

ACE CONTROL-E

REF A7040

6 x1 mL

Pour d'autres langues
Für andere Sprachen
Para otras lenguas
Per le altre lingue
Dla innych języków

Para outras línguas
Για τις άλλεςλώσεις
Für andra språk
For andre språk
For andre sprog



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ASSIGNED VALUES

The assigned values are lot specific and can be found on the enclosed component list. Values were assigned using Trinity Procedure No.305-UV and may not apply if other methods are used.

INTENDED USE

ACE Control-E is intended for use as a control in the determination of angiotensin converting enzyme (ACE). It serves to estimate test precision and to detect systematic analytical deviations that may arise from reagent/instrument variations.

REAGENT

MATERIALS PROVIDED

ACE Control-E, Catalog No. A7040
Lyophilized preparation containing ACE (porcine) in a buffered human serum base with stabilizers and preservatives.

PRECAUTIONS

ACE Control-E is for "In Vitro Diagnostic Use". Normal precautions exercised in handling laboratory reagents should be followed. Dispose of waste observing all local, state and federal laws.

ACE Control-E is a POTENTIALLY BIOHAZARDOUS MATERIAL. Source materials from which this product was derived were found negative for HBsAg and for antibodies against HCV, HIV-1 and HIV-2 by approved test methods. However, since no test method can offer complete assurance that infectious agents are absent, this product should be handled observing the same safety precautions employed when handling any potentially infectious material.

Angiotensin converting enzyme is classified as a reproductive hazard in California Proposition 65.

Refer to Material Safety Data Sheet for any updated risk, hazard or safety information.

MATERIALS REQUIRED BUT NOT PROVIDED

- Deionized water
- Pipet calibrated to deliver 1.0 ml

PREPARATION

1. Add 1.0 ml water to vial of ACE Control-E.
2. Swirl gently and allow to stand for 5 minutes.
3. Invert gently and mix well until dissolution is complete.
Swirl gently to mix before each use.

STORAGE AND STABILITY

Store ACE Control-E in the refrigerator (2–8°C). Vial label bears expiration date.

After reconstitution, ACE Control-E solution is stable for at least 7 days in refrigerator (2–8°C).

DETERIORATION

Do not use ACE Control-E if there is evidence of microbial growth.

GENERAL INSTRUCTIONS FOR USE

Treat ACE Control-E in the same manner as test samples in the assay for angiotensin converting enzyme.

EXPECTED VALUES

Refer to the enclosed component list for expected values.










Failure to obtain the results within the expected range for the ACE Control may indicate product deterioration. A study of each component in the instrument/reagent system should be performed to identify the actual problem.

Each laboratory should establish a quality control program and determine the mean and standard deviation on a day-to-day basis as a QC monitor.

Trinity Biotech, Inc., warrants that its products conform to the information contained in this and other Trinity Biotech publications. Purchaser must determine the suitability of the product for its particular use.

ORDERING INFORMATION

KIT	Item	Quantity
Catalog No.	ACE Controls	
A6040	Normal	6x1 mL
A7040	Elevated	6x1 mL

 Manufactured	CONTROL N Normal Control	CONT Contents
EC REP Authorized Representative	CONTROL I Intermediate Control	SUBS Substrate
 Consult accompanying documents	CONTROL E Elevated Control	REAG Reagent
REF Product Number	CAL Calibrator	DIL Diluent
LOT Lot	C.F. Coefficient Factor	ACT Activator
 Use by	RNG Range	IVD For In Vitro Diagnostic use
 Caution, consult accompanying documents	STD Standard	 Biohazard
 Store at 2-8°C	 Store at 2-30°C	 or Hazard
 Trinity Biotech USA Jamestown, NY 14701 Tel. 1 800-325-3424 Fax: 716-488-1990	EC REP CE	Trinity Biotech plc Bray Co. Wicklow, Ireland Tel. 353 1 2769800 Fax 353 1 2769888 www.trinitybiotech.com

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