diatron

D-DIMER

2°C 8°C

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

REF 1419-1182 **Packaging:** 6 x 8 mL (R1) + 6 x 4 mL (R2)

Σ 312

INTENDED USE
Reagents for In Vitro quantitative automated determination of D-Dimer in human plasma in the general patient population. Measurements of D-Dimer may be used as an aid for detection and estimation of the severity of intravascular coagulation and fibrinolysis.

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
D-Dimer is a small protein fragment, present in the blood after a blood clot is degraded (fibrinolysis) by plasmin. D-Dimer contains a chemical bond, connecting the two fibrin monomers, that is not present in fibrinogen, so D-dimer is specific to fibrin degradation. The quantitation of D-Dimer allows detection and estimation of the severity of intravascular coagulation and fibrinolysis. Its determination is therefore valuable in monitoring anticoagulant therapy and for ruling out pulmonary embolism (PE), deep vein thrombosis (DVT), and disseminated intravascular coagulation2 (DIC).

METHOD PRINCIPLE
The method is based on Latex-enhanced immunoturbidimetry. Monoclonal Anti- D-Dimer antibodies in the reagent react with D-Dimer antigen in the sample, forming antigen/antibody complexes that increase the solution's turbidity.

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)
Tris HCl 125 mM, pH 7.2	Latex particles coated with mouse anti-human D-Dimer monoclonal antibodies 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). 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**
Reagents are ready to use. Shake gently before placing on analyzer. The vials bear barcodes for automatic recognition by Pictus® P700 or 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, reagents remain stable for 1 month when stored in the reagent sampler of the Diatron Pictus® P700 or P500 analyzers.

⚠ **SAMPLE** Li-heparin plasma may be used as specimen. Use established Good Laboratory Practices for sampling, transport and separation from blood cells. Do not use hemolyzed, contaminated or turbid sample specimens. Anti-coagulants other than Li-heparin have not been tested and should not be used. Centrifuge sample as soon as possible, and store properly if analysis cannot take place right after sample separation. D-Dimer remains stable in serum or plasma for 8 hours at 20 - 25°C, 4 days at 2 - 8°C and 6 months at –20°C. Do not freeze thawed samples.

CALIBRATION Diatron offers MEDICON D-Dimer Calibrator (1478-1182) traceable to Medicon Master Lot for calibration. Calibrate the assay every 2 weeks on the Diatron Pictus® P700 or P500 analyzers. Calibration should also be repeated after major maintenance is performed on the analyzer, after a critical part is replaced, or when a significant shift in control values occurs. Traceability: No internationally accepted reference material for the determination of D-Dimer exists.

QUALITY CONTROL Diatron offers MEDICON 2 level controls (code no. 1478-1186) for quality control. Target values for D-Dimer should be verified with the corresponding working protocol. Results outside the specified values even after recalibration could be due to reagent deterioration, instrument malfunction or error during test procedure.

MATERIALS REQUIRED BUT NOT PROVIDED WITH THE KIT
- D-Dimer Calibrator
- Quality control material
- Diatron Pictus® analyzer
- Usual laboratory equipment
- 0.9% NaCl

REFERENCE INTERVALS
There is no internationally accepted standard material or method for the determination of D-Dimer. Suggested reference values for plasma with current method are < 0.5 μg FEU*/ml.
** FEU = Fibrinogen Equivalent Units*

⚠ **WASTE DISPOSAL**
This product contains sodium azide (NaN3), 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.
nearity 15 – 7.0 μg FEU/ml
Hook Effect: >100 μg FEU/ml

Lowest detection limit 0.14 μg FEU/ml
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. Diatron Pictus® 700 and 500 analyzers allow for the automatic dilution and repetition. See analyzer User's Manual, or contact Diatron or MEDICON for instructions.
Precision: Precision is estimated on two concentration levels of analyte according to CLSI protocol EP 5-A (20 consecut 2 runs per day, 2 repeats per run).

Pictus® P700 and P500	
Mean (μg FEU/mL)	**%CV**
0.71	4.39
1.73	1.40
Mean (μg FEU/mL)	**TOTAL %CV**
0.71	5.00
1.73	2.78

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

	(Insignificant up to)
Triglycerides	1980 mg/dL
Hemoglobin	500 mg/dL
Bilirubin	50 mg/dL
Conj. Bilirubin	50 mg/dL
RF	1000 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 = 0.927X + 0.001 R=0.9600 N=70 Sample range = 0.15 – 6.67 μg FEU/ml

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SYMBOLS

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

MEDICON HELLAS S.A. - Melitona 5-7, 153 44 Gerakas, Greece. Tel: +302106606000 - Fax: +302106612666 – www.mediconsa.com

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CE IVD