

EVER Scientific

DIAGNOSTICS DIVISION

ISE / METABOLITE LINEARITY TEST SET

INTENDED USE:

ISE / Metabolite 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 analytes included are Glucose (GLU), Lactate (LAC), Creatinine (CREAT), Sodium (Na⁺), Potassium (K⁺), Calcium (CA), Lithium (Li⁺), Chloride (Cl⁻), Magnesium (Mg⁺⁺), Urea Nitrogen (BUN), and Phosphorous (P).

ISE / Metabolite Linearity Test Sets are designed to be compatible with all popular chemistry analyzers. Each kit has six (6) dilution levels filled in dropper bottles of 5mL each. A linear relationship exists among all levels of each set.

SUMMARY:

ISE / Metabolite Linearity Test Sets contain purified chemicals stabilized within an aqueous solution. Six levels are provided to establish the relationship between theoretical and actual performance of each specified analyte. Depending upon the range and sensitivity of your instrument's test method for a specific analyte, you will be able to run a minimum of 4 of these prediluted levels. 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 sodium, potassium, calcium, chloride, lithium, magnesium, glucose, lactate, urea nitrogen, creatinine, phosphorous.

STORAGE AND STABILITY:

ISE / Metabolite linearity control materials are stable until the expiration date printed on the dropper bottle when stored at 2-8°C. Dispose if gross contamination is visible.

INSTRUCTIONS FOR USE:

ISE / Metabolite Linearity Test Sets are ready-to-use, and require no reconstitution. Materials contained herein should be treated in the same manner as patient samples. If dilutions or pre-treatment are required as part of the testing procedure, follow the instrument manufacturer's instructions.

Before actual sampling, gently invert dropper bottle several times to ensure homogeneity of materials. With pipette, aspirate liquid from ampule 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:

Every ISE / Metabolite Linearity Test Set is prepared in a manner such that an equal distance exists between each consecutive level. This dilution scheme is consistent with the NCCLS recommendation for preparing calibration verification materials. Using this method of dilution, Levels 1 and 6 are prepared. Once targeted, Levels 2, 3, 4 and 5 are prepared by combining Levels 1 and 6 in the following proportional scheme:

Level 2 is a mixture of four parts Level 1 and one part Level 6.
Level 3 is a mixture of three parts Level 1 and two parts Level 6.
Level 4 is a mixture of two parts Level 1 and three parts Level 6.
Level 5 is a mixture of one part Level 1 and four parts Level 6.

Values can be determined using the recovered values for Levels 1 and 6. Using this method, the following formula applies:

$$\text{Level 2} = 0.80 (\text{Level 1}) + 0.20 (\text{Level 6})$$

$$\text{Level 3} = 0.60 (\text{Level 1}) + 0.40 (\text{Level 6})$$

$$\text{Level 4} = 0.40 (\text{Level 1}) + 0.60 (\text{Level 6})$$

$$\text{Level 5} = 0.20 (\text{Level 1}) + 0.80 (\text{Level 6})$$

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
Sodium (Na ⁺)	80 – 200 mmol/L
Potassium (K ⁺)	1.5 – 12.0 mmol/L
Calcium (CA)	2.0 – 14.0 mg/dL
Chloride (Cl ⁻)	60 – 190 mmol/L
Lithium (Li ⁺)	0.3 – 8.0 mmol/L
Magnesium (Mg ⁺⁺)	0.1 – 7.0 mg/dL
Glucose (GLU)	20 – 700 mg/dL
Lactate (LAC)	2.7 – 160 mg/dL
Creatinine (CREAT)	1.5 – 22.0 mg/dL
Urea Nitrogen (BUN)	1.0 – 150 mg/dL
Phosphorous (P)	1.0 – 14.0 mg/dL

SUPPLEMENTAL PRODUCTS:

If you require a zero or near zero point during your calibration verification studies, Ever Scientific manufactures an Aqueous-Based Zero-Dilution matrix:

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 Multi-Analyte Linearity Test Set.

REORDERING INFORMATION:

ISE / METABOLITE LINEARITY TEST SET
 CAT. NO.: ES5035
 CONFIGURATION: 6 x 1 x 5mL (DROPPERS)

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.

ISE / METABOLITE LINEARITY WORKSHEET

Lot. No: _____ Exp: _____ Test Date: _____

EXAMPLE CALCULATION USING RECOVERED VALUES

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1	3	3
2	$0.8(3) + 0.2(21) = 6.6$	6.9
3	$0.6(3) + 0.4(21) = 8.4$	8.1
4	$0.4(3) + 0.6(21) = 13.8$	14.2
5	$0.2(3) + 0.8(21) = 17.4$	17.1
6	21	21

ANALYTE – Sodium (Na⁺)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Potassium (K⁺)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Calcium (CA)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Chloride (Cl)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Lithium (Li⁺)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Magnesium (Mg⁺⁺)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Glucose (GLU)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Lactate (LAC)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Urea Nitrogen (BUN)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Creatinine (CREAT)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE – Phosphorous (P)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		