

A PRIMER ON CALIBRATION VERIFICATION

What is Calibration Verification?

Calibration Verification is a procedure where materials of known concentration are tested on an instrument in the same manner as actual patient specimens. This is a procedure used by laboratories to verify whether or not an instrument is accurately measuring samples throughout its entire reportable range.

What are Linearity Controls?

Linearity Controls are the specially engineered materials that laboratories require in order to perform actual calibration verification. These controls are expressly formulated with known concentrations of specific analytes that are in direct proportion to one another, and which are segmented into different 'levels'. These levels are then run through an instrument in order to validate its calibration. After running a linearity control, technicians verify that the results given by an instrument are directly proportional to one another in the same manner as the individual 'levels' that were just run on the the instrument.

Do All Clinical Laboratories Perform Calibration Verifications?

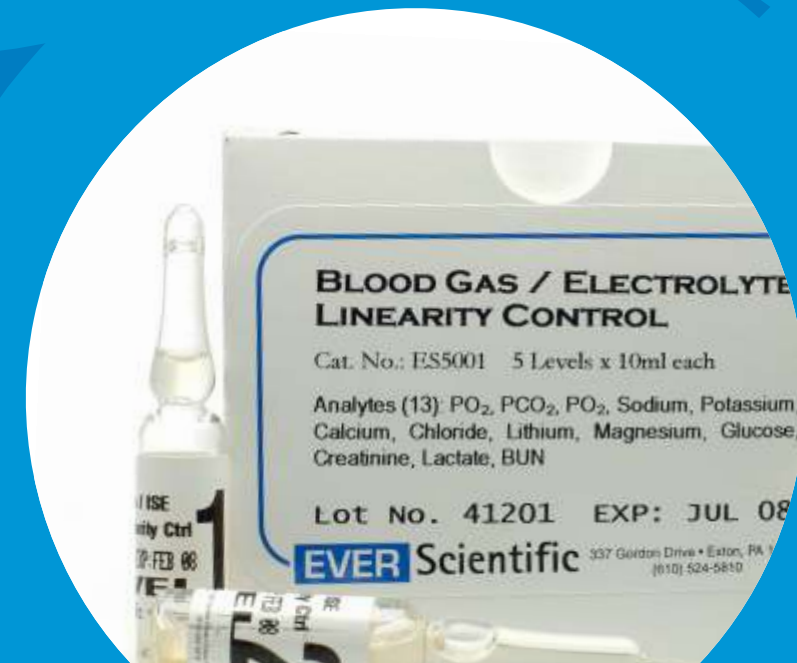
Yes, or they will be performing it soon. According to the final clarification of Clinical Laboratory Improvement Amendments (CLIA), released in January 2003, any laboratory that carries out 'moderately complex' tests is required to perform calibration verification on their instrument. While laboratories were given a 2-Year cycle to ensure their compliance with these regulations, the rules outlined in CLIA will be fully enforced by the Center for Disease Control (CDC) as of April 24, 2005.

How Often Do Clinical Laboratories Perform Calibration Verification?

At least twice a year, for documentation purposes. But also whenever the following events occur:

- ❖ After any major preventative maintenance, or when critical parts affecting an instrument's performance are replaced.
- ❖ After a laboratory switches lot numbers on the reagents it uses in conjunction with an instrument.
- ❖ After a laboratory receives unusual readings from an instrument, and it wants to rigorously verify that instrument's performance and accuracy.

**LINEARITY CONTROLS
OVERVIEW**



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SYNOPSIS OF PRODUCT BENEFITS

LIQUID STABLE & READY TO USE

- ❖ Unlike lyophilized alternatives, all of our products are ready to use, and require no reconstitution. Not only does this save technicians valuable time, *it also reduces the risk that they will introduce pre-analytical errors* into a testing method.
- ❖ All of our products have *minimum stability of 2-3 years*, which means that technicians can save any unused materials for a later date. With lyophilized alternatives, a product may have to be discarded in as little as 24 hours after reconstitution.
- ❖ All of our products have a *minimum fill size of 5mL per level*. This is far more generous than many of our competitors, whose fill sizes may be as meager as 1-3mL per level.
- ❖ Because we are an independent provider of calibration verification materials, *we do not face the same conflicts of interest that OEMs do* in evaluating instrument performance. This makes us an ideal supplier of linearity controls for clinical labs and hospitals.
- ❖ We provide data reduction services free of charge to all of our customers via email.

INNOVATIVE TECHNOLOGY & VALUE

- ❖ Our unique stabilization technology enables us to combine more analytes within a single control. This *cuts by more than half* the number of products a lab must purchase in order to validate frequently tested constituents.
- ❖ With other Liquid Stable alternatives (i.e. the Casco Cal-Ver Product Line), clinicians must run *7 separate linearity controls* in order to obtain the same coverage of analytes that Ever Scientific provides with only three *3 linearity controls*.
- ❖ Fewer products means that laboratories save considerable time when performing calibration verifications with our product offering.
- ❖ Fewer products also means that laboratories *realize significant cost savings* when using our controls. They are no longer forced to buy more product than is actually needed, nor do they run the risk of wasting unused product because of short expiry.
- ❖ We are the only company on the market that engineers *protein-based* Blood Gas / ISE Linearity Controls, as well as *physiologically significant* Co-Ox Linearity Controls. These products are far more advanced than what is currently offered by RNA Medical or any of the OEMs.

SUPERIOR SHELF-LIFE & STABILITY: THE AMPULE-BASED ALTERNATIVE

- ❖ We are one of the only companies on the market that engineers Liquid Stable Linearity Controls *with guaranteed stabilities of 24 - 36 months*. Many of our competitors can only guarantee 9 - 18 months (and some as little as six months!).
- ❖ The 1mL fill size of our ampule-based linearity controls allows laboratories to perform each of their calibration verification *runs with minimum waste* of IVD materials. Because we provide 30 ampules with each kit (6 Levels, 5 ampules per level), a laboratory can perform *5 calibration verification runs per level*.
- ❖ The extended shelf-life of our ampule-based products enables labs *to minimize lot-to-lot variability* when performing calibration verification.
- ❖ Our ampule-based product also *eliminates any possibility of oxygen contamination*. This provides laboratories with a linearity control that possesses superior stability over vial or dropper-based alternatives.



LINEARITY CONTROLS PRODUCT LISTING

Ever Sci Cat. No.	Cardinal Cat. No.	Product Name	Parameters	Formulation
ES5010	EVES010	Multi-Analyte Linearity (Vial Configuration)	Total Protein, Uric Acid, Albumin, Creatinine, Glucose, BUN, Lactate, Phosphorous, Sodium, Potassium, Calcium, Chloride, Lithium, Iron, Magnesium, Cholesterol, Triglycerides, CO2	6 Levels 5mL per level
ES5020	EVES020	Multi-Analyte Linearity (Ampule Configuration)	Total Protein, Uric Acid, Albumin, Creatinine, Glucose, BUN, Lactate, Phosphorous, Sodium, Potassium, Calcium, Chloride, Lithium, Iron, Magnesium, Cholesterol, Triglycerides, CO2	6 Levels 5mL per level
ES5015	ES5015	Enzyme Linearity (Vial Configuration)	ALT, AST, AMY, ALP, CK, LD, GGT	6 Levels 5mL per level
ES5021	ES5021	Enzyme Linearity (Ampule Configuration)	ALT, AST, AMY, ALP, CK, LD, GGT	6 Levels 5mL per level
ES5011	ES5011	Bilirubin Linearity	Total Bilirubin and Direct Bilirubin	6 Levels 5mL per level
ES5001	ES5001	Blood Gas / ISE Linearity (Protein-Based)	pH, PCO2, PO2, Sodium, Potassium, Calcium, Chloride, Lithium, Magnesium, Creatinine, Lactate, Glucose, BUN	5 Levels 10mL per level
ES5035	ES5035	ISE / Metabolite Linearity (Dropper)	Magnesium, Lactate, Glucose, Creatinine, Sodium, Potassium, Calcium, Chloride, Lithium, Phosphorous	6 Levels 5mL per level
ES5003	ES5003	I.L. Co-Ox Linearity	RHb, O2Hb, COHb, MET, VOL%O2	5 Levels 10 mL per level
ES5005	ES5005	Radiometer Co-Ox Linearity	tHb, HbO2, HBO2SAT, HBCO, MET, O2CT	5 Levels 10mL per level
ES5007	ES5007	Bayer Co-Ox Linearity	tHb, O2CT, O2SAT, COHb, MET	5 Levels 10 mL per level

NEW PRODUCTS AND SERVICES (DURING THE NEXT 3-6 MONTHS)

- ❖ Therapeutic Drug Monitoring Linearity Control
- ❖ Urine Chemistry Linearity Control
- ❖ Lipoprotein Linearity Control
- ❖ Web-Based Data Reduction Program with Pier Comparison

