ARCON N- ARCON P CONTROL LEVEL I-II

En

REF: A3910	**ARCON N (Level I Control)**	**5 x 5 mL**
REF: A3912	**ARCON N (Level I Control)**	**5 x 5 mL**
REF: A3913	**ARCON N (Level I Control)**	**5 x 5 mL**
REF: A3920	**ARCON P (Level II Control)**	**5 x 5 mL**
REF: A3922	**ARCON P (Level II Control)**	**5 x 5 mL**
REF: A3923	**ARCON P (Level II Control)**	**5 x 5 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

Arcon N – Arcon P Control Level I-II are for quality control and calibration of the parameters stated in the value sheet.

CONTENTS / MATERIALS PROVIDED

Arcon N (Level I Control)
REF: A3910
Package: 5 x 5 mL **Lyophilized**

Arcon N (Level I Control)
REF: A3912
Package: 5 x 5 mL **Lyophilized**

Arcon N (Level I Control)
REF: A3913
Package: 5 x 5 mL **Lyophilized**

Arcon P (Level II Control)
REF: A3920
Package: 5 x 5 mL **Lyophilized**

Arcon P (Level II Control)
REF: A3922
Package: 5 x 5 mL **Lyophilized**

Arcon P (Level II Control)
REF: A3923
Package: 5 x 5 mL **Lyophilized**

A3910 / A3920 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.

CONTROL STABILITY

Temperature-Conditions	Stability
Dry form and stored in a dark place at +2/+8°C	Expiry date on the vial.
Diluted and stored in a dark place at +25°C	8 hours
Diluted and stored in a dark place at +2/+8°C	2 days
Diluted, stored in a dark place and frozen at -20°C	30 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.
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. Alkaline phosphatase level increases during the wait after mixing. Therefore, the diluted or dissolved calibrator serum should be kept at +25°C for 1 hour before ALP measurement.
8. Bilirubins are stable in the dark, and if the serum is exposed to light, bilirubin activity decreases (Bilirubins are affected by light in powdered, frozen and thawed sera forms).
9. Bilirubins are stable in dark environment for 8 hours at +2/+8°C after dissolving.

10. Bilirubin control serums cannot be refrozen and cannot be stored at +15/+25°C.
11. After being dissolved, bicarbonate in the serum is stable for 8 hours in closed cap and 1 hour in open cap.
12. 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.
13. It is necessary to be careful against infectious agents in calibrator serum measurements.

PREPARATION OF CONTROL

Lyophilized serum control 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.

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 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.
Contains sodium azide.

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. Tiets Textbook of Clinical Chemistry and Molecular Diagnostics, 4th ed. St. Louis, MO, Elsevier Saunders; 2006:2263.
2. S.Dean Allıson, Mark C.Mannıng, Theodore W.Randolph, Kım Mıddleton, Ashley Davıs, John F.Carpenter. Optimization Of Storage Of Lyophilized Actin Using Combinations Of Disaccharides And Dextran. Journal Of Pharmaceutıcal Scıences.89/2,199- 214(2000)

TRADEMARKS

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ARCON N- ARCON P CONTROL LEVEL I-II

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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