

## ARCHEM RF CALIBRATOR

# En

REF: TA120S	RF Calibrator	5 x 3 mL
REF: TA122S	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: TA120S

Package: 5 x 3 mL Lyophilized

REF: TA122S

Package: 5 x 2 mL Lyophilized

#### For use with:

Archem RF Turbidimetric reagent

Archem RF Calibrator (REF: TA120S, TA122S) 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

#### 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](http://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.
3. 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, 4<sup>th</sup> 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.



**Archem Sağlık Sanayi ve Tic. A.Ş.**

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SYMBOLS	
<b>IVD</b>	In Vitro Diagnostic Medical Device
<b>LOT</b>	Lot Number
<b>CAL</b>	Calibrator
<b>CONTROL</b>	Control
<b>GTIN</b>	Global Trade Item Number
<b>REF</b>	Reference Number
<b>FOR USE WITH</b>	Identifies Products to Be Used Together
<b>PRODUCT OF TURKEY</b>	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests

Archem  
 DIAGNOSTICS