

Final Report

Test name : Test 06-28-2002 2/1

Simulation database

Measure Option: MeasureOption-Kinetic-405nm-Inflection

Property	Value	Property	Value
Technique	Kinetic	Measurement interval	00:00:30
Shaking before measurement	00:00:30 Medium	Filter wavelength	405 nm
Incubation	00:10:00	Stop Criteria	Stop by Inflection
Temperature	37 C		

E-Signature(s) of the Measure Option:

* Signed by Quality Controller as approver at 2002.06.28 11:12:56

Temperature during Measurement (Celsius)

Average	Maximum	Minimum
36.95	37	36.9

Fixed Assets and Expendables

Supply type	LOT number	Equipment type	Serial number
Microplate	0250100	Pipette, 20-200 ul	450120
Dilution tube, 10 ml	0700102	Pipette, 100-1000 ul	850475
Pipet tip, 200 ul	0200450	Pipette, 100 ul, Finn, 8 channel	445700
Pipet tip, 1000 ul	0100048	Vortex	265800
Reagent reservoir, 100 ml	0652500	-	-

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Test Components

Standard	Lysate	Diluting agent	Substrate	Stop reagent
OS4110	OL6612	OW7850	n/a	n/a

Properties of applied Method

Property	Value	Property	Value
Method Name	Method-Routine-WPS_Raw 1.00	Measurement Procedure	Chromogenic
Type of Method	Routine	Lysatum Sensitivity	0.005 EU/ml
Sample Specification	WPS1401-1.Raw	Calculation Procedure	Standard Kinetic Chrom. Calculation
Was the Method Approved at the time of Measurement?	YES	PPC type	Screening PPC
Technique	Kinetic	PPC Concentration	0.5 EU/ml

E-Signature(s) of the Method:

* Signed by Quality Controller as approver at 2002.06.28 11:13:25

Standard replicates: 2


Replicate	Concentration
STD1	0.005
STD2	0.05
STD3	0.5
STD4	5
STD5	50

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Legend for Approval

Image	Meaning
	Meets requirement

Instrument Check Results

Instrument check	Checked?	Result	Date & Time
Handshake	Yes	Passed	n/a
Filter (405 nm)	Yes	Passed	2002.06.28 11:06:51
Transfer (Home/Eject)	Yes	Passed	2002.06.28 11:06:51
Quick measure (405 nm)	Yes	Passed	2002.06.28 11:06:51
Heater unit	Yes	Passed	2002.06.28 11:06:51
Shake	Yes	Passed	2002.06.28 11:06:51

*No OOS Entries**Signatures*

Event	Signature
Method approved by	(not yet approved)
Batch created by	Quality Controller at 2002.06.28 11:00:16
Test created by	Quality Controller at 2002.06.28 11:00:30
Measure performed by	Quality Controller at 2002.06.28 11:01:46

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Suitability Requirements

Suitability	Value	Apply
Min. number of valid standards	3	✓
Max. CV% of replicates	10.00	✓
Min. standard curve correlation	-0.980	✓
Min. standard curve slope	-	N/A
Max. standard curve slope	-	N/A
PPC recovery lower limit (%)	-50.00	✓
PPC recovery upper limit (%)	100.00	✓

Sample LogID: S01_2002-04-08 (seq.1) (WPS1401-1.Raw)
LotNr: WPS1401/04

Dilution	PPC	Conc. (EU/ml)	CV%	Qual.	Decision
1	-	0.997	1.27	✓	Use
1	0.5	0.465	3.35	✓	-
		0.997	1.27		Accepted

Property	Value	Property	Value
Sampled by	Steven Sampler at 2002.04.06 07:00:01	Logged in by	Demo at 2002.04.08 15:07:26
Submitter	QC Lab.	Order measure	Quality Controller at 2002.06.28 11:11:06

This Sample is not electronically signed.

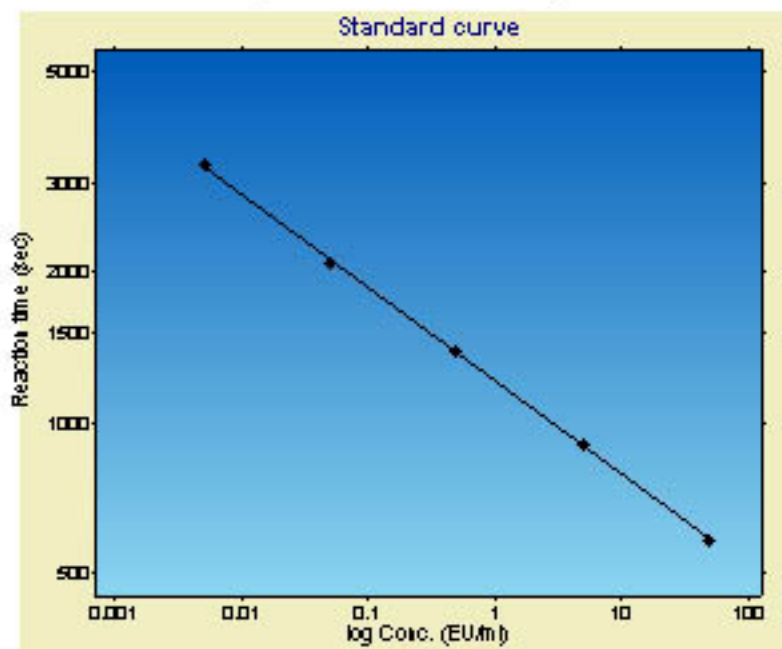
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Sample replicates: 2

Filter wavelength	Dilution
SMP1	1:1

*Standard curve parameters*

Slope	Y-Intercept	Correlation	Qualification	Comment
-0.185	3.082	-0.999	✓	Standard curve OK

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Simulation database

Continued..

Event	Signature
Plate approved by	Quality Controller at 2002.06.28 11:11:06