

Urgent field safety notice

Product:

ARTICLE NUMBER	PRODUCT NAME	LOT NUMBER
GHI131-10SI	MRX PT Owren's	19088

Explanation

Customers using MRX Owren's PT lot 19088 reconstituted according to 1X-method have noted that the instrument sometimes generates error messages when testing controls and patient samples, making it necessary to rerun samples. The problems are related to the occurrence of larger amounts of precipitation than normally found in the reagent, when this specific lot is reconstituted according to the 1X-method.

Due to this it is necessary to stop using GHI131-10SI lot 19088.

Description of the problem

Several customers have had problems with instrument flags and error messages when testing patient samples using lot 19088 and it has been necessary to run multiple repeats before obtaining a result. Some vials of lot 19088 are affected, showing large amounts of precipitates and for some of these vials results with the error message, "Initial fluctuation drop", are obtained. After repeating the analysis, results are ok without flag.

Patient impact

No incorrect results for patient samples have been reported. MRX PT Owren's is, however, used for Warfarin dosage and if the results are incorrect there is a risk that Warfarin is given in incorrect dosage, and MediRox therefore recommend caution and that lot 19088 is not used. If the dosage is lowered when it should be unaltered or increased this can result in an increased risk of thrombosis for the patient. If the dosage is increased when should be unaltered or decreased this can result in an increased risk of bleeding.

According to IFU, controls shall be analysed regularly, and if control values are out of specification the reagent shall not be used for analysis of patient samples.

Necessary actions to be taken by the user

Stop using lot 19088. Since the precipitates in the reagent, GHI131-10SI lot 19088, is suspected to be the reason for instrument flags and when running patient samples, it is necessary to stop using lot 19088.

Make sure that this urgent field safety notice is distributed and read by all personnel involved.

Evaluate the risk if results from patient samples may have been affected and take necessary actions.

Contact information

If you have any questions please contact Quality Manager Linda Östling, +46 (0)155 45 44 17, quality@medirox.se.

Confirmation form

Fill in and return this form to quality@medirox.se within 10 business days of receiving this notice.

Date:

Name of organisation:

Name:

Titel:

Address:

City:

E-mail address:

Phone number:

Country:

- I confirm that I have reviewed this urgent field safety notice from Medirox regarding lot 19088
- I have followed the instructions and implemented the actions described. If not, state the reason in the section comment below.

Have you received instrument error messages when using GHI131-10SI lot 19088

Yes

No

Instrument in use:

Have you had problems with precipitation in reconstituted reagent GHI131-10SI lot 19088

Yes

No

Have you received reports of illness or personal injury related to the identified stability issue?

Yes

No

Comment:

Date:.....

Signature:.....