CUSTOMER INFORMATION

URGENT FIELD SAFETY NOTICE

False results due to interference by Eltrombopag

Date	April 23rd, 2020	
Products	Bilirubin Auto Direct FS	Product code 1 0821…
	Bilirubin Auto Total FS	Product code 1 0811…
	Creatinine FS	Product code 1 1711…
	Creatinine PAP FS	Product code 1 1759…
Lot	all lots	

Explanation

Eltrombopag can cause serum/plasma discoloration and interference with results of the above mentioned assays.

Eltrombopag is an oral thrombopoietin receptor agonist that is used for treatment of certain patient groups with chronic immune thrombocytopemia. It is highly coloured and several reports showed that it can cause pH-dependent discoloration of plasma/serum. Interferences are also dependent on the Eltrombopag concentration and the wavelength of the photometer.

Impact on patient results

Patients treated with Eltrombopag, may receive falsely low/high results if the following reagents are used:

Bilirubin Auto Direct FS
Bilirubin Auto Total FS
Creatinine FS
Creatinine PAP FS

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.

Measures

If laboratory results of above mentioned assays are inconsistent with clinical observations for patients treated with Eltrombopag, measurements should be repeated using another method.

Eltrombopak (CAS Registry Number: 496775-61-2) is used as oral thrombopoietin receptor agonist. Due to known side effects, other therapeutics are preferred; Eltrombopak 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 Diagnostic Systems GmbH · Alte Strasse 9 · 65558 Holzheim · Germany
www.diasys-diagnostics.com · QM@diasys.de

CUSTOMER INFORMATION

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,

Isabella Wieland
Strategic Product Management Reagents

DiaSys Diagnostic Systems GmbH · Alte Strasse 9 · 65558 Holzheim · Germany
www.diasys-diagnostics.com · QM@diasys.de