# URGENT FIELD SAFETY NOTICE

**INFORMATION HDL-c direct FS, Product code: 1 3561**

**Carryover of Bilirubin Auto Total FS in HDL-c direct FS on respons®910**

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| Date | 2022-04-27 | |
| Product | HDL-c direct FS | Product code: 1 3561 |
| Analyzer | response®910 or similar clinical-chemistry analyzers | |
| Explanation | During internal control measurements, a carryover effect of Bilirubin Auto Total FS into HDL-c direct FS was discovered on the DiaSys respons®910. Internal verification showed that values for HDL-cholesterol (HDL-c) deviate when Bilirubin Auto Total FS is performed prior to the determination of HDL-c. The carryover effect of Bilirubin Auto Total FS only occurs on clinical-chemistry analyzers that pipette reagent and sample with the same needle; the risk is even increased if the same needle is used to mix the solution. Internal investigations have shown that the use of washing solutions will not overcome the effect completely. Thus, in addition to the extension of the carryover evasion table by this reagent pair, HDL-c direct FS and Bilirubin Auto Total FS should be determined in separate runs. DiaSys will immediately provide the corresponding information in the respons®910 Instructions for Use (IFU). | |
| Impact on patient results | The simultaneous determination of HDL-c direct FS and Bilirubin Auto Total FS on respons®910 respectively comparable clinical chemistry analyzers in one run may result in HDL-c deviations of more than 15% despite adjusted carryover evasion table and additional washing steps. | |
| Measures | **Please inform immediately all users about the carryover of Bilirubin Auto Total FS in HDL-c direct FS on respons®910 and comparable clinical chemistry analyzers. Both reagents should be determined in separate runs.**<br><br>Results of both reagents determined on the same instrument that performs pipetting and mixing with only one needle must be evaluated with caution. Please discuss with the head of the laboratory whether the determined patient values should be repeated. | |

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 May 13, 2022.

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www.diasys-diagnostics.com · Please return confirmation of receipt to qm@diasys.de

DiaSys
Diagnostic Systems

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

Kind regards,

Malte Hilsch

Strategic Product Management Reagents