

EVER Scientific DIAGNOSTICS DIVISION

BILIRUBIN LINEARITY TEST SET

Lot. No.: 50308 EXP: MARCH 2007

INTENDED USE:

Bilirubin 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 are Direct Bilirubin (DBIL) and Total Bilirubin (TBIL).

Bilirubin Linearity Test Sets are designed to be compatible with all popular chemistry analyzers. Each kit we manufacture comes with 30 ampules of 1mL each, with 5 ampules allotted per prediluted level. 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. A linear relationship exists among all levels of each set.

SUMMARY:

Bilirubin Linearity Test Sets contain purified bilirubin stabilized within a bovine albumin solution. Six levels are provided to establish the relationship between 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. The control solutions can also be used to troubleshoot problems with chemistry systems, reagents, and / or calibration anomalies.

INGREDIENTS:

Purified Bilirubin from bovine source is stabilized and preserved in a bovine albumin solution.

STORAGE AND STABILITY:

Bilirubin Linearity Control materials are stable until the expiration date printed on the ampule when stored at 2-8° C, and away from light. Opened ampules *must be used within the same working day* or else discarded. Dispose if gross contamination is visible.

Ever Scientific
Bilirubin Linearity Test Set

INSTRUCTIONS FOR USE:

Bilirubin 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 additional dilutions or pre-treatment are required as part of your testing procedure, please consult the instructions of your instrument manufacturer.

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 (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 calculations for them (free of charge). 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. After sampling all levels in duplicate or triplicate, calculate a Mean Recovered Value for each, and record in the worksheet space provided. Theoretical Values for each level can then be obtained by multiplying the Mean Recovered Value of Level 4 with the "Linearity Factors" provided below:

Linearity Factors

Level 1	0.1
Level 2	0.4
Level 3	0.7
Level 4	1.0
Level 5	1.5
Level 6	2.0

SAMPLE CALCULATION:

If the Mean Recovered value for Level 4 = 10.1, you can calculate Theoretical Values by multiplying 10.1 by the "Linearity Factor" associated with each level. For example:

Calculations:	Theoretical Value	Mean Recovered Value
Level 1 = 10.1 X 0.1	1.0	1.1
Level 2 = 10.1 X 0.4	4.0	4.0
Level 3 = 10.1 X 0.7	7.0	7.1
Level 4 = 10.1 X 1.0	10.1	10.1
Level 5 = 10.1 X 1.5	15.2	14.9
Level 6 = 10.1 X 2.0	20.2	20.4

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 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	Typical Range
Direct Bilirubin (DBIL)	1 – 20mg/dL
Total Bilirubin (TBIL)	1.5 – 30mg/dL

Free Data-Reduction Service: Download Electronic Submission Forms at <http://www.eversci-linearity.com>

REORDERING INFORMATION:

BILIRUBIN LINEARITY TEST SET
CAT. No.: ES5011
CONFIGURATION: 6 x 5 x 1mL (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.

**BILIRUBIN LINEARITY
WORKSHEET**

Product Code: ES5011 Lot#: _____

Expiration Date: _____

Documentation Date: _____

BILIRUBIN LINEARITY FACTORS

LEVEL	LINEARITY FACTOR
1	0.1
2	0.4
3	0.7
4	1.0
5	1.5
6	2.0

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LEVEL	LINEARITY FACTOR
1	0.1
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6	2.0

ANALYTE - DIRECT BILIRUBIN (DBIL)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE - DIRECT BILIRUBIN (DBIL)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE - TOTAL BILIRUBIN (TBIL)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		

ANALYTE - TOTAL BILIRUBIN (TBIL)

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		
5		
6		