IVD

CE

MediRox

Instructions for Use [EN]

MRX Routine Abnormal Control

REF K5040

For *In vitro* Diagnostic Use.

1 Intended use

For quality control of the assays MRX PT Owren, MRX PT Owren S, MRX PT Owren W, MRX PT Quick, MRX APTT, MRX Antithrombin, MRX Fib Clauss, MRX Red D-dimer, MRX Green D-dimer and MRX Blue D-dimer. Intended to be used by professional laboratory personnel using coagulation analysers.

2 Background and principle of method

For background information and principle of the method, refer to the Instructions for Use associated with each individual assay (K5011, K5024, K5025, K5026, K5027, K5028, K5029, K5030, K5031, K5033, K5034, K5035).

3 Components

MRX Routine Abnormal Control consists of:
10 × 1 mL lyophilised citrated human plasma enriched with D-dimer, additives of protein components from bovine plasma and preservatives.

4 Metrological traceability

Refer to the Certificate of Analysis for the lot-specific concentration of each individual test/analyte.

Specifications for each test/analyte are listed below:

Test/analyte	Specification
PT Owren INR	2.3 - 2.9
PT Quick INR	1.9 - 2.9
APTT	54 - 66 s
Fibrinogen	1.0 - 1.5 g/L
Antithrombin	0.35 - 0.55 IU/mL
D-dimer DDU	800 - 1200 ng/mL
D-dimer FEU	2000 - 3000 ng/mL

The reported values of each new lot MRX Routine Abnormal Control are assigned as follows:

Test/analyte	Assignment procedure
PT Owren INR	With MRX PT Owren against a calibrator with traceability to WHO IRP 67/40 (via RBT 90) determined by the WHO reference procedure (manual tilt tube technique).
PT Quick INR	With MRX PT Quick against in-house reference material with traceability to WHO IRP 67/40 (via RBT/05) determined by the WHO reference procedure (manual tilt tube technique).
APTT	N/A
Antithrombin	With MRX Antithrombin against SSC/ISTH Secondary Coagulation Standard with traceability to WHO International Standard (NBISC code: 08/258).
Fibrinogen	With MRX Fib Clauss against SSC/ISTH Secondary Coagulation Standard with traceability to WHO International Standard Fibrinogen Plasma (NBISC code: 09/264).
D-dimer (DDU)	With MRX Red D-dimer against a calibrator with traceability to a working calibrator assigned according to ISO 17511:2003, section 5.6.[1]
D-dimer (FEU)	With MRX Red D-dimer against a calibrator with traceability to a working calibrator assigned according to ISO 17511:2003, section 5.6.[1]

5 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.

The control contains material of human origin. Each donor has been tested by approved methods and found negative for the presence of HBsAg and anti-HIV I & II and anti-HCV. However, as no method can offer complete assurance that infectious agents are absent, this material should be handled as potentially infectious.

The control contains Bovine Serum Albumin (< 4.0%) for stability, and bovine plasma. The animals were approved by veterinarians by ante- and post-mortem inspections. However, as no method can offer complete assurance, this material should be handled as potentially infectious.

The control contains sodium azide (less than 0.001%) to prevent microbial growth; use proper disposal procedures.

6 Preparation

- Before opening, carefully tap the vial against a surface to collect the lyophilised material at the bottom.
- Add 1.00 mL deionised water (e.g. MRX Laboratory Water, K5036). The water temperature should be 15 - 25 °C.
- Reseal the vial and let it stand for approximately 15 minutes at 15 - 25 °C.
- Gently mix by swirling or rotating until the content is completely reconstituted.

7 Storage and stability

Store at 2 - 8 °C. After reconstitution, stable for 24 hours at 2 - 25 °C in the closed original vial, provided no contamination occurs.

8 Specimen collection and preparation

For specimen collection and preparation, refer to the Instructions for Use associated with each individual assay (K5011, K5024, K5025, K5026, K5027, K5028, K5029, K5030, K5031, K5033, K5034, K5035).

9 Procedure

For description of procedure, refer to the Instructions for Use associated with each individual assay (K5011, K5024, K5025, K5026, K5027, K5028, K5029, K5030, K5031, K5033, K5034, K5035).

10 Material required but not provided

Coagulation analyser, pipettes and the following:

Reagent	REF
MRX PT Owren	K5026/K5027/K5028
MRX PT Quick	K5024/K5025
MRX APTT	K5029/K5030
MRX Antithrombin	K5033
MRX Fib Clauss	K5031
MRX Red D-dimer	K5034
MRX Green D-dimer	K5011
MRX Blue D-dimer	K5035

Control material	REF
MRX Routine Normal Control	K5039

Solutions	REF
Deionised water for reconstitution e.g. MRX Laboratory Water	K5036
Saline solution for dilution, e.g. MRX Sodium Chloride Diluent	K5046
Phosphate buffered saline (PBS) for dilution, e.g. MRX PBS Diluent	K5047

11 Quality control

To maintain consistent assay results, it is recommended that control plasmas are assayed at regular intervals. MRX Routine Controls (K5039/K5040) are recommended for the assays MRX PT Owren, MRX PT Cwren S, MRX PT Owren W, MRX PT Quick, MRX APTT, MRX Antithrombin, MRX Fib Clauss, MRX Red D-dimer, MRX Green D-dimer and MRX Blue D-dimer. Each laboratory should establish a control range to determine the allowable variation in the day-to-day performance of the test, as well as appropriate intervals for analysing controls in accordance with good laboratory practice. Recalibration is suggested, as a minimum, whenever control plasmas are not within the acceptable range and each time a new batch of reagent is used.

12 Results

For reporting of results, refer to the Instructions for Use associated with each individual assay (K5011, K5024, K5025, K5026, K5027, K5028, K5029, K5030, K5031, K5033, K5034, K5035).

Document ID: IFU-4594 Version: 2.0 Issue date: 2022-04-04

13 Expected values

For expected values, refer to the Instructions for Use associated with each individual assay (K5011, K5024, K5025, K5026, K5027, K5028, K5029, K5030, K5031, K5033, K5034, K5035).

14 Limitations and interfering substances

For limitations and interfering substances, refer to the Instructions for Use associated with each individual assay (K5011, K5024, K5025, K5026, K5027, K5028, K5029, K5030, K5031, K5033, K5034, K5035).

15 Analytical performance characteristics

For analytical performance characteristics, refer to the Instructions for Use associated with each individual assay (K5011, K5024, K5025, K5026, K5027, K5028, K5029, K5030, K5031, K5033, K5034, K5035).

16 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.

17 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.

18 References

1. EN ISO 17511:2003 In vitro diagnostic medical devices – Measurement of quantities in biological samples – Metrological traceability of values assigned to calibrators and control materials

19 Definition of symbols

	Manufacturer		Use-by date
	CE mark		Temperature limit
	In vitro diagnostic medical device		Biological risks
	Catalogue number		Contains biological material of animal origin
	Batch code		Contains human blood or plasma derivatives
 nordicbiomarker.com/IFU	Consult electronic instructions for use		

20 Revision history

Version	Changes to previous version
2.0	Addition of MRX Green D-dimer (K5011). Added languages. Correction of article number for MRX Blue D-dimer (K5035).