

TruLab ACE Level 2

Order Information

Cat. No. 5 9310 99 10 046 Level 2 Kit size 3 x 1 mL

Intended Use

Assayed quality control to monitor the analytical performance of quantitative in vitro determination of angiotensin-converting enzyme (ACE) activity on automated photometric systems.

Description

TruLab ACE is a liquid stable control based on human plasma.

The control is used with the DiaSys test ACE FS.

Level 2 is in the pathological range.

Storage

The control, both opened and unopened, must be stored at 2 – 8°C. Avoid contamination. Do not freeze.

Stability

Unopened: Up to the date of expiry indicated on the kit

Opened: 16 weeks

Proper storage and handling of this product must be observed.

Warnings and Precautions

1. Contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. Contains material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. Each individual blood donation used for production of TruLab ACE was found to be non-reactive when tested with approved methods for HBsAg, anti-HIV 1+2 and anti-HCV. As there is no possibility to exclude definitely that products derived from human blood transmit infectious agents, it is recommended to handle the control with the same precautions used for patient specimens.
4. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
5. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
6. The summary of safety and performance (SSP) may be accessed on the website of the European Database on Medical Devices (EUDAMED) via the following link: <https://ec.europa.eu/tools/eudamed>
7. Please refer to the safety data sheets (SDS) and take the necessary precautions for the use of calibrators and controls.
8. For professional use only.

Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

Warning: Handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Preparation

The control is ready to use.

Materials Required

General laboratory equipment

Procedure

Please refer to the reagent package insert for instructions for use.

Target Value

The target value has been determined using the DiaSys test ACE FS, calibrated by DiaSys TruCal ACE calibrator. Calibrator value has been made traceable to the molar extinction coefficient of the FAPGG method from Beneteau B, Baudin B et al. [1].

Target value may vary with reagents and methods used.

Value listed below is valid for the indicated lot only.

Each laboratory should establish corrective action in case of deviations in control recovery.

Literature

1. Beneteau B, Baudin B, Morgant G, Giboudeau J, Baumann FC. Automated kinetic assay of angiotensin-converting enzyme in serum. Clin Chem. 1986 May;32(5):884-6. PMID: 3009054.
2. Biosafety in Microbiological and Biomedical Laboratories, U.S. Department of Health and Human Services, Washington June 2020 (HHS Publication 6th Edition 604 pages).

Additions and/or changes in the document are highlighted in grey. Deletions are communicated via customer info by stating the edition no. of the package insert/instruction for use.



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| | Lot No. | Expiry Date | Target Value | Range |
|--------------------|---------|-------------|--------------|----------------|
| TruLab ACE Level 2 | 38452 | 2026-11-14 | 99.6 U/L | 74.7 – 125 U/L |