

CHANGE NOTIFICATION

Notification number	PZ_2311_01	Date	20.11.2023
Change number	118		
Subject of the change	Application programs for CRP ULTRA determination optimization on biochemical analyzers.		
Affected products	Cat no	Product name	
	7-225	ACCENT-200 CRP ULTRA	
Change category	<input type="checkbox"/> raw materials <input type="checkbox"/> quality control <input type="checkbox"/> packages <input checked="" type="checkbox"/> informations provided with the product <input type="checkbox"/> manufacturing <input type="checkbox"/> final product <input type="checkbox"/> other		
Change description	<p style="text-align: center;">APPLIES ONLY TO USERS OF ANALYZERS: ACCENT-200 and ACCENT-200 II GEN !!!</p> <p>Application program for CRP ULTRA determination has been optimized on ACCENT-200 and ACCENT-200 II GEN analyzers - changes included: wavelength, sample volume and reading time – (<i>Attachment 1</i>).</p> <p>The new application program is also included in the updated instructions for use.</p>		
Reason for change	Improvement of correlation results obtained for patients samples.		
Implementation	November 2023		
Additional information	<p>The above change does not affect the performing of determination, functionality and stability of product.</p> <p>The current instructions for use can be found on the website – www.cormaydiagnostics.com.</p>		
Attachments	<i>Attachment 1</i> - Application program on ACCENT-200 and ACCENT-200 II GEN analyzers.		

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

Quality Assurance Manager