

URGENT FIELD SAFETY NOTICE

Decreasing calibration stability for LDL-c direct FS on respons[®]910 within one day

Date	2022-07-27	
Product	LDL-c direct FS	Cat. No.: 1 4131 99 10 921
Explanation	Initiated by a customer complaint, the calibration stability for reagent LDL-c direct FS on respons [®] 910 has been reviewed. The internal investigation revealed that calibration stability is decreasing through the day. The cause of the change in calibration stability is a temperature effect that occurs when refrigerated reagent warms up during the day. DiaSys will immediately provide an updated version of the respons [®] 910 instruction for use (IFU) considering this effect.	
Impact on patient results	Measurements of controls and patient samples may lead to deviating results.	
Measures	Since the reduced calibration stability can be detected by control recovery, DiaSys strongly recommends measuring dedicated controls TruLab Lipid Level 1 / 2 in each run in which LDL-c direct FS reagent is used. Previous patient results measured without appropriate recovery of dedicated controls on respons [®] 910 should be reassessed by laboratory management or remeasured.	

DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations, we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we ask you to fill in and sign the attached confirmation of receipt as proof that you have received and communicated this information to all concerned customers. Please return it by fax or as scan until August 10, 2022.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Best regards,

Malte Hilsch
Strategic Product Management Reagents