

**CHANGE NOTIFICATION**

Notification number	<b>PZ_2309_01</b>	Date	05.09.2023
Change number	106		
Subject of the change	<p>Application programs for HbA1c DIRECT determination optimization.</p> <p>Assigning the analyzers to the group of devices with lower control values in the assigned values sheets for CORMAY HbA1c DIRECT CALIBRATORS and CORMAY HbA1c DIRECT CONTROLS.</p> <p>The calibrator value for level 2 of CORMAY HbA1c DIRECT CALIBRATORS re-determination.</p>		
Affected products	Cat no	Product name	
	4-300 4-301 4-328 4-308	PRESTIGE 24i HbA1c DIRECT PRESTIGE 24i HbA1c DIRECT CORMAY HbA1c DIRECT CONTROLS CORMAY HbA1c DIRECT CALIBRATORS	
Change category	<input type="checkbox"/> raw materials <input type="checkbox"/> quality control <input type="checkbox"/> packages <input type="checkbox"/> informations provided with the product <input type="checkbox"/> manufacturing <input checked="" type="checkbox"/> final product <input type="checkbox"/> other		
Change description	<p style="text-align: center;"><b>APPLIES ONLY TO USERS OF ANALYZERS: <u>Biolis 24i Premium and Biolis 30i !!!</u></b></p> <p>1. Application programs for HbA1c DIRECT determination have been optimized on Biolis 24i Premium and Biolis 30i analyzers – the sub-reading time has been removed (<i>Attachment 1</i>).</p> <p>2. In the assigned values sheets for:</p> <ul style="list-style-type: none"> <li>• <b>CORMAY HbA1c DIRECT CALIBRATORS lots: 207-41, 210-42, 304-43, 305-44, 307-45</b> and</li> <li>• <b>CORMAY HbA1c DIRECT CONTROLS lots: 207-3838, 211-3939, 305-4040, 307-4141</b></li> </ul> <p>the analyzers Biolis 24i Premium and Biolis 30i have been assigned to the group of devices with lower calibrator/ control values. The updated value sheets are attached to the Change Notification (<i>Attachments 2-10</i>).</p> <p>3. Additionally, in the assigned values for <b>CORMAY HbA1c DIRECT CALIBRATORS lots 207-41, 210-42, 304-43</b>, the calibrator value of level 2 has been re-determined. The new value is 8,2%. The updated value sheets are attached to the Change Notification (<i>Attachments 2-4</i>).</p>		
Reason for change	Improvement of the results obtained with patient samples.		
Implementation	September 2023		
Additional information	<p>The above changes do not affect the performing of determination, functionality and stability of products.</p> <p>The changes will have a positive effect on accuracy of obtained results of glucated hemoglobin.</p>		

Attachments	<p><i>Attachment 1</i> – Instruction for use of Prestige 24i HbA1c DIRECT.</p> <p><i>Attachment 2</i> – Assigned values sheet for CORMAY HbA1c DIRECT CALIBRATORS lot 207-41.</p> <p><i>Attachment 3</i> – Assigned values sheet for CORMAY HbA1c DIRECT CALIBRATORS lot 210-42.</p> <p><i>Attachment 4</i> – Assigned values sheet for CORMAY HbA1c DIRECT CALIBRATORS lot 304-43.</p> <p><i>Attachment 5</i> – Assigned values sheet for CORMAY HbA1c DIRECT CALIBRATORS lot 305-44.</p> <p><i>Attachment 6</i> – Assigned values sheet for CORMAY HbA1c DIRECT CALIBRATORS lot 307-45.</p> <p><i>Attachment 7</i> – Assigned values sheet for CORMAY HbA1c DIRECT CONTROLS lot 207-3838.</p> <p><i>Attachment 8</i> – Assigned values sheet for CORMAY HbA1c DIRECT CONTROLS lot 211-3939.</p> <p><i>Attachment 9</i> – Assigned values sheet for CORMAY HbA1c DIRECT CONTROLS lot 305-4040.</p> <p><i>Attachment 10</i> – Assigned values sheet for CORMAY HbA1c DIRECT CONTROLS lot 307-4141.</p>
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If there are any questions or concerns with respect to this change, please feel to contact your Area Sales Managers.

Quality Assurance Coordinator