

Eximius Control Plus Art. No: MRX 180 Tripel Set Haemostasis Controls

INTENDED USE

Eximius Control PLUS is intended for use as quality control plasma for coagulation assays in the normal and abnormal range.

SUMMARY AND PRINCIPLE

The controls are intended for the assessment of precision and accuracy of coagulation analyses such as PT (Quick and Owren method), APTT, Fibrinogen, Antithrombin, Thrombin Time (Thrombin Time is only applicable for Level 1), D-dimer, Plasminogen, Protein C, Protein S and Factors.

- Level 1: All analytes are within the normal range except for D-dimer which is slightly increased.
- Level 2 and 3: All analytes are within abnormal range.

PRODUCT DESCRIPTION

MRX180 Eximius Control PLUS Tripel Set kit consists of:

- MRX181 Normal Control Level 1 4 x 1mL lyophilized plasma
- MRX182 Abnormal Control Level 2 4 x 1mL lyophilized plasma
- MRX183 Abnormal Control Level 3 2 x 1mL lyophilized plasma

This product is prepared from human blood plasma, with added purified biochemicals and preservatives. The controls are provided in lyophilized form for increased stability.

PRECAUTIONS

Biological source material. Handle as potentially infectious. Each human donor unit used to manufacture this control was tested by CE accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), Anti-HCV and HIV-antibodies.

This product is for **In Vitro Diagnostic Use**.

RECONSTITUTION

Reconstitute each vial with 1.0 mL of distilled or deionized water. The water temperature should be 15-25°C. Replace the stopper and allow the control to stand for 15-30 minutes, swirling occasionally.

Before use gently invert the vial several times and verify visually that all material is completely dissolved.

STORAGE AND STABILITY

Unopened control is stable until the expiration date shown on the vial when stored at 2 - 8°C. Stability after reconstitution at 2-25°C in sealed original vial:

- Fibrinogen, APTT, Protein S, Protein C, Thrombin Time, Antithrombin, Plasminogen, and D-dimer Level 1 and 2 54 hours
- PT (Owren and Quick) and D-dimer Level 3 24 hours

Factors should be analysed within 1 hour after reconstitution.

To freeze a reconstituted control is common practice, but due to different freezing and thawing processes and other environmental factors that may affect the product, it is up to each user to verify functionality and stability of the product after such procedure.

PROCEDURE

After reconstitution the control should be handled in the same manner as a fresh citrated plasma and run in accordance with the instructions accompanying the instrument, kit, or reagent being used.

LIMITATIONS

This control is designed as control plasma for the monitoring of coagulation assays. The product is not intended for use as a standard/calibrator. Deviations may indicate possible problems with one or more components in the test system.

ASSIGNED VALUES

Mean values and ± 2 SD ranges printed in this insert are determined by User Groups with specific reagents and instruments, in combination with mathematical correction algorithms. The reported values should only be considered as indicative and each laboratory should establish own means and reference ranges.

Note that results may differ considerably depending on laboratory techniques, instrument settings and reagent depending factors.

The control values should be re-established whenever any of the system variables is modified.

PERFORMANCE CHARACTERISTICS

Precision: Within run precision was assessed over multiple runs using specific lots of reagents and control. The coefficient of variation obtained in this study was:

- Level 1: $\leq 1\%$ for Thrombin Time, PT Owren, PT Quick, Free Protein S, Plasminogen; $\leq 2\%$ for, APTT, Protein C, Antithrombin; $\leq 3\%$ for D-dimer $\leq 5\%$ for Fibrinogen.
- Level 2: $\leq 1\%$ for Protein C, Free Protein S; $\leq 2\%$ for Plasminogen; $\leq 3\%$ for Antithrombin, APTT; $\leq 5\%$ for PT Owren, PT Quick, Fibrinogen; $\leq 6\%$ for D-dimer.
- Level 3: $\leq 1\%$ for Plasminogen, $\leq 2\%$ for Protein C, Free Protein S; $\leq 3\%$ for PT Owren, $\leq 5\%$ for PT Quick, Antithrombin, D-dimer; $\leq 6\%$ Fibrinogen and $\leq 7\%$ for APTT.

This product is a freeze-dried product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values, the control requires proper storage and handling as described.