

HbA1c Calibrator 4 Levels

En

REF: VT-019 HbA1c Calibrator 4 Levels 4 x 0.5 mL

Changes made in the instructions for use are marked as grey.

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

Validity 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

Archem HbA1c Calibrator 4 Levels

REF: VT-019

Package: 4 x 0.5 mL Lyophilized

VT-019 contain the human blood.

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

IVD

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. Safety data sheets are available at www.validity.com.tr or you may contact your local representative.

STORAGE AND STABILITY

1. Validity HbA1c Direct Immunoturbidimetric Calibrator Set (4 Levels) are stable until the expiration date when stored +2 to +8 °C.
2. Opened calibrators are stable 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

Presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCES

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 Pathogen*

HbA1c Calibrator 4 Levels







En



Archem Sağlık Sanayi ve Tic. A.Ş. (With official contract based manufacturing agreement with Validity Sağlık Hiz. Sanayi A.Ş. Company)
 Mahmutbey Mah. Halkalı Cad. No:124 Kat:4
 Bağcılar/İstanbul/Turkey
 Tel: + 90 212 444 08 92
 Fax: +90 212 629 98 89
 info@archem.com.tr www.archem.com.tr
 info@validity.com.tr www.validity.com.tr



SYMBOLS

| | |
|---|---|
| IVD | In Vitro Diagnostic Medical Device |
| LOT | Lot Number |
| CAL | Calibrator |
| GTIN | Global Trade Item Number |
| REF | Reference Number |
| FOR USE WITH | Identifies Products to Be Used Together |
| PRODUCT OF TURKEY | Product of Turkey |
|  | Manufacturer |
|  | Expiration Date |
|  | Temperature Limits |
|  | Consult Instructions for Use |
|  | Caution |
|  | Number of Tests |