

# EVER Scientific

## DIAGNOSTICS DIVISION

### MULTI-ANALYTE LINEARITY TEST SET

Lot. No.: 50312

Expiration: MARCH 2007

#### INTENDED USE:

Multi-Analyte Linearity 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 Total Protein (TP), Albumin (ALB), Uric Acid (UA), Creatinine (CREAT), Glucose (GLU), Blood Urea Nitrogen (BUN), Lactate (LAC), Phosphorous (P), Sodium (Na<sup>+</sup>), Potassium (K<sup>+</sup>), Calcium (Ca<sup>++</sup>), Chloride (Cl<sup>-</sup>), Lithium (Li<sup>+</sup>), Iron (FE), Magnesium (Mg<sup>++</sup>), Cholesterol (CHOL), Triglycerides (TRIG), and Carbon Dioxide (CO<sub>2</sub>).

Multi-Analyte Linearity Test Sets are designed to be compatible with all popular chemistry analyzers, and provide clinicians with 6 Dilution Levels of 5mL each. They come in two different configurations. The first version consists of 6 vials that are filled with 5mL each (i.e. one vial per level). The second version consists of 30 ampules that are filled with 1mL each (i.e. five ampules per level). Both versions are manufactured such that a linear relationship exists between all levels.

#### SUMMARY:

Multi-Analyte 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 chemicals for albumin, calcium, cholesterol, chloride, carbon dioxide, creatinine, glucose, iron, lactate, lithium, magnesium, phosphorus, potassium, sodium, total protein, triglyceride, urea nitrogen, and uric acid are stabilized and preserved in a bovine albumin solution.

#### STORAGE AND STABILITY:

When stored and refrigerated at 2 to 8° C, Multi-Analyte 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. Opened vials must be tightly capped and immediately returned to refrigeration after each use. Dispose if gross contamination is visible.

#### INSTRUCTIONS FOR USE:

Multi-Analyte 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.

*For Ampules:* 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.

*For Vials:* Gently mix the contents of each vial before sampling to ensure homogeneity. With pipette, aspirate liquid from vial and transfer to one or more sample cups. Replace cap immediately and store at 2 to 8°C.

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 Ever 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 downloaded from the following web location:

<http://www.eversci-linearity.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.

\*Note: Given that low concentrations of sodium and chloride cannot be read by most chemistry analyzers, these analytes are targeted independently of other constituents. For this reason, the linear relationship they share is also different from other constituents.

#### Linearity Factors for Sodium (Na<sup>+</sup>) and Chloride (Cl<sup>-</sup>)

Level 1	0.500
Level 2	0.667
Level 3	0.834
Level 4	1.000
Level 5	1.334
Level 6	1.667

#### Linearity Factors for All Other Analytes

Level 1	0.250
Level 2	0.500
Level 3	0.750
Level 4	1.000
Level 5	1.750
Level 6	2.500

#### SAMPLE CALCULATION:

If the Mean Recovered value for Level 4, Glucose = 282mg/dL, you can calculate Theoretical Values by multiplying 282 by the "Linearity Factor" associated with each level. Example:

Calculations:	Theoretical Value	Mean Recovered Value
Level 1 = 282 x 0.125	35.3	36.1
Level 2 = 282 x 0.375	105.8	107.2
Level 3 = 282 x 0.625	176.3	175.3
<b>Level 4 = 282 x 1.000</b>	<b>282.0</b>	<b>282.0</b>
Level 5 = 282 x 1.750	493.5	493.1
Level 6 = 282 x 2.500	705.0	707.2

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
Albumin (ALB)	0.6 – 6.0 mg/dL
Total Protein (TP)	1.2 – 12 g/dL
Cholesterol (CHOL)	50 – 500 mg/dL
Triglycerides (TRIG)	67.5 – 675 mg/dL
Calcium (CA)	2 – 20 mg/dL
Glucose (GLU)	70 – 700mg/dL
Phosphorous (P)	1.2 – 12 mg/dL
Urea Nitrogen (BUN)	13 – 130 mg/dL
Uric Acid (UA)	1.5 – 15 mg/dL
Magnesium (Mg <sup>++</sup> )	0.6 – 6.0 mg/dL
Potassium (K <sup>+</sup> )	1.4 – 14 mmol/dL
Iron (Fe)	71 – 710 µg/dL
Creatinine (CREAT)	2.5 – 25 mg/dL
Lactate (LAC)	12 – 120 mg/dL
Lithium (Li <sup>+</sup> )	0.7 – 7.0 mmol/dL
Carbon Dioxide (CO <sub>2</sub> )	4 – 40 mmol/dL
*Chloride (Cl <sup>-</sup> )	48 – 160 mmol/dL
*Sodium (Na <sup>+</sup> )	72 – 240 mmol/dL

**\* When computing Theoretical Values for Chloride and Sodium, please be sure to use special linearity factors provided in this insert. The linear relationship for these two analytes is different from other constituents.**

#### SUPPLEMENTAL PRODUCTS:

A zero or near zero point during your calibration verification studies is strongly advised. Ever Scientific manufactures an Aqueous-Based Zero-Dilution matrix that is compatible with this Multi-Analyte Linearity Test Set:

AQUEOUS-BASED ZERO / DILUTION MATRIX  
CAT. No.: ES5051  
CONFIGURATION: 10mL DROPPER BOTTLE

Note: This product can also be used as a zero or diluting factor for Ever Scientific's ISE / Metabolite Linearity Test Set.

#### REORDERING INFORMATION:

MULTI-ANALYTE LINEARITY TEST SET  
CAT. No.: ES5010 OR ES5020  
CONFIGURATION: 6 x 1 x 5mL (VIALS) OR 6 x 5 x 1mL (AMPULES)

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

Tel: 610-524-5810  
Fax: 610-524-5814  
Email: [sales@everscientific.com](mailto:sales@everscientific.com)

EVER SCIENTIFIC  
337 Gordon Drive, Exton, PA 19341, USA  
(Please allow 3-7 days for delivery)

**MULTI-ANALYTE LINEARITY CONTROL WORKSHEET**

Cat. No.: ES5015 or ES5021 Lot#: \_\_\_\_\_

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

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

**ANALYTE – Phosphorus (P)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Lithium (Li+)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**MULTI-ANALYTE LINEARITY FACTORS**

LEVEL	Na+ & Cl-	ALL OTHER ANALYTES
1	0.500	0.250
2	0.667	0.500
3	0.834	0.750
<b>4</b>	<b>1.000</b>	<b>1.000</b>
5	1.334	1.750
6	1.667	2.500

**ANALYTE – Urea Nitrogen (BUN)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Carbon Dioxide (CO<sub>2</sub>)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Albumin (ALB)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Uric Acid (UA)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**\*ANALYTE – Chloride (Cl-)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Total Protein (TP)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Magnesium (MG++)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**\*ANALYTE – Sodium (Na+)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
*1		
*2		
*3		
*4		
*5		
*6		

**ANALYTE – Cholesterol (CHOL)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Potassium (K+)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE –**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Triglycerides (TRIG)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Iron (FE)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE –**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Calcium (CA)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Creatinine (CREAT)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE –**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Glucose (GLU)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**ANALYTE – Lactate (LAC)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**MULTI-ANALYTE LINEARITY FACTORS**

LEVEL	Na+ & Cl-	ALL OTHER ANALYTES
1	0.500	0.250
2	0.667	0.500
3	0.834	0.750
<b>4</b>	<b>1.000</b>	<b>1.000</b>
5	1.334	1.750
6	1.667	2.500