

Application description

MRX143 D-Dimer on Sysmex CA series

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Intended use

This application has been developed on a Sysmex CA1500 but other CA instruments (CA560, CA7000 and CS2100i) uses the same protocol. For CS2100i a XML file for direct download to the system is available.

The MRX143 D-dimer reagent has been developed as a replacement for Trinity AutoDimer 1431 and can normally be directly interchanged on board system with the same protocol. Evaluation studies shows a close correlation (r^2 0.99) and identical cut off value. See references under additional information on page 5 or contact sales@medirox.se for further information

Reagens information MRX143 D-Dimer

MRX143 D-Dimer is a micro particle-enhanced immunoassay for the quantitative determination of D-dimer in human plasma. MRX143 D-Dimer is suitable for coagulation and clinical-laboratory instruments using turbidimetric detection in the 600 - 800 nm wavelength range.

MRX143 560-800nm D-Dimer 5x4ml Latex, 5x7ml Reaction Buffer

Recommended but not included accessories:

Art no	Description	Assay
MRX144	D-Dimer calibrator 3.2	3.2 mg/L
GHI162 or GHI164	Normal Control	0.3-0.5 mg/L
GHI167b or GHI170	Abnormal Control	0.7-1.2 mg/L
GHI168	Abnormal Control Level 2	>4.0 mg/L

Specimen Collection and Preparation

Collect samples in 9 volumes of blood and 1 volume of 3.2% buffered sodium citrate (0.105 M). Centrifuge at 3000xg for 10 min. Citrate plasma samples may be stored at room temperature for 2 hours or at 2-8 °C for 18 hours. A single freeze-thaw cycle does not affect the assay response.

Assay Preparation

Please define all the reagents listed above in the reagent information section of the software, either as reagents, standards or controls as appropriate. (See Operator Manual Chapter 11-5)

Assay Protocol

Choose a blank protocol position and input the following protocol.

Sample vol.		55µL
Diluent vol.	Saline	55µL
Rinse		None
Second Dilution		20µL
Diluent vol.	None	0 µL
Rinse		None
Factor Plasma	None	0 µL
Push-out Solution.	No	µL
Rinse (Pre./Post.)	None	None
First Reagent	MRX 143 Buffer	80µL 30 sec
Push-out Solution.	No	0µL
Rinse (Pre./Post.)	None ^x X 0	Clean I x1

Second reagent	MRX143 Latex	80µL 90 sec
Push-out Solution.	No	0µL
Rinse (Pre./Post.)	None ^x X0	Clean I x 1
Third reagent	None	0µL
Push-out Solution.	No	0µL
Rinse (Pre./Post.)	None ^x X0	None
Detector	Immuno	For LPIA
Sens / Wavelength	High Sens	D-Dimer Inc
Maximum Time		/ 800nm 195 sec

Standard Curve Calibration

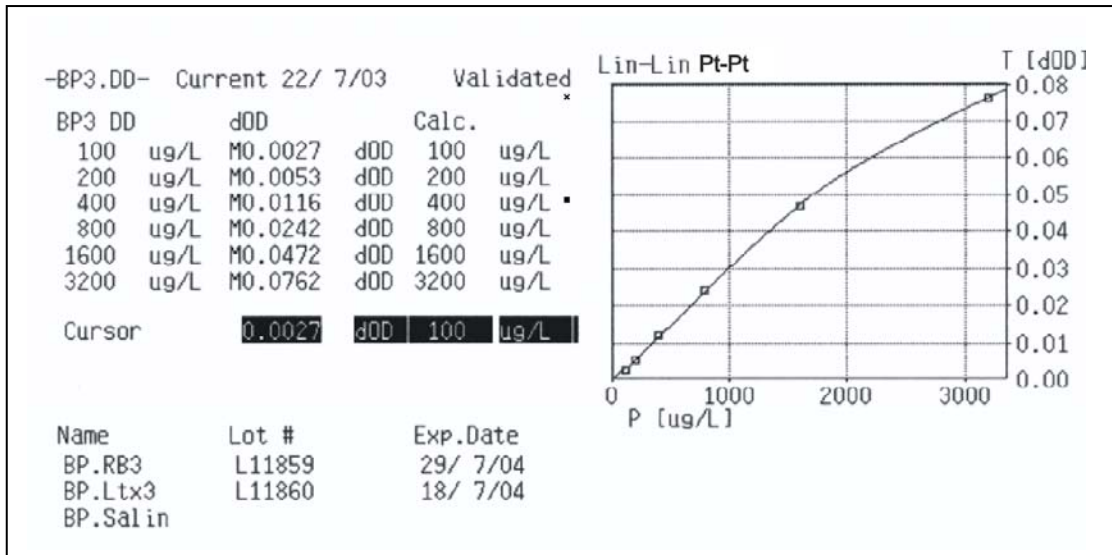
(Also refer to Operator Manual Chapter 8)

Please enter your analysis parameter settings for the assay as µg/L for the units, xxxx as the number format and, Lin-Lin Pt-Pt as the curve method.

In the Standard Curve screen please set up the curve to be run in auto dilution and analysis mode using the following calibration points: 1/1, 1/2, 1/4, 1/8, 1/16, 1/32.

Return to the work-list and run the standard curve.

Standard Curve Example



Note: The 'M' flag indicates that results have been entered manually. The values given above are the mean of processing three curves with duplicate readings taken at each data point (n = 6)

Typical Routine Standard Curve Data

$\mu\text{g/L}$	MEAN	SD	Min	Max	CV(%)
3200	0.0762	0.0012	0.0748	0.0778	1.59
1600	0.0472	0.0009	0.0458	0.0480	1.84
800	0.0242	0.0008	0.0230	0.0249	3.12
400	0.0116	0.0010	0.0106	0.0132	8.77
200	0.0053	0.0003	0.0048	0.0058	6.27
100	0.0027	0.0005	0.0020	0.0034	17.11

Note: A new calibration curve should be performed periodically, whenever you change the lot of reagent that you are using or if the controls deviate from their defined limits.

Quality Control (Refer also to Operator Manual Chapter 7)

Recommended Controls to use are:

GHI162 or GHI164	Normal control	0.3-0.5 mg/L
GHI167b or GHI170	Abnormal Control	0.7-1.2 mg/L
GHI168	Abnormal Control Level 2	>4.0 mg/L

Please configure the quality control material in the reagent setting section of the software, refer to the instruction for use for the current lot for the assayed values and target ranges.

For more information on MediRox coagulation controls visit www.medirox.se or contact sales@medirox.se for information.

Additional information.

For detailed description of the reagents characteristics and other documentation please refer to:

MRX143&147 Multi Platform D-Dimer Brochure
MRX143 Clinical Evaluation
MRX143 Components & Specifications
MRX143 Specificity Report
MRX143 Evaluation Report
MRX143&147 Application Development Guide

Visit also download section at www.medirox.se or contact sales@medirox.se for more information.