVEL 1 (Cat. No 5-174 / 5-176) lot XXX-03X,</li> <li>- CORMAY MULTICALIBRATOR LEVEL 2 (Cat. No 5-175 / 5-177) lot XXX-03XX and XXX-04X.</li> </ul> </li> </ol> <p>The new values have been placed in Erratum NDE_2204_01 (Attachment 2).</p>	
Necessary actions	
<ul style="list-style-type: none"> <li>• read carefully Advisory Note and Erratum NDE_2204_01 (Attachment 2),</li> <li>• update the application program on analyzer before use (Attachment 1),</li> <li>• <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  
 Quality Assurance  
 Podpisany przez: Anna Smolira