



Dialine Diagnostic Systems Pte Ltd

627A Aljunied Road #08-12 Biztech Centre Singapore 389842

Tel : (65) 6747 2009 Fax : (65) 6247 7516

Email : dialinesys@yahoo.com

Business Registraton No : 200007902E

URGENT FIELD SAFETY NOTICE

Sulfasalazine- and sulfapyridine interference in test based on HAD(H) and/or NADP(H) reaction principle.

Date: 22 June 2018

Product:

Product Name	Product Code
ALAT IFCC mod.	2 261 052
CK-MB	2 225 052

Explanation:

Due to the strong absorption of sulfasalazine and aulfapyridine at 340nm, tests with NAD(H) and/or NAHP(H) reaction principle can be affected

Impact on Patient result:

Product Name	Sulfasalazine	Sulfapyridine
ALAT IFCC mod.	>-10% deviation in serum concentrations higher than 20 mg/dL sulfasalazine	>-10% deviation in serum concentrations higher than 20 mg/dL sulfapyridine
CK-MB	>+10% deviation in serum concentrations higher than 2 mg/dL sulfasalazine	No interference



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Measure :

The above-mentioned Dialine Products are affected. This information serves as labelling or identification until the appropriate updated package inserts are available. A corresponding note will be inserted in the section "Warning 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.

Dialine has announced the field safety notice to the relevant authorities of Singapore.

Please handle necessary announcements to authorities in your country if necessary.

We have attached the "Confirmation of Receipt" to ensure you have received the above mentioned information and communicated to all concerned customers.

Please send it back to us by 28 June 2018.

Thank you,

With best regards,

Chiyo Yorizane



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Sulfasalazine- and sulfapyridine interference in test based on HAD(H) and/or NADP(H) reaction principle.

Date: 22 June 2018

Product:

Product Name	Product Code
ALAT IFCC mod.	1 261 024

Explanation:

Due to the strong absorption of sulfasalazine and aulfapyridine at 340nm, tests with NAD(H) and/or NAHP(H) reaction principle can be affected

Impact on Patient result:

Product Name	Sulfasalazine	Sulfapyridine
ALAT IFCC mod.	>-10% deviation in serum concentrations higher than 20 mg/dL sulfasalazine	>-10% deviation in serum concentrations higher than 20 mg/dL sulfapyridine



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Measure :

The above-mentioned Brand "Biorex" Products are affected. This information serves as labelling or identification until the appropriate updated package inserts are available. A corresponding note will be inserted in the section "Warning 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.**

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