



PHOENIX DIAGNOSTICS

MULTI-ANALYTE LINEARITY TEST SET

Lot No.: 21001

Expiration: OCT 15

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⁺), Potassium (K⁺), Calcium (Ca⁺⁺), Chloride (Cl⁻), Lithium (Li⁺), Iron (FE), Magnesium (Mg⁺⁺), Cholesterol (CHOL), Triglycerides (TRIG), and Carbon Dioxide (CO₂).

Multi-Analyte 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:

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:

Simply enter data into our secured reduction web-based reduction program. To obtain username and password, please provide the information below to the following email address:

sales@phoenixdiagnostics.com

Company name, address, email address, type of kit purchased & provider

If you already have a username and password, simply log in to enter your data.

***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⁺) and Chloride (Cl⁻)

| | Na/Cl |
|----------------|------------------|
| Level 1 | 0.52/0.40 |
| Level 2 | 0.70/0.65 |
| Level 3 | 0.85/0.75 |
| Level 4 | 1.00/1.00 |
| Level 5 | 1.35/1.50 |
| Level 6 | 1.70/1.90 |

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 0.250 | 70.5 | 71.0 |
| Level 2 = 282 x 0.500 | 141.0 | 140.6 |
| Level 3 = 282 x 0.750 | 211.3 | 210.4 |
| Level 4 = 282 x 1.000 | 282.0 | 282.0 |
| 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

| Analyte | Range |
|-----------------------------------|--------------------|
| Albumin (ALB) | 0.57 – 5.70 g/dL |
| Total Protein (TP) | 1.3 – 13 g/dL |
| Cholesterol (CHOL) | 49 – 490 mg/dL |
| Triglycerides (TRIG) | 61 – 610 mg/dL |
| Calcium (CA) | 1.6-16 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 ⁺⁺) | 0.6 – 6.0 mg/dL |
| Potassium (K ⁺) | 1.8 – 18 mmol/dL |
| Iron (Fe) | 70 – 700 µg/dL |
| Creatinine (CREAT) | 2.50 – 25 mg/dL |
| Lactate (LAC) | 6 – 120 mg/dL |
| Lithium (Li ⁺) | 0.35 – 7.0 mmol/dL |
| Carbon Dioxide (CO ₂) | 3 – 60mmol/dL |
| *Chloride (Cl ⁻) | 55-156 mmol/dL |
| *Sodium (Na ⁺) | 75 – 235 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. Phoenix Diagnostics manufactures an Aqueous-Based Zero-Dilution matrix that is compatible with this Multi-Analyte Linearity Test Set:

AQUEOUS-BASED ZERO / DILUTION MATRIX
CAT. No.: PH5051
CONFIGURATION: 10mL DROPPER BOTTLE

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

REORDERING INFORMATION:

MULTI-ANALYTE LINEARITY TEST SET
CAT. No.: PH5020
CONFIGURATION: 6 x 3 x 1 mL (AMPULES)

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

Tel: 508-655-8310
Fax: 508-655-8273
Email: sales@phoenixdiagnostics.com

Phoenix Diagnostics

MULTI-ANALYTE LINEARITY CONTROL WORKSHEET

Cat. No.: PH5020B 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 | 0.125 |
| 2 | 0.667 | 0.375 |
| 3 | 0.834 | 0.750 |
| 4 | 1.000 | 1.000 |
| 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 (CO₂)

| 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 | 0.125 |
| 2 | 0.667 | 0.375 |
| 3 | 0.834 | 0.750 |
| 4 | 1.000 | 1.000 |
| 5 | 1.334 | 1.750 |
| 6 | 1.667 | 2.500 |