Procalcitonin Control

En

REF ZA94-1

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 Procalcitonin Control is for use in the control of the Procalcitonin Turbidimetric assay on the Architect cSystems.

Archem Procalcitonin Control

REF: ZA94-1

Package: 1x1 mL Level I
1x1 mL Level II **Lyophilized**

For use with;

Archem Procalcitonin Turbidimetric reagent
REF: ZA55

SUMMARY AND PRINCIPLE

The use of control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices (GLP).

CONTENTS / MATERIALS PROVIDED

Archem Procalcitonin Control **(REF: ZA94-1)** contain the human serum.
Sodium Azide (0.09%) is added as preservative.

Materials Required But Not Provided:

1. Class A volumetric pipette for delivery of 1.0 mL
2. Distilled or deionized water meeting the specifications equivalent to USP (United States Pharmacopeial Convention) purified water.
3. Archem Procalcitonin Turbidimetric Reagent

PRECAUTIONS (General and Users)

IVD

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.
Control 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 human-based products should be handled in accordance with good laboratory practices using appropriate precautions.
Safety Data Sheets are available at 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 Procalcitonin Control is stable until the expiration date when stored +2 to +8 °C.
2. Archem Procalcitonin Control is stable for 30 days when stored -20°C and protected from light. (Freeze and thaw once only)
3. Criterion for the stability data stated by Archem: Recovery values are within ±10% of initial value.

PREPARATION OF CONTROL

Lyophilized serum control should be reconstituted by adding 1.0 mL of distilled or deionized water. Close the vial and let stand for 30 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam.

INDICATIONS OF INSTABILITY OR DETERIORATION

Presence of extreme turbidity or microbial growth may indicate deterioration.

REFERENCES

1. EU-Dir 1999/11 Commission Directive of 8 March 1. 1999 adapting to technical progress the principles of Good Laboratory Practice as specified in Council Directive 87/18/EEC
2. Directive 2000/54/EC. Official Journal of the European Communities No. L262 from October 17, 2000.

TRADEMARKS

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SYMBOLS

IVD	In Vitro Diagnostic Medical Device
LOT	Lot number
REF	Reference Number
GTIN	Global Trade Item Number
CONT	Control
VALUE	Value
REAGENT	Reagent
FOR USE WITH	Identifies Products to Be Used Together
CONTAINS: AZIDE	Contains sodium azide
PRODUCT OF TURKEY	Product of Turkey
CONVENTIONAL UNITS	Conventional Units
	Caution
	Manufacturer
	Expiration Date
	Temperature limitation
	Consult instructions for use