

Urgent field safety notice

Products

ARTICLE NUMBER	PRODUCT NAME	LOT NUMBER
GHI131-4	MRX Owren's PT	All
GHI131-10	MRX Owren's PT	All
GHI131-10SI	MRX Owren's PT	All
GHI131-20	MRX Owren's PT	All

Description

The information described in the Urgent Field Safety Notice, dated November 11 2019, regarding a stability change (due to the risk of precipitation forming in the reagent) from 7 to 3 days for reagent reconstituted according to the 1X method and stored at 2-8°C has been revised.

The revision is based on data from further internal investigations that show that a minor change in the 1X storage instruction prevents the formation of precipitation and keeps the reagent stable for 5 days.

Patient impact

No incorrect results for patient samples have been reported due to precipitation in the reagent. MRX Owren's PT 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 recommends caution.

Changes in the instructions for use and the reagent stability specification

To avoid precipitation in reagent reconstituted according to the 1X method, when intending to use the reagent over several days at 2-8°C, it is necessary to keep the reconstituted reagent at 15-25°C for the first 24 hours before use. After that the reagent can be stored at 2-8°C and remains stable and free from precipitation for 5 days.

Necessary actions to be taken by the user

If you are using the 1X reconstitution method, implement the changed instructions outlined in the previous section and observe the updated stability specification.

Applicable to all reconstitution and storage methods: Do not use reagent if precipitation occurs. Make sure that this urgent field safety notice is distributed and read by all personnel concerned.

Contact information

For further information and questions, please do not hesitate to 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:

Title:

Address:

City:

E-mail address:

Phone number:

Country:

- I confirm that I have reviewed this urgent field safety notice from MediRox
- I have followed the instructions and implemented the actions described

Date:.....

Signature:.....