IVD

CE

MediRox

Instructions for Use [EN]

MRX PBS Diluent

REF K5047

For *In vitro* Diagnostic Use.

1 Intended use

For dilution of samples and calibrators to enable analysis with *in vitro* diagnostic reagents for use in haemostasis diagnostics. Intended to be used by professional laboratory personnel.

2 Components

MRX PBS Diluent consists of:
10 × 5 mL phosphate buffered saline solution and preservatives.

3 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 PBS Diluent contains sodium azide (less than 0.1%) and 2-methylisothiazol-3(2H)-one (less than 0.0015%) to prevent microbial growth; use proper disposal procedures.

EUH208: Contains 2-methylisothiazol-3(2H)-one. May produce an allergic reaction.
EUH210: Safety data sheet available on request.

4 Preparation

Ready to use.

5 Storage and stability

Store at 2 - 8 °C. After opening, stable for 4 weeks at 2 - 25 °C in the closed original vial, provided no contamination occurs.

6 Material required but not provided

- Analyser (refer to the Instructions for Use of the reagent for validated combinations).
- Pipettes.
- Reagents.
- Calibrators and samples intended to be diluted.

7 Procedure

This cevice is an accessory to *in vitro* diagnostic reagents. For procedures, refer to the Instructions for Use of the reagent and to the instrument-specific application sheet. Note that if MRX PBS Diluent is used in combination with other devices not provided by Nordic Biomarker, the combination must be validated in accordance with Regulation (EU) 2017/746.

8 Reporting of incidents

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

9 Additional information

A paper copy of these Instructions for Use is available on request. Contact your local distributor.

10 Definition of symbols

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

11 Revision history

Version	Changes to previous version
2.0	Change of document name to IFU-6507 due to release of IVDR CE marked kits.