

# CUSTOMER INFORMATION

## URGENT FIELD SAFETY NOTICE

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

Date June 07, 2018

Product

Product name	Product code
CK-MB FS	35794
GLDH FS DGKC	G 82100, 24681, G 213117

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
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.

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 users. 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,

i. V. Yvonne Zimmermann

Sales Assistent and QM

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