**CUSTOMER INFORMATION** 

CC: Chairman Medical Board and relevant Head of Departments

## URGENT FIELD SAFETY NOTICE

## Sulfasalazine- and sulfapyridine interference in tests based on NAD(H) and/or NADP(H) reaction principle.

Date May 28, 2018

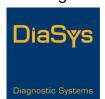
Product Product name Product code ALAT (GPT) FS (IFCC mod.) 1 2701 ATP Hexokinase FS 1 6201 **CK-MBFS** 1 1641 **GLDH FS DGKC** 1 2411 Explanation Due to the strong absorption of sulfasalazine and sulfapyridine at 340 nm Tests with NAD (H) and / or NADP (H) reaction principle can be affected. Product Sulfasalazine Sulfapyridine Impact on > -10% deviation in serum > -10% deviation in serum patient results ALAT (GPT) FS (IFCC mod.) concentrations higher than concentrations higher than 20 mg/dL sulfasalazine 20 mg/dL sulfapyridine Sulfasalazine interferes > -10% deviation in serum even in low concen-ATP Hexokinase FS concentrations higher than 20 mg/dL sulfapyridine trations in patient samples with low ATP > +10% deviation in serum concentrations CK-MB FS No interference higher than 2 mg/dL sulfasalazine > -10% deviation in serum > -10% deviation in serum GLDH FS DGKC concentrations higher than concentrations higher than 1 mg/dL sulfasalazine 12 mg/dL sulfapyridine 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.

Sulfasalazine and sulfapyridine medication may lead to false results in patient samples. Blood collection must be done before drug administration.

Please inform all users of the affected products immediately.

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## **CUSTOMER INFORMATION**

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 **June 15, 2018**.

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

Kind regards,

Leonie von Tietzen und Hennig

**Tecnical Product Management** 

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