AZER SCIENTIFIC™
189 Twin County Rd. Morgantown, PA 19543
610-524-5810 azersci.com

HbA1C Linearity Test Set

INTENDED USE:

HbA1C 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. .

HbA1C Linearity Test Sets are designed to be compatible with all popular chemistry analyzers. Each kit we manufacture comes with 0.5mL 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 for this specific analyte. A linear relationship exists among all levels of each set.

SUMMARY:

HbA1C 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 materials for HbA1C are stabilized and preserved in human serum matrix.

STORAGE. STABILITY, AND PRECAUTIONS:

HbA1C Linearity Control materials are stable until the expiration date printed on the ampule when stored at -20C, and away from light. Opened ampules ***must be used within the same working day*** or else discarded. Dispose if gross contamination is visible.

Because this product is of human origin, it has been tested with U.S. Food and Drug Administration (FDA) approved methods and found to be negative for HIV, HCV and HBSAg antibodies. Since no test method is able to offer complete assurance that any or all contagious agents harmful to humans are absent, this material should be handled as though capable of transmitting infectious diseases. This product may also contain other human source material for which there is no approved test. The FDA recommends such samples be handled at the Centers for Disease Control's Biosafety Level 2.

INSTRUCTIONS FOR USE:

HbA1C Linearity Test Sets are liquid stable and ready-to-use. 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 Azer 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. To obtain spreadsheets, you can reach us at:

info@AzerSci.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 3 with the "Linearity Factors" provided below:

Linearity Factors

Level 1	0.35
Level 2	0.50
Level 3	1.00
Level 4	1.50

SAMPLE VALUES:

Calculations:	*Theoretical Value*	*Linearity Factor*
Level 1	4.2%	0.35
Level 2	6.0%	0.50
Level 3	11.9%	1.0
Level 4	17.9%	1.50

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 URL:

http://www.phppo.cdc.gov/clia/regs/subpart_i.aspx#493.931

Analyte	Typical Range
HbA1C	4.2-17.9%

REORDERING INFORMATION:

HbA1C Linearity Test Set
Cat. No.: ES5070
Configuration: 4 x 3 x 0.5mL (Ampules)
Lot: 0710070,1,2,3 Exp: OCT 09

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

Tel: 610-524-5810
Fax: 610-301-9046
Email: info@azersci.com

Please allow 3-7 days for delivery.

Azer Scientific
189 Twin County Rd. Morgantown, PA 19543

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HbA1C Linearity Worksheet

Product Code: ES5070 Lot#: _____

Expiration Date: _____

Documentation Date: _____

HbA1C LINEARITY FACTORS

LEVEL	LINEARITY FACTOR
1	0.35
2	0.50
3	1.00
4	1.500

ANALYTE – HbA1C

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
1		
2		
3		
4		

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LEVEL	LINEARITY FACTOR
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ANALYTE – HbA1C

LEVEL	THEORETICAL VALUE	RECOVERED VALUE
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