

ARCHEM RF CALIBRATOR

En

REF: TA121S RF Calibrator 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 RF Calibrator is for use in the calibration of the RF Turbidimetric assay.

RF Calibrator

REF: TA121S

Package: 5 x 2 mL Lyophilized

For use with:

Archem RF Turbidimetric reagent

REF: DMT120/ At120/ BY120/ BY121/ 8A120/ 8A121

Archem RF Calibrator (REF: TA121S) contain the human serum.

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.
3. Archem RF Turbidimetric Reagent
REF: DMT120/ At120/ BY120/ BY121/ 8A120/ 8A121

STANDARDIZATION

The traceability of the method is verified using NIBSC 97/662 for RF Calibrator values.

PRECAUTIONS (General and Users)

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 humanbased 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. Unopened Archem RF Calibrator is stable until the expiration date when stored +2 to +8 °C.
2. Opened calibrators are stable 2 days when stored in a dark place +2 to +8°C.

Archem RF Calibrator is stable 30 days when stored -20°C.

PREPARATION OF CALIBRATOR

Lyophilized calibrator should be reconstituted by adding distilled or deionized water with the amount stated on the label. Close the vial and wait for 30 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. Do not shake.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

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 and Calibrator 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

CAL

Calibrator

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



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