

### CHANGE NOTIFICATION

Notification number	<b>PZ_2312_01</b>	Date	15.12.2023
Change number	098, 102 and 103		
Subject of the change	Change No 98 - Classification and/or labelling change.		
	Change No 102 – Nomenclature of calibrators and controls components unification.		
	Change No 103 – Way of delivering assigned values change.		
Affected products	Cat no	Product name	
	SeeL Attachment 1	SeeL Attachment 1	
Change category	<input type="checkbox"/> raw materials <input type="checkbox"/> packages <input type="checkbox"/> manufacturing	<input type="checkbox"/> quality control <input checked="" type="checkbox"/> informations provided with the product <input type="checkbox"/> final product <input type="checkbox"/> other	
Change description	<u>Change No 098:</u> The classification and labelling of: <ul style="list-style-type: none"> <li>• <b>CORMAY AMMONIA / ETHANOL CONTROLS,</b></li> <li>• <b>CORMAY URINALYSIS CONTROLS</b></li> </ul> And labelling of: <ul style="list-style-type: none"> <li>• <b>CORMAY Lp(a) CALIBRATOR,</b></li> <li>• <b>CORMAY Lp(a) CONTROL N i P,</b></li> <li>• <b>CORMAY URINE CONTROL LEVEL 1 i LEVEL 2,</b></li> <li>• <b>CORMAY SERUM HN i HP</b></li> </ul> Has been changed.  The current labelling is presented in Attachment 1.		
	<u>Change No 102:</u> The unified names of calibrators and controls components have been implemented. Since implementation of this change, individual components of the calibrators and controls on the labels and in the instructions for use will be shorter and consistent for all products, which will affect their readability.  The changes are presented in Attachment 1.		
	<u>Change No 103:</u> The way of delivering assigned values for calibrators and controls has been changed. Since implementation of this change, the assigned values will no longer be included in instruction for use and they will be presented: <ul style="list-style-type: none"> <li>• on vial's label (in case of: <b>CORMAY HDL/LDL CALIBRATOR, CORMAY MICROALBUMIN CALIBRATOR i CORMAY CYSTATIN C CONTROLS</b>) or</li> <li>• in the value sheet (<b>CORMAY HbA1c DIRECT CALIBRATORS i CORMAY HbA1c DIRECT CONTROLS</b>).</li> </ul> In order to improve identification, identification numbers have been assigned to the value sheet - this change applies to both newly prepared documents (for the products listed above) and products for which the assigned values were		

	<p>already provided in this form (<b>CORMAY IMMUNO-MULTICAL, CORMAY MULTICALIBRATOR LEVEL 1 i LEVEL 2, CORMAY IMMUNO-CONTROL I, II i III, CORMAY URINE CONTROL LEVEL 1 i LEVEL 2, CORMAY SERUM HN i HP</b> oraz <b>CORMAY URINALYSIS CONTROLS</b>).</p> <p>Detailed information and list of products affected by the change are presented in Appendix 1</p>
Reason for change	<p><u>Change No 098:</u> Fulfilling the requirements of the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 taking into account Adaptation to Technical Progress (ATP) to the CLP Regulation.</p> <p><u>Change No 102:</u> Compliance with legal requirements for technical documentation.</p> <p><u>Change No 103:</u> Optimization of assay sheet preparation or updating process.</p>
Implementation	December 2023
Additional information	<p>The above change does not affect the performing of determination, functionality and stability of calibrators and controls.</p> <p>Products with the new labelling, unified names and changed way of delivering assigned values will be available for sale beginning from mid-December 2023. Products without implemented changes may also be available – while stocks last.</p> <p>Using calibration and control materials wear personal protective equipment and follow the new classification of the calibrators and controls.</p> <p>Updated material safety data sheet (MSDS) is available at: <a href="https://cormaydiagnostics.com/customer-support/documents">https://cormaydiagnostics.com/customer-support/documents</a></p>
Attachments	Attachment 1 - Summary of products affected by the changes: 098, 102 and 103

If there are any questions or concerns with respect to this change, please feel to contact your Area Sales Managers.

Quality Assurance Manager