

Application of Biophen DiXal on ACL TOP range 0-0,5 µg/ml

1. REAGENTS

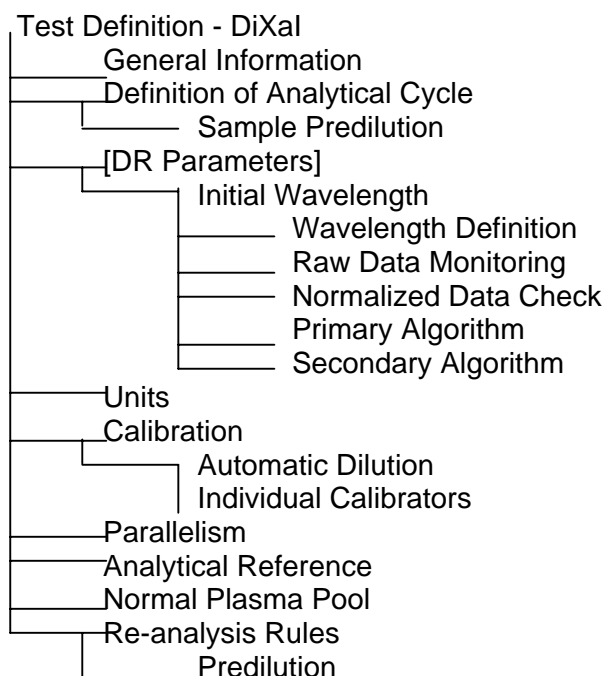
Follow the instructions on the kit insert for preparation and stability of the reagents.

Create under material definition the next reagents:

- **DiXal R1:** for the FXa reagent, Int. Reagent, use clean B diluted (130 µl) for cleaning.
- **DiXal R2:** for the Substrate, Start Reagent, use System clean (130 µl) for cleaning.
- **DiXal R3:** for the Buffer, Sample Diluent, no extra cleaning needed.

2. ANALYZER PROGRAMMING

Follow order of analyzer tree to program



General Information

Test Code	DiXal	Test Number	xxx
Test Name	Biophen DiXal	QC Number	xxx

Test
Initial Test Version

Modified Test Version

User Comments

Enable drift test

[Parent Test]	<input type="text"/>	↓
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Enable matched-pair test

Master Test	<input type="text"/>	↓
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Enable dependence test

Definition of Analytical Cycle

Wavelength Acquisition

Initial Wavelength

W-405	↓	nm
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Acquisition Duration

Acquisition Duration	50	↓	S
		↑	
Time	20	↓	S
		↑	

Extended Acquisition Duration

Extended Acquisition Duration		↓	S	
		↑		
[OC Number]		Test Code		DiXal

Load Cycle

Number of Replicates

1	↓
	↑

<input checked="" type="checkbox"/>	Name of Material	Type	[Volume Loaded]	Incubation Limit
	Sample		60	
	DiXal R1	Int. reagent	60	100.000-120.000
	DiXal R2	Releasing reagent	60	

Total volume in cuvette

180	μl
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Sample Predilution

Enable sample predilution

General	Mixture/Sample	Diluent
---------	----------------	---------

Dilution Parameterization

Parts, sample	1	↓ ↑	
Parts, diluent	19	↓ ↑	
Minimum sample volume	10	↓ ↑	μl

Volumes		
Sample	Mixture	Diluent
10	0	190

Enable mixing

Mixture volume	60	↓ ↑	%	Number of cycles	1	↓ ↑
				— Rinsing after mixing	1	↓ ↑

Enable sample predilution

General	Mixture/Sample	Diluent
---------	----------------	---------

Volumes

Head space volume	0	↓ ↑	μl
Air volume	15	↓ ↑	μl
[Transport air volume]	30	↓ ↑	μl
Head space volume	0	↓ ↑	μl

Rinsing

Duration	1	↓ ↑
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Enable sample predilution

General	Mixture/Sample	Diluent
---------	----------------	---------

DiXal R3		↓	
Head space volume	0	↓ ↑	μl
Air volume	15	↓ ↑	μl
[Transport air volume]	30	↓ ↑	μl
Head space volume	0	↓ ↑	μl

Wavelength Definition

Initial Wavelength Enable alerts
 Enable errors

Enable reference method

Hz

Enable normalization method

Absorbance

Smoothing Method: Sliding Smoothing

<input checked="" type="checkbox"/> Enable smoothing 1	Number of points	<input type="text" value="3"/> <input type="button" value="↓"/> <input type="button" value="↑"/>
<input checked="" type="checkbox"/> Enable smoothing 2	Number of points	<input type="text" value="3"/> <input type="button" value="↓"/> <input type="button" value="↑"/>
<input checked="" type="checkbox"/> Enable smoothing 3	Number of points	<input type="text" value="3"/> <input type="button" value="↓"/> <input type="button" value="↑"/>

Raw Data Monitoring

Enable raw data monitoring

Enable first monitoring point

Error threshold

Alert threshold

Enable last monitoring point

Error threshold

Alert threshold

Enable control signal

Minimum signal

Maximum signal

% max. rejected values
 %

Enable substitution method

Extrapolation

Enable sequential curve monitoring

Min Follows Max

Enable spike removal

% maximum delta

% maximum rejected points

Enable substitution method

Extrapolate

Enable baseline by moving SD

Percentage of time
 %

Window size
 s

Normalized Data Check

- Enable normalized delta checks
 Enable normalized delta curve lower limit Enable calibrated delta check results

Min. Limit Error	100.000	↓ ↑
Min. Limit Alert	100.000	↓ ↑

Max. Tolerance	0.000	↓ ↑	%
Max Tolerance Alert	0.000	↓ ↑	%

Baseline check	Endpoint check
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Enable baseline check
 Hz

	↓ ↑
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Enable mean check
 Target Value

0.000	↓ ↑
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Error Tolerance	10	↓ ↑	%	Error Limit	0.000	0.000
Alert Tolerance	10	↓ ↑	%	Alert Limit	0.000	0.000

Enable SD Check
 Error Limit

20.000	↓ ↑
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 Alert Limit

20.000	↓ ↑
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Primary Algorithm

- Enable primary algorithm Kinetics

<ul style="list-style-type: none"> <input type="radio"/> End point <input checked="" type="radio"/> Linear Kinetic <input type="radio"/> Threshold <input type="radio"/> 1st drift <input type="radio"/> 2nd drift <input type="radio"/> Delta <input type="radio"/> End-Initial <input type="radio"/> Statistic 	<ul style="list-style-type: none"> <input type="radio"/> Slope of Curve <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <tr> <td style="padding: 2px;">Initial Time</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">S</td> <td style="padding: 2px;">Duration</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">S</td> </tr> </table> <ul style="list-style-type: none"> <input checked="" type="radio"/> Delta Curve <p style="margin-left: 20px;">Method <table border="1" style="display: inline-table; border-collapse: collapse; margin-left: 10px;"> <tr><td style="padding: 2px;">Baseline/Endpoint averages</td><td style="text-align: center; padding: 2px;">↓</td></tr> </table></p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="padding: 2px;">Initial Time</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">S</td> <td style="padding: 2px;">Baseline duration</td> <td style="text-align: center; padding: 2px;">1.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">S</td> </tr> <tr> <td style="padding: 2px;">Duration</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">S</td> <td style="padding: 2px;">End point time</td> <td style="text-align: center; padding: 2px;">1.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">S</td> </tr> </table> <p style="margin-left: 20px;"> <input type="checkbox"/> Enable linear regression SD error check <input type="checkbox"/> Enable linear regression SD warning </p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="padding: 2px;">Error: limit AND</td> <td style="text-align: center; padding: 2px;">10.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">Alert: limit AND</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> </tr> </table> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Enable negative calculation <input type="checkbox"/> Enable initial control part <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="padding: 2px;">Duration</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> <td style="padding: 2px;">S</td> <td style="padding: 2px;">Error: max. limit</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> </tr> </table> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="padding: 2px;">Alert: max. limit</td> <td style="text-align: center; padding: 2px;">0.000</td> <td style="text-align: center; padding: 2px;">↓ ↑</td> </tr> </table>	Initial Time	0.000	↓ ↑	S	Duration	0.000	↓ ↑	S	Baseline/Endpoint averages	↓	Initial Time	0.000	↓ ↑	S	Baseline duration	1.000	↓ ↑	S	Duration	0.000	↓ ↑	S	End point time	1.000	↓ ↑	S	Error: limit AND	10.000	↓ ↑	Alert: limit AND	0.000	↓ ↑	Duration	0.000	↓ ↑	S	Error: max. limit	0.000	↓ ↑	Alert: max. limit	0.000	↓ ↑
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Second Algorithm

<input type="checkbox"/> Enable secondary algorithm <input type="radio"/> End point <input type="radio"/> Kinetics <input type="radio"/> Threshold <input type="radio"/> 1st drift <input checked="" type="radio"/> 2nd drift <input type="radio"/> Delta <input type="radio"/> End-Initial <input type="radio"/> Statistical	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">1st drift</td> <td style="width: 50%;">2nd drift</td> </tr> <tr> <td colspan="2" style="text-align: center;">Smoothing</td> </tr> <tr> <td style="padding: 2px;">Method</td> <td style="padding: 2px;">Slope ↓</td> </tr> <tr> <td style="padding: 2px;">Number of points</td> <td style="padding: 2px;">3 ↓ ↑</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Peak Search Method</td> </tr> <tr> <td style="padding: 2px;">Last maxima peak</td> <td style="padding: 2px;">↓</td> </tr> </table>	1st drift	2nd drift	Smoothing		Method	Slope ↓	Number of points	3 ↓ ↑	Peak Search Method		Last maxima peak	↓								
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Units

Unit Parameterization Results

✓	Unit	Unit Type	Label	Ⓞ	[de c]	Normal Limits	Therapeutic Limits	Linearity Limit	Test Limits
	Milli absorb	Measured	mAbs/min	<input type="checkbox"/>	2				
	µg/ml	Calibrated	µg/ml	<input type="checkbox"/>	2	-10.00-0,50		-10,00-0,50	-10,00-0,50
	ng/ml	Calibrated	ng/ml	<input type="checkbox"/>	1	-10000.0-500.0		-10000.0-500.0	-10000.0-500.0
				<input type="checkbox"/>					
				<input type="checkbox"/>					
				<input type="checkbox"/>					
				<input type="checkbox"/>					
				<input type="checkbox"/>					
				<input type="checkbox"/>					

Unit selection test results Unit 1 <input type="text" value="Milliabsorbance/min"/> ↓ Unit 2 <input type="text" value="µg/ml"/> ↓ Unit 3 <input type="text" value=""/> ↓ Unit 4 <input type="text" value=""/> ↓	Primary unit configuration Primary unit <input type="text" value="µg/ml"/> ↓ <input checked="" type="checkbox"/> Enable Max. Difference Max. Difference <input type="text" value="10"/> ↓ ↑ %	Reactional curve visualization parameters <input checked="" type="checkbox"/> Enable automatic scale <input type="radio"/> Raw data <input checked="" type="radio"/> Normalized (absorbance) Min. Y-axis <input type="text" value="0.000"/> ↓ ↑ Max. Y-axis <input type="text" value="3000.000"/> ↓ ↑ mAbs
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Calibration

Calibrations

General	Frequency	[DR Parameters]
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General

Number of repetitions

Cal. Unit

Calibration Mode

Cal. by automatic dilution

Individual calibrators

Enable cal. importation

Imported Test

Type imported

Imported Unit

Calibrations

General	Frequency	DR Parameters
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Enable outlier removal

Enable extrapolation

Enable % CV check

Mathematical Model

Linear Regression Spline

High Limit	0.000	<input type="button" value="↓"/> <input type="button" value="↑"/>
Low Limit	0.000	<input type="button" value="↓"/> <input type="button" value="↑"/>

Linear Regression

X-Axis Transformation Y-Axis Transformation

Enable slope control

Theoretical Slope Tolerance % limits -

Enable control intercept point

Theoretical Intercept Point Tolerance limits -

Enable [R2 control]

R2 minimum

Automatic Dilution

General	Calibrator	Diluent
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Dilutions

Calibrator Value	<input style="width: 100%;" type="text"/> ↓ ↑ %	<input checked="" type="radio"/> Define points by dilution % <input type="radio"/> Define points by concentration
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Concentration	Target Value	Min. replicates	% CV max	Calibrator Volume	Mixture Volume	Diluent Volume
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0
		1	5.000	0	0	0

Enable mixing

Sample Predilution

Mixture	<input style="width: 100%;" type="text" value="100"/> ↓ ↑ %	Sample Volume <input style="width: 100%;" type="text" value="1"/> ↓ ↑	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 50%;">Dilution Point</td><td style="width: 50%;"></td></tr> <tr> <td style="width: 33%;">Sample Volume</td> <td style="width: 33%;">Mixture Volume</td> <td style="width: 33%;">Diluent Volume</td> </tr> <tr><td> </td><td> </td><td> </td></tr> <tr><td> </td><td> </td><td> </td></tr> </table>	Dilution Point		Sample Volume	Mixture Volume	Diluent Volume						
Dilution Point														
Sample Volume	Mixture Volume	Diluent Volume												
Number of cycles	<input style="width: 100%;" type="text" value="1"/> ↓ ↑													
Rinsing after mixing	<input style="width: 100%;" type="text" value="1"/> ↓ ↑ S													

Individual Calibrators

Calibration Points

Point	Calibrator-Material	Target Value (U/ml)	Min. replicates	% CV Max.
1	CAL 1	0	2	10
2	CAL2	0,25	2	10
3	CAL3	0,50	2	10
4				
5				
6				
7				
8				

Parallelism

Parallelism

Parallelism: [OC Code] Test Code

Analytical Cycle	Data Expression
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Number of repetitions	<input style="width: 100%;" type="text" value="1"/> ↓ ↑
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Enable AR control

Diluent

	Sample	Mixture	Diluent
Concentration	Vol.	Vol.	Vol.

Analytical Reference

Enable analytical reference (AR)

General	Frequency
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Calibration Control

Tolerance	5	↓	↑	%
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Limits from	1.47	to	1.63	U/ml
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Control versus AR

Material:		↓
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Unit:		↓
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Target:		↓	↑
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Tolerance:	5	↓	↑	%
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Limits:	from		to	
---------	------	--	----	--

Normal Plasma Pool

Enable Normal Plasma Pool (NPP)

General	Frequency
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NPP Mode:	Normal median values	↓
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NPP Material:		↓
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Calibration Drift

Method:	Mean of calibration point replicates	↓
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Calibration Point:		↓
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NPP Value:		↓	↑	U/ml
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NPP:	1.00	↓	↑	mAbs/min
------	------	---	---	----------

Re-analysis Rules

Enable re-analysis

Result Limits	[DR Error]
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Verification Unit:	%	↓
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Rule	Same Test	Extended Test	Re-analysis Dilution
High Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High Therapeutic Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Therapeutic Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High-Linearity Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low-Linearity Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test: high limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test: low limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High Limit of Test: Unit of Measure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Limit of Test: Unit of Measure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High Limit of Calibration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Limit of Calibration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Predilution

Enable sample predilution

General	Mixture/Sample	Diluent
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Dilution Parameterization

Parts, sample:	1	↓ ↑
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Parts, diluent:	2	↓ ↑
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Minimum sample volume:	8	↓ ↑	μl
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Sample	Mixture	Diluent
Vol.	Vol.	Vol.

			Total Volumes
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Enable mixture

Mixture vol.:	100	↓ ↑	%	Number of cycles	1	↓ ↑	
				Rinsing after mixing	1	↓ ↑	S