# ACE CONTROL

2°C 8°C

REF 1578-1165 **Packaging:** 2 x 3 x 1 mL

**INTENDED USE**
Material for internal quality control of Angiotensin Converting Enzyme assays using Medicon reagent with Diatron Pictus® P700 and P500 analyzers. For in vitro diagnostic use only by trained laboratory professionals.

**COMPOSITION**
Lyophilized preparation containing porcine ACE in human serum matrix, stabilizers, preservative.

⚠ **WARNINGS – PRECAUTIONS**
- The material is designed for in vitro diagnostic use only.
- Every donor used for the preparation of this material was tested and found negative for HbsAg, anti-HCV, anti-HIV 1 and 2 by FDA approved methods. However, since no test method can offer complete assurance that infectious agents are absent, this product should be handled observing the same precautions employed when handling any potentially infectious material.
- Any serious incident that may occur in relation to this device must be reported by the user to the manufacturer and the competent authority of the country in which the user and/or the patient is established!

⚠ **PREPARATION**
Remove the rubber stopper very carefully. As the material is packed under vacuum, sudden air influx may force material out of the vial. Reconstitute by adding exactly 1 ml of cold (2°-8°C) deionized or distilled water.
Place the rubber stopper back on the vial, swirl gently 2-3 times and let it stand for 5 minutes for the lyophilized material to dissolve. Mix gently to obtain a homogeneous mixture. Ideally use a hematology tubes mixer for 20 minutes. Avoid foaming.
Replace cap immediately after use and store at 2-8°C. Unsuitable storage, handling, or errors during the analytical procedure may give erroneous results.

**MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT**
- ACE reagent
- Automated biochemical analyzer
- Common laboratory equipment.

⚠ **STORAGE - STABILITY**
Unopened the material is stable up to the expiry date stated on the label. After reconstitution the working solution is stable for 1 week when stored capped at 2-8°C.

⚠ **DETERIORATION**
**The material should not be used:**
- After the expiration date.
- After prolonged exposure to direct sunlight or high temperature.

**TEST PROCEDURE**
Refer to the user's manual of the analyzer for the quality control process.
Each laboratory should establish its own control frequency, however good laboratory practice suggests that controls be tested each date patient samples are tested and each time calibration is performed.
The results obtained by any individual laboratory may vary from the given mean value but should fall within the corresponding acceptable ranges given in the enclosed table. If any trends or sudden shifts in values are detected, review all operating parameters.
Each laboratory should establish guidelines for corrective actions to be taken if controls do not recover within the specified limits. Make sure the LOT on the vial is the same as on the value sheet accompanying the material.

⚠ **WASTE DISPOSAL**
Dispose of all waste material in accordance with local guidelines. Safety data sheet is available for professional use on request by MEDICON.

**ASSIGNED VALUES – Lot specific**
Please refer to the value sheet for the specific lot available at https://medicondoc.com.

**SYMBOLS**

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|---|---|
| Manufacturer | IVD *In vitro* diagnostic medical device |
| Temperature Limit | REF Catalogue Number |
| Caution | Biological Risks |

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