Test Definition Report

✓ **Enabled** **Test code** MRX143 **Test name** D-dimer MRX143 **Test number** 500

General information

Test code MRX143
Test name D-dimer MRX143
LIS number
Test number 500
Lock manual ordering
Assay

Assay release number
Test modification number 253
User revision comment
IL revision comment

Manual validation required

Analytical cycle definition

Acquisition - wavelength

Primary wavelength 671 nm

Acquisition - time

Standard time 220 s
Delay time 10 s

Load cycle

Number of replicates 1

Material Name	Type	Load Volume	Incubation Range
Sample		15	20.000 - 55.000
D-dimer RB MRX143	Intermediate reagent	95	20.000 - 55.000
D-dimer Latex MRX143	Start reagent	55	

Total cuvette volume 165 µL

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Material/Sample Load Cycle Definition

Material **Sample**

Aspiration information

Head volume	0 µL	Material/Sample volume	15 µL
Airgap	15 µL	Transport airgap	15 µL
Head volume airgap	0 µL	Total volume	45 µL

Dispensation information

Enhanced dispense
Enable mix

✓ Incubation range 20.000 - 55.000 s

Before Aspiration Rinse / Clean & Rinse

Enable rinse / clean & rinse before aspiration

After Dispensation Rinse / Clean & Rinse

Lock rinse / clean & rinse

✓ Rinse

Time 1 s
Enable agitation

Clean & rinse

Material **D-dimer RB MRX143** **Intermediate reagent**

Aspiration information

Head volume	0 µL	Material/Sample volume	95 µL
Airgap	15 µL	Transport airgap	15 µL
Head volume airgap	0 µL	Total volume	125 µL

Dispensation information

Enhanced dispense
Enable mix

✓ Incubation range 20.000 - 55.000 s

Before Aspiration Rinse / Clean & Rinse

Enable rinse / clean & rinse before aspiration

After Dispensation Rinse / Clean & Rinse

✓ Rinse

Time	1 s	Frequency	Between changes in material only
Enable agitation			

Clean & rinse

Material **D-dimer Latex MRX14** **Start reagent**

Aspiration information

Head volume	0 µL	Material/Sample volume	55 µL
Airgap	15 µL	Transport airgap	15 µL
Head volume airgap	0 µL	Total volume	85 µL

Dispensation information

Enhanced dispense
Enable mix

Before Aspiration Rinse / Clean & Rinse

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Material/Sample Load Cycle Definition

Material D-dimer Latex MRX14 | Start reagent

Enable rinse / clean & rinse before aspiration

After Dispensation Rinse / Clean & Rinse

✓ Rinse

Time	1 s	Frequency	Between changes in material only
Enable agitation			

Clean & rinse

Enable sample pre-dilution

✓ Alternative pre-dilution

Use extended acquisition time

Diluted LIS number

Test code MRX143(D)

Dilution definition

Number of parts sample	1
Number of parts diluent	14
Minimum aspiratable volume	15 µL

Volumes (µL)

Sample	Mixture	Diluent
15		210

✓ Enable mix

Mix volume	50 %
Number of cycles	2
Rinse after mix	1 s

Sample/Mixture

Volumes

Head volume	0 µL
Airgap	15 µL
Transport airgap	15 µL
Head volume airgap	0 µL

Before Aspiration Rinse / Clean & Rinse

Enable rinse / clean & rinse before aspiration

After Dispensation Rinse / Clean & Rinse

✓ Rinse

Time	1 s
Enable agitation	1

Clean & rinse

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Diluent

Volumes

Material	Factor Diluent	
Head volume	0	µL
Airgap	15	µL
Transport airgap	15	µL
Head volume airgap	0	µL

Before Aspiration Rinse / Clean & Rinse

Enable rinse / clean & rinse before aspiration

After Dispensation Rinse / Clean & Rinse

✓ Rinse

Time	1 s	Frequency	Between changes in material only
Enable agitation	1		

Clean & rinse

✓ DR Parameters - Primary wavelength - Wavelength definition

Primary wavelength: 671 Enable warnings ✓ Enable errors

✓ Enable normalization method Absorbance

Smoothing

✓ Enable smooth 1	Number of points	14
✓ Enable smooth 2	Number of points	14
✓ Enable Smooth 3	Number of points	14

Enable raw data checks

✓ Enable normalized data checks

Baseline Check

✓ Enable baseline check Number of seconds 10.000

✓ Enable primary algorithm

Linear kinetic

✓ Slope of curve Start time 30.000 s Time 180.000 s

✓ Enable linear regression SD error check SD error limit 1.500

✓ Enable secondary algorithm

Linear kinetic

✓ Delta of curve

Method	Exact start/end time
Start time	25.000 s
End time	55.000 s

✓ Enable negative calculation

✓ Enable initial slope check

Time	20.000 s		
Maximum error limit	175.000	Maximum warning limit	125.000

Result units

Unit selection **Milliabsorbance/min** **mAbs/min**

Unit	Milliabsorbance/min	Unit type	Measured
Label	mAbs/min	Decimals	1 IL Unit
User defined label			

✓ Enable normal range Range -999999.9 - 999999.9

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Unit selection **Milliabsorbance/min** **mAbs/min**

Allow negative results (QC jobs excluded)

Unit selection **ng/mL** **ng/mL**

Unit	ng/mL	Unit type	Calibrated
Label	ng/mL	Decimals	0 IL Unit
User defined label			

✓ Enable test range

Range	50 - 4000		
Alternate range	0 - 0	Extended range	-999999 - 999999

Allow negative results (QC jobs excluded)

Primary unit cfg.

Primary unit **ng/mL**

Patient result selection

Unit 1	ng/mL
Unit 2	
Unit 3	
Unit 4	

Measured result curve display settings

✓ Enable auto scale

Raw ✓ Normalized

Y-Axis minimum Y-Axis maximum

0.000 - 3000.000 mAbs

Calibration

✓ Enable calibration

General

Number of replicates	4	
Calibration unit	ng/mL	
Calibration mode	✓ Automatic dilutions process	Prediluted calibrators

Test not feasible when no validated calibration

Force mode with reduced clean

Enable import calibration

Frequency

Enable frequency

DR Parameters

✓ Enable extrapolation Lower limit 1.000 Upper limit 3600.000

✓ Enable outlier removal

Math Model

Math model	Spline	First concentration	1
X Axis transformation	No transformation	Last concentration	5
Y Axis transformation	No transformation		

✓ Automatic dilution

✓ Define points by % dilution Define points by target concentration

Dilution process

Direct	✓ Serial
Single dilution	✓ Batch

Calibrator target value 2755.000 ng/mL

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						Volumes (µL)			Predilution volumes (µL)			DR Checks Configuration Raw Data Check Def						DR Checks Configuration Norm. Data Check Def.					
Conc.	Target value	Min. Replic	% CV Max.	%Max. mean	%Min. mean	Calibrator	Mixture	Diluent	Sample	Mixture	Diluent	First Point	Last Point	Signal	Curve Sequence	Enable spike removal	Baseline By Moving SD	Norm. Delta Upp. Lim.	Norm. Delta Low. Lim.	Calibrated Result Delta	Baseline	Endpoint	Multiple Threshold
100.00	2755	1	5.000			243															✓		
50.00	1378	1	5.000	100.000	0.000		118	118													✓		
25.00	689	1	5.000	100.000	0.000		110	110													✓		
12.50	344	1	5.000	100.000	0.000		94	94													✓		
6.25	172	1	5.000	100.000	0.000		63	63													✓		

Minimum aspiratable volume 30

✓ Enable mix

Mix volume	50	%
Number of cycles	2	
Rinse after mix	1	s

Calibrator

Volumes

Material	DD Calibrator3200	
Head volume	0	µL
Airgap	15	µL
Transport airgap	15	µL
Head volume airgap	0	µL

Before Aspiration Rinse / Clean & Rinse

Enable rinse / clean & rinse before aspiration

After Dispensation Rinse / Clean & Rinse

✓ Rinse

Time 1

Enable agitation

Clean & rinse

Diluent

Volumes

Material	Factor Diluent	
Head volume	0	µL
Airgap	15	µL
Transport airgap	15	µL
Head volume airgap	0	µL

Before Aspiration Rinse / Clean & Rinse

Enable rinse / clean & rinse before aspiration

After Dispensation Rinse / Clean & Rinse

✓ Rinse

Time 1 Frequency Between changes in material only

Enable agitation

Clean & rinse

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✓ **Enabled** **Test code** MRX143 **Test name** D-dimer MRX143 **Test number** 500

Enable parallelism

Enable NPP

✓ **Enable rerun**

Result Ranges

Result unit to test: ng/mL

Rule	Same Test	Extended Test	Alternative pre-dilution
Above Test Range			✓
Below Test Range			✓