

# ARCHEM PROTEIN CONTROL AND CALIBRATOR

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REF: PCN01	Protein Control Serum I	5x1 mL
REF: PCN02	Protein Control Serum I	5x5 mL
REF: PCN03	Protein Control Serum I	5x1 mL
REF: PCN04	Protein Control Serum I	5x5 mL
REF: PCN05	Protein Control Serum II	5x1 mL
REF: PCN06	Protein Control Serum II	5x5 mL
REF: PCN07	Protein Control Serum II	5x1 mL
REF: PCN08	Protein Control Serum II	5x5 mL
REF: PC30	Protein Calibrator	5x1 mL
REF: PC31	Protein Calibrator	5x5 mL
REF: PC32	Protein Calibrator	5x1 mL
REF: PC33	Protein Calibrator	5x5 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 Protein Control and Calibrator is for quality control and calibration of the parameters stated in the value sheet.

## CONTENTS / MATERIALS PROVIDED

Protein Control Serum I  
**REF: PCN01**  
 Package: 5 x 1 mL **Lyophilized**

Protein Control Serum I  
**REF: PCN02**  
 Package: 5 x 5 mL **Lyophilized**

Protein Control Serum I  
**REF: PCN03 (For Beckman)**  
 Package: 5 x 1 mL **Lyophilized**

Protein Control Serum I  
**REF: PCN04 (For Beckman)**  
 Package: 5 x 5 mL **Lyophilized**

Protein Control Serum II  
**REF: PCN05**  
 Package: 5 x 1 mL **Lyophilized**

Protein Control Serum II  
**REF: PCN06**  
 Package: 5 x 5 mL **Lyophilized**

Protein Control Serum II  
**REF: PCN07 (For Beckman)**  
 Package: 5 x 1 mL **Lyophilized**

Protein Control Serum II  
**REF: PCN08 (For Beckman)**  
 Package: 5 x 5 mL **Lyophilized**

Protein Calibrator  
**REF: PC30**  
 Package: 5 x 1 mL **Lyophilized**

Protein Calibrator  
**REF: PC31**  
 Package: 5 x 5 mL **Lyophilized**

Protein Calibrator  
**REF: PC32 (For Beckman)**  
 Package: 5 x 1 mL **Lyophilized**

Protein Calibrator  
**REF: PC33 (For Beckman)**  
 Package: 5 x 5 mL **Lyophilized**

PCN01 / PCN02 / PCN03 / PCN04 / PCN05 / PCN06 / PCN07 / PCN08 / PC30 / PC31 / PC32 / PC33 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.

## CALIBRATOR AND CONTROL STABILITY

Temperature-Conditions	Stability
Dry form and stored at +2/+8°C	Expiry date on the vial.
Diluted and stored at +25°C	8 hours
Diluted and stored at +2/+8°C	2 days
Diluted, frozen and stored at -20°C	60 days

## LIMITATIONS

1. Please open the vial caps carefully. When you open, be careful not to scatter any powdery substance around or to escape from the vial.

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2. Dissolve with distilled water with volume stated on the vial. Injector should not be used for the transfer process since there may be errors between 5-20% in liquid transfer with the injector. Use calibrated micropipettes.
3. Temperature of dry serum in the vial and distilled water must be +20/+25°C. After adding distilled water, close the vial cap tightly and store at +25°C around 5-10 minutes.
4. Wait for 30 minutes for dissolving process and mix thoroughly by gently inverting the vial at regular intervals, do not shake. Avoid formation of bubbles or foam. Protect from light. It is recommended to use a rotational mixer for routine mixing procedures.
5. After reconstitution, the calibrator and control serums are usually divided into small quantities (150-250 microliters) into Eppendorf tubes or sample cups of the device and stored in the refrigerator for freezing process. For serums prepared in this way, it is absolutely necessary to leave the serum at +25°C for 30 minutes before dividing it into small quantities. Do not refreeze after the serum is frozen and thawed once.
6. Calibrator and control serum precipitation is faster than normal serum. In order for the first and last parts to be homogeneous and to avoid precipitation, perform the process as fast as possible during separation.
7. The quality of the distilled water to be used in the dilution of the calibrator serum is very important. There may be significant deviations in the values due to bacterial contamination.
8. It is necessary to be careful against infectious agents in calibrator serum measurements.

### PREPARATION OF CALIBRATOR AND CONTROL

Lyophilized serum calibrator and control should be reconstituted by adding distilled or deionized water with the amount stated on the label. Close the vial and wait for 20 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.

### 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. 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)

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## TRADEMARKS







Archem Protein Control and Calibrator 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

<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