# D-DIMER KIT

**REF:** K-707

For *in vitro* diagnostic use. **Store at 2°-8°C**

## INTENDED USE

Immunoturbidimetric reagent for the quantitative determination of D-Dimer concentration in human plasma on optical coagulometers at 400-470nm.

**Background**

At wound healing blood clots will be broken down by the process of fibrinolysis. Thereby, fibrin degradation products (FDP) such as D-Dimer (DD) occur in the plasma. Elevated level are found in clinical conditions such as deep vein thrombosis (DVT), pulmonary embolism (PE) and disseminated intravascular coagulation (DIC)[1-2]. High D-dimer levels during pregnancy are associated with complications[3]. Because of the high sensitivity negative results can be used to exclude DVT or PE. However imaging tests (like ultrasonic) must be applied for diagnosis of DVT or PE.

## CONTENTS AND DETERMINATIONS

| | |
|---|---|
| Product | D-Dimer Kit |
| Cat.No. | K-707 |
| Latex | 1 x 5 ml |
| Reaction Buffer | 1 x 7 ml |
| Sample Dilution Buffer | 1 x 7 ml |
| D-Dimer Calibrator | 1 x 1 ml |
| D-Dimer Control N | 1 x 1 ml |
| D-Dimer Control A | 1 x 1 ml |

Determinations:

| | |
|---|---|
| Coatron M | 65 Det. |
| Coatron A4 | 65 Det. |
| Coatron A6 | 110 Det. |

## PREPARATION

**Latex**: liquid, ready to use.

Contains micro particle coated with monoclonal antibodies MA-8D3 suspended in a buffer solution containing stabilizers detergent and preservatives. Agitate the latex by repeatedly the vial after storage. Allow the latex to equilibrate at the working temperature of the instrument for 30 min before use.

**Reaction Buffer**: liquid, ready to use.

Contains stabilizers detergent and preservatives.

**Sample Dilution Buffer**: Saline Solution, Ready to use

**D-Dimer Calibrator and D-Dimer Control**: dried, contains lyophilized human plasma enriched for D-dimer, reconstitute with 1 ml distilled water.

## STORAGE AND STABILITY[4]

Unopened reagents and controls loose about 1% activity per month and should be used within expiration date and stored at 2-8°C.

Opened reagent:

| | 2-8 ºC | 20-25 ºC | 37ºC | Aliquot |
|---|---|---|---|---|
| Latex and Buffer | 4 weeks | 8 hours | 8 hours | 6m at 2-8°C |
| D-Dimer Calibrator and D-Dimer Control | 24 hours | 8 hours | 2 hours | 30d at -20°C |

Split D-Dimer reagent into aliquots of two or more vials (siliconised glass) immediately, if longer stability is required after opening. Dissolved plasma can be refrozen only one time in aliquots (120-150µl). Stored at -20°C in closed polypropylene tubes, the aliquots must be used within 30 days.

## PRECAUTIONS

Avoid contact with skin and eyes. Wear suitable protective clothing. Dispose components in compliance with local regulations for infectious material. All components are checked for HIV, HBV, HCV. However products from human blood should be considered as potentially infectious.

## SPECIMEN COLLECTION AND STORAGE[6]

1.Obtain venous blood by clean vein puncture.
2.Immediately mix 9 parts blood with 1 part sodium citrate (3.2% or 3.8%) and mix well.
3.Centrifuge the specimen at 1500g for 15 min. (platelet < 10000/µl)
4.Separate plasma after centrifugation and store in plastic or siliconised glass tube.
5.Use plasma within 8 hours, otherwise store frozen and thaw just prior to use.

## PROCEDURE

A. Automated Method:

| | | A4 | | A6 | |
|---|---|---|---|---|---|
| PAT | Patient | 25uL | CP2 | 15µl | CP3 |
| BUF | Sample Diluent | 0µl | P39 | 0µl | P79 |
| CLR | - | 0µl | - | 0µl | - |
| DP | - | 0µl | P00 | 0µl | P00 |
| R0 | - | 0µl | P00 | 0µl | P00 |
| R1 | Reaction Buffer | 50µl | P37 | 30µl | P52 |
| R2 | Latex Reagent | 75µl | P38 | 45µl | P53 |

| | A4 | A6 |
|---|---|---|
| Incubation | 60s | |
| Maxtime | 180s | |
| Unit | 30721 | |
| Method | Imun | |
| Math | Lin | |
| CT-Mech | No | |
| Deadtime | 21s | |

| | A4 | A6 |
|---|---|---|
| SENS | 0 | |
| POINTS | 2 | |
| MIX | No | |
| Clean | 1 | 3 |
| Multi | 0 | 0 |
| S-Corr | 0% | |
| T-Corr | 0% | |

B. Manual Method:

| System setup | OD-Corr | Coag.-Corr |
|---|---|---|
| Coatron M1 (400nm) Firmware C1.20 | 180 | 120 |
| Coatron M2 (400nm) Firmware C1.15 | 0% | 0% |
| Coatron M4 (400nm) Firmware C1.11b | 0% | 0% |

1. Pipette 25 µl plasma to cuvette(s).
2. Add 50 µl Reaction Buffer.
3. Incubate for 2 – 10 min.
4. Add 75 µl prewarmed Latex and mix at least "15x" with pipette. (Avoid air bubbles during mixing and do not touch cuvette, if double cuvettes are used.)

## CALIBRATION

A calibration must be performed every 3 month. Make dilutions of D-Dimer Calibrator with sample dilution buffer.

Refer to the table below.

| | Concentration | Sample | Sample Diluent |
|---|---|---|---|
| Cal. 1 | ~ 3000 ng/ml | 200 µl D-Dimer Calibrator | - |
| Cal. 2 | ~ 1500 ng/ml | 200 µl D-Dimer Calibrator | 200 µl |
| Cal. 3* | 1 ng | - | - |

* This point is not measured, but just the zero point entered as 1ng=1mE

## EXPECTED RESULTS

Results below CUT-OFF value can be regarded as D-dimer negative and are typical for normal healthy normal subjects. Elevated levels are observed in causes of PE, DVT (deep venous thrombosis) or DIC or trauma.

D-Dimer results can be reported in D-dimer units (DDU) or Fibrinogen Equivalent Units (FEU). 1 FEU is equal to l.74 DDU. Cormay is using DDU in certificates.

## QUALITY CONTROL

D-Dimer Control or other commercial D-Dimer control plasma should be used for reliable quality control of performance at a frequency in accordance with good laboratory practice (GLP). Ensure that calibration data are not older than 3 months.

## LIMITATIONS

Great care must be taken to minimize variations which may occur by seemingly insignificant factors.

Laboratory Techniques and Requirement

1. Appropriate mixing of cuvette after test start is required.
2. Don't touch cuvette during measurement - single cuvettes may useful.
3. Very bright external UV light sources like sunlight will interfere result

Interferences

1. Bilirubin: No affect below <0.1 g/l
2. Hemoglobin: No affect below <4.0 g/l
3. Heparin: No affect
4. Lipids No affect below <2.5 g/l. Samples above 5.0 g/l will give false low DD results and must diluted and repeated.

**PERFORMANCE CHARACTERISTICS**

The quantification limit is 150ng/ml (DDU). Results below should considered as "<150".

Samples > 5000ng/ml should be re-assayed 1:4 diluted with Saline Solution.

Precision: Appropriate mixing is required to achieve good accuracy.

D-Dimer Control A CV. <8% (within run)

D-Dimer Control N CV. <10% (within run)

**PERFORMANCE:**

| CUT-OFF | Sensitivity | Specifity | NPV | PPV |
|---|---|---|---|---|
| DDU=200ng/ml | 97% | 62% | 99% | 41% |

**WARRANTY**

This product is warranted to perform in accordance with its labelling and literature. P.Z. Cormay disclaims any implied warranty of merchantability or fitness for any other purpose, and in no event will P.Z. Cormay be liable for any consequential damages arising out of aforesaid express warranty.

**REFERENCES**


1. Elms, M.J. et al. Rapid detection of cross-linked fibrin degradation products in plasma using monoclonal antibody-coated latex particles. J. of Clin. Path. 85:360-364, 1986.
2. Declerk, P. et al. Fibrinolytic response and fibrin fragment D-dimer levels in patients with deep vein thrombosis. Thrombosis and Haemostasis 58:1024-1029, 1987.
3. Ballegeer, V. et al. Fibrinolytic response to venous occlusion and fibrin fragment D-dimer levels in normal and complicated pregnancy. Thrombosis and Haemostasis 58:1030-1032, 1987.
4. National Committee for Clinical Laboratory Standards: Guidelines for the Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing and Performance of Coagulation Assays.



**MANUFACTURER**

**PZ CORMAY S.A.**
22 Wiosenna Street,
05-092 Łomianki, POLAND
tel.: +48 (0) 22 751 79 10
fax: +48 (0) 22 751 79 14
http://www.cormay.pl



11/13/11/13