

ARCHEM RHEUMATOID CONTROL

En

REF: RCN06	Rheumatoid Control Liquid I	5 x 2 mL
REF: RCN07	Rheumatoid Control Liquid II	5 x 2 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 Rheumatoid Control Liquid Level I-II is for quality control of the parameters stated in the value sheet.

CONTENTS / MATERIALS PROVIDED

Rheumatoid Control Liquid Level I

REF: RCN06

Package: 5 x 2 mL **Liquid**

Rheumatoid Control Liquid Level II

REF: RCN07

Package: 5 x 2 mL **Liquid**

RCN06 / RCN07 contain the human serum.

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 and stored at +2/+8 °C	Expiry date on the vial
Opened and stored at +25°C,	8 hours
Opened and stored at +2/+8°C	2 days
Opened, frozen and stored at -20°C	90 days

PREPARATION OF CONTROL

Control is ready for use.

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.

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.

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REFERENCES

1. Burtis CA, Ashwood ER, Bruns DE, editors. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis, MO, Elsevier Saunders; 2006:2263.
2. S.Dean Allison, Mark C.Manning, Theodore W.Randolph, Kim Middleton, Ashley Davis, John F.Carpenter. Optimization Of Storage Of Lyophilized Actin Using Combinations Of Disaccharides And Dextran. Journal Of Pharmaceutical Sciences.89/2,199- 214(2000)

TRADEMARKS

Archem Rheumatoid Control 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