PHOENIX DIAGNOSTICS

BILIRUBIN LINEARITY TEST SET

Lot. No.: 21004 **EXP: OCT 15**

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 18 ampules of 1mL each, with 3 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.

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:

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.

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: For more info, please contact us at sales@phoenixdiagnostics.com

REORDERING INFORMATION:

BILIRUBIN LINEARITY TEST SET
CAT. NO.: PH5011S
CONFIGURATION: 6 x 1 x 1mL (AMPULES)

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

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

Please allow 3-7 days for delivery.

Phoenix Diagnostics, Inc.
8 Tech Circle, Natick, MA 01760.

BILIRUBIN LINEARITY WORKSHEET

Product Code: PH5011S 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

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		

BILIRUBIN LINEARITY WORKSHEET

Product Code: PH5011S Lot#: _____

Expiration Date: _____

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BILIRUBIN LINEARITY FACTORS

LEVEL	LINEARITY FACTOR
1	0.1
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3	0.7
4	**1.0**
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6	2.0

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		