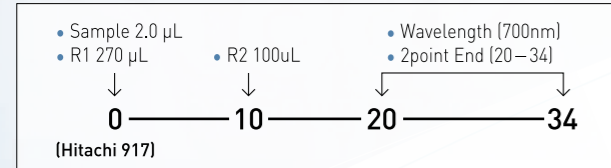
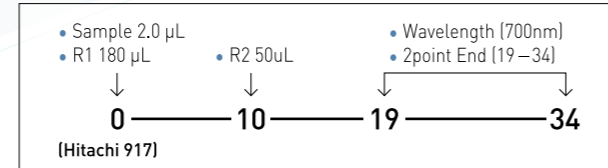


5. Parameter

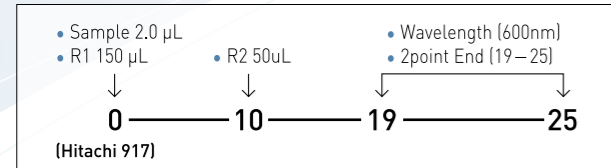
Nanopia™ TDM Phenitoin



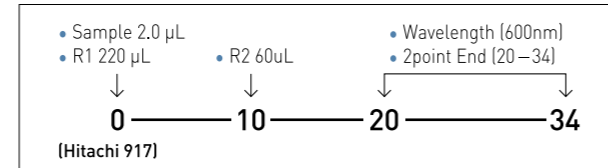
Nanopia™ TDM Phenobarbital



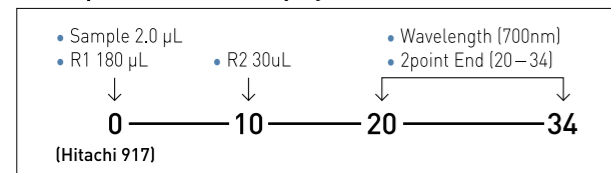
Nanopia™ TDM Valproic Acid



Nanopia™ TDM Carbamazepine



Nanopia™ TDM Theophyline



Therapeutic Drug Monitoring Reagents For Diagnostics Manufacturers and Distributors

Therapeutic Drug Monitoring Reagent

Item		Storage	Expiry Date	Packaging size
Nanopia™ TDM Phenitoin	PHT Antibody Solution 1 PHT Latex Solution 2	2~8 °C	19 months	54mL x1 20mL x1
Nanopia™ TDM Phenobarbital	PB Antibody Solution 1 PB Latex Solution 2	2~8 °C	24 months	36mL x1 10mL x1
Nanopia™ TDM Valproic Acid	VPA Antibody Solution 1 VPA Latex Solution 2	2~8 °C	20 months	30mL x1 10mL x1
Nanopia™ TDM Carbamazepin	CBZ Antibody Solution 1 CBZ Latex Solution 2	2~8 °C	14 months	44mL x1 12mL x1
Nanopia™ TDM Theophyline	THE Antibody Solution 1 THE Latex Solution 2	2~8 °C	16 months	36mL x1 6mL x1
Calibrator for Nanopia™ TDM		2~8 °C	24 months	2mL x 6conc.
Sample Dilution Solution for Nanopia™ TDM		2~8 °C	24 months	10mL x1

- — Nanopia™ TDM **Phenitoin**
- — Nanopia™ TDM **Phenobarbital**
- — Nanopia™ TDM **Valproic Acid**
- — Nanopia™ TDM **Carbamazepine**
- — Nanopia™ TDM **Theophyline**

Features

1. Ready-to-use liquid reagent based on latex turbidimetric immunoassay
2. Suitable for use on various types of automated analyzer
3. Excellent calibration stability
4. One calibrator for 5 types of assay (PHT, PB, VPA, CBZ, THE)

"Nanopia" is a trademark owned by SEKISUI MEDICAL CO.,LTD.JAPAN,and are registered in Japan and/or other countries.

1. Measurement Procedure

A fixed amount of antibody is added to the sample, and the mixture is allowed to react. The amount of antibody that is consumed in this reaction is dependent on the amount of drug present in the sample. Subsequently, drug-coated latex, which reacts with the remaining unreacted antibody to form aggregates, is added to this reaction mixture. Since the degree of aggregation depends on the drug concentration, the change in absorbance caused by this aggregation is measured to determine the sample's drug concentration.

If no drug is present in the sample, the latex aggregation will proceed unhindered, resulting in high absorbance. As the sample drug concentration increases, aggregation is inhibited and the absorbance will be lower.

2. Calibration Stability

Calibration curves generated by using Nanopia™ TDM are stable for approximately 1 month. Therefore, running costs can be reduced even if the number of samples is small. In addition, urgent testing is facilitated by taking away the need to prepare a calibration curve each time.

3. One Calibrator for 5 Types of Assay

The calibrator for Nanopia™ TDM is a single calibrator for 5 types of assay (Phenitoin, Phenobarbital, Valproic acid, Carbamazepine, Theophylline). This can contribute to reduced running costs and shorter turn around time (TAT) if many items are tested simultaneously.

4. Basic Performance Data

Antiepilepsy Drug Phenitoin

Nanopia™ TDM Phenitoin

Measurement Range Hitachi 917

0.7~40µg/mL

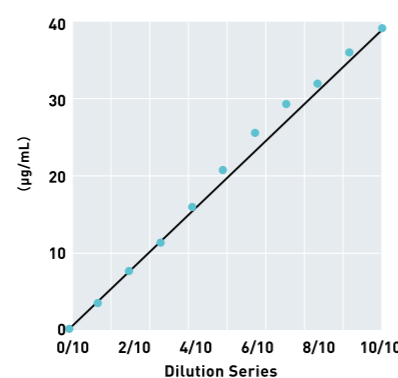
Within-run Reproducibility

	Value(µg/mL)		
	Sample1	Sample2	Sample3
n	20	20	20
Mean	6.9	14.1	25.6
S.D.	0.2	0.3	0.5
C.V.(%)	2.6	2.4	2.1
Max.	7.1	14.6	26.5
Min.	6.4	13.4	24.8

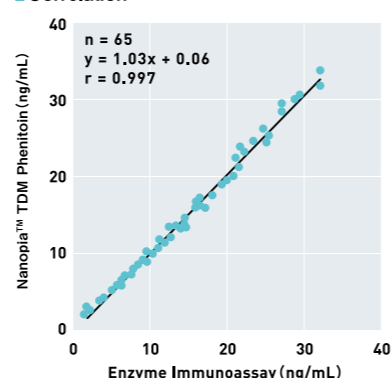
Interference

Interfering Substance	Amount Added	Value(µg/mL)	
		Base Sample	Including Interfering Substance
Unconjugated Bilirubin	20mg/dL	13.5	13.3
Conjugated Bilirubin	20mg/dL	13.3	13.1
Hemoglobin	500mg/dL	13.5	13.0
Lipid emulsion	3000 formazin turbidity	13.2	13.1
Ascorbic acid	50mg/dL	13.6	13.0

Linearity



Correlation



Antiepilepsy Drug Phenobarbital

Nanopia™ TDM Phenobarbital

Measurement Range Hitachi 917

0.8~80µg/mL

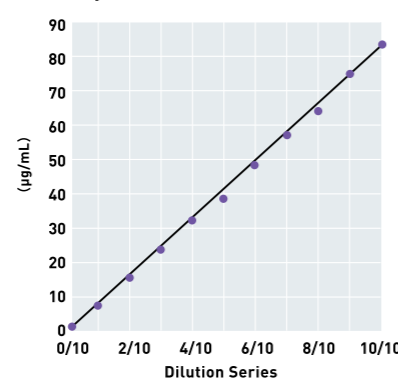
Within-run Reproducibility

	Value(µg/mL)		
	Sample1	Sample2	Sample3
n	20	20	20
Mean	10.2	25.1	51.9
S.D.	0.2	0.5	2.0
C.V.(%)	1.4	2.0	3.8
Max.	10.6	26.3	54.7
Min.	9.9	24.3	48.2

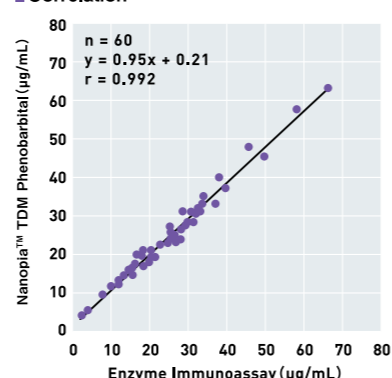
Interference

Interfering Substance	Amount Added	Value(µg/mL)	
		Base Sample	Including Interfering Substance
Unconjugated Bilirubin	20mg/dL	26.9	27.1
Conjugated Bilirubin	20mg/dL	27.3	26.9
Hemoglobin	500mg/dL	27.2	27.4
Lipid emulsion	3000 formazin turbidity	26.7	27.1
Ascorbic acid	50mg/dL	27.0	27.1

Linearity



Correlation



Antiepilepsy Drug Valproic Acid

Nanopia™ TDM Valproic Acid

Measurement Range Hitachi 917

12~150µg/mL

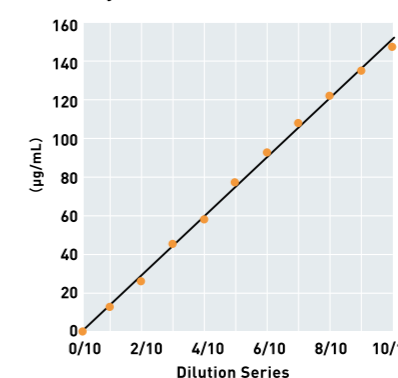
Within-run Reproducibility

	Value(µg/mL)		
	Sample1	Sample2	Sample3
n	20	20	20
Mean	32.9	66.3	109.2
S.D.	1.4	1.2	1.1
C.V.(%)	4.3	1.8	1.0
Max.	35.2	69.9	112.5
Min.	29.4	64.8	107.3

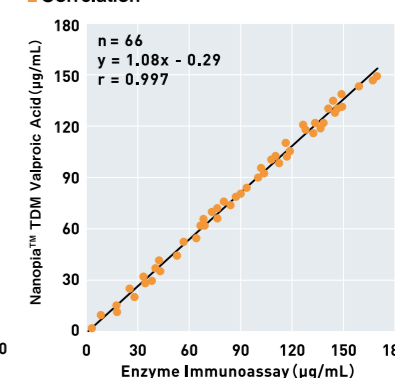
Interference

Interfering Substance	Amount Added	Value(µg/mL)	
		Base Sample	Including Interfering Substance
Unconjugated Bilirubin	20mg/dL	59.7	60.2
Conjugated Bilirubin	20mg/dL	59.3	58.1
Hemoglobin	500mg/dL	59.7	58.9
Lipid emulsion	3000 formazin turbidity	60.9	60.3
Ascorbic acid	50mg/dL	59.7	60.5

Linearity



Correlation



Antiepilepsy Drug Carbamazepine

Nanopia™ TDM Carbamazepine

Measurement Range Hitachi 917

0.4~20µg/mL

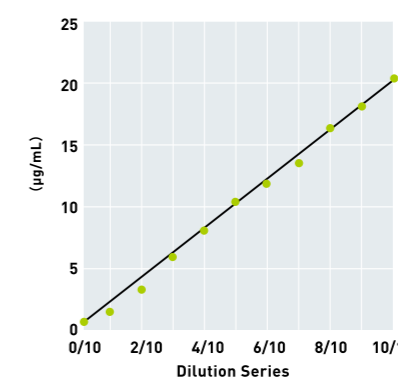
Within-run Reproducibility

	Value(µg/mL)		
	Sample1	Sample2	Sample3
n	20	20	20
Mean	3.0	9.5	15.6
S.D.	0.08	0.2	0.2
C.V.(%)	2.7	1.6	1.3
Max.	3.2	10.0	15.9
Min.	2.9	9.3	15.2

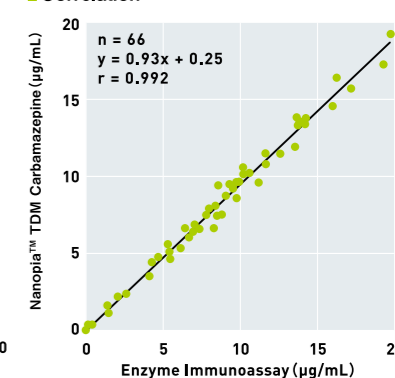
Interference

Interfering Substance	Amount Added	Value(µg/mL)	
		Base Sample	Including Interfering Substance
Unconjugated Bilirubin	20mg/dL	8.3	8.2
Conjugated Bilirubin	20mg/dL	8.0	8.2
Hemoglobin	500mg/dL	8.3	8.3
Lipid emulsion	3000 formazin turbidity	8.1	8.6
Ascorbic acid	50mg/dL	8.7	8.8

Linearity



Correlation



Bronchodilator Theophylline

Nanopia™ TDM Theophylline

Measurement Range Hitachi 917

0.2~40µg/mL

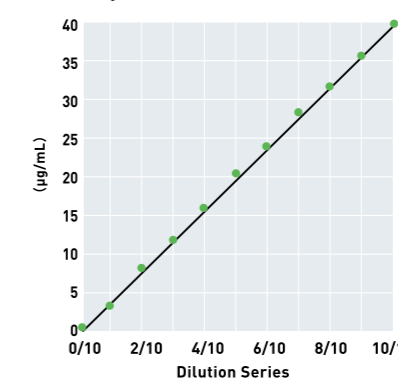
Within-run Reproducibility

	Value(µg/mL)		
	Sample1	Sample2	Sample3
n	20	20	20
Mean	4.4	14.5	29.7
S.D.	0.07	0.1	0.3
C.V.(%)	1.6	0.8	0.9
Max.	4.6	14.8	30.2
Min.	4.3	14.3	29.2

Interference

Interfering Substance	Amount Added	Value(µg/mL)	
		Base Sample	Including Interfering Substance
Unconjugated Bilirubin	20mg/dL	14.3	14.3
Conjugated Bilirubin	20mg/dL	14.5	14.3
Hemoglobin	500mg/dL	14.6	14.4
Lipid emulsion	3000 formazin turbidity	14.3	14.5
Ascorbic acid	50mg/dL	14.5	14.5

Linearity



Correlation

