diatron

ACE

Specifically for use with Diatron PICTUS® 700 and PICTUS® 500 Analyzers

2°C – 8°C

REF 1419-1162 **Packaging:** 6 x Lyoph. (R1) + 6 x 10 mL (R2)

Σ 240

INTENDED USE
Reagents for In Vitro quantitative automated determination of Angiotensin Converting Enzyme - ACE (EC 3.4. 15.1) in samples of human serum from the general patient population. Measurements of ACE are to be used along with other in vitro and in vivo tests and physical examination by licensed physicians, as an aid for diagnosis of sarcoidosis.

This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers.
For in vitro diagnostic use only by trained laboratory professionals.

CLINICAL SIGNIFICANCE
Increased ACE levels are observed in cases of sarcoidosis, scleroderma, Gaucher's disease, leprosy, alcoholic cirrhosis, active histoplasmosis, tuberculosis, pneumonic embolism, Hodgkin's disease, myeloma, hyperthyroidism, amyloidosis, primary biliary cirrhosis, idiopathic pulmonary fibrosis.

METHOD PRINCIPLE
The UV kinetic method is used. The determination of angiotensin converting enzyme is based on measuring the rate of change of absorbance at 340/750 nm, during the hydrolysis of N-[3-(2-(furyl) acryloyl]-L-phenylalanylglycylglycine (FAPGG) substrate into N-[3-(2-(furyl)acryloyl]-L-phenylalanine (FAP) and glycylglycine.

METHOD LIMITATIONS
Refer to the book "Effects of Preanalytical Variables on Clinical Laboratory Tests" for possible interference of other pharmaceutical agents in this particular test. Interference of other agents is described in the "Clinical Guide to Laboratory Tests». This reagent is formulated specifically for use with Diatron Pictus® P700 and P500 analyzers. For additional information please contact customer support at Diatron or Medicon.

REAGENT COMPOSITION

Reagent 1 (R1)	Reagent 2 (R2)
FAPGG: 3.3 mM Non-reactive ingredients, preservative	Boric acid: 45 mM Tetraborate: 7.8 mMNon-reactive ingredients, preservative

⚠ **WARNINGS – PRECAUTIONS**

- This reagent is designed for in vitro diagnostic use. In vitro diagnostic reagents can be hazardous. They should be handled according to good laboratory techniques. Avoid inhalation and contact with eyes and skin.
- Samples should be considered as potentially infectious. Handle with special caution.
- This reagent contains sodium azide (NaN_3) ≤ 0.1%. Avoid swallowing and contact of the reagent with skin and mucous membranes.
- 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!
- Dispose all waste according to national laws.
- MSDS is available by Diatron or MEDICON upon request.

⚠ **PREPARATION**
Add the entire contents of R2 into vial R1. Ensure that all of R2 has been transferred to the R1 vial. Shake until completely mixed. The reconstituted reagent is ready to use and is placed on the corresponding position on the analyzer. The vials bear barcodes for automatic recognition by Diatron Pictus® P700 / P500 analyzers.

⚠ **REAGENT DETERIORATION**
The reagents should not be used:

- When they do not exhibit the specified linearity or control values lie outside the acceptable range after recalibration.
- After prolonged exposure to sunlight or high temperature.

⚠ **SHELF LIFE**
Unopened reagents are stable at 2°– 8°C up to the expiry date stated on the label. Once opened, R1 and R2 remain stable for 6 weeks when stored in the cooled reagent tray of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Serum may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. ACE is stable in serum samples for 7 days when stored at 2 – 8°C, and up to 6 months when stored at –20°C. Allow capped frozen samples in room temperature to thaw. Mix carefully thawed samples before analysis. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON ACE Calibrator (1578-1160), traceable to MEDICON internal calibrator. Calibrate the assay when a new lot of reagent is installed. The analyzer will automatically perform a Reagent Blank measurement every 2 weeks. Calibration should be repeated when a new lot of reagent is used, after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs.

QUALITY CONTROL Diatron offers MEDICON ACE Control, Normal – Elevated (1578-1165) for quality control. Control recovery should lie within the acceptable range. Results outside the acceptable range even after recalibration could be due to reagent deterioration, unsuitable storage conditions or control deterioration, instrument malfunction, or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT

- ACE calibrator
- Quality control material
- Diatron Pictus® analyzer
- Common laboratory equipment

REFERENCE INTERVALS
Serum: 8 - 57 U/L for adults
The reference interval for paediatric patients may be up to 50% higher than that of adults. Serum ACE activity is influenced by ACE gene I/D polymorphism, with DD genotype demonstrating higher values than DI and II genotypes. Reference values are based on current bibliography. Each laboratory should determine its own expected values as dictated by good laboratory practices.

⚠ **WASTE DISPOSAL**
This product contains sodium azide (NaN_3), which forms sensitive explosive compounds with copper or lead. Flush waste pipes with water after the disposal of undiluted reagent in order to avoid azide build up in the drain pipes.

SPECIFIC PERFORMANCE CHARACTERISTICS
The following values are representative of the reagent performance on Diatron Pictus® P700 or P500 analyzers. The reagent performance has been evaluated on other types of analyzers, covering all requirements of the 98/79 IVD Directive. A list of analyzers with the corresponding performance characteristics is available in the special leaflet accompanying the insert. The results taken in your laboratory may differ from these values.
Linearity 7 to 120 U/L
Lowest detection limit 8.79 U/L
The lowest detection limit (LDL) is defined as the lowest concentration of analyte that is distinguishable from zero. A sample free of analyte is assayed 20 times within the assay and the LDL is calculated as the absolute mean plus three standard deviations.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP 5-T (20 consecutive days, 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Level (U/L)	**%CV**
26	4.85
58	2.26
Level (U/L)	**TOTAL %CV**
26	6.58
58	4.67

INTERFERENCES - Criterion: recovery within ±10% from target value

	(Insignificant up to)
Triglycerides	3000 mg/dL
Hemoglobin	400 mg/dL
Bilirubin	20 mg/dL
Conj. Bilirubin	20 mg/dL

Correlation: A comparison was performed between this reagent on a Diatron Pictus® P700 and P500 analyzer and another commercially available product. The results were as follows:
Y = 1.0481X – 8.9557 R=0.9503 N=40 Sample range = 1.2 – 178.7 U/L

BIBLIOGRAPHY

1. Tietz, NW, ed. Clinical Guide to Laboratory Tests. 3rd. ed. Philadelphia: W.B. Saunders Company Ltd., 1995.
2. Burtis, CA and Ashwood, ER, ed. Tietz Textbook of Clinical Chemistry. 2nd. ed. Philadelphia: W.B. Saunders Company Ltd., 1994.
3. Jacobs, DJ, Demott, WR, Grady, HJ, Horvat, RJ, Huestis, DW and Kasten, BL, JR, eds. Laboratory Test Handbook. 4th. ed. Ohio, Hudson: Lexi-Comp Inc., 1996.
4. Young DS. Effects of Preanalytical Variables on Clinical Laboratory Tests. 2nd. ed. Washington, DC: The American Association for Clinical Chemistry Press, 1997.

SYMBOLS

Manufacturer
IVD *In vitro* diagnostic medical device
Temperature Limit
REF Catalogue Number
Caution
Σ Contains sufficient for <n> tests

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CE IVD