

URGENT FIELD SAFETY NOTICE

Drug interference in tests based on trinder reactions

Date July 6, 2015

Product	Product code	Product code
Cholesterol FS	5 ' version 1 1350 ..	10 ' version 1 1300 ..
Creatinine PAP FS	1 1759 ..	
Glucose GOD FS	5 ' version 1 2550 ..	10 ' version 1 2500 ..
Glucose/Hemoglobin IS	1 2491 99 10 760	
HDL-C Immuno FS	1 3521 ..	
LDL-C Select FS	1 4121 ..	
NEFA FS	1 5781 ..	
Phospholipids FS	1 5741 ..	
Triglycerides FS	5 ' version 1 5760 ..	10 ' version 1 5710 ..
Uric acid FS TBHBA	1 3021..	
Uric acid FS TOOS	1 3001 ..	

Explanation N-acetylcysteine (NAC), acetaminophen and metamizole administered in therapeutic concentrations, will cause interferences in so-called trinder reactions. Trinder reactions are based on a color reaction in which hydrogen peroxide (H₂O₂) is formed and subsequently reacts with amino-antipyrine, a phenol derivative and peroxidase as catalyst. Peroxidase reactions are disturbed to different extents by above mentioned medications.

Impact on patient results Interference by N-acetylcysteine (NAC), acetaminophen and metamizole causes falsely low results.

Measures The above-mentioned DiaSys products are affected. This information serves as labeling or identification until the appropriate updated package inserts are available. A corresponding note will be inserted in the section "Warnings and Precautions" of all package inserts for the products mentioned.
To carry out the above-mentioned tests, blood withdrawal should be performed prior to administration of drugs.

CUSTOMER INFORMATION

Please inform all users of the affected products immediately.

DiaSys has announced the 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; the attached report form for corrective actions may help you.

Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back to us by fax or as scan until **July 20th, 2015**.

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

Kind regards,

Irene Delseith

Strategic Product Management

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