

HbA1c CONTROL

**For Usage With;
Immunturbidimetric Systems and HPLC Systems**

**REF: B1019HC HbA1c Control Set (2 Levels)
1 x 0.5 mL**

Instruction inside package must be carefully followed at usage. Quality of results cannot be warranted if there are any deviations from the instructions in this package. This control set is for in vitro diagnostic (IVD) use only.

INTENDED USE

Control for automated systems. HbA1c Control Set is for use in the control of quantitative immunturbidimetric method HbA1c automated clinical chemistry, HPLC based HbA1c analysis and semi-automated analyzers as specified in the enclosed value sheets. HbA1c controls are lyophilized materials based on hemolyzed human blood. The concentrations of the control components have been adjusted to ensure optimal control of the appropriate immunturbidimetric methods on clinical chemistry analyzers and HPLC based HbA1c analyzers.

SUMMARY AND PRINCIPLE

The use of Control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Two levels of controls are available to allow control and monitorization intended automated or semi-automated biochemistry analyzers and HPLC based HbA1c analyzers.

Beinquality HbA1c Direct Immunturbidimetric Control SET (2 Levels)

Package: 1 x 0.5 ML Lyophilized

For use with;

- HbA1c Direct Immunturbidimetric reagents
- HbA1c Indirect Immunturbidimetric reagents
- HPLC Method HbA1c Reagents and Analyzers
- POCT Method HbA1c Reagents and Analyzers

CONTENTS / MATERIALS PROVIDED

Beinquality HbA1c Control Set (2 Levels) contains the human blood. This product is prepared from human whole blood and contains normal and abnormal Hb and A1c proteins, preservatives and stabilizers. The control is provided in lyophilized form for increased stability.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Class A volumetric variable or fixed pipette for delivery of 0.5 mL
2. Distilled or deionized water meeting specifications equivalent to USP purified water.
3. Any system (Eg: HPLC) / reagent that allow to test HbA1c values.
4. For immunturbidimetric systems: Hemoglobin A1c Reagent Set

STANDARDIZATION AND ASSIGNMENT OF VALUES

The traceability of the method is verified using NGSP Certificate of Traceability. The set point value of the controls were obtained by assaying representative samples of the entire lot against materials referenced to NGSP values using the Beinquality HbA1c Direct Reagent Set and HPLC Systems

The control values were derived from replicate analyses and are specific for this lot of product. Product has been tested/confirmed by HPLC method and Immunturbidimetric method. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents or by manufacturer test method modifications. It is recommended that each laboratory establish its own target values, limits-ranges and use those provided only as guides.

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.

Human source material.

Control 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.

This product should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used. 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-



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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 (SDS) are available at www.beinquality.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 Beinquality for information in English: +(90) 212 447 00 75 (Turkey) (7:30-17:50/except weekends)

STORAGE AND STABILITY

1. Beinquality HbA1c Direct Immunturbidimetric Control Set (2 Levels) are stable until the expiration date when stored +2 /+8 °C.
2. Once opened and diluted controls are stable **30 days** when stored at dark place +2/+8°C.
3. Once opened and diluted controls are stable **12 Hours** when stored at +15/+25°C.
4. Diluted controls are stable **3 months** when stored at (-15)-(-25)°C (when frozen once)
5. Reconstitute and store tightly capped in a dark place, kept free of contamination.
6. Criterion for the stability data stated by Beinquality: Recovery values are within ±10% of initial value.

PREPARATION OF CONTROL

1. Using a volumetric pipet, reconstitute each vial with 0.5 mL of distilled or deionized water.
2. After reconstitution replace the stopper and allow the control to stand for 30 minutes, swirling occasionally.
3. Some methods may use different volumes for reconstitution.
4. Dissolve the contents of the vial by swirling gently to avoid the formation of foam.
5. Portioning (allocation) is not allowed. Never divide any HbA1c Control into small portioning.
6. **Avoid storage at R.T. at segments inside priority sections** after aspiration!
7. After reconstitution with deionized water; store control inside **Sample Cup** and close tightly, store at +2 /+8 °C for 30 days. Don't transfer back to vial.
8. Remix your controls just prior to use. Before sampling, gently invert the vial several times to ensure homogeneity.
9. Do NOT mix by vortex. Don't shake.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

LIMITATIONS & PRECAUTIONS

1. Check expiration date of the product on the vial. Discard outdated products.
2. Repeated thaw process is not allowed.
3. If there is evidence of microbial contamination or excessive turbidity in the reconstituted product, discard the vial.
4. Do not pipette by mouth.
5. Avoid contact with skin and mucous membranes.
6. This product should not be disposed in general waste, but should be disposed with infectious medical waste.
7. SDS can be obtained at www.beinquality.com.tr, by calling +(90) 212 447 00 75 (Turkey), or by calling your local supplier.

ANALYTIC PERFORMANCE

This product is a freeze-dried product. Product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values and optimum values the controls requires proper storage and handling as described.

The concentrations or % values of the control components are lot-specific. The exact control values are given in the value sheets.

BIBLIOGRAPHY

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*.

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TRADEMARKS

Beinquality HbA1c Control is a trademark of Beinquality A.Ş. In various jurisdictions.

Customer Service:
Contact to:
Beinquality A.Ş.

GLOSSARY OF HARMONIZED SYMBOLS

IVD	<i>In Vitro</i> Diagnostic Medical Device
LOT	Lot number
REF	Reference Number (Catalog No.)
GTIN	Global Trade Item Number
CON	Control
VALUE	Value
PRODUCT OF TURKEY	Product of Turkey
CONVENTIONAL UNITS	Conventional Units
	Caution
	Manufacturer
	Expiration date
	Temperature limitation
	Consult instructions for use



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