HbA1c Direct Immunoturbidimetric Calibrator Set (4 Levels)

En

REF 01R97-01

FOR USE WITH
ARCHITECT

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 Direct Immunoturbidimetric Calibrator Set (4 Levels) are for use in the calibration of the HbA1c Direct Immunoturbidimetric assay on the Architect cSystems.

HbA1c Direct Immunoturbidimetric Calibrator Set (4 Levels)

REF: 01R97-01
Package: 4x0.5 mL **Lyophilized**

For use with;

HbA1c Direct Immunoturbidimetric reagent

REF:	01R87-21	01R87-31
	01R87-41	01R87-51

CONTENTS / MATERIALS PROVIDED

HbA1c Direct Immunoturbidimetric Calibrator Set (4 Levels) (**REF:** 01R97-01) contains the human serum. Sodium Azide (0.09 %) is added as a preservative.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Class A volumetric pipette for delivery of 0.5 mL
2. Distilled or deionized water meeting specifications equivalent to USP purified water.
3. HbA1c Direct Immunoturbidimetric reagent

REF:	01R87-21	01R87-31
	01R87-41	01R87-51

STANDARDIZATION

The traceability of the method is verified using

1. Primary: NGSP Certificate of Traceability.
2. Secondary: With European reference Laboratory (ESRL≠9)

PRECAUTIONS (General and Users)

IVD

For in Vitro Diagnostic Use.
Do not use components beyond the expiration date.
Contains sodium azide.
EUH032 Contact with acids liberates very toxic gas.

Do not mix materials from different kit lot numbers.
Human source material.

Calibrator can contain preservatives (as Sodium Azide or others) which total concentration is lower than the limits mentioned in Directive 67/548/ CEE and 88/379 CEE.

Treat as potentially infectious. Each plasma donor unit used in the preparation of this product has been tested by an FDA-approved method and found nonreactive for the presence of HBsAg, HCV, HIV-Ag and antibody to HIV 1/2. Because no known test method can offer complete assurance that hepatitis B virus, Human Immunodeficiency Virus (HIV) or other infectious agents are absent, all human-based products should be handled in accordance with good laboratory practices using appropriate precautions. Safety Data Sheets are available at www.archem.com.tr or contact your local representative. Emergency Phone Number: In emergency situation please contact the National Poison Solidarity Center (Turkey) for information in Turkish: (114) (24 hours/7 days). Please contact with Archem for information in English: +(90) 212 444 0 892 (Turkey) (8:30-18:30/ except Sundays)

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 **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.
Never divide any HbA1c Control or HbA1c Calibrator into small portioning. **Avoid storage at room temperature at segments inside priority sections** after aspiration!
After reconstitution with deionized water; store calibrator inside **Sample Cup** and close tightly, store at +2 to +8 ºC for 30 days. Don't transfer back to vial. Don't shake.

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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 Pathogens.

TRADEMARKS

Customer Service:
Contact Archem Diagnostics Industry A.Ş

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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 limitation
	Consult instructions for use
	Caution
	Sufficient for