IVD

CE

MediRox

Instructions for Use [EN]

MRX PT Buffer

REF K5037, K5038, K5061

For *In vitro* Diagnostic Use.

1 Intended use

Intended for dilution of citrated human plasma samples when analysing prothrombin time (PT) using MRX PT Owren assays. Intended to be used by professional laboratory personnel using automated coagulation analysers.

2 Background and principle of method

For background information and principle of the method, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

3 Components

MRX PT Buffer consists of a Hepes buffer with sodium chloride, tri-sodium citrate and preservatives.

MRX PT Buffer is available in the following packaging sizes:

REF	No of vials	Volume
K5037	10	5 mL
K5038	6	100 mL
K5061	10	10 mL

4 Warnings and precautions

Wear suitable clothing for protection. Avoid contact with skin and eyes. Do not empty into drains. Waste must be disposed of in accordance with local regulations.

MRX PT Buffer contains sodium azide (less than 0.1%) to prevent microbial growth; use proper disposal procedures.

5 Preparation

Ready to use. Mix by inverting the vial before use.

6 Storage and stability

Store at 2 - 25 °C. After opening, stable for 8 weeks at 2 - 25 °C in the closed original vial, provided no contamination occurs. For information regarding on-board stability, refer to the respective instrument-specific application sheet. Do not store in direct sunlight.

7 Specimen collection and preparation

For specimen collection and preparation, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

8 Procedure

For description of procedure, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

9 Material required but not provided

MRX PT Buffer is an accessory to the following MRX assays:

Reagent	REF
MRX PT Owren	K5026
MRX PT Owren W	K5027
MRX PT Owren S	K5028

10 Quality control

For quality control, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

11 Results

For reporting of results, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

12 Expected values

For expected values, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

13 Limitations and interfering substances

For limitations and interfering substances, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

14 Analytical performance characteristics

For Analytical performance characteristics, refer to the Instructions for Use associated with MRX PT Owren assays (K5026, K5027, K5028).

15 Reporting of incidents

Any serious incidents that occur in relation to this device shall be reported to Nordic Biomarker as well as the national competent authority in which the user is established.

16 Additional information

A paper copy of these Instructions for Use is available on request. Contact your local distributor.
The instrument-specific application sheet is available from your local distributor.

17 Definition of symbols

	Manufacturer		Batch code
	CE mark	 nordicbiomarker.com/IFU	Consult electronic instructions for use
	In vitro diagnostic medical device		Use-by date
	Catalogue number		Temperature limit

18 Revision history

Version	Changes to previous version
6.0	Section 6: Information regarding on board stability transferred from the IFU to instrument-specific application sheets. Updated storage temperature for opened vial.