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-MB FS	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.

Impact on patient results

Product	Sulfasalazine	Sulfapyridine
ALAT (GPT) FS (IFCC mod.)	> –10% deviation in serum concentrations higher than 20 mg/dL sulfasalazine	> –10% deviation in serum concentrations higher than 20 mg/dL sulfapyridine
ATP Hexokinase FS	Sulfasalazine interferes even in low concen-trations in patient samples with low ATP	> –10% deviation in serum concentrations higher than 20 mg/dL sulfapyridine
CK-MB FS	> +10% deviation in serum concentrations higher than 2 mg/dL sulfasalazine	No interference
GLDH FS DGKC	> –10% deviation in serum concentrations higher than 1 mg/dL sulfasalazine	> –10% deviation in serum concentrations higher than 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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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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