

Urgent Field Safety Notice

Uric Acid TBHBA, Enzymatic, colorimetric

FSCA-Identifizier: 2020-04 Uric Acid TBHBA

Risk of falsely low results due to Phenindione interference

Date 28.04.2020

Attention Distributors and users of below listed products

Details on affected devices:

Product: **Uric Acid TBHBA, Enzymatic,colorimetric**

Catalogue Number: D95459, D98461, D00463, D00464, D83911, D0441917, DA0847, DT1047, DK0744

Lots: 150120, 150519, 150419, 150319, 150219, 150119, 150518

Description of the problem:

Due to market observations it was detected that reagents using TBHBA as trinder components show interference with Phenindione. As consequence patients treated with Phenindione may receive falsely low results.

The risk of misdiagnosis and inappropriate therapy exists, especially if results are assessed separately. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other diagnostic findings.

Reagent kits of DIALAB *Uric Acid TBHBA* that were produced at DIALAB previous to 2020-04-27 (please find listed affected lot numbers) do not contain this warning in the instruction for use.

Advise on action to be taken by the user:

- **DIALAB Uric Acid TBHBA must not be used for determination of patients, treated with Phenindione.** Results obtained from patients under phenindione therapy with the abovementioned assays, should not be used for diagnosis. Measurements should be repeated using another method. As an alternative, e.g. Uric Acid AOX are available. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings. Phenindione (CAS Registry Number: 83-12-5) is used as anticoagulant. Due to known side effects, other therapeutics are preferred and phenindione is prescribed in exceptional cases only. The instructions for use, chapter 'Warnings and Precautions', were updated accordingly. **Please inform all concerned users of the product about this information immediately.**
- Please assure that goods of the existing stock get provided to customers only together with the attached actualized instructions for use and this FSN.
- Please fill out the attached Confirmation Form and send it back to us until **27.05.2020**.

Transmission of this Field Safety Notice:

- This Field Safety Notice needs to be passed on all those who need to be aware within your organisation or to any organisation where potentially affected devices have been transferred to.
- Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact Reference Person:

Mag. Lorenz Miller, Safety Officer, DIALAB GmbH

Phone: +43 2236 660910-48, e-mail: miller@dialab.at

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency.

Best regards,

Mag. Lorenz Miller
Safety Officer, DIALAB GmbH

Confirmation Form

Uric Acid TBHBA, Enzymatic, colorimetric

FSCA-Identifier: 2020-04 Uric Acid TBHBA

Urgent Customer Information, Phenindione interference

Distributor/Customer Details:

Company Name	
Address	

The undersigned confirms that all required actions have been implemented for and all concerned parties have been made aware of this Field Safety Notice.

Completed By	
Telephone / E-Mail	
Date	
Signature	

Please complete this form and send it via e-mail until **27.05.2020** to safety@dialab.at.

Thank you for your efforts!