

Urgent field safety notice

Products

ARTICLE NUMBER	PRODUCT NAME	LOTNUMBER
GHI131-10SI	MRX Owren's PT	All

Description of the problem

Customers using MRX Owren's PT reconstituted according to 1X-method have sometimes noted error messages from their instrument when analysing controls and patient samples, making it necessary to rerun samples to obtain a result. The problems are reported to be related to the occurrence of precipitation found in the reagent.

Patient impact

No incorrect results for patient samples have been reported. 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.

Specification changes necessary to avoid future problems

To avoid precipitation, it is necessary to change the information in IFU regarding the specified stability for MRX Owren's PT reconstituted according to 1X-method, stored at 2-8°C, from 7 to 3 days.

For 1X-method reconstituted reagent stored at 15-25°C, 2X method reconstituted reagent stored at 2-8°C and 2X-method storage at 15-25°C specified stability remains unchanged.

Necessary actions to be taken by the user

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.

Use 1X-method reconstituted reagent stored at 2-8°C for a maximum 3 days after reconstitution.

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

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:

Titel:

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. If not, state the reason in the section comment below.

1. We have used MRX Owren's PT reagent reconstituted according to 1X-method stored at 2-8°.

- ☐ Yes
- ☐ No

2. We have used MRX Owren's PT reagent reconstituted according to 1X-method stored at 2-8°C and observed precipitation.

- ☐ Yes
- ☐ No

3. If yes, have you had problems with the analyse related to the precipitation?

- ☐ Yes
- ☐ No

If yes describe what kind of problems

Date:.....

Signature:.....

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