

# COPPER CALIBRATOR

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**REF: ZA77    Copper Calibrator    5 x 4 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 Copper Calibrator is for calibration of the Copper Liquid assay.

### CONTENTS / MATERIALS PROVIDED

Archem Copper Calibrator

**REF: ZA77**

Package: 5 x 4 mL **Liquid**

### For use with:

Archem Copper Liquid Reagent  
Archem Copper Control

**ZA77** does not 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.

### STANDARDIZATION

The traceability of the method is verified using NIST SRM 3114.

### CALIBRATOR STABILITY

Temperature-Conditions	Stability
Unopened at +2/+25°C	Expiry date on the vial.
Opened and stored at +2/+25°C	45 days

### PREPARATION OF CALIBRATOR

Calibrator 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](http://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.

## REFERENCES

1. Occupational Safety and Health Standards: bloodborne pathogens. (29 CFR Part 1910.1030). Fed. Register. July 1, 2001; 17:260–273.
2. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.

## TRADEMARKS







Archem Copper Calibrator is a trademark of ARCHEM Sağlık Sanayi ve Tic. A.Ş. in various jurisdictions.



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## SYMBOLS

<b>IVD</b>	In Vitro Diagnostic Medical Device
<b>LOT</b>	Lot Number
<b>CAL</b>	Calibrator
<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