

CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

Interference of Phenindione

Creatinine PAP FS **Product code 1 1759...**
Uric acid FS TBHBA **Product code 1 3021...**

Falsely low results due to interference by Phenindione

Date	April 23rd, 2020	
Products	Creatinine PAP FS	Product code 1 1759...
	Uric acid FS TBHBA	Product code 1 3021...
Lot	all lots	
Explanation	<p>Based on market observations, DiaSys Creatinine PAP FS was tested for interference by phenindione. Reagents using a principle similar to Creatinine PAP FS were included in the interference testing.</p> <p>During the evaluation, reagents using HTIB (Creatinine PAP FS) and reagents using TBHBA as trinder component showed interference by phenindione.</p> <p>The trinder components HTIB (3-hydroxy 2,4,6 triiodo benzoic acid) and TBHBA (2,4,6-tribromo-3-hydroxybenzoic acid) are chemically related in structure. The derivatives differ from each other by the exchange of the halide substituents. The three iodine substituents of HTIB are replaced by bromine atoms in TBHBA.</p>	
Impact on patient results	<p>Patients treated with phenindione, may receive falsely low results if the following reagents are used:</p> <ul style="list-style-type: none">a) Creatinine PAP FSb) Uric acid FS TBHBA <p>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.</p>	

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Measures

Above mentioned assays must not be used for determination of patients, treated with phenindione.

Results obtained from patients under phenindione therapy with the above mentioned assays, should not be used for diagnosis. Measurements should be repeated using another method. As an alternative, e.g. Creatinine Jaffe or Uric acid TOOS 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 users of the affected products immediately.

DiaSys has announced the urgent 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.

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 **May 21st, 2020**.

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

Kind regards,

