

HbA1c Control Set

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|-------------|-------------------|------------|
| REF: HBCN01 | HbA1c Control Set | 2 x 0.5 mL |
| REF: HBCN02 | HbA1c Control Set | 2 x 0.5 mL |
| REF: HBCN03 | HbA1c Control Set | 2 x 0.5 mL |
| REF: HBCN04 | HbA1c Control Set | 2 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

Archem HbA1c Control Set is for quality control of HbA1c Liquid assay.

CONTENTS / MATERIALS PROVIDED

Archem HbA1c Control Set (2 Levels)

REF: HBCN01

Package: 2 x 0.5 mL Lyophilized

REF: HBCN02

Package: 2 x 0.5 mL Lyophilized

REF: HBCN03

Package: 2 x 0.5 mL Lyophilized

REF: HBCN04

Package: 2 x 0.5 mL Lyophilized

For use with:

HbA1c Liquid Reagent

HbA1c Calibrator Set (4 Levels)

HBCN01 contains 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.

CONTROL STABILITY

| Temperature-Conditions | Stability |
|-------------------------------------|--------------------------|
| Unopened at +2/+8°C | Expiry date on the vial. |
| Diluted and stored at +2/+8°C | 30 days |
| Diluted and stored at +15/+25°C | 12 hours |
| Diluted, frozen and stored at -20°C | 60 days |

LIMITATIONS

1. Please open the vial caps carefully. When you open, be careful not to scatter any powdery substance around or to escape from the vial.
2. Dissolve with distilled water with volume stated on the vial. Injector should not be used for the transfer process since there may be errors between 5-20% in liquid transfer with the injector. Use calibrated micropipettes.
3. Temperature of dry serum in the vial and distilled water must be +20/+25°C. After adding distilled water, close the vial cap tightly and store at +25°C around 5-10 minutes.
4. Wait for 30 minutes for dissolving process and mix thoroughly by gently inverting the vial at regular intervals, do not shake. Avoid formation of bubbles or foam. Protect from light. It is recommended to use a rotational mixer for routine mixing procedures.
5. Do not refreeze after the serum is frozen and thawed once.
6. Control serum precipitation is faster than normal serum. In order for the first and last parts to be homogeneous and to avoid precipitation, perform the process as fast as possible during separation.
7. The quality of the distilled water to be used in the dilution of the control serum is very important. There may be significant deviations in the values due to bacterial contamination.
8. It is necessary to be careful against infectious agents in control serum measurements.

PREPARATION OF CONTROL

Lyophilized serum control should be reconstituted by adding distilled or deionized water with the amount stated on the label. Close the vial and wait for 30 minutes. After reconstitution, serum must be stored in the sample cup and should not be transferred back to the vial.

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Do not portion the serum. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake. Avoid storage at +25°C after using.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

PRECAUTIONS



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.archem.com.tr or you may contact your local representative.

WARNINGS

IVD: For in Vitro Diagnostic use only.
Do not use expired reagents.
Reagents with two different lot numbers should not be interchanged.
For professional use.
Follow Good Laboratory Practice (GLP) guidelines.
Contains sodium azide.

CAUTION: Human source samples are processed with this product. All human source samples must be treated as potentially infectious materials and must be handled in accordance with OSHA standards.

Danger

H317 :May cause allergic skin reaction.

Precaution

P280 :Use protective gloves / clothes / glasses / mask.

P264 :Wash your hands properly after using.

P272 :Contaminated work clothes should not be allowed to be used outside of the workplace.

Intervention

P302+P352 :Wash with plenty of water and soap if it contacts with skin.

P333+P313 :Seek medical help if it irritates your skin or develops rash.

P362+P364 :Remove contaminated clothes and wash properly before using.

Disposal

P501 :Dispose the vials and contents according to the local regulations.

REFERENCES

1. Council Directive (2000/54/EC). Official Journal of the European Communities No. L262 from Oct. 17, 2000.
2. 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
3. Clinical and Laboratory Standards Institute, H26-A2, Validation, verification, and quality assurance of automated hematology analyzers; Approved Guideline - Second Edition.
4. 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).
5. American Diabetes Association, Inc. Position Statement: Standards of Medical Care in Diabetes—2008. In: *Diabetes Care* 2008;31(Suppl 1):S12–S54.
6. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, *Occupational Exposure to Bloodborne Pathogens*.

TRADEMARKS

Archem HbA1c Control Set is a trademark of ARCHEM Sağlık Sanayi ve Tic. A.Ş. in various jurisdictions.



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| SYMBOLS | |
|---|---|
| IVD | In Vitro Diagnostic Medical Device |
| LOT | Lot Number |
| CONTROL | Control |
| 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 |

