

EVER Scientific

DIAGNOSTICS DIVISION

MULTI-ENZYME LINEARITY TEST SET

Lot. No. 50400

Expiration: APRIL 2007

INTENDED USE:

Multi-Enzyme Linearity Test Sets are intended for in vitro diagnostic use in verifying reportable ranges and determining linearity in automated, semi-automated and manual chemistry systems. The enzymes included are Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Amylase (AMY), Aspartate Aminotransferase (AST), Creatine Kinase (CK), Gamma-Glutamyl Transferase (GGT), Lactate Dehydrogenase (LD), and Lipase (LIP).

Multi-Enzyme 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-Enzyme Linearity Test Sets are used to establish a relationship between the theoretical and actual performance of a specified analyte. This control set will assist in the documentation of linearity, calibration verification and verification of linear range required by many inspection agencies. These test sets can also be used to troubleshoot problems with chemistry systems, reagents, and / or calibration anomalies.

INGREDIENTS:

Purified enzymes are stabilized and preserved in a bovine albumin solution. The sources for these enzymes are as follows:

Alkaline Phosphatase (ALP) - calf intestine
Alanine Aminotransferase (ALT) - porcine heart
Amylase (AMY) - porcine pancreas
Aspartate Aminotransferase (AST) - porcine heart
Creatine Kinase (CK) - porcine heart
Gamma-Glutamyl Transferase (GGT) - bovine kidneys
Lactate Dehydrogenase (LD) - chicken heart

STORAGE AND STABILITY:

When stored at -10 to -20°C, Multi-Enzyme Linearity Test Sets are stable until the expiration date printed on ampule or vial. **Do NOT store in a frost-free freezer.** Opened ampules *must be used within the same working day* or else discarded. Opened vials must be tightly capped and immediately returned to a freezer after use. Discard if gross contamination is visible.

INSTRUCTIONS FOR USE:

Multi-Enzyme Linearity Test Sets are frozen products, and must be allowed to thaw at room temperature before use (i.e. 20 to 25° C). 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 instructions of your instrument 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 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 -10 to -20°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>

Ever Scientific
Multi-Enzyme Linearity Test Set

Free Data-Reduction Service: Download Electronic Submission Forms at <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:

Linearity Factors

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 = 364, you can calculate Theoretical Values by multiplying 364 by the "Linearity Factor" associated with each level. Example:

<i>Calculations:</i>	<i>Theoretical Value</i>	<i>Mean Recovered Value</i>
Level 1 = 364 x 0.250	91	89
Level 2 = 364 x 0.500	182	185
Level 3 = 364 x 0.750	273	269
Level 4 = 364 x 1.000	364	364
Level 5 = 364 x 1.750	637	640
Level 6 = 364 x 2.500	910	905

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 its 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

Analyte	Typical Range
Alkaline Phosphatase (ALP)	100 – 1000 U/L
Alanine Aminotransferase (ALT)	95 – 950 U/L
Amylase (AMY)	160 – 1600 U/L
Aspartate Aminotransferase (AST)	90 – 900 U/L
Creatine Kinase (CK)	165 – 1650 U/L
Gamma-Glutamyl Transferase (GGT)	105 – 1050 U/L
Lactate Dehydrogenase (LD)	85 – 850 U/L

SUPPLEMENTAL PRODUCTS:

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

PROTEIN-BASED ZERO / DILUTION MATRIX
CAT. NO.: ES5050
CONFIGURATION: 10ML DROPPER BOTTLE

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

REORDERING INFORMATION:

MULTI-ENZYME LINEARITY TEST SET
CAT. NO.: ES5015 OR ES5021
CONFIGURATION: 6X1x5mL (VIALS) OR 6X5x1 mL (AMPULES)

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

Tel: 610-524-5810
Fax: 610-524-5814
Email: sales@everscientific.com

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

**MULTI-ENZYME LINEARITY
CONTROL WORKSHEET**

Cat. No.: ES5015 or ES5021 Lot#: _____

Expiration Date: _____

Documentation Date: _____

**MULTI-ENZYME LINEARITY
FACTORS**

LEVEL	LINEARITY FACTOR
1	0.125
2	0.375
3	0.625
4	1.000
5	1.750
6	2.500

ANALYTE – Alkaline Phosphatase (ALP)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Alanine Aminotransferase (ALT)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

**MULTI-ENZYME LINEARITY
CONTROL WORKSHEET**

Cat. No.: ES5015 or ES5021 Lot#: _____

Expiration Date: _____

Documentation Date: _____

**MULTI-ENZYME LINEARITY
FACTORS**

LEVEL	LINEARITY FACTOR
1	0.125
2	0.375
3	0.625
4	1.000
5	1.750
6	2.500

ANALYTE – Alkaline Phosphatase (ALP)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Alanine Aminotransferase (ALT)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Amylase (AMY)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Aspartate Aminotransferase (AST)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Creatine Kinase (CK)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Gamma-Glutamyl Transferase (GGT)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Lactate Dehydrogenase (LD)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE –

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE –

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE –

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Amylase (AMY)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Aspartate Aminotransferase (AST)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Creatine Kinase (CK)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Gamma-Glutamyl Transferase (GGT)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Lactate Dehydrogenase (LD)

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE –

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE –

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		

ANALYTE –

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		