

## ETHANOL CONTROL LEVEL I-II

# En

**REF: ELCN1 Ethanol Control Level I 2 x 1 mL**  
**REF: ELCN2 Ethanol Control Level II 2 x 1 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 Ethanol Control Level I-II are for quality control of the Ethanol Liquid assay.

### CONTENTS / MATERIALS PROVIDED

Archem Ethanol Control Level I

**REF: ELCN1**

Package: 2 x 1 mL **Liquid**

Archem Ethanol Control Level II

**REF: ELCN2**

Package: 2 x 1 mL **Liquid**

### For use with;

Archem Ethanol Liquid Reagent  
 Archem Ethanol Calibrator

### CONTROL STABILITY

Temperature-Conditions	Stability
Unopened, in the temperature conditions specified on the label	Expiry date on the vial.
Opened and stored at +2/+8°C	1 day

### 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,

Rev: V1.1 Date: 10.2021

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.

## ETHANOL CONTROL LEVEL I-II

# En

### REFERENCES

1. Burtis CA, Ashwood ER, Bruns DE, editors. Tiets 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 Ethanol Control I-II are trademarks of ARCHEM Sağlık Sanayi ve Tic. A.Ş. in various jurisdictions.



**Archem Sağlık Sanayi ve Tic. A.Ş.**  
Mahmutbey Mah. Halkalı Cad. No:124 Kat:4  
Bağcılar/İstanbul/Turkey  
Tel: + 90 212 444 08 92  
Fax: +90 212 629 98 89  
info@archem.com.tr www.archem.com.tr

### SYMBOLS

	In Vitro Diagnostic Medical Device
	Lot Number
	Control
	Global Trade Item Number
	Reference Number
	Identifies Products to Be Used Together
	Product of Turkey
	Manufacturer
	Expiration Date
	Temperature Limits
	Consult Instructions for Use
	Caution
	Number of Tests