COPPER CONTROL LEVEL I-II

For Usage With;
Immunoturbidimetric Systems

REF:	**A1017CO Copper Control Level I**	**5 X 4 mL**
	A1018CO Copper Control Level II	**5 x 4 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 is for in vitro diagnostic (IVD) use only.

INTENDED USE

Control for automated systems. COPPER CONTROL LEVEL I-II is for use in the control of quantitative immunoturbidimetric method COPPER CONTROL LEVEL I-II automated clinical chemistry. COPPER CONTROL LEVEL I-II are lyophilized materials contains human serum. The concentrations of the control components have been adjusted to ensure optimal control of the appropriate immunoturbidimetric methods on clinical chemistry 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 control are available to allow control intended automated or semi-automated biochemistry analyzers.

Beinquality COPPER CONTROL LEVEL I-II Immunoturbidimetric Control (2 Level)

Package: 5 x 4 mL **Liquid**

For use with;

- COPPER CONTROL LEVEL I-II Direct Immunoturbidimetric reagents
- COPPER CONTROL LEVEL I-II Indirect Immunoturbidimetric reagents

CONTENTS / MATERIALS PROVIDED

Beinquality COPPER CONTROL LEVEL I-II (2 Level) do not contain the human serum.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Class A volumetric pipette for liquid transfer.
2. Distilled or deionized water meeting specifications equivalent to USP purified water.
3. For immunoturbidimetric systems: COPPER CONTROL LEVEL I-II 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. The control values were derived from replicate analyses and are specific for this lot of product. Product has been tested/confirmed and Immunoturbidimetric 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 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.
Controls 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-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

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with Beinquality for information in English: +(90) 212 447 00 75 (Turkey) (7:30–17:50/except weekends)

STORAGE AND STABILITY

1. Unopened at +2/+8°C – Expiry date on the vial.
2. Opened and stored at +2/+8°C – 45 days
3. Criterion for the stability data stated by Beinquality: Recovery values are within ±10% of initial value.

PREPARATION OF CONTROLS

1. The contents of the vial by swirling gently to avoid the formation of foam.
2. Portioning (allocation) is not allowed. Never divide any COPPER CONTROL LEVEL I-II into small portioning.
3. **Avoid storage at R.T. at segments inside priority sections** after aspiration!
4. Store controls inside **Sample Cup** and close tightly. Don't transfer back to vial.
5. Remix your controls just prior to use. Before sampling, gently invert the vial several times to ensure homogeneity.
6. 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

Product manufactured under rigid quality control standards. To obtain consistent vial-to-vial assay values and optimum uncertainty 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. US Department of Labor, Occupational Safety and Health Administration, 29 CFR Part 1910.1030, *Occupational Exposure to Bloodborne Pathogens*.

TRADEMARKS

Customer Service:
Contact to:
Beinquality Sağlık Sanayi ve Ticaret A.Ş.

CE

Beinquality Sağlık Sanayi ve Ticaret A.Ş.
Mahmutbey Mahallesi, Halkalı Caddesi
No: 124/31 Bagcilar / ISTANBUL TURKEY
Tlf: + 90 212 447 00 75
info@beinquality.com.tr
www.beinquality.com.tr

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GLOSSARY OF HARMONIZED SYMBOLS

IVD	*In Vitro* 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