



## HbA1c Calibration Verification / Linearity Test Kit

### INTENDED USE

**VALIDATE** HbA1c Calibration Verification / Linearity Test Kit solutions are intended for *in vitro* diagnostic use in the determination of linearity, calibration verification and verification of reportable range on automated instrument systems for the following analyte: % Glycohemoglobin A1c (HbA1c).

Each test kit consists of one bottle each of Levels 1 through 5. Each bottle contains 1.5 milliliters. There exists a linear relationship among Levels 1 through 5.

### SUMMARY

The **VALIDATE** HbA1c Calibration Verification / Linearity Test Kit contains Glycohemoglobin A1c in human whole blood. Multiple levels are provided to establish the relationship between theoretical and actual performance of Glycohemoglobin A1c. The **VALIDATE** HbA1c Calibration Verification / Linearity Test Kit will assist in the documentation of linearity, calibration verification and verification of linear range required by many inspection agencies. The solutions will also provide assistance when troubleshooting instrument systems, reagent problems and calibration anomalies.

### REAGENTS

#### Reactive Ingredients:

Glycohemoglobin A1c in a human whole blood matrix.

#### Nonreactive Ingredients:

Preservatives and stabilizers.

### Precautions and Warnings:

#### For In Vitro Diagnostic Use

Disposal of all waste materials should be in accordance with local guidelines.

### WARNING: Potentially Biohazardous

Human source material is considered potentially biohazardous. Material of human origin used in the manufacture of this test kit was tested at the donor level using FDA or CE approved methods and found to be non-reactive for HBV, HCV and HIV. Because no test method can offer complete assurance that infectious agents are absent, these specimens should be handled and treated as potentially infectious.

### STORAGE AND STABILITY

**VALIDATE** HbA1c Calibration Verification / Linearity Test Kits are stored at -10° to -25°C. **Do NOT store in a frost-free freezer.**

Test kits are stable until the expiration date printed on the bottle and storage container when stored according to instructions.

### PREPARATION

Prior to use, remove the **VALIDATE** HbA1c Calibration Verification / Linearity Test Kit from storage and allow to come to room temperature (18° to 25°C). Invert gently several times before dispensing.

To maximize stability, it is recommended that exposure to room temperature be minimized. Tightly cap opened bottles and return to -10° to -25°C immediately after dispensing.

Discard any solutions that appear to have gross bacterial contamination.

The **VALIDATE** HbA1c Calibration Verification / Linearity Test Kit should be treated in the same manner as patient samples. If dilutions or pre-treatment are required as part of the testing procedure, follow the manufacturer's instructions.

### ASSAY

Analyze each level in replicates. If following the CLSI EP6 guidelines for linearity, use a random analytical sequence to assay each level.

### CALCULATION OF RESULTS

**VALIDATE** Calibration Verification / Linearity material is prepared in a manner such that an equal distance (delta) exists between each consecutive level. This dilution scheme is consistent with the CLSI EP6 recommendation for preparing linearity sets.

Two examples for calculating the theoretical values of Levels 1 through 5 are provided below.

#### Example 1:

Choose two consecutive levels and calculate the delta between the recovered values. The following example demonstrates the use of the delta between Levels 2 and 3 to calculate the theoretical value for Levels 1, 4 and 5:

Level 3 - Level 2 = Delta

Level 1 Theoretical = Level 2 Recovered - Delta

Level 4 Theoretical = Level 3 Recovered + Delta

Level 5 Theoretical = Level 4 Theoretical + Delta

**NOTE:** The user can select the calculated delta between any two consecutive levels to calculate the theoretical values. Typically, the user should choose an area of recovery known to be linear for the method being studied.

#### Example 2:

Theoretical values can be determined using the recovered values for Levels 1 and 5. Using this method, the following formulas apply:

Level 2 Theoretical =  $0.75 * (\text{Level 1}) + 0.25 * (\text{Level 5})$

Level 3 Theoretical =  $0.5 * (\text{Level 1}) + 0.5 * (\text{Level 5})$

Level 4 Theoretical =  $0.25 * (\text{Level 1}) + 0.75 * (\text{Level 5})$

After theoretical values are calculated, for each analyte plot the expected (Theoretical) value on the x-axis versus the Recovered value on the y-axis using standard linear graph paper. If the system is linear, the plot should approximate a straight line. The point at which the line is no longer straight can be used to determine the limit of linearity or the reportable range.

Data reduction is available from LGC Maine Standards. Commercially available linear regression software may also be used. The software should provide data point display and x-y graphical presentation. Linear regression should be interpreted using standard statistical analysis and the results should be compared with the instrument manufacturer's claims for linearity or with individual laboratory performance requirements. The degree of acceptable nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

### LIMITATIONS

**VALIDATE** HbA1c Calibration Verification / Linearity Test Kit is not intended for use as routine quality control materials or calibration materials.

### EXPECTED VALUES

**VALIDATE** HbA1c Calibration Verification / Linearity Test Kits are manufactured such that an equal distance (delta) exists between levels as recommended by CLSI EP6 for assessing linearity. As the distance between levels is equal, any two levels can be held to be 'true' when assayed and the theoretical values for each of the other three levels can be calculated allowing this test kit to be used on multiple automated instrument systems.

### Typical VALUES

Actual results obtained may vary depending on instrumentation, methodology and assay temperature. Results may also be dependent on the accuracy of the instrument / reagent system calibration. The degree of acceptable nonlinearity is an individual judgment based on methodology, clinical significance and medical decision levels of the test analyte.

Typical recovered values for Level 1 and Level 5 are presented in the table below. Typical values for mid-levels are based on an equal distance (delta) between levels.

605to Lot#: 65AY189190		Typical Recovered Values on Tosoh				
Analyte	Units	Level 1	Level 2	Level 3	Level 4	Level 5
HbA1c	%	4.1	7.4	10.8	14.1	17.4

### ORDERING INFORMATION

ORDER NO.: 605to

**VALIDATE** HbA1c

Calibration Verification / Linearity Test Kit: 5 x 1.5 mL

For technical assistance or to place an order, call:

1-800-377-9684

+1-207-892-1300

+1-207-892-2266 Fax

[msc.sales@LGCGroup.com](mailto:msc.sales@LGCGroup.com)

[msc.techsupport@LGCGroup.com](mailto:msc.techsupport@LGCGroup.com)

[www.mainestandards.com](http://www.mainestandards.com)

Please allow 5 to 7 days for delivery



[www.mainestandards.com](http://www.mainestandards.com)

