



# PHOENIX DIAGNOSTICS

## MULTI-ENZYME LINEARITY TEST SET

**Lot. No. 21000      Expiration: OCT 15**

### 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), and Lactate Dehydrogenase (LD).

Multi-Enzyme Linearity Test Sets are designed to be compatible with all popular chemistry analyzers, providing clinicians with 7 dilution levels, and 3 ampules of 1ml each per level. They 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 Phoenix Diagnostics' 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:

[linearity@phoenixdiagnostics.com](mailto:linearity@phoenixdiagnostics.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	0.125
Level 2	0.250
Level 3	0.500
Level 4	0.750
<b>Level 5</b>	<b>1.000</b>
Level 6	1.750
Level 7	2.500

### SAMPLE CALCULATION:

If the Mean Recovered value for Level 5 = 364, you can calculate Theoretical Values by multiplying 364 by the "Linearity Factor" associated with each level. Example:

Calculations:	Theoretical Value	Mean Recovered Value
Level 1 = 364 x 0.125	46	48
Level 2 = 364 x 0.250	91	89
Level 3 = 364 x 0.500	182	185
Level 4 = 364 x 0.750	273	269
<b>Level 5 = 364 x 1.000</b>	<b>364</b>	<b>364</b>
Level 6 = 364 x 1.750	637	640
Level 7 = 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](http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.931)

Analyte	Typical Range
Alkaline Phosphatase (ALP)	118-2372 U/L
Alanine Aminotransferase (ALT)	62-1242 U/L
Amylase (AMY)	152-3042 U/L
Aspartate Aminotransferase (AST)	65-1318 U/L
Creatine Kinase (CK)	137-2754 U/L
Gamma-Glutamyl Transferase (GGT)	58-1166 U/L
Lactate Dehydrogenase (LD)	168-3366 U/L

### SUPPLEMENTAL PRODUCTS:

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

PROTEIN-BASED ZERO / DILUTION MATRIX  
 CAT. NO.: PH5050  
 CONFIGURATION: 1 OML DROPPER BOTTLE

### REORDERING INFORMATION:

MULTI-ENZYME LINEARITY TEST SET  
 CAT. NO.: PH5021  
 CONFIGURATION: 7X3X1 mL (AMPULES)

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

Tel: 508-655-8310  
 Fax: 508-655-8273  
 Email: [sales@phoenixdiagnostics.com](mailto:sales@phoenixdiagnostics.com)

Phoenix Diagnostics  
 8 Tech Circle, Natick, MA 01760  
 (Please allow 3-7 days for delivery)

**MULTI-ENZYME LINEARITY  
CONTROL WORKSHEET**

Cat. No.: PH5021 Lot#: \_\_\_\_\_

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

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

**MULTI-ENZYME LINEARITY  
FACTORS**

LEVEL	LINEARITY FACTOR
1	0.125
2	0.250
3	0.500
4	0.750
5	<b>1.000</b>
6	1.750
7	2.500

**ANALYTE – Alkaline Phosphatase (ALP)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		
7		

**ANALYTE – Alanine Aminotransferase (ALT)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		
7		

**MULTI-ENZYME LINEARITY  
CONTROL WORKSHEET**

Cat. No.: PH5021B Lot#: \_\_\_\_\_

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

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

**MULTI-ENZYME LINEARITY  
FACTORS**

LEVEL	LINEARITY FACTOR
1	0.125
2	0.250
3	0.500
4	0.750
5	<b>1.000</b>
6	1.750
7	2.500

**ANALYTE – Alkaline Phosphatase (ALP)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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5		
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**ANALYTE – Alanine Aminotransferase (ALT)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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7		

**ANALYTE – Aspartate Aminotransferase (AST)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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**ANALYTE – Creatine Kinase (CK)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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4		
5		
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7		

**ANALYTE – Gamma-Glutamyl Transferase (GGT)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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**ANALYTE – Amylase (AMY)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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5		
6		
7		

**ANALYTE – Aspartate Aminotransferase (AST)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
2		
3		
4		
5		
6		
7		

**ANALYTE – Creatine Kinase (CK)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
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3		
4		
5		
6		
7		

**ANALYTE – Gamma-Glutamyl Transferase (GGT)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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3		
4		
5		
6		
7		

**ANALYTE – Lactate Dehydrogenase (LD)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
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4		
5		
6		
7		

**ANALYTE – Lactate Dehydrogenase (LD)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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7		

**ANALYTE – \_\_\_\_\_**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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**ANALYTE – \_\_\_\_\_**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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7		

**ANALYTE – \_\_\_\_\_**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
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4		
5		
6		
7		

**ANALYTE – Amylase (AMY)**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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4		
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6		
7		

**ANALYTE – \_\_\_\_\_**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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**ANALYTE – \_\_\_\_\_**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
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**ANALYTE – \_\_\_\_\_**

LEVEL	THEORETICAL VALUE	EXPERIMENTAL VALUE
1		
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