

## 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 (H<sub>2</sub>O<sub>2</sub>) 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,

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Strategic Product Management

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## Confirmation of receipt

Please confirm that the customer information below is received by your facility:

### Drug interference in tests based on trinder reactions

Herewith I confirm that above named customer information reached me and is forwarded to the users of these DiaSys products.

Customer name: \_\_\_\_\_

Contact person: \_\_\_\_\_  
(same as signature)

Date / Signature: \_\_\_\_\_

Please send this fax to DiaSys Diagnostic Systems GmbH (Holzheim / Germany)

Fax-Number: +49-6432-9146-32

Thank you for your efforts!

## Empfangsbestätigung

Bitte bestätigen Sie, dass Sie die folgende Kundeninformation erhalten haben.

### Medikamenten-Interferenz in Tests, die auf Trinder Reaktionen basieren

Hiermit bestätigen wir, dass wir die oben genannte Kundeninformation erhalten und an unsere Kunden weitergeleitet haben.

Name des Distributors: \_\_\_\_\_

Kontaktperson: \_\_\_\_\_  
(Name des Unterzeichners)

Datum / Unterschrift: \_\_\_\_\_

Bitte senden Sie das ausgefüllte und unterzeichnete Dokument per Fax an: DiaSys Diagnostic Systems GmbH (Holzheim / Deutschland)

Fax-Nummer: +49-6432-9146-304

Vielen Dank für Ihre Bemühungen!