TECO DIAGNOSTICS
1268 N. Lakeview Ave.
Anaheim, CA 92807
1-800-222-9880

HbA1c CALIBRATOR SET
(4 Levels)

Package insert instructions must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this package.

INTENDED USE
HbA1c Calibrator Set is for calibration of the HbA1c Liquid assay. Calibration: by entering the value on the label on the calibrator vial or the values specified on the value sheet.

CONTENTS / MATERIALS PROVIDED
HbA1c Calibrator Set

Sodium Azide (0.09 %) is added as preservative.

Materials Required But Not Provided:
1. Class A volumetric pipette for liquid transfer
2. Distilled or deionized water meeting the specifications equivalent to USP (United States Pharmacopeial Convention) purified water.

STANDARDIZATION
The traceability of the method for HbA1c Calibrator Set values is provided by the National Glycohemoglobin Standardization Program (NGSP).

PRECAUTIONS
For in Vitro Diagnostic Use.

Do not use components beyond the expiration date.
Do not mix materials from different kit lot numbers.

Human source material. Treat as potentially infectious material. Each plasma donor used in the preparation of this product has been tested by an FDA-approved method and found negative for the presence of HIV 1/2 HBsAg, HCV, HIV-Ag antibodies. However, none of the known testing methods can offer complete assurance that the hepatitis B virus, Human Immunodeficiency Virus (HIV) or infectious agents are not present. All human-based products should be handled in accordance with Good Laboratory Practice (GLP) principles using appropriate precautions.

STORAGE AND STABILITY
1. HbA1c Direct Immunoturbidimetric Calibrator Set (4 Levels) are stable until the expiration date when stored +2 to +8 ˚C.
2. Opened calibrators are stable for 30 days when stored at dark place +2 to +8°C. Reconstitute and store tightly capped in a dark place, kept free of contamination.

PREPARATION OF CALIBRATOR
Lyophilized calibrator should be reconstituted by adding 0.5 mL of distilled or deionized water. Close the vial and let stand for 30 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Don't shake. When the calibrator is ready, transfer the entire calibrator in the vial to sample cups compatible with your device. Never divide the HbA1c calibrators into small portions. Do not transfer the contents back to the vial.

INDICATIONS OF INSTABILITY OR DETERIORATION
The presence of extreme turbidity or microbial growth may indicate deterioration.

RFERENCES
1. EU-Dir 1999/11 Commission Directive of 8 March 1999 adapting to technical progress the principles of Good Laboratory Practice as specified in Council Directive 87/18/EEC
2. Gabbay, K.H., Hasty, K., Breslow, J.L., Ellison, R.C., Bunn, H.F., and Gallop, P.M., J. Clin. Endocrinol. Metab. 44, 859 (1977).
3. American Diabetes Association, Inc. Position Statement: Standards of Medical Care in Diabetes— 2008. In: Diabetes Care 2008;31(Suppl 1):S12–S54.
4. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens.

G560-E-001:10/2023

Manufactured by:

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