



**AZER SCIENTIFIC™**

189 Twin County Rd. Morgantown, PA 19543  
610-524-5810 azersci.com

## THERAPEUTIC DRUG MONITORING LINEARITY TEST SET

### INTENDED USE:

Therapeutic Drug Monitoring Test Sets are for in vitro diagnostic use in verifying reportable ranges and determining linearity in automated, semi-automated and manual chemistry systems. The analytes included are Acetaminophen, Amikacin, Carbamazepine, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Lithium, Methotrexate, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, and Vancomycin.

Therapeutic Drug Monitoring Linearity Test Sets are designed to be compatible with all popular chemistry analyzers, providing clinicians with 6 dilution levels, and 3 ampules of 1ml each per level. They are manufactured such that a linear relationship exists between all levels.

### SUMMARY:

Therapeutic Drug Monitoring Linearity Test Sets are used to establish the relationship between theoretical and actual performance of specified analytes. This control set will assist in the documentation of linearity, calibration verification and verification of linear range required by many inspection agencies. The control solutions can also be used to troubleshoot problems with chemistry systems, reagents, and / or calibration anomalies.

### INGREDIENTS:

Purified materials for Acetaminophen, Amikacin, Carbamazepine, Digoxin, Disopyramide, Ethosuximide, Gentamicin, Lidocaine, Lithium, Methotrexate, N-Acetylprocainamide, Phenobarbital, Phenytoin, Primidone, Procainamide, Quinidine, Salicylate, Theophylline, Tobramycin, Valproic Acid, and Vancomycin are stabilized and preserved in a human serum matrix.

### STORAGE AND STABILITY:

When stored and refrigerated at 2 to 8° C, Therapeutic Drug Monitoring Linearity Test Sets are stable until the expiration date printed on the ampule or vial. Opened ampules **must be used within the same working day** or else discarded. Dispose if gross contamination is visible.

### INSTRUCTIONS FOR USE:

Therapeutic Drug Monitoring Linearity Test Sets are ready-to-use, and require no reconstitution. Depending upon the range and sensitivity of your instrument's test method, you will be able to run a minimum of 4 prediluted levels, and a maximum of 6 for a specific analyte. Materials contained herein should be treated in the same manner as patient samples. If additional dilutions or pre-treatment are required as part of your testing procedure, please consult the user manual of your instrument's manufacturer.

Before actual use, hold ampule by the top and shake gently. Then with light tapping, restore all liquid to the bottom. Break open carefully to avoid cutting of fingers – using the complementary ampule snapper provided with this test set. With pipette, aspirate liquid from ampule and transfer to one or more sample cups.

Duplicate or triplicate runs are advised when performing calibration verification.

### CALCULATION OF RESULTS:

Users of our Linearity Test Sets are strongly advised to calculate their results via Azer Scientific's free data reduction service. The computational method and graphical analyses deployed in our reports are far more rigorous than the manual procedures outlined below. In addition, we can save clinicians considerable time by performing all of their calculations for them at no cost. Simply enter data into our customized MS Excel spreadsheets, and email them to the address provided. Spreadsheets can be obtained by emailing us at the following address:

[info@AzerSci.com](mailto:info@AzerSci.com)

If performing calculations manually, however, the following considerations will apply. After sampling each level in duplicate or triplicate, calculate a Mean Recovered Value for each, and record in the worksheet space provided. Theoretical Values for each level can be obtained by multiplying the Mean Recovered Value of **Level 4** with the "Linearity Factors" provided below.

#### Linearity Factors

Level 1	0.100
Level 2	0.400
Level 3	0.700
<b>Level 4</b>	<b>1.000</b>
Level 5	1.500
Level 6	2.000

### SAMPLE CALCULATION:

If the Mean Recovered value for Level 4 = 10.1, you can calculate Theoretical Values by multiplying 10.1 by the "Linearity Factor" associated with each level. For example

Calculations:	Theoretical Value	Recovered Value
Level 1 = 10.1 X 0.10	1.01	0.97
Level 2 = 10.1 X 0.40	4.04	4.14
Level 3 = 10.1 X 0.70	7.07	7.23
<b>Level 4 = 10.1 X 1.0</b>	<b>10.10</b>	<b>9.87</b>
Level 5 = 10.1 X 1.50	15.15	15.32
Level 6 = 10.1 X 2.00	20.20	19.92

In order to assess the linearity of a specific test method, plot results on standard linear graph paper using "Theoretical" as X-axis and "Recovered" as Y-axis.

### EXPECTED VALUES:

Each lot of product is manufactured in such a way that a linear relationship exists between all levels. Actual results obtained may vary depending upon instrumentation and methodology used, as well as assay temperature. Results may also depend upon the accuracy of the instrument and reagent calibration. The degree of acceptable non-linearity is an individual judgment based upon a test analyte's methodology, clinical significance and medical decision levels.

Technicians are advised to consult the analytical limits defined by the Clinical Laboratory Improvement Act of 1988 (CLIA '88). These criteria specify the *total error allowed* for most analytes in question, and they can be referenced at the following web address:

[http://www.phppo.cdc.gov/clia/regs/subpart\\_i.aspx#493.931](http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.931)

Analyte	Range
Acetaminophen	13.7 – 274.0 µg/mL
Amikacin	2.0 – 40.0 µg/mL
Carbamazepine	1.0 – 20.0 µg/mL
Digoxin	0.24 – 4.8 ng/mL
Disopyramide	0.35 – 7.0 µg/mL
Ethosuximide	6.8 – 136.0 µg/mL
Gentamicin	0.6 – 12.0 µg/mL
Lidocaine	0.68 – 13.5 µg/mL
Lithium	0.25 – 5.0 mmol/L
Methotrexate	0.05 – 1.0 µmol/mL
N-Acetylprocainamide	1.5 – 29.0 µg/mL
Phenobarbital	4.0 – 80.0 µg/mL
Phenytoin	2.4 – 47.0 µg/mL
Primidone	1.1 – 22.0 µg/mL
Procainamide	1.0 – 20.0 µg/mL
Quinidine	0.4 – 8.2 µg/mL
Salicylate	50.0 – 1000.0 µg/mL
Theophylline	2.0 – 40.0 µg/mL
Tobramycin	0.88 – 17.5 µg/mL
Valproic Acid	7.8 – 156.0 µg/mL
Vancomycin	4.8 – 96.0 µg/mL

### REORDERING INFORMATION:

THERAPEUTIC DRUG MONITORING LINEARITY TEST SET  
CAT. No.: ES5030

CONFIGURATION: 6 X 3 X 1 mL (AMPULES)

**For technical assistance or to place an order, please call:**

Tel: 610-524-5810

Fax: 610-901-3046

Email: [info@azersci.com](mailto:info@azersci.com)

Azer Scientific

189 Twin County Rd. Morgantown, PA 19543

(Please allow 3-7 days for delivery)

**THERAPEUTIC DRUG MONITORING  
LINEARITY WORKSHEET**

Cat. No.: ES5030 Lot#: \_\_\_\_\_

Expiration Date: \_\_\_\_\_

Documentation Date: \_\_\_\_\_

**THERAPEUTIC DRUG LINEARITY FACTORS**

LEVEL	ALL OTHER ANALYTES
1	0.100
2	0.400
3	0.700
4	<b>1.000</b>
5	1.500
6	2.500

**ANALYTE – Acetaminophen**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Amikacin**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Carbamazepine**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Digoxin**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Disopyramide**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Ethosuximide**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Gentamicin**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Lidocaine**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Lithium**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Methotrexate**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – N-Acetylprocainamide**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Phenobarbital**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Phenytoin**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Primidone**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Procainamide**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Quinidine**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Salicylate**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Theophylline**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Tobramycin**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Valproic Acid**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE - Vancomycin**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE –**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		